

MEDIVATORS® RAPIDAER



Operators Manual

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Language Version
Original Instructions in English.



0088

CE Marking certifies that this equipment conforms to the following EEC directives:
Medical device directive 93/42/EEC
Low Voltage Equipment – 72/23/EEC
CE marking directive 93/68 EEC
Electromagnetic Compatibility – 89/336/EEC



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INTRODUCTION:

RAPIDAER DESCRIPTION:

The Medivators® range of automated endoscope re-processors, cover a wide range of capabilities to suit your particular requirements. RAPIDAER is the latest in the range, which now offers the user full pass through compliance to meet the requirements of BS EN 15883 Parts 1 & 4, SHTM2030 & CFPP01-06.

The RAPIDAER is a single chamber machine processing a single multiple channel endoscope per cycle in an easy to load basket. The machine has the same unparalleled external scope cleaning performance and integral individual channel cleaning facility as the Autoscope Isis providing a fully compliant re-processing performance.

Included in the automated wash cycle time of approx.17 minutes, is the automated leak test facility, and continuous channel monitoring. DATA records include operator, endoscope, and wash cycle information, together with the unique identification of the connection manifold being cross referenced against the endoscope channels of the endoscope.

PROCESS CYCLE

The normal re-processing cycle is in 7 stages.

1. Leak Test
2. Gross Wash and lumen patency check
3. Detergent wash
4. Detergent Rinse,
5. Disinfectant Clean,
6. Disinfectant Rinse.
7. Air flush

The operator also has the option to perform a "Manual Leak Test" with the door open, prior to the wash cycle



UNDERSTANDING RAPIDAER:

RAPIDAER is a fully compliant self contained pass-through endoscope reprocessing machine.

Designed to re-process one endoscope in each cycle, RAPIDAER offers a full cycle process with-in 17 - 18 minutes of pressing the start button. *(subject to a 5 minute disinfectant contact time and the incoming water temperature)*

Likewise loading the scopes is quick and efficient, by the use of the scope carrier basket design. Scopes can pre-loaded into their carrier baskets ready to be loaded in to the RAPIDAER machine, as soon as the re-processed scope is removed.

PASS THROUGH TECHNOLOGY:

RAPIDAER offers a compact footprint design that can be easily delivered and installed with access through standard size doorways. The pass through function of RAPIDAER allows the owner to split the re-processing task into separate areas, either in the same room, or separate rooms, by incorporating RAPIDAER into a dividing wall.

“Dirty Side” for loading used scopes & un-loading scopes that don’t complete their re-processing cycle.

“Clean Side” for unloading re-processed scopes only.

TRACE ABILITY:

RAPIDAER incorporates all the information that you require:
Operators have to log onto the machine, by use of a Tag, or ID & PIN for both loading & un-loading

The connection manifold and the endoscopes have to be logged onto the machine by use of a Tag, which identifies the channel configuration for irrigation and checks the hub and the manifold have the same channel connections.

Any access to the user configuration and set-up options, requires a log in, either by use of a TAG, or “ID & PIN”.

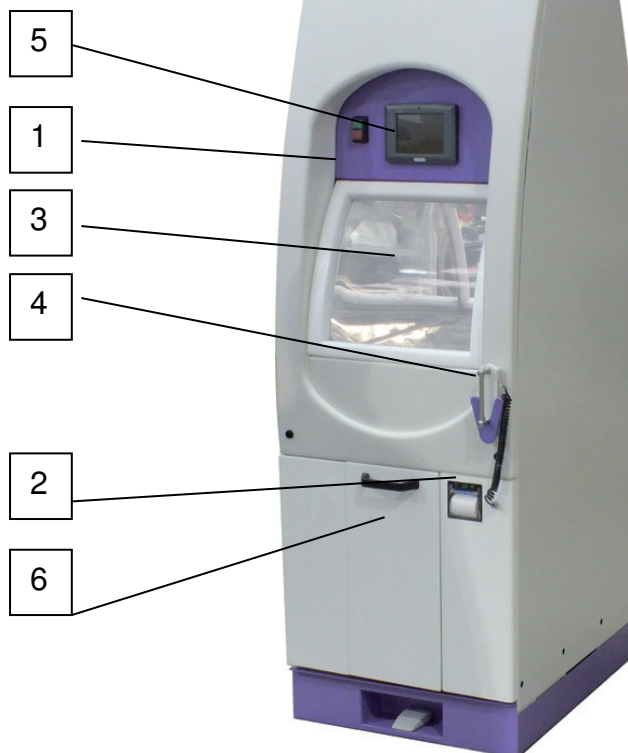
All information is captured in the RAPIDAER computer memory, and can be transferred when required via a USB data storage device, or the unit can be linked directly to a traceability system.

A printout is produced as part of each cycle, with the option for a comprehensive print out:- detailed report.



FIND YOUR WAY AROUND RAPIDAER: "DIRTY SIDE" SCOPE LOADING SIDE

1. ON / OFF switches
2. Printer (optional on this side)
3. Process Chamber
4. Tag Reader
5. Control Panel touch screen (onboard computer)
6. Chemical storage chamber



"CLEAN SIDE" SCOPE UN-LOADING SIDE

The clean side has

- Emergency stop Button
- Printer
- Access to Process Chamber
- Tag Reader
- Control Panel Read out for cycle status



ON/ OFF SWITCHES:

The On/Off switches are located on the top left of the load side (dirty side) of the RAPIDAER adjacent to the control panel.

GREEN is ON
RED is OFF



EMERGENCY STOP BUTTON: (CLEAN SIDE ONLY)

There is an emergency stop button on the top left of the unload side (clean side) of RAPIDAER.



TAG READER:

The TAG readers are on both sides of the RAPIDAER machine, and are positioned to give the best possible ergonomic interaction with the operator and scope carrier baskets during loading and unloading.



CHEMICAL CHAMBER:

The Chemical chamber is on the Dirty Scope, load side of the machine.



RAPIDAER CONNECTIONS:

ELECTRICAL CONNECTIONS:

RAPIDAER will be connected to a 32 amp, 50Hz, 240 V single phase supply.

The connection point for each RAPIDAER machine should have an isolator switch located close to one side of the RAPIDAER machine, (pass through installations)

If an engineer is working on the RAPIDAER machined he may require to disconnect the power supply and lock this isolator for health and safety requirements.



SUPPLY WATER:

The incoming water supply to the RAPIDAER should be from an RO plant. The RO is connected to the machine at the top where there is an aseptic sampling point and isolation tap. The machine will use 44 litres per cycle.

WASTE WATER:

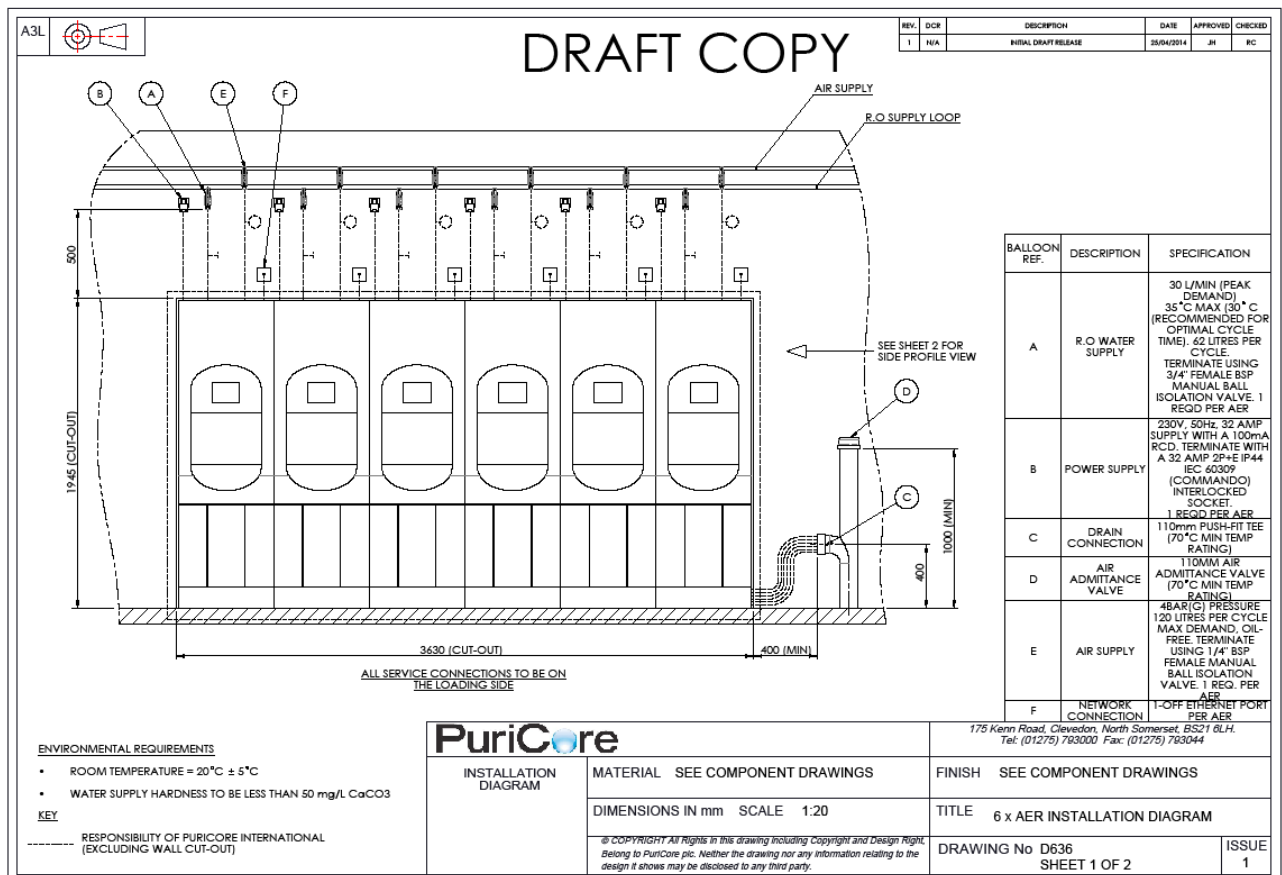
Waste water from the RAPIDAER should flow directly to a standard vented drain.

Always ensure that the water supply is turn on before using the RAPIDAER machine.

AIR PURGE SUPPLY:

A medical grade air supply should be connected to the top of the machine with an line gauge to allow operators to see the air pressure that is being supplied.

CONNECTION DIAGRAM





SPECIFICATION

Model	RapidAER
Dimensions	600mm (w) x 800mm (d) x 1930mm (h)
Processing Time	17 minutes
Disinfectant	Rapicide PA two part, single shot, Peracetic acid based disinfectant
Detergent	Mediclean Plus alkaline single shot detergent
Power Requirements	230v, 50hz, 32 amp supply
Class 1 equipment	Protective Earth required
Connection to supply	IEC 60309 industrial coupler
Water Requirements	64 litres per processed scope
Construction	Steel frame, Polycarbonate doors, Plastic cover panels.
Noise Level	<58 dBA
Weight	240Kg
Process Capacity	1 large flexible endoscope per cycle
Environmental Operation Conditions	
Operating Temperature Range	Ambient (0-40 °C)
Humidity	20%- 90%



OPERATOR - RAPIDAER INTERFACE

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

The operator has various options on how to interface with the RAPIDAER machine.

For ease of use, speed and efficiency the RAPIDAER machine is configured to operate using a TAG system.

There are three types of TAGS:

The Operator TAG:- which contains all the relevant data about the operative.

The Scope TAG:- which contains all the relevant data about the endoscope.

The Connection Manifold TAG – which contains all the details about endoscope connection

(All of these are covered in more detail on the following pages).

The TAGS are pre-programmed by the RAPIDAER manager with all the relevant details. The TAG system allows the operator to follow the prompts / instructions on the computer screen, and by presenting the TAG to the tag reader, the RAPIDAER machine will progress onto the next step in the process.

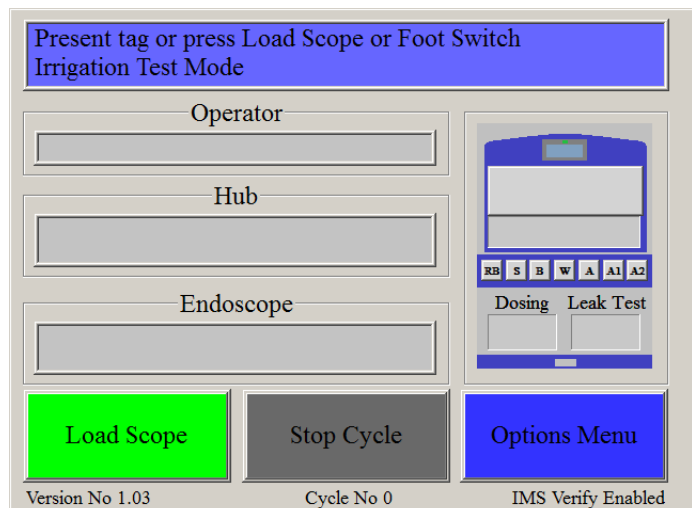
However, should the operator not have their TAG for whatever reason, RAPIDAER also has the option to allow access through the computer touch screen.

Each operator will also have an identification number and a PIN, these can be used to identify the operator to the RAPIDAER manually.

The operator will also be required to use the computer touch screen during the endoscope loading process. The buttons that are active and can be pressed to select an option or confirm a question, are always coloured in green.

The only other button that can be pressed is the Pause button, active once the cycle has started.

To operate a touch screen button, the operator should gently, but firmly press their finger on the button on the computer screen.





RAPIDAER CONTROL PANELS:

DIRTY SIDE (LOAD SIDE) CONTROL TOUCH SCREEN



CLEAN SIDE (UN-LOAD SIDE) CONTROL PANEL





OPERATOR ID

PERSONAL IDENTIFICATION NUMBER (PIN)

Under the “Hospital protocols” section of the RAPIDAER control functions, you are required to choose a PIN and sequential ID number for each operator or manager who has access to your RAPIDAER machine.

The PIN should be a confidential identification known only to the assignee, and the RAPIDAER manager.

It is recommended that a secure log or record of the PIN's should be kept by the hospital (RAPIDAER manager) to cover for the event of an operator losing their TAG, and forgetting their PIN.

It doesn't matter if operators choose a PIN that someone else already has, because it has to be used with their unique sign on ID number.

Once an ID & PIN and a TAG have been assigned to a user's log on, the operator does not need to use their PIN because all the necessary information is stored on the operator TAG.

The operators ID & PIN will be required if a TAG is lost or stolen; so that the operator can access the RAPIDAER machine manually. The ID & PIN are also needed to re-assign a new TAG for the operator.

Please refer to the following section on TAG's , for lost or damaged TAG's



OPERATOR ID TAG:



Fig: Tag 1

Each operator that is assigned to your Autoscope RAPIDAER machine, should be allocated a unique personal TAG.

The operator ID TAG provides several functions:

- 1) Identifies the operator.
- 2) Automatically logs the operator into the RAPIDAER machine.
- 3) Automatically confirms the operator's access level status.
- 4) The TAG is required to open the RAPIDAER doors for both loading & unloading.
- 5) If a tag is lost or stolen. The RAPIDAER Manager should assign a new tag to the operator, this will disable the lost TAG.

SCOPE ID TAG:



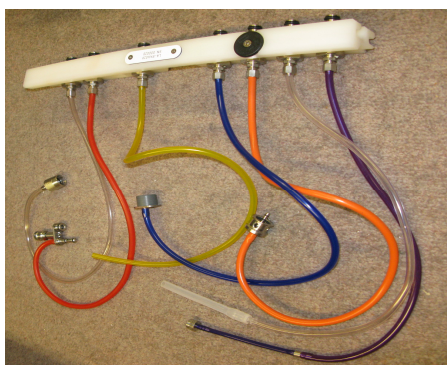
Fig : Tag 2

Each Scope that will be re-processed in the RAPIDAER requires a unique identification TAG rated to IP68.

This will identify the scope to the RAPIDAER machine, automatically confirming the parameters for cleaning and testing etc.

The TAG will also allow the endoscope to be tracked within the DATA storage and printouts.

CONNECTION HUBS



THE CONNECTOR HUB.

This is used with each scope that is installed into the carrier basket. There are a large number of hubs with connections dedicated to number of channels in that particular family of endoscopes. The hubs vary dependant on manufacturer and the individual connectors required to fit the individual channels.



CONNECTOR HUBS ID TAG



The connector hub tag is similar to endoscope ID tag and is rated to IP68. The information stored on the tag allows for the number of channel that are connected to be verified against the number on channels on the endoscope tag and then during the process these connections are monitored.

NOTE: All accessories used with the RapidAER, and to connect the endoscopes must comply to Cantel Medical's specification.

PRE-LOADING A SCOPE:

PREPARING THE SCOPE BASKET:

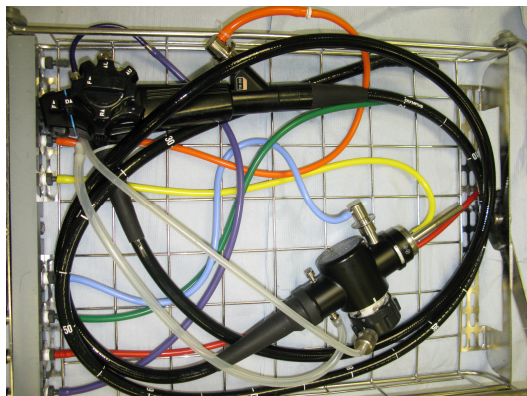
The RAPIDAER machine uses a scope carrier basket to house the scope in the machine. The basket is pre-loaded with the scope on a worktop, and placed into the RAPIDAER when ready.

On completion of the wash cycle, the scope is removed in its basket, so that another scope basket can be loaded and washed whilst the previous scope is removed from the basket.

The carrier basket can then be returned to the load side, for re-loading with more scopes.

Take an empty basket and then select the correct hub for the endoscope to be reprocessed. Each type of endoscope will have a specific connection manifold with the correct number of channel connectors suitable for that family of endoscopes.

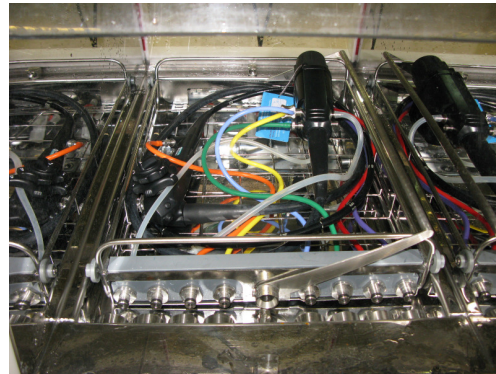
The manifold is slid into the end of the basket, the scope is then placed in the basket and the connections made to the scope.





LOADING THE SCOPE INTO THE RAPIDAER MACHINE

Open the RAPIDAER load door, using the operator tag or foot pedal.



Place the end of the basket on the side guides and slide the basket forward into the chamber until it rests totally in the base area.



Pull the basket back towards the front of the machine to locate the connectors into the irrigation ports on the inside front face of the chamber. When located, lock in position by moving the locking arm across the basket.

When the scope is loaded securely, Check the computer screen, and answer the question regarding channel separators, before closing the door,

UN-LOADING A SCOPE FROM THE RAPIDAER MACHINE:

To unload a scope, it is the reverse of the load operation.

When the computer instructs that the unload door can be opened, the operator should present their TAG to identify the unload operator and then retag or use the foot switch to open the clean side door.

Move the locking arm across to unlock the connections and then slide the basket upwards and remove through the clean door.

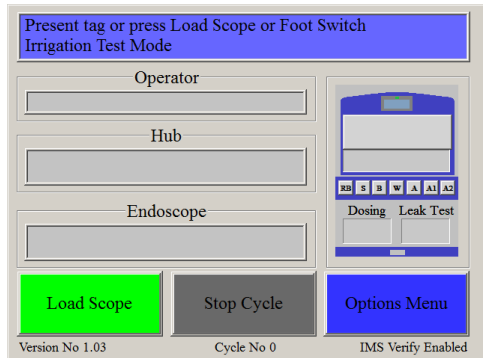
Close the door using the tag or foot switch.

The RAPIDAER machine will not proceed to the next step until the door has been closed properly.



How to “LOG ON” RAPIDAER

RAPIDAER functions via the onboard touch screen computer. The following steps show how to LOG ON to RAPIDAER using the touch screen.



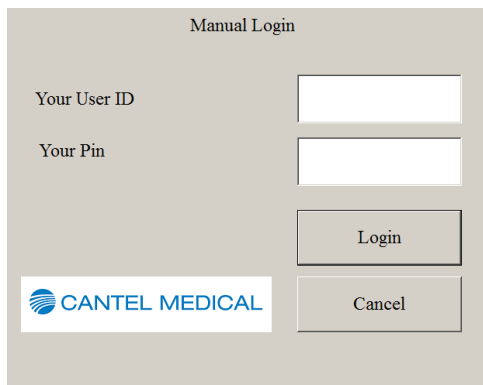
RAPIDAER Home screen

When at rest, the RAPIDAER will display the Home Screen.

In order to access the operating system, present the operator TAG to the reader.

Alternatively, touch the green box as indicated.

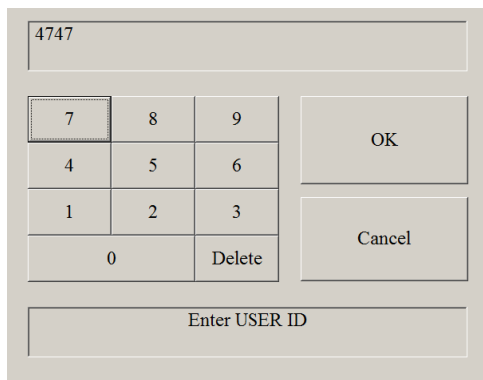
If the TAG is used, the door can then be opened by using the operator tag again or pressing the foot switch, and the RAPIDAER will ask for the Scope ID.



If the green box is pressed, the computer will proceed to the LOG ON screen

LOG ON screen

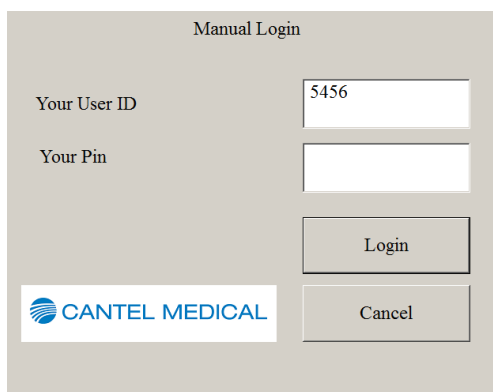
Touch the user ID box to input the users 4 digit reference number via the Key Pad screen



The numerical Key pad screen

Enter the user 4 digit ID number

Press OK to accept



Enter PIN

Touch the PIN box to activate the numerical keypad



7	8	9	OK
4	5	6	
1	2	3	Cancel
0	Delete		

Enter User Pin

The numerical Key pad screen

Enter the user 4 digit PIN

Press OK to accept


Manual Login

Your User ID

Your Pin

Login

Cancel

 CANTEL MEDICAL

Now press LOG ON

The door will open and the RAPIDAER will ask for the hub and scope ID

All the information displayed on the screen will be stored in the Data Log:
ie: User ID, name, PIN, TAG, including dates & times.



AUTOMATIC RE-PROCESS CYCLE

The normal re-processing cycle for either a one or two scope process is in 7 stages.

1. Leak Test
2. Gross Wash and Lumen Patency
3. Detergent wash
4. Rinse
5. Disinfectant Clean
6. Disinfectant Rinse
7. Air flush

The Computer display on the Load side of the RAPIDAER machine is the main user interface. Most of the wash cycle sequence can be performed by the use of the Operator TAG, Manifold TAG and the Endoscope TAG. Additional operator input is by pressing buttons on the touch screen.

The touch screen buttons are all indicated when they are active and are mostly located across the bottom of the computer screen.

The computer screen display prompts and instructs the operator on the physical actions to be taken during the load and un-load sequences.

During the wash cycle process, the computer screen displays the stage of the cycle that is being performed. This information is repeated on the unload side, scrolling display.

Other information displayed on the screen includes:

The load operator for each scope
The hub identification
The endoscope identification
The PAUSE cycle button.



CYCLE SEQUENCE

The following information will be displayed at each stage of the cycle in the purple information box on the computer “dirty side” (Load side), and will also be scrolling across the, Machine Status Display, on the “clean side” (Un-Load side)

SCOPE LOAD SEQUENCE

- 1) RAPIDAER Ready Tag or Log On
- 2) Load Operator ID recorded
- 3) Load basket
- 4) Present Hub Tag
- 5) Hub ID recorded
- 6) Present Endoscope TAG
- 7) Endoscope ID recorded
- 8) Close door
- 9) Fitted Channel Separators?
- 10) Press Start

WASH CYCLE SEQUENCE

- 11) Leak Test and detergent dose measured
- 12) Gross Wash & Lumen patency check
- 13) Dose Detergent, Detergent Wash (Solution will be heated if water temperature lower than required)
- 14) Detergent Rinse
- 15) Dose Disinfectant solutions
- 16) Disinfectant contact (Solution will be heated if water temperature lower than required)
- 17) Disinfectant Rinse
- 18) Air Purge

SCOPE UNLOAD SEQUENCE

- 19) Present operatorTAG to open door
- 20) Un-load operator ID recorded
- 21) Unload & close door
- 22) Rotating to unload position 2
- 23) RAPIDAER READY (Tag or Log On)



USING THE RAPIDAER MACHINE

To start an automatic cycle, simply perform the following procedures.

SWITCHING THE RAPIDAER MACHINE ON.

First ensure that the power supply is switched on at the isolator. This should be located on the wall, close to the machine.

Then ensure that the water supply is turned on.

It is also important to take regular water samples to ensure that the supply RO water is clean.



Then press the GREEN start button.

This is located on the Top Left Hand Side of RAPIDAER, on the Load Side of the machine.

When the start button is pressed the computer will display the initialising screen. Once the RAPIDAER computer has booted up all the required configurations, the touch screen will display the Home Page

The Main Computer screen will stay on the Home Page, until a re-processing cycle is started.



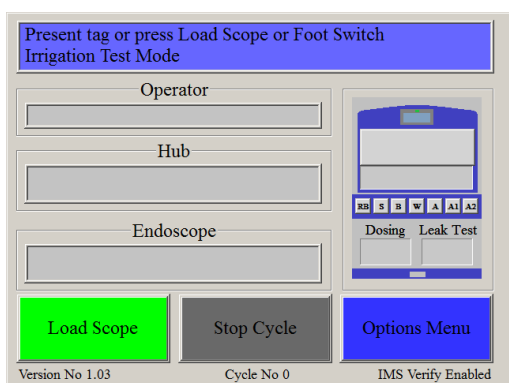
USING THE RAPIDAER MACHINE – RUNNING A CYCLE:

On switch on the RAPIDAER computer will load the standard home screen

The Main Computer screen will stay on the Home Page, until you start a re-processing cycle.

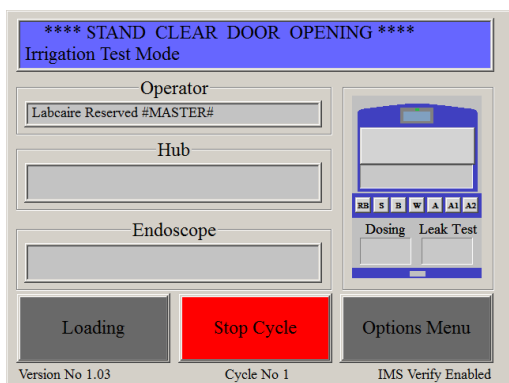
To use the RAPIDAER machine:

The operator needs to follow the instructions in the blue box at the top of the screen.



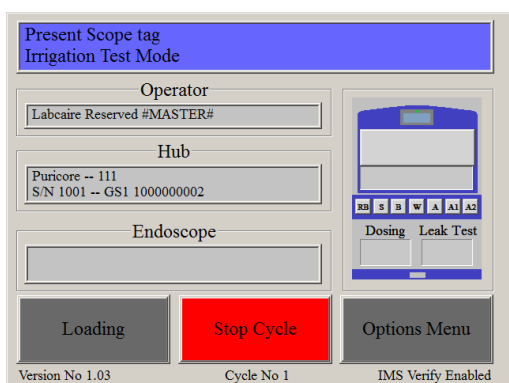
Present the Operator ID TAG to the TAG Reader. This identifies the operator as an approved user.

If the foot switch or load scope button is pressed then the operator will be asked to tag in or log on before proceeding.



NB: the operator DATA box now has the user ID displayed. This will be recorded for all information regarding this cleaning cycle.

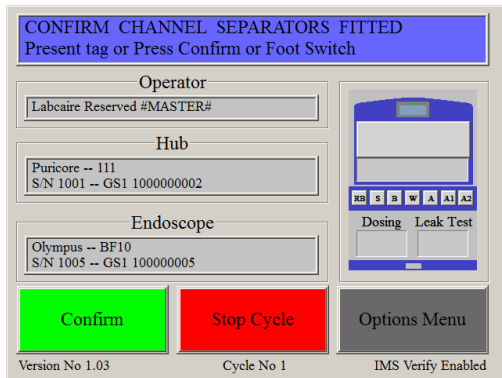
Present the operator ID tag or use the foot switch to open the door. Load the basket and endoscope in to the chamber and the use the tag reader wand to identify the hub.



The DATA boxes now have the user ID and the hub ID

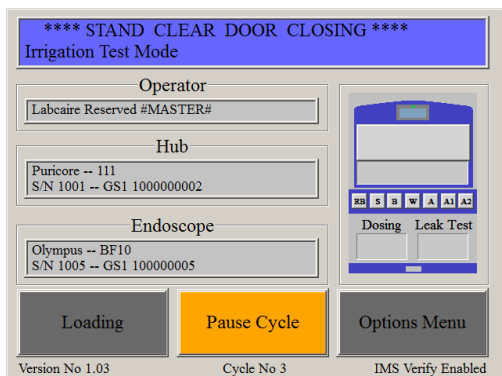
Use the tag reader wand to identify the endoscope.

The DATA boxes now have the user ID, the hub ID and the endoscope ID.



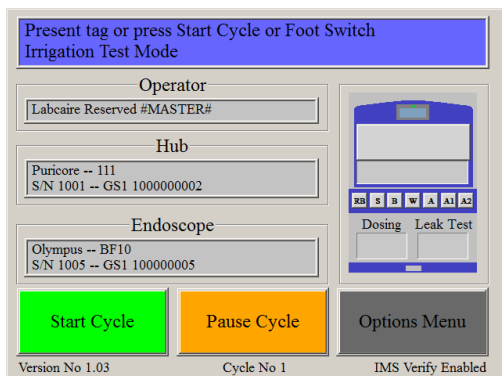
The operator will be asked to confirm if the channel separators have been fitted.

If separators are not required, still select Confirm.



On confirming the channel separators are fitted the door will close automatically.

Pause Cancel will allow the cycle to be stopped and return to the beginning of the load sequence.



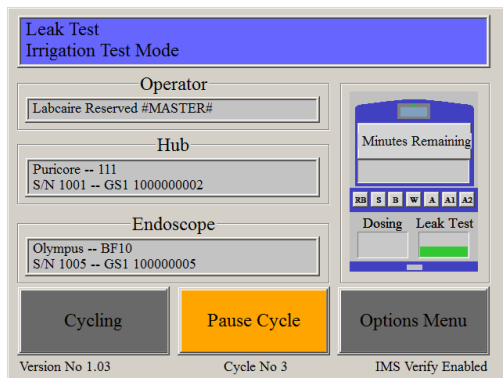
Press the green "START CYCLE" button on the left side of the touch screen, present the user tag to the tag reader or press the foot switch to start the cycle.

If a scope is loaded without presenting the Tag to the Tag Reader, the RAPIDAER machine will not let the software continue to the next stage.

This is achieved by means of the door not closing, until the endoscope Tag is presented to the Tag Reader.

Only then; will RAPIDAER allow you to continue to perform a wash cycle.

The RAPIDAER machine will automatically proceed with the leak test & cleaning cycles.



Firstly RAPIDAER performs an initial Leak Test.

At the same time it will prepare for the wash cycle.



The phase of the cycle is displayed in the blue box at the top of the screen

The duration of the cycle is displayed in minutes

The time remaining will count down in whole minutes

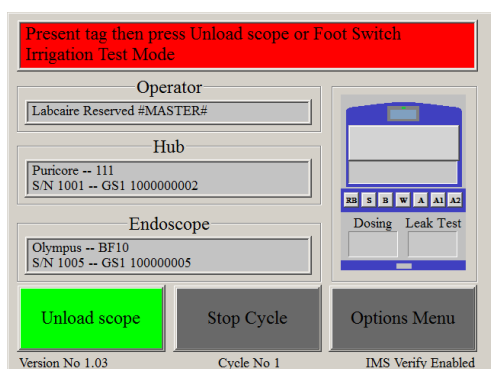
The final sequence of the cycle is the air purge which flushes the rinse water out the scope channels.

At the end of the process cycle RAPIDAER will inform you if the scope has passed or failed.

A failure will usually be indicated at the relevant point during the process cycle.

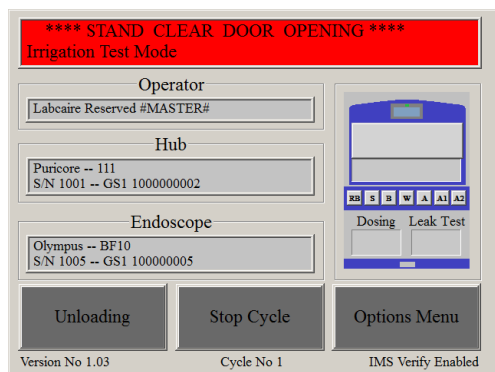
NB: Coloured buttons are active, press them to activate the function. Grey buttons are de-activated or display information only.

SCOPE PASS UNLOAD PROCESS



The Unload operator must use their ID tag to identify themselves to the RAPIDAER machine on the unload side.

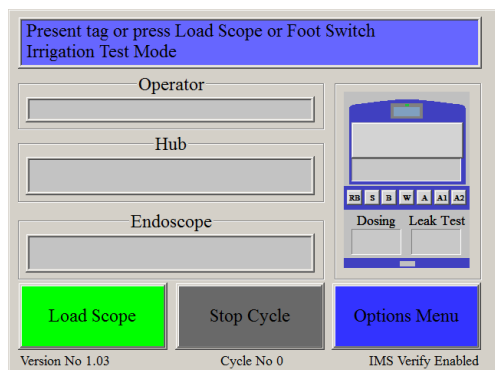
When the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.



The Un-load operator's ID will be recorded on the computer, and this information will be included on the print out, which appears on the clean side for the passed cycle.

When the door is open, remove the basket and endoscope.

Remove the cycle printout from the printer.



Close the door by using the operator ID tag or foot switch.

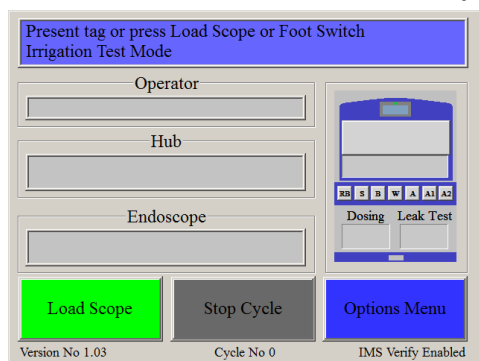
When the door is closed, the RAPIDAER returns to the HOME PAGE ready for loading to commence the next cycle.

Any scope that fails to pass all the criteria can only be removed from the "dirty side" Load side of the RAPIDAER machine.

The operator must present their Tag to the Tag reader to unload.

SCOPE FAIL UNLOAD PROCESS

The process to remove the endoscope from a failed cycle is the same as for a pass cycle except the Unload operator must use their ID tag to identify themselves on the load 'dirty' side of the machine.



Once the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.

The cycle printout will be given on the load 'dirty' side of the machine.

When the door is open, remove the basket and endoscope.

Close the door by using the operator ID tag or foot switch.

RAPIDAER will return to the HOME PAGE ready for loading to commence the next cycle.

Unload the endoscope from the basket and assess the problem from the data given before reprocessing the endoscope.



OPTIONS MENU

The options button allows various functions to be carried out by the user and for an administrator to use the 'Hospital Protocol' section to add endoscopes, operators and hubs to the data base.

Press the 'Options menu' button on the right hand side of the home page.

The 'Log In' screen will be displayed. Either present the operator tag to the tag reader or enter your user ID and PIN as covered on page 16

Options Menus

User Menu

Administration Menu

SELF DISINFECT:

The thermal self disinfect can be set to come on at a predetermined time so the process is completed before the machine is required for reprocessing the endoscopes used that day.

There is also a 'Start Now' button on this screen, so a self disinfect process can be started when ever required



OPENING DOORS:

To open a door when prompted to by the screen instruction, you will be required to present your operator TAG to the RAPIDAER machine or use the foot switch. The door will unlock and open automatically.

Should you wish to open the access door at other times, or if the operator is not in possession of their TAG. Then the operator will be required to access the OPTIONS menu in order to open the door.

To do this, the operator must first. Select the OPTIONS button on the HOME PAGE This will then take you to the options selection screen.

HOME PAGE - Press the OPTIONS button to select:

LOG ON - The operator should use either their ID tag or enter ID number and PIN.

Press the OPEN DOOR button.

The door will 'unlock', so that it can be opened.

RETRIEVING A SCOPE:

Should the operator need to retrieve a scope from the RAPIDAER machine, other than in the normal sequence of a wash cycle; then this can be achieved by the following steps.

Scope Failed message - Press the abort button.

Press the "Options" Button

OPTIONS" Log on Screen - Present TAG to the tag reader or Enter user ID number & PIN

Then press Log On to proceed

OPTIONS Menu

Press the "OPEN DOOR" button
This will open the Dirty Side door only.



OPENING THE CHEMICAL STORAGE DRAWER:

To access the chemicals, the operator must first press the GREEN OPTIONS button on the RAPIDAER computer screen. This will then take you to the options selection screen.

Press the OPTIONS button to select:

LOG ON OPTIONS MENU by the operator either using their ID TAG or manually not entering their ID number and PIN.

Now press the “OPEN CHEMICAL CHAMBER” button.

The drawer will unlock, and the operator can manually pull the door open.

NB: the air extract fan will operate to contain and remove any odours via the carbon filter.

Select the chemical to be added, detergent, Base or Activator by touching the screen to highlight the chemical to be changed.

Pass the chemical bottle, with the label side facing the tag reader, across the bottle tag reader and the new bottle batch number will appear in the new

chemical boxes. Press OK to confirm the data.

Put the chemical bottle in the drawer and then change the lid over to the pick up lid in the unit.

IF the tag reader or the bottle label does not activate the new number correctly the the number can be added manually.

Press the Batch number area by the 'new' section.

A screen will appear that allows the new batch number to be entered.

Similarly select the serial number and enter this in the same way.

Finally add the expiry date for the chemical in the date boxes.

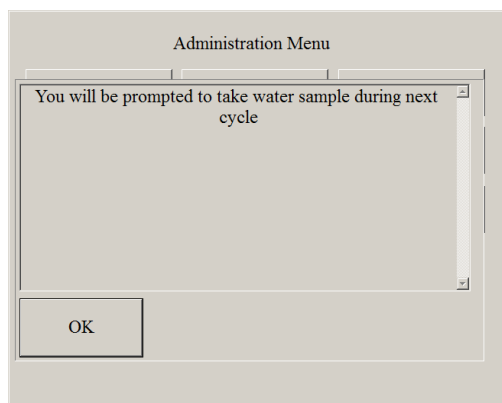


ACTIVATE FLUSH SYSTEM ROUTINE:

This facility flushes all the complete system and dosing pots so that they are at the correct status for a new cycle to be started. This facility should be used when the wash cycle has been interrupted and RAPIDAER is out of synchronisation.

WATER SAMPLE

This option can be selected to allow a prompt to be given when the last rinse is being done and the water sample should be taken.

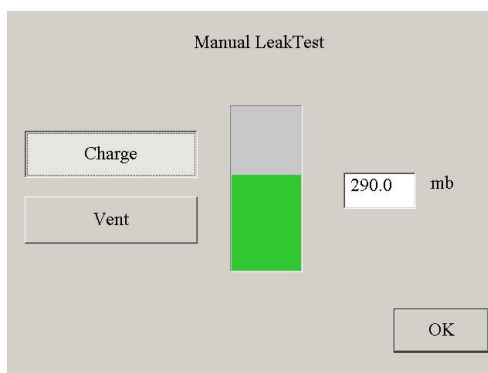


Select OK and the cycle will emit an alarm when the final rinse stage is reached in the next cycle.

ENGINEERING.

This button is not displayed in the normal user mode, it only becomes active when the engineer has a special USB key in the machine.

LEAK TEST:



In the event of a leak test failure, a manual leak test can be carried out in the machine. This will pressurise the scope to the required 290 mbar and by watching the screen any leak can be detected by the slow decrease of the pressure reading.



SET TIME

The date and time can be changed to the local time at the location of the unit.

Select the time and date on the UP/DOWN arrows and press save to confirm the new date and/or time.

PRINT CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

This function is in the Hospital Protocols for personnel with ADMIN access.

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

This function is in the Hospital Protocols for personnel with ADMIN access

HOSPITAL PROTOCOLS

These screens can only be accessed by users that have been given 'ADMIN' rights during the set up of the user's tag.

An operator with user access only will not be allowed to access the "Hospital Protocol" menus.

Functions within Hospital Protocols

Add a NEW operator/user
 EDIT an existing operator's details
 Assign a NEW scope ID
 EDIT an existing scope ID
 Add a NEW connector hub
 EDIT a connector hub
 Print a last cycle ticket
 Print a cycle report
 Print the last self disinfect cycle ticket
 Copy files



ADD A NEW USER

Press the “New Operator” button on the Screen

The operator ID is sequentially assigned by RapidAER automatically.
Every Operator will have a unique ID number.

To enter an operator name:
Touch the white text box

Touch screen type writer pad.

Input the new operator's name.

Then press OK.

The name will now appear in the white text box.

To enter the user PIN
Touch the White text box .

Touch screen number pad:
Type in the 4 digit PIN for the new operator according to your SOP.
(standard operating procedure) Then press OK!

The PIN will not be displayed on the screen
Only a symbolic representation, this is for security reasons.

It is recommended that you keep a record of the PIN elsewhere.

To assign a TAG, present the new TAG to the tag reader.



All the operator details are now installed and linked to the ID TAG.

Next assign access rights and press the 'Inactive' box to make the operator 'Active'.

Access Rights

To assign the new operators access capabilities; Press the relevant Description to tick the boxes.

Then press OK:

Access Rights:

For basic machine operation access:- tick the User box

For access to set up new scopes, users or hubs or copy data files:- tick the Admin box.

The Admin access automatically gives an operator user rights to run a cycle.

The New Operator is now installed into the RapidAER computer.

EDIT AN EXISTING USER'S DETAILS

Press the "Edit User" button on Screen

Select the operator to be edited by touching the operators name on the screen.

Then press edit operator

The operator details will be displayed.

Select and modify their Access Rights, or re-assign a new Tag.

Then press OK.

The edit function is now complete.



ADD A NEW CONNECTION HUB ID

Press the 'Add Hub' button on the Menu screen

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

The complete hub list will appear

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

Select the hub to be added

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be added

Press OK

Max Flows

Suction 1800

Biopsy 0

Water 0

Air 0

Aux 1 0

Aux 2 1800

RB Min Pres 0

Make CANCEL

Model RAH008

Dept

Serial No

GS1

Tag

Adding Hub Type RAH008

OK Cancel

To add the information touch the white box adjacent to 'Dept'.

Endoscopy

q w e r t y u i o p

a s d f g h j k l

z x c v b n m

Number Space Delete

Shift - \

Clear . @

Enter Department

OK Cancel

Type in the department name and Press OK



Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	
Air	0	GS1	
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Next add the serial number that is on the new hub serial number plate. (Each hub has its own serial number so individual hubs of the same type number can be identified.)

Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	012345
Air	0	GS1	334
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Complete the data by selecting each box and typing in the data.

Finally present the tag fixed onto the hub to the tag reader to add this data.

Press OK to save the new hub data.

NOTE The max. Flow values on the right side of the screen give the disconnect alarm and cannot be altered. Any changes that are required to these flows must be made by a Cantel Medical engineer after testing the hub with the respective endoscope.

This new connector hub can now be used in the RapidAER machine.

EDIT AN EXISTING HUB ID

Press the 'Edit Hub' button on the screen. This allows a hub to be edited and assigned to another department or for a hub to be deleted from the hub list in the RapidAER computer.

RA002 S/N 1008 RA017 S/N 1011 RA020 S/N 1012 RA022 S/N 1013 RA038 S/N DSFS	<input type="button" value="Delete"/>
<input type="button" value="Select Hub to Edit"/>	<input type="button" value="OK"/> <input type="button" value="Cancel"/>

The list of connection hubs that have been stored in your RapidAER machine will be displayed

A hub can now be edited or deleted



Select the hub by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be edited

Press OK if hub to be edited

The Hub information page will appear.

Now make your alterations as per the “add new hub” procedures, selecting any of the data that has a white box and changing as necessary.

Then press OK to Save the new data.

If the hub is no longer to be used then the delete button can be selected after the hub has been selected in the hub list displayed in the edit scope process as above.

Select ‘Yes’ and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

To exit this process then press ‘Cancel’

ADD A NEW ENDOSCOPE ID

Press the “Add Scope” button on the Menu Screen

The Scope Information page will appear. Now fill-in the boxes in sequence.

Press the “Make” box on the touch screen



Olympus

q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
z	x	c	v	b	n	m			

Number	Space	Delete
Shift	- \	Enter Manufacturer
Clear	~	
	@	OK Cancel

The key pad will appear.

Enter the manufacturer of the scope eg. Olympus, Pentax , Storz etc

Then press the OK button to enter the data.

Min Flows		Make	Olympus
Suction	100	Model	
Biopsy	100	Dept	
Water	50	Serial No	
Air	50	GS1	
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK	Cancel

Press the “Model” box on the touch screen

Gastroscope

q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
z	x	c	v	b	n	m			

Number	Space	Delete
Shift	- \	Enter Model
Clear	~	
	@	OK Cancel

The key pad will appear.

Enter the model of the scope eg. Gastroscope, Broncoscope etc

Then press the OK button to enter the data.

Continue to add the Department, Serial number, GS1 number if known in the same way as the Make and Model, typing in the data and pressing OK after each entry.

Min Flows		Make	Olympus
Suction	100	Model	Gastroscope
Biopsy	100	Dept	Endoscopy
Water	50	Serial No	GIF1246789
Air	50	GS1	F234
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK	Cancel

To complete the new endoscope entry present the scope tag to the tag reader to assign that tag to the data entered.

The tag data will be entered in the tag box.

Press OK to save the data to the RapidAER data base.

This new scope can now be re-processed using the RapidAER machine.



EDIT AN EXISTING SCOPE ID

Press the 'Edit Scope' button on the screen. This allows a tag to be edited and assigned to another scope or for a scope to be deleted from the endoscope list in the RapidAER computer.

The list of scopes that have been allocated by the user which are stored in your RapidAER machine will be displayed

A scope can now be edited or deleted

Select the scope by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the scope that is to be edited

Press OK if scope to be edited

The Scope information page will appear.

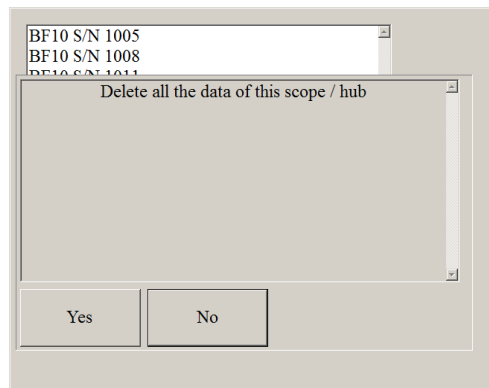
Now make your alterations as per the "add new scope" procedures, selecting any of the data and changing as necessary.

Then press OK to Save the new data.

Whenever this scope is re-processed in the RapidAER machine the new details will be logged and recorded.



If the endoscope is no longer to be reprocessed then the delete button can be selected after the endoscope has been selected in the endoscope list displayed in the edit scope process as above.



Select 'Yes' and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

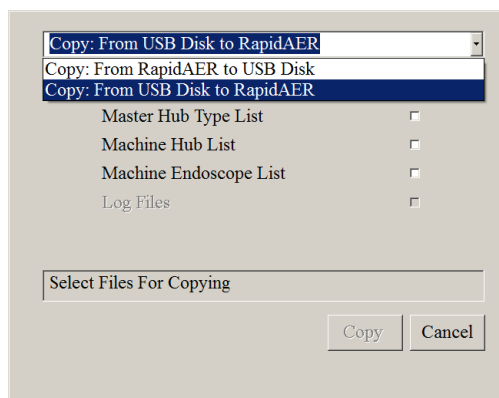
To exit this process then press 'Cancel'

Select 'No' and the screen returns to the scope list with endoscope still visible.

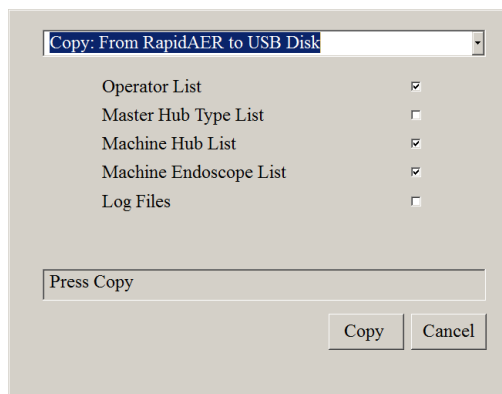
To exit this process then press 'Cancel'

COPY FILES

This button allows files to be copied onto the RapidAER computer or copied from the RapidAER computer. This allows the operator, endoscope, and department hub lists to be copied from machine to machine so data only has to be entered once.



From the arrow along side the top box select if files are to be copied onto the RapidAER from a USB key or whether files are to be copied from the RapidAER onto a USB key.



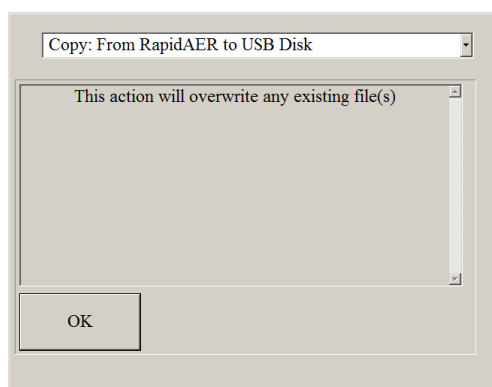
So to copy files from machine to machine after adding new operators, endoscopes or hubs

Select From RapidAER to USB disc

Tick the files to be copied – Operator list, machine hub list or machine endoscope list

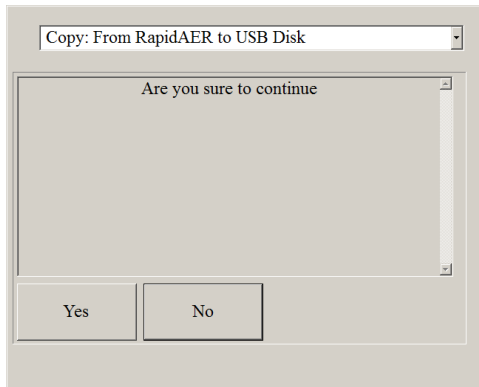
Note: Log Files can only be copied from the RapidAER to the USB Drive

Press 'Copy'

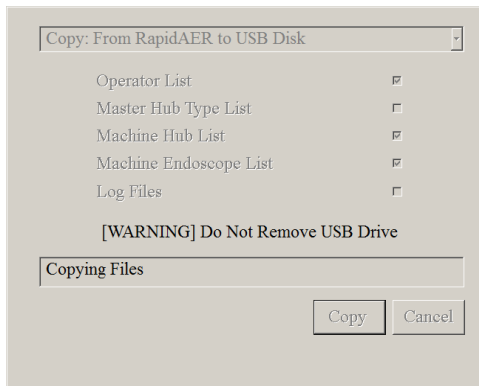


A message will appear to alert the operator that any files on the USB disc with the same name will be overwritten.

Select OK to acknowledge the message

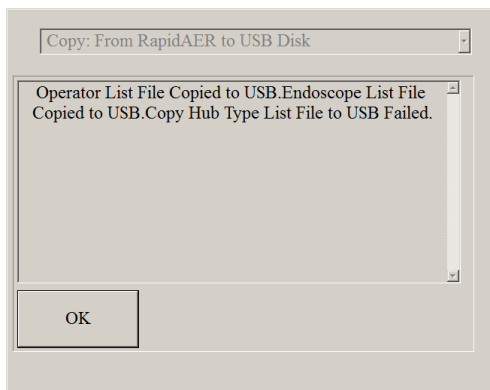


Press 'Yes' to continue the transfer or 'No' to exit



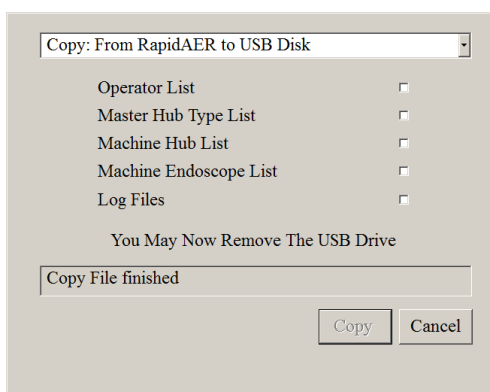
The files are now being copied.

Do not remove the USB drive



The screen indicates that the files have been copied or that a list has failed to copy.

Press OK



The final screen informs the operator that the copy file instruction is complete and the USB drive can be removed.

Press cancel to exit

To copy the files from the USB Drive to the next RapidaER machine, insert the USB drive in the slot adjacent to the screen on the dirty side of the machine. Go to Hospital Protocols and select 'Copy Files' follow the same process as above but initially select 'Copy: From USB Disk to RapidaER'



LOG FILES

These can be selected to be copied onto the USB drive as the above process and they can then be downloaded onto a hospital computer for analysis.

PRINT CYCLE REPORT

This will print a detailed report of the cycle that has just been completed. For more information see Printouts.

PRINT LAST CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

AUDIBLE ALARMS

INFORMATION ALARM:

When the RAPIDAER machine has completed the endoscope cleaning cycle, it will emit a single beep audible alarm, to indicate that the machine is ready for unloading

WARNING ALARMS:

When ever there is a visual warning alarm on the computer screen, the RAPIDAER machine will also emit a continuous audible alarm.

To stop this audible alarm, the operator needs to accept / acknowledge the visual alarm on the computer screen, by responding to the computer instruction or prompt.

POWER INTERRUPTION:

If the power source to the RAPIDAER is interrupted, the volt free contacts will enable a remote signal to indicate an alarm.

If the power supply to RAPIDAER is interrupted, then the RAPIDAER machine will need to be manually switched on, using the green button, on the front of the machine.



However if the RAPIDAER machine was performing a wash cycle when the power was interrupted; then, when the power is re-connected, the RAPIDAER machine will emit an audible alarm, linked with the wash cycle fail indication on the computer screen.

REMOTE ALARMS:

When ever there is a major alarm on the RAPIDAER machine, that would require immediate attention, eg: water leakage, power failure, self disinfect chemical bottles empty. Then the alarm will be duplicated via the volt free contacts, which will active either a visual or audible alarm in a remote location of the hospitals choosing. Eg: estate dept, BMS room, RAPIDAER managers office.



DATA SYSTEMS

The RAPIDAER AER machine has data storage and retrieval options for various types of data.

LOG DATA:

This is the cycle log record for every wash cycle and scope that has been processed in the RAPIDAER AER machine.

This data can be downloaded on to a USB key for achieving or the machine can be networked and the data transferred every cycle.

IMS:

(Independent Monitoring System)

This is a separate measuring system to confirm that the wash cycle parameters are within the tolerance that is required.

There are two levels of data retrieval obtainable through this system.

Level 1:- Process cycle history in an excel.csv spread sheet format.

Level 2:- the Full IMS data screen which will require the Cantel Medical IMS.net software package

Operator Data:

This is a history of every operator (present and previous) that has had access to the RAPIDAER machine.

Connector Hub Data:

This is a record of every connector hub present & previous that has been ID logged into the RAPIDAER AER machine, including the hub number, serial number and TAG ID.

Endoscope Data:

This is a record of every scope present & previous that has been ID logged into the RAPIDAER AER machine, including the make, model, serial number and TAG ID.



DATA STORAGE:

The RAPIDAER onboard computer has the capacity to store a large volume of information.

The memory allocated to cycle DATA storage will be able to store 250,000 wash cycles of information.

The information stored is formatted on an excel spread sheet, so that DATA retrieval is user friendly in both operator programme knowledge, and also in computer software compatibility.

The DATA storage format contains a heading with:

- The Department identification,
- The RAPIDAER machine serial number,
- The software version number.

DATA Storage Topic Headings:

- Date:
- Time:
- Pass / fail
- SD date
- SD time
- SD No:
- Operator ID
- Operator Name
- Un-load Operator ID
- Un-load Operator Name
- Contact time (seconds)
- Scope ID
- Manufacturer
- Model
- Serial Number
- Department
- Leak Test
- Raiser Bridge
- Channels Irrigated
- Comments
- Cycle Name
- Leak Test
- Number of Faults
- Reason Code
- Reason.



PRINTOUTS

The RAPIDAER provides a “hard copy” printout for the process that has been performed. This is in addition to the DATA being stored on the RAPIDAER computer which can be retrieval via a USB key or by direct connection to a Track and Trace system.

There are five label printout configurations:

Cycle Complete	= When a wash cycle has been completed.
Cycle terminated	= When a wash cycle has automatically stopped.
Cycle terminated	= When a wash cycle has been manually stopped
Test Label	= Engineer access only
Detailed Process Report	= RAPIDAER Hospital Protocol access required

The printers are located on the front of the machine:

On a pass through machine there will be a print out on the “clean side” (un-load side) for a ‘pass’ cycle and on the ‘dirty side’ (loading side) for a ‘failed’ cycle.

Below are example labels that depict the type of information that will be presented on the printouts



CYCLE COMPLETE 'PASS' PRINTOUT

(-----)	
(-----)	
(--Wash Cycle Pass --)	Cycle Pass/ Fail identification
(-----)	
(Cantel RapidAER)	
(Serial No RA0009)	RapidAER serial number
(-----)	
(Start 09h 44m)	Cycle start time:
(End 10h 02m)	Cycle finish time:
(Date 20-10-2014)	Date
(-----)	
(Cycle No. 52)	Unique sequential cycle number
(-----)	
(Load Operator 1)	
(Name Paul)	Loading operator identification
(-----)	
(Unload Operator 1)	
(Name Paul)	Un-Loading operator identification
(-----)	
(--Hub-----)	
(Cantel A3 Testroom)	Connection Hub used for the process
(Serial No 1)	
(GS1 1)	
(-----)	
(--Endoscope--)	
(Olympus Gastroscope)	Scope ID – including Make & Model
(Serial No GIFH260)	Serial No & GS1 No
(GS1 1)	
(-----)	
(IMS Verify Enabled)	IMS Status
(-----)	
(Control Pass)	Status of IMS & Control system at end of cycle
(IMS Verify Pass)	Pass confirmation
(-----)	
(Contact Time 5minutes)	Disinfectant Contact Time
(-----)	
(Last SD 20-10-2014 at 06h 00m)	RapidAER self disinfect information.
(-----)	
(Suction Av Flow 2185ml)	
(Biopsy Av Flow 1775ml)	
(Water Av Flow 120ml)	Average Flows in each of the channels during the
(Air Av Flow 85ml)	process including Raiser Bridge & Leak Test
(Aux 1 Av Flow 400ml)	Pressures
(Aux 2 Av Flow 900ml)	
(RB Av Pres 3850mb)	
(Leak Test Av Pres 300mb)	
(-----)	
(---Conductivity---)	
(Detergent 764µs)	Conductivity of each phase of the cycle
(Disinfectant 1150 µs)	
(Final Rinse 35 µs)	
(-----)	
(---Temperature---)	
(Detergent 25.1 deg)	Temperature of each phase of the cycle
(Disinfectant 26.1 deg)	
(Final Rinse 24.9 deg)	
(-----)	
(Chemical Batch/serial No)	
(Detergent D412/1134)	Chemical Batch / Serial numbers of each of the
(Part B B3321/889)	chemicals used for the process
(Part A A6543/996)	
(-----)	



CYCLE COMPLETE 'FAIL' PRINTOUT

There are two types of 'Fail' cycle and this is when the control or IMS system do the cycle checks and one or more parameters are outside the range allowed. The second failure is a manual abort by an operator. An example of each is given below.

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       10h 40m     )
( End         11h 02m     )
( Date        20-10-2014  )
(-----)
( Cycle No.   53          )
(-----)
( Load Operator 1      )
( Name         Paul      )
(-----)
( Unload Operator 1     )
( Name         Paul      )
(-----)
(  --Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled    )
(-----)
( Control      Fail       )
( IMS Verify   Fail       )
(-----)
( Fault: 9044 Manual Abort (dis wash) )
( Fault: 9045 IMS: RB Flow duration   )
( Fault: 9024 IMS Aux 1 Low flow (0)   )
(           (dis wash)                )
( Fault: 9049 IMS conductivity        )
(           (dis wash)                )
(-----)
```

Cycle Pass/ Fail identification

RapidAER serial number

Cycle start time:

Cycle finish time:

Date

Unique sequential cycle number

Loading operator identification

Un-Loading operator identification

Connection Hub used for the process

Scope ID – including Make & Model
Serial No & GS1 No

IMS Status

Status of IMS & Control system at end
of cycle

Fault codes – reason for failure

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       11h 24m     )
( End         11h 42m     )
( Date        20-10-2014  )
(-----)
( Cycle No.   54          )
(-----)
( Load Operator 1      )
( Name         Paul      )
(-----)
( Unload Operator 1     )
( Name         Paul      )
(-----)
(  --Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled    )
(-----)
( Control      Pass       )
( IMS Verify   Fail       )
(-----)
( Fault: 9048 IMS Irr temp 180.1 C     )
(           (Leak Test)                )
( Fault: 9048 IMS Irr temp 600.6 C     )
(           (Gross Wash)               )
( Fault: 9048 IMS Irr temp 600.6 C     )
(           (DetWash)                  )
( Fault: 9048 IMS Irr temp 600.6 C     )
(           (DetRinse)                 )
( Fault: 3035 IMS Irrigation temp      )
(           sensor fault (6006)        )
(-----)
```



CYCLE PRINTOUTS FOR SELF DISINFECT

There are two printouts for Self Disinfect Cycle Pass and Cycle Fail. Examples are both are shown below.

```
(-----)
(-----)
(  -Self Disinfect Passed--  )
(-----)
( Cantel      RapidAER      )
( Serial No   RA0009       )
(-----)
( Start       07h 29m      )
( End         08h 31m      )
( Date        20-10-2014   )
(-----)
( Cycle No.   11           )
(-----)
( Operator    1             )
( Name        Paul         )
(-----)
( Unload Operator 1       )
( Name        Paul         )
(-----)
( IMS Verify  Enabled     )
(-----)
( Control     Pass         )
( IMS Verify  Pass        )
(-----)
( Temp Stage 1 86.1deg     )
( Temp Stage 1 85.1deg     )
( Temp Stage 1 85.5deg     )
( Contact Time 10          )
(-----)
```

```
(-----)
(-----)
(  -Self Disinfect Failed ----  )
(-----)
( Cantel      RapidAER      )
( Serial No   RA0009       )
(-----)
( Start       07h 59m      )
( End         09h 14m      )
( Date        21-10-2014   )
(-----)
( Cycle No.   7            )
(-----)
( Operator    1             )
( Name        Paul         )
(-----)
( Unload Operator 1       )
( Name        Paul         )
(-----)
( IMS Verify  Enabled     )
(-----)
( Control     Fail         )
( IMS Verify  Fail        )
(-----)
( Fault: 9053 Spray system running )
( with empty sump (Recirc stage 2) )
( Fault: 9048 IMS Circ temp 64.5 C )
( (Recirc stage 2) )
( Fault: 9048 IMS Temp Su 63.7 C )
( (Recirc stage 2) )
(-----)
```



CHANGING PRINTER PAPER:

The printer is located as shown in the “Find your way around RAPIDAER” diagrams



The printers are located on the right hand side just below the chamber on both sides of the machine.



To access the paper roll,
Press the GREEN button on the top of the printer and the paper holder falls open.



To input a new paper roll, simply place the replacement paper roll into the printer as shown with the feed off section to the top, pull some paper forward, to create a tongue.



Push the paper holder closed, and tear off the excess paper against the serrated edge.

RAPIDAER printer is now ready for use.



To feed paper forward from the roll, press the button on the RIGHT.



ESSENTIAL OPERATING PRACTICES.

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

To ensure endoscopes are correctly disinfected it is important the following points are observed.

1. The machine thermal self-disinfection is carried out each day, before use.
2. The disinfectant contact parameter times are pre-programmed into the machine. The soak times must be determined by the manufacturer of the disinfectant and the Hospital Infection Control Department.
(Please refer to the tables in the "Disinfectant Types" section)
3. The manufacturer's instructions on the manual pre-cleaning, machine cleaning and disinfection of endoscopes must be followed at all times. The efficiency of the process depends on an efficient pre-clean and brushing through of the internal channels prior to disinfection.
4. It is most important that the endoscope internal channels are disinfected. The quality of the rinse water should be monitored at routine intervals.
5. The RAPIDAER must not be positioned within a risk area of anaesthetic equipment.

HOSPITAL PROTOCOLS:

Within the HOSPITAL PROTOCOL Menu, the user access protected CYCLE & SELF DISINFECT Menus allows for the defining of the following operational criteria:

RAPIDAER Hospital Protocol Menu
<i>Set & Edit Operator ID</i>
<i>Set & Edit Connection Hub ID</i>
<i>Set & Edit Endoscope ID</i>
<i>Copy Files</i>
<i>Reprint last cycle data</i>
<i>Reprint last self Disinfect cycle data</i>
<i>Print a detailed cycle report</i>



DISINFECTANT WARNINGS:

Disinfectants are hazardous substances and controlled by COSHH Regulations. Manufacturers must supply Safety Hazard Data Sheets to cover the use of their products.

The following Points should also be considered for use in this application.

1. Personal protection equipment should be worn when handling disinfectants or endoscopes. Suitable gloves, eye / face protection and apron.
2. The opening of disinfectants and closing of empty containers should be carried out, inside a suitable ventilated area.
3. The hospital should establish a procedure for safe storage, handling and disposal of disinfectant containers.
4. The hospital should establish a procedure for accidental spillage.
5. The RAPIDAER will provide a safe system for transfer of disinfectant to the chamber, during processing and disposal of used disinfectant. However, attention should be given to the room environment (ventilation) etc. see installation drawings. Correct ventilation will minimise problems if a spillage occurs.
6. The carbon filter should be changed every year to keep emissions below exposure limits.
7. Any disinfection contact should be washed off immediately and referred for medical attention.



DISINFECTANT TYPES:

The machine is compatible with two Peracetic Acid, single use disinfectants, for use on endoscopes, but the following points must be observed (see table below).

- A. The manufacturer of the Endoscope should be contacted for advice on chemical compatibility. Warrantees may only be valid on approved disinfectants.
- B. The Hospital Protocol and disinfection soak time should be approved by the disinfectant manufacturer and the Hospital Infection Control Department.
- C. Disinfectants activated with powders should not be used in RAPIDAER.
- D. Silicone based de-foamers should not be used in RAPIDAER.

DISINFECTANT NAME	DISINFECTANT TYPE	CARBON FILTER TYPE
Rapicide PA	single use peracetic acid	ACI
Purisept	single use peracetic acid	ACI

DISINFECTANT CONTACT TIME PARAMETERS		
disinfectant name	specific scopes	contact time
Rapicide	all	5 minutes
Purisept	all	5 minutes



DISINFECTION OF SCOPES:

CONNECTION OF ENDOSCOPES TO IRRIGATION CHANNELS:

Connection of the Endoscope to the irrigation lines is a critical procedure and as such great care must be taken to ensure correct connection. Connector hubs are available from Cantel Medical (UK) Ltd for each of the main types of the endoscope.

These connectors ensure that each channel is separated fully and therefore irrigated completely. Liquid is pumped into the endoscope from the light source end and passes completely through the length of the endoscope in a single motion.

It is essential that all channels are securely connected to prevent a cycle failure occurring.

RAPIDAER will remind the operator as part of the sequential screen prompts to check that channel separators have been installed.

NB: Certain scopes need to be sterilised after washing in an AER (Automated Endoscope Re-processor). The RAPIDAER AER should not be used as a replacement for sterilisation.

ENDOSCOPE STORAGE AFTER DISINFECTION PROCESS

Note:

Following the automatic disinfection cycle, the endoscope should be dried prior to long term storage, and can be hung directly into a Puricore Endoscope Drying Cabinet where the drying process will be carried out automatically, using dry compressed air, prior to longer storage of the endoscope in the clean environment of the cabinet. Alternatively the endoscope should be dried according to the endoscope manufacturer's protocol.



EU REGULATIONS:

Medical Devices Directive 93/42/EEC

Chemical Washer Disinfectors are a Class 2b medical device and the design, manufacture, installation and service are controlled under this directive. See Compliance for details of Puricore's accreditation.

Chemical Hazards - COSHH Regulations

Disinfectants are hazardous chemicals and it is necessary to perform a risk assessment covering all stages of use. The manufacturer of the disinfectant will supply Safety Hazard Data Sheets for their products.

See section on Disinfectant Types and Disinfectant Warnings.

The RAPIDAER should be tested at least every fourteen months to comply with this regulation.

BIOLOGICAL HAZARDS:

There is a risk to staff and patients from endoscopic procedures. The hospital should have its own procedures to control risk at each stage of the process.

TRAINING:

All staff using the RAPIDAER should be fully trained and certified on the use of the equipment.

Puricore Clinical Nurse Advisors will provide training sessions at each RAPIDAER installation, for the training and certification of operators and management staff.

Please contact Puricore for further details of training and availability.

VALIDATION:

The Autoscope RAPIDAER is manufactured to comply with BS EN 15883 Pt 1 & Pt 4, CFPP 01-06 and SHTM 2030. It should be fully validated according to table C1 of the BS EN 15883 Pt 1 & Pt 4 at the time of installation, followed by quarterly and annual re-validations.

COMPLIANCE:

Medical Devices Directive 93/42/EEC

Puricore International Ltd is approved to ISO 13485:2003 to design, manufacture and install chemical washer disinfectors.

Puricore International Ltd is approved to ISO 9001/EN46001 to service chemical washer disinfectors.

CE Marking

CE marking is applied to medical devices under Medical Devices Directive 93/42/EEC.



DECLARATION OF CONFORMITY



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Medical Device Directive Essential Requirements Checklist Declaration of Conformity

Description of Device
Product(s):

RapidAER

Assessment of Product based upon:

Certification of Quality System

Certificate No: LRQ 0954199/A
Issued by: LRQA

Date: 01/12/11

Essential Requirements Checklist

Prepared by: Regulatory Affairs

Date: 10/02/14

Technical File

Prepared by: Regulatory Affairs
Document number

Date: 10/02/14
2G-011

Product Classification:

Determine product classification based upon the requirements in MDD and Medical Devices Regulations 2002:

☐ Class I ☒ Class IIb ☐ Class III

Approvals:

Based on a review of the above documents, we hereby declare that the above products comply with the following EC directives:

- Medical Devices Directive 93/42/EEC as amended by 2007/47/EC
- Electro Magnetic Compatibility Directive 2004/108/EC
- Low Voltage Directive 2006/95/EC
- Machinery Directive 2006/42/EC
- Waste Electrical and Electronic Equipment Directive 2002/95/EC
- BS EN ISO 15883-1:2009
- BS EN ISO 15883-4:2009

Approved By: Neil Blewitt
Managing Director

Signature: _____

Date: _____

8th July 2014



Recommended actions to be taken for

"PERACETIC ACID" SPILLAGE

1. Evacuate the area.
2. Seal off the area to non-essential staff.
3. Put on protective clothing outside the affected area (boots, gown, apron, nitrile gloves, respirator face mask, goggles – NOT visors,).
4. On entry into the affected area – open all available windows (ie ventilate area) BUT DO NOT leave a door open into a corridor.
5. If it is a concentrate solution, absorb the excess with an inert material such as sand.
6. Put the contaminated sand into the disposal bag and seal tightly. Place this into a second disposal bag and seal tightly again. Contact your disposal company to collect it.
7. If it is a diluted solution or a small volume of concentrate, Dilute the solution with copious amounts of water and flush to drain.
8. Wash the floor area thoroughly with water.
9. Clean off boot soles before leaving the area.
10. Change any clothing that may have come into contact with the chemicals.



CONSUMABLES:

Description	Part No	Delivery lead time
1. Air Extract Carbon Filter	IS-LA 7014	5 Days
2. Printer Rolls (Pack of 20)	IS 795732	5 Days
3. Mediclean Plus Detergent (2 x 5 litre bottles)	900540	5 Days
4. Rapicide Disinfectant Part A	900530	5 Days
Rapicide Disinfectant Part B	900531	5 Days
5. Autowipes Disinfectant Wipes (6 x 200 wipe drums)	900505	5 Days



GENERAL CARE:

RAPIDAER is manufactured in the UK from quality materials, however any machine benefits from care and attention.

The exterior of RAPIDAER is manufactured from epoxy powder coated steel and polyurethane moulded panels. The use of abrasive cleaning agents should always be avoided. It is recommended that a warm soapy solution, or mild, diluted cleaning disinfectant is used.

The process chamber is manufactured from stainless steel with a smooth mirror finish. Gouges and scratches will enable biofilm and thus promote bug growth. Care should be taken at all times not to damage the surface finish of your process chamber.

ACTIVATED CARBON AIR FILTRATION

When the chemical drawer is opened, the airflow fan will operate creating a negative pressure in the drawer which helps prevent any fumes from escaping towards the operator.

The exhaust air from the chemical drawer is filtered at the point of discharge from the bottom of the machine, through an activated carbon filter.

This filter should be tested at each service visit, and should be changed at least every 12 months, or sooner if required.

This filter is located in the base of the RAPIDAER machine, together with the air flow fan.

NB: The carbon filter must be changed every 12 months.

NB:
TO ENSURE THAT THE AIR AND CARBON FILTERS ARE FITTED CORRECTLY,
THEY SHOULD ALWAYS BE INSTALLED BY A QUALIFIED ENGINEER.



ROUTINE MAINTENANCE:

RAPIDAER should be regularly maintained. Once the new equipment has been installed, commissioned and certified by a qualified Test Person (TP), you should adhere to the recommended service intervals.

Engineer visits = 2 per year at six monthly intervals, these consist of:

1 annual ~ Regular service every 52 weeks.

1 six monthly ~ Routine engineer inspections, every 26 weeks:

In between engineer visits, it is the responsibility of the user to ensure that the RAPIDAER machine is kept in the correct working status.

Regular water samples should be tested, and the water filters changed as required. The frequency for changing the wall mounted water filters will be site dependant, and will vary according to the supply water quality.



MACHINE SELF DISINFECTION:

The reason for self disinfect is to prevent the development of biofilm and micro-organisms, whilst the machine is not processing scopes

The self disinfect cycle is a thermal process, and will happen automatically during the night at the preselected time. There is also a self disinfect button in the options menu should it be necessary to carry out a self disinfect cycle at any other time.

The self disinfect process will be disabled when the RAPIDAER machine is used for any purpose whatsoever, or is not left in the start screen at the end of the day.

If the RAPIDAER is not used following the completion of the self disinfect protocol, it will repeat the above procedure the next night at the selected time.

Note:

It is important to ensure that no endoscope has been left in the machine at the end of the day and the start screen is displayed.

NB: during installation, some customers will require that all test results are returned prior to the RAPIDAER AER machine being used with endoscopes.

This will preclude the user training from taking place until these results are collated, which could take several weeks.

During such a period as this, the RAPIDAER machine will be set up to run self disinfect schedules over night to maintain the cleanliness of the machine.



CHEMICAL STORAGE DRAWER:

The chemical drawer is located on the dirty side (Load side) of the RAPIDAER machine.

Handles are fitted to allow you to open the chamber drawer.

You should always clean up any spillages caused during the changing or loading of Chemical bottles immediately.

CHANGING CHEMICALS:

When a chemical storage bottle is empty, the RAPIDAER computer screen will show a pop up warning box to tell the operator that a chemical bottle needs to be changed.

There will also be an audible alarm sounding, and the wash cycle “if in progress” will pause.

To change the bottles: First open the storage drawer , undo the cap and remove from the bottle.

Lift out the empty bottle. Ensure the replacement bottle is the same chemical.

Scan the data on the RFID tag on the front label of the new bottle, this will insert the lot number of the chemical, the expiry date and the serial number of the bottle.

Loosen the cap on the bottle with a bottle spanner and then put the bottle in the drawer.

Remove the cap on the bottle and replace with the pick-up cap.

Do the cap up tightly and closed the chemical drawer.

If a wash cycle was in progress when the bottle was changed, the operator should press the continue button in the pop up window to continue with the wash cycle.



DOOR LOCK – MANUAL OVERRIDE:

The door is actuated and held in position by air pressure and an electrical door lock, so no access can be gained during a cycle.

In the event of a power failure, the air pressure vessel will automatically empty, the door lock will release to the open position and thus the door can be manually pushed open to access any endoscope that may be in the chamber.



WATER SAMPLE PROTOCOL

RAPIDAER IS SAMPLED DURING THE FINAL RINSE AS THE SAMPLE PORT IS IN THE FEED TO THE CHAMBER. THE SAMPLE TAKEN SHOULD BE A MINIMUM OF 250MLS

1. PREPARE NECESSARY EQUIPMENT NEEDED I.E.: STERILE GLOVES, STERILE WATER SAMPLING BOTTLE, ALCOHOL WIPES AND RELEVANT LABORATORY FORM.
2. PREPARE RAPIDAER SAMPLE PORT BY RUNNING OFF 20MLS OF DISINFECTANT DURING THE DISINFECTANT PHASE OF THE CYCLE. WEARING PPE (MASK AND GLOVES), REMOVE THE BLUE PROTECTOR FROM THE END OF THE SAMPLE PORT, OPEN THE SCREW KNOB, ALLOW THE DISINFECTANT TO RUN OUT AND THEN CLOSE THE SAMPLE KNOB. DISCARD THE DISINFECTANT DOWN THE DRAIN AND RINSE CONTAINER.
3. WIPE DOWN WORK AREA WITH ALCOHOL WIPE, AND OPEN PACKET OF STERILE GLOVES. IN ADDITION, OPEN ANOTHER ALCOHOL WIPE AND DROP ONTO GLOVES. TAKE LID OFF SAMPLE CONTAINER.
4. WASH HANDS WITH HIBISCRUB OR EQUIVALENT E.G.: BETADINE SCRUB.
5. PUT ON GLOVES USING ASEPTIC TECHNIQUE AND KEEP HANDS ABOVE WAIST LEVEL AND AWAY FROM THE BODY
6. WHEN THE FINAL RINSE IS STARTED, TAKE AN ALCOHOL WIPE AND WIPE THE SAMPLE OUTLET .
7. DURING THIS RINSE, OPEN THE SAMPLE KNOB AND ALLOW AT LEAST 50MLS TO RUN INTO A WASTE CONTAINERS, THEN TAKE THE STERILE BOTTLE AND PLACE GENTLY UNDER THE SAMPLE OUTLET AND FILL THE SAMPLE BOTTLE. CLOSE THE SAMPLE KNOB AND FIT THE BLUE PROTECTOR.
8. PLACE LID ON BOTTLE, AND DRY THE OUTSIDE.
9. FILL IN THE LABEL AND ATTACH TO THE BOTTLE.
10. FILL OUT THE APPROPRIATE FORM GIVING DETAILS OF SAMPLE SOURCE, TIME AND DATE ETC. AND SEND AS SOON AS POSSIBLE TO THE LABORATORY.
11. FILL OUT THE RAPIDAER WEEKLY VALIDATION TEST LOG, WITH THE RELEVANT DETAILS.

ASEPTIC TECHNIQUE MUST BE USED WHEN OBTAINING A WATER SAMPLE



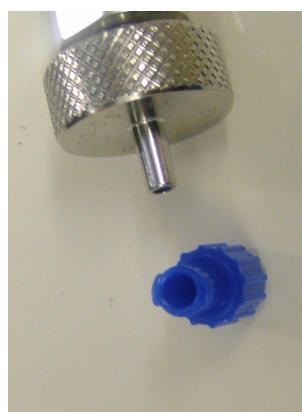
WHERE TO FIND THE WATER SAMPLING PORT.

The special water sample port is located on the left hand side just below the chamber on the loading side of the chamber.

Water Sampling Port

Water sampling in the RAPIDAER offers the user the facility to collect water from the point of application, as close to the contact with the scope as possible.

The water and Chemicals that pass through the pipework holding the sample point is the same as the irrigation feed to the scope channels.



The sample port has a blue cover which should always be replaced to help keep the fitting clean. You can fill this with alcohol when replacing it, after taking a water sample.



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MEDIVATORS® RAPIDAER



Operators Manual

Issue 01 – September 2014



Language Version
Original Instructions in English.



0088

CE Marking certifies that this equipment conforms to the following EEC directives:
Medical device directive 93/42/EEC
Low Voltage Equipment – 72/23/EEC
CE marking directive 93/68 EEC
Electromagnetic Compatibility – 89/336/EEC



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INTRODUCTION:

RAPIDAER DESCRIPTION:

The Medivators® range of automated endoscope re-processors, cover a wide range of capabilities to suit your particular requirements. RAPIDAER is the latest in the range, which now offers the user full pass through compliance to meet the requirements of BS EN 15883 Parts 1 & 4, SHTM2030 & CFPP01-06.

The RAPIDAER is a single chamber machine processing a single multiple channel endoscope per cycle in an easy to load basket. The machine has the same unparalleled external scope cleaning performance and integral individual channel cleaning facility as the Autoscope Isis providing a fully compliant re-processing performance.

Included in the automated wash cycle time of approx.17 minutes, is the automated leak test facility, and continuous channel monitoring. DATA records include operator, endoscope, and wash cycle information, together with the unique identification of the connection manifold being cross referenced against the endoscope channels of the endoscope.

PROCESS CYCLE

The normal re-processing cycle is in 7 stages.

1. Leak Test
2. Gross Wash and lumen patency check
3. Detergent wash
4. Detergent Rinse,
5. Disinfectant Clean,
6. Disinfectant Rinse.
7. Air flush

The operator also has the option to perform a "Manual Leak Test" with the door open, prior to the wash cycle



UNDERSTANDING RAPIDAER:

RAPIDAER is a fully compliant self contained pass-through endoscope reprocessing machine.

Designed to re-process one endoscope in each cycle, RAPIDAER offers a full cycle process with-in 17 - 18 minutes of pressing the start button. *(subject to a 5 minute disinfectant contact time and the incoming water temperature)*

Likewise loading the scopes is quick and efficient, by the use of the scope carrier basket design. Scopes can pre-loaded into their carrier baskets ready to be loaded in to the RAPIDAER machine, as soon as the re-processed scope is removed.

PASS THROUGH TECHNOLOGY:

RAPIDAER offers a compact footprint design that can be easily delivered and installed with access through standard size doorways. The pass through function of RAPIDAER allows the owner to split the re-processing task into separate areas, either in the same room, or separate rooms, by incorporating RAPIDAER into a dividing wall.

“Dirty Side” for loading used scopes & un-loading scopes that don’t complete their re-processing cycle.

“Clean Side” for unloading re-processed scopes only.

TRACE ABILITY:

RAPIDAER incorporates all the information that you require:
Operators have to log onto the machine, by use of a Tag, or ID & PIN for both loading & un-loading

The connection manifold and the endoscopes have to be logged onto the machine by use of a Tag, which identifies the channel configuration for irrigation and checks the hub and the manifold have the same channel connections.

Any access to the user configuration and set-up options, requires a log in, either by use of a TAG, or “ID & PIN”.

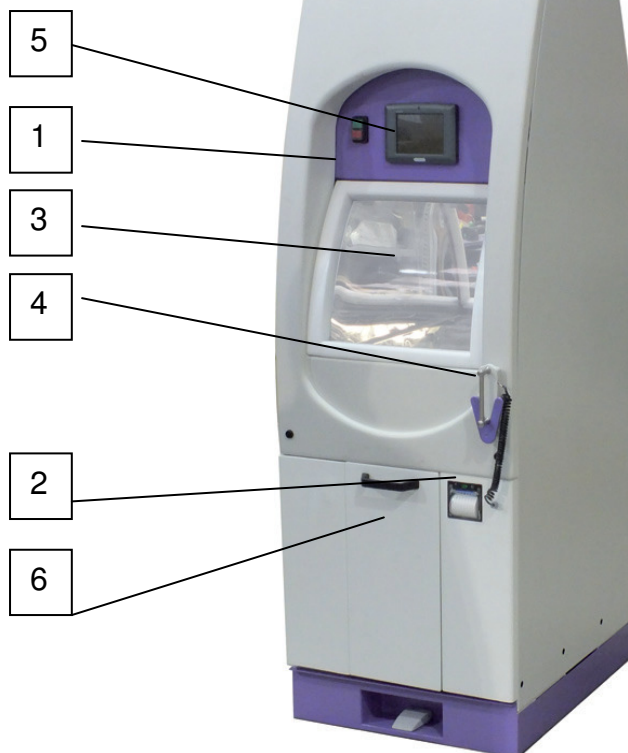
All information is captured in the RAPIDAER computer memory, and can be transferred when required via a USB data storage device, or the unit can be linked directly to a traceability system.

A printout is produced as part of each cycle, with the option for a comprehensive print out:- detailed report.



FIND YOUR WAY AROUND RAPIDAER: "DIRTY SIDE" SCOPE LOADING SIDE

1. ON / OFF switches
2. Printer (optional on this side)
3. Process Chamber
4. Tag Reader
5. Control Panel touch screen (onboard computer)
6. Chemical storage chamber



"CLEAN SIDE" SCOPE UN-LOADING SIDE

The clean side has

- Emergency stop Button
- Printer
- Access to Process Chamber
- Tag Reader
- Control Panel Read out for cycle status



ON/ OFF SWITCHES:

The On/Off switches are located on the top left of the load side (dirty side) of the RAPIDAER adjacent to the control panel.

GREEN is ON
RED is OFF



EMERGENCY STOP BUTTON: (CLEAN SIDE ONLY)

There is an emergency stop button on the top left of the unload side (clean side) of RAPIDAER.



TAG READER:

The TAG readers are on both sides of the RAPIDAER machine, and are positioned to give the best possible ergonomic interaction with the operator and scope carrier baskets during loading and unloading.



CHEMICAL CHAMBER:

The Chemical chamber is on the Dirty Scope, load side of the machine.



RAPIDAER CONNECTIONS:

ELECTRICAL CONNECTIONS:

RAPIDAER will be connected to a 32 amp, 50Hz, 240 V single phase supply.

The connection point for each RAPIDAER machine should have an isolator switch located close to one side of the RAPIDAER machine, (pass through installations)

If an engineer is working on the RAPIDAER machined he may require to disconnect the power supply and lock this isolator for health and safety requirements.



SUPPLY WATER:

The incoming water supply to the RAPIDAER should be from an RO plant. The RO is connected to the machine at the top where there is an aseptic sampling point and isolation tap. The machine will use 44 litres per cycle.

WASTE WATER:

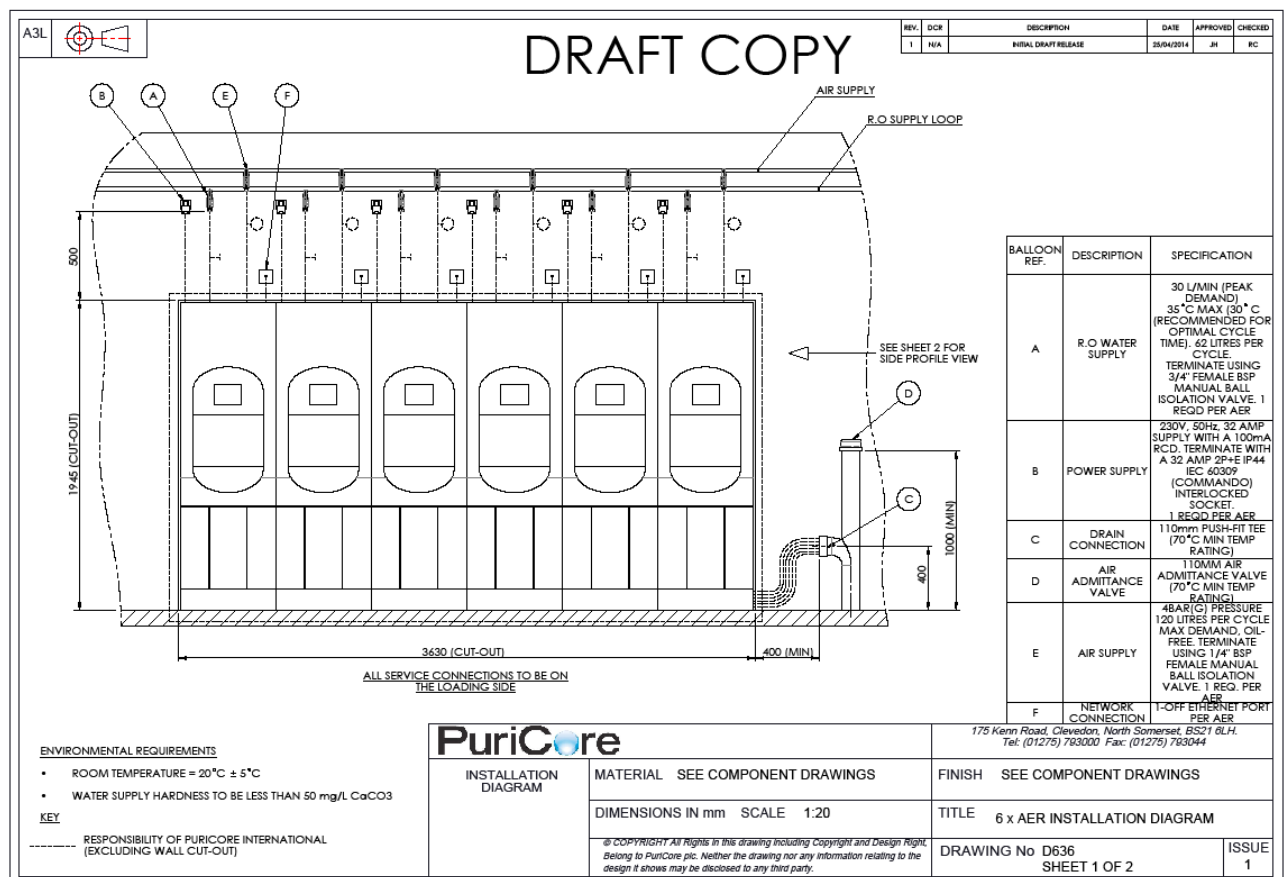
Waste water from the RAPIDAER should flow directly to a standard vented drain.

Always ensure that the water supply is turn on before using the RAPIDAER machine.

AIR PURGE SUPPLY:

A medical grade air supply should be connected to the top of the machine with an line gauge to allow operators to see the air pressure that is being supplied.

CONNECTION DIAGRAM





SPECIFICATION

Model	RapidAER
Dimensions	600mm (w) x 800mm (d) x 1930mm (h)
Processing Time	17 minutes
Disinfectant	Rapicide PA two part, single shot, Peracetic acid based disinfectant
Detergent	Mediclean Plus alkaline single shot detergent
Power Requirements	230v, 50hz, 32 amp supply
Class 1 equipment	Protective Earth required
Connection to supply	IEC 60309 industrial coupler
Water Requirements	64 litres per processed scope
Construction	Steel frame, Polycarbonate doors, Plastic cover panels.
Noise Level	<58 dBA
Weight	240Kg
Process Capacity	1 large flexible endoscope per cycle
Environmental Operation Conditions	
Operating Temperature Range	Ambient (0-40 °C)
Humidity	20%- 90%



OPERATOR - RAPIDAER INTERFACE

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

The operator has various options on how to interface with the RAPIDAER machine.

For ease of use, speed and efficiency the RAPIDAER machine is configured to operate using a TAG system.

There are three types of TAGS:

The Operator TAG:- which contains all the relevant data about the operative.

The Scope TAG:- which contains all the relevant data about the endoscope.

The Connection Manifold TAG – which contains all the details about endoscope connection

(All of these are covered in more detail on the following pages).

The TAGS are pre-programmed by the RAPIDAER manager with all the relevant details. The TAG system allows the operator to follow the prompts / instructions on the computer screen, and by presenting the TAG to the tag reader, the RAPIDAER machine will progress onto the next step in the process.

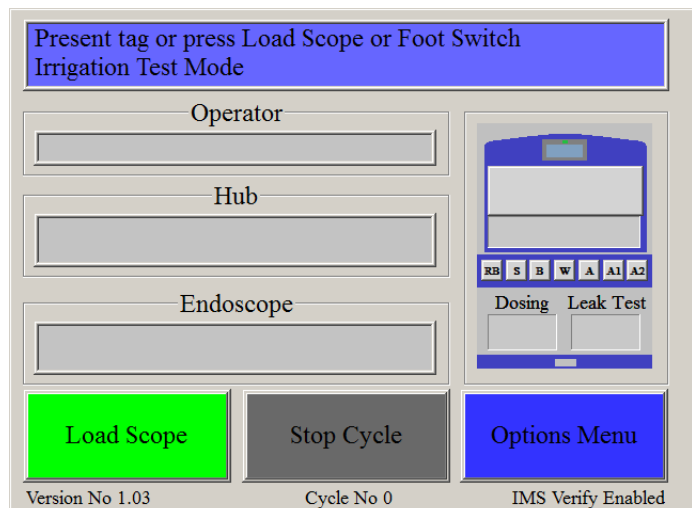
However, should the operator not have their TAG for whatever reason, RAPIDAER also has the option to allow access through the computer touch screen.

Each operator will also have an identification number and a PIN, these can be used to identify the operator to the RAPIDAER manually.

The operator will also be required to use the computer touch screen during the endoscope loading process. The buttons that are active and can be pressed to select an option or confirm a question, are always coloured in green.

The only other button that can be pressed is the Pause button, active once the cycle has started.

To operate a touch screen button, the operator should gently, but firmly press their finger on the button on the computer screen.





RAPIDAER CONTROL PANELS:

DIRTY SIDE (LOAD SIDE) CONTROL TOUCH SCREEN



CLEAN SIDE (UN-LOAD SIDE) CONTROL PANEL





OPERATOR ID

PERSONAL IDENTIFICATION NUMBER (PIN)

Under the “Hospital protocols” section of the RAPIDAER control functions, you are required to choose a PIN and sequential ID number for each operator or manager who has access to your RAPIDAER machine.

The PIN should be a confidential identification known only to the assignee, and the RAPIDAER manager.

It is recommended that a secure log or record of the PIN’s should be kept by the hospital (RAPIDAER manager) to cover for the event of an operator losing their TAG, and forgetting their PIN.

It doesn’t matter if operators choose a PIN that someone else already has, because it has to be used with their unique sign on ID number.

Once an ID & PIN and a TAG have been assigned to a user’s log on, the operator does not need to use their PIN because all the necessary information is stored on the operator TAG.

The operators ID & PIN will be required if a TAG is lost or stolen; so that the operator can access the RAPIDAER machine manually. The ID & PIN are also needed to re-assign a new TAG for the operator.

Please refer to the following section on TAG’s , for lost or damaged TAG’s



OPERATOR ID TAG:



Fig: Tag 1

Each operator that is assigned to your Autoscope RAPIDAER machine, should be allocated a unique personal TAG.

The operator ID TAG provides several functions:

- 1) Identifies the operator.
- 2) Automatically logs the operator into the RAPIDAER machine.
- 3) Automatically confirms the operator's access level status.
- 4) The TAG is required to open the RAPIDAER doors for both loading & unloading.
- 5) If a tag is lost or stolen. The RAPIDAER Manager should assign a new tag to the operator, this will disable the lost TAG.

SCOPE ID TAG:



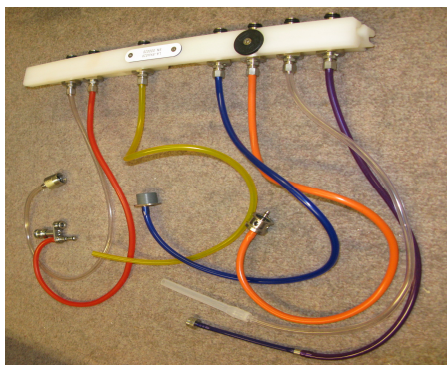
Fig : Tag 2

Each Scope that will be re-processed in the RAPIDAER requires a unique identification TAG rated to IP68.

This will identify the scope to the RAPIDAER machine, automatically confirming the parameters for cleaning and testing etc.

The TAG will also allow the endoscope to be tracked within the DATA storage and printouts.

CONNECTION HUBS



THE CONNECTOR HUB.

This is used with each scope that is installed into the carrier basket. There are a large number of hubs with connections dedicated to number of channels in that particular family of endoscopes. The hubs vary dependant on manufacturer and the individual connectors required to fit the individual channels.



CONNECTOR HUBS ID TAG



The connector hub tag is similar to endoscope ID tag and is rated to IP68. The information stored on the tag allows for the number of channel that are connected to be verified against the number on channels on the endoscope tag and then during the process these connections are monitored.

NOTE: All accessories used with the RapidAER, and to connect the endoscopes must comply to Cantel Medical's specification.

PRE-LOADING A SCOPE:

PREPARING THE SCOPE BASKET:

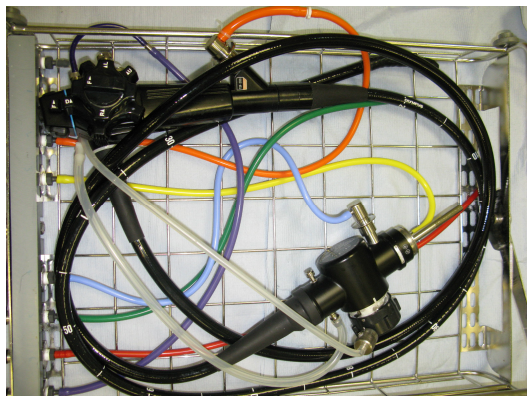
The RAPIDAER machine uses a scope carrier basket to house the scope in the machine. The basket is pre-loaded with the scope on a worktop, and placed into the RAPIDAER when ready.

On completion of the wash cycle, the scope is removed in its basket, so that another scope basket can be loaded and washed whilst the previous scope is removed from the basket.

The carrier basket can then be returned to the load side, for re-loading with more scopes.

Take an empty basket and then select the correct hub for the endoscope to be reprocessed. Each type of endoscope will have a specific connection manifold with the correct number of channel connectors suitable for that family of endoscopes.

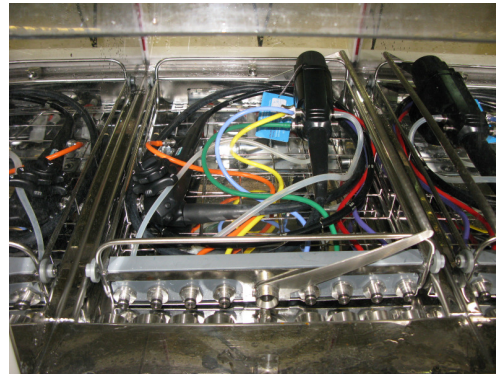
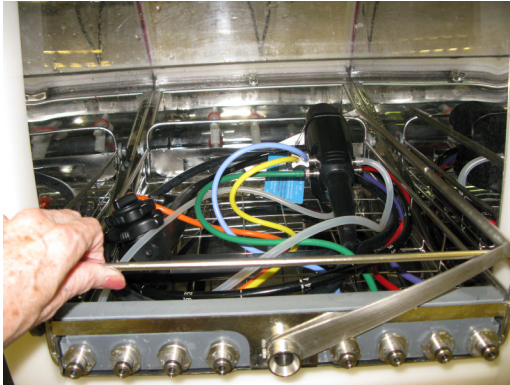
The manifold is slid into the end of the basket, the scope is then placed in the basket and the connections made to the scope.





LOADING THE SCOPE INTO THE RAPIDAER MACHINE

Open the RAPIDAER load door, using the operator tag or foot pedal.



Place the end of the basket on the side guides and slide the basket forward into the chamber until it rests totally in the base area.



Pull the basket back towards the front of the machine to locate the connectors into the irrigation ports on the inside front face of the chamber. When located, lock in position by moving the locking arm across the basket.

When the scope is loaded securely, Check the computer screen, and answer the question regarding channel separators, before closing the door,

UN-LOADING A SCOPE FROM THE RAPIDAER MACHINE:

To unload a scope, it is the reverse of the load operation.

When the computer instructs that the unload door can be opened, the operator should present their TAG to identify the unload operator and then retag or use the foot switch to open the clean side door.

Move the locking arm across to unlock the connections and then slide the basket upwards and remove through the clean door.

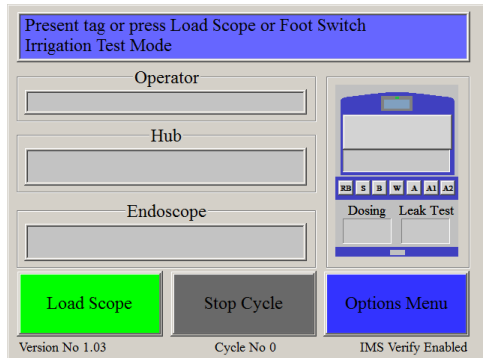
Close the door using the tag or foot switch.

The RAPIDAER machine will not proceed to the next step until the door has been closed properly.



How to “LOG ON” RAPIDAER

RAPIDAER functions via the onboard touch screen computer. The following steps show how to LOG ON to RAPIDAER using the touch screen.



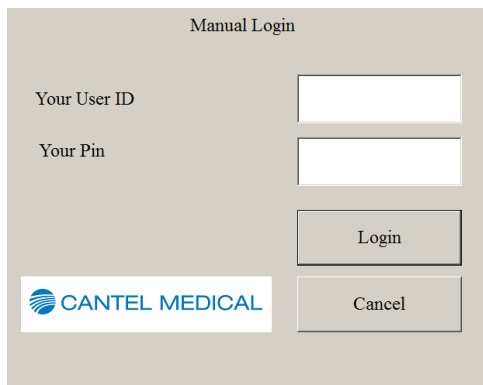
RAPIDAER Home screen

When at rest, the RAPIDAER will display the Home Screen.

In order to access the operating system, present the operator TAG to the reader.

Alternatively, touch the green box as indicated.

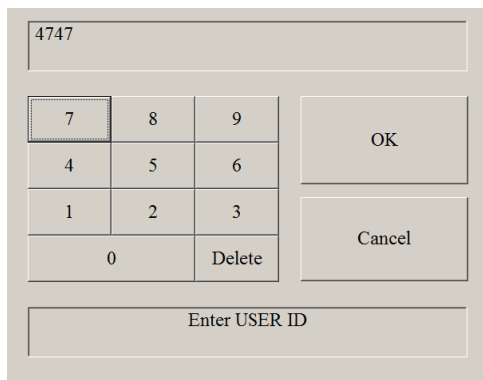
If the TAG is used, the door can then be opened by using the operator tag again or pressing the foot switch, and the RAPIDAER will ask for the Scope ID.



If the green box is pressed, the computer will proceed to the LOG ON screen

LOG ON screen

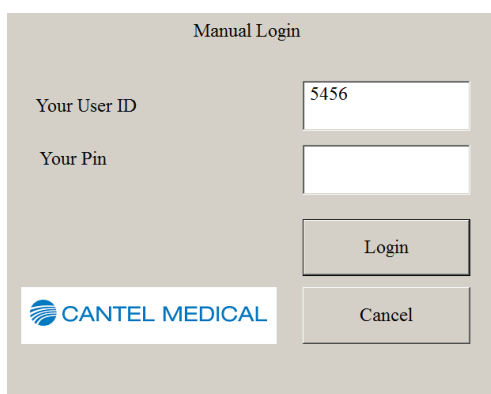
Touch the user ID box to input the users 4 digit reference number via the Key Pad screen



The numerical Key pad screen

Enter the user 4 digit ID number

Press OK to accept



Enter PIN

Touch the PIN box to activate the numerical keypad



7	8	9	OK
4	5	6	
1	2	3	Cancel
0	Delete		

Enter User Pin

The numerical Key pad screen

Enter the user 4 digit PIN

Press OK to accept


Manual Login

Your User ID

Your Pin

Login

Cancel

 CANTEL MEDICAL

Now press LOG ON

The door will open and the RAPIDAER will ask for the hub and scope ID

All the information displayed on the screen will be stored in the Data Log:
ie: User ID, name, PIN, TAG, including dates & times.



AUTOMATIC RE-PROCESS CYCLE

The normal re-processing cycle for either a one or two scope process is in 7 stages.

1. Leak Test
2. Gross Wash and Lumen Patency
3. Detergent wash
4. Rinse
5. Disinfectant Clean
6. Disinfectant Rinse
7. Air flush

The Computer display on the Load side of the RAPIDAER machine is the main user interface. Most of the wash cycle sequence can be performed by the use of the Operator TAG, Manifold TAG and the Endoscope TAG. Additional operator input is by pressing buttons on the touch screen.

The touch screen buttons are all indicated when they are active and are mostly located across the bottom of the computer screen.

The computer screen display prompts and instructs the operator on the physical actions to be taken during the load and un-load sequences.

During the wash cycle process, the computer screen displays the stage of the cycle that is being performed. This information is repeated on the unload side, scrolling display.

Other information displayed on the screen includes:

The load operator for each scope
The hub identification
The endoscope identification
The PAUSE cycle button.



CYCLE SEQUENCE

The following information will be displayed at each stage of the cycle in the purple information box on the computer “dirty side” (Load side), and will also be scrolling across the, Machine Status Display, on the “clean side” (Un-Load side)

SCOPE LOAD SEQUENCE

- 1) RAPIDAER Ready Tag or Log On
- 2) Load Operator ID recorded
- 3) Load basket
- 4) Present Hub Tag
- 5) Hub ID recorded
- 6) Present Endoscope TAG
- 7) Endoscope ID recorded
- 8) Close door
- 9) Fitted Channel Separators?
- 10) Press Start

WASH CYCLE SEQUENCE

- 11) Leak Test and detergent dose measured
- 12) Gross Wash & Lumen patency check
- 13) Dose Detergent, Detergent Wash (Solution will be heated if water temperature lower than required)
- 14) Detergent Rinse
- 15) Dose Disinfectant solutions
- 16) Disinfectant contact (Solution will be heated if water temperature lower than required)
- 17) Disinfectant Rinse
- 18) Air Purge

SCOPE UNLOAD SEQUENCE

- 19) Present operatorTAG to open door
- 20) Un-load operator ID recorded
- 21) Unload & close door
- 22) Rotating to unload position 2
- 23) RAPIDAER READY (Tag or Log On)



USING THE RAPIDAER MACHINE

To start an automatic cycle, simply perform the following procedures.

SWITCHING THE RAPIDAER MACHINE ON.

First ensure that the power supply is switched on at the isolator. This should be located on the wall, close to the machine.

Then ensure that the water supply is turned on.

It is also important to take regular water samples to ensure that the supply RO water is clean.



Then press the GREEN start button.

This is located on the Top Left Hand Side of RAPIDAER, on the Load Side of the machine.

When the start button is pressed the computer will display the initialising screen. Once the RAPIDAER computer has booted up all the required configurations, the touch screen will display the Home Page

The Main Computer screen will stay on the Home Page, until a re-processing cycle is started.



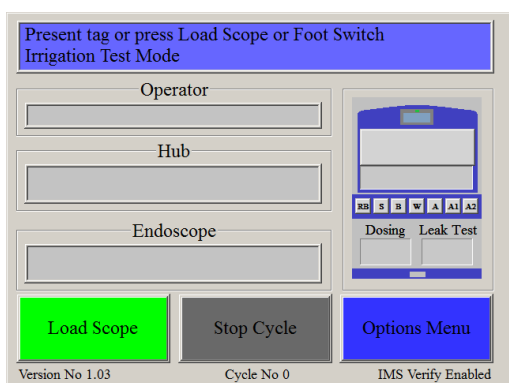
USING THE RAPIDAER MACHINE – RUNNING A CYCLE:

On switch on the RAPIDAER computer will load the standard home screen

The Main Computer screen will stay on the Home Page, until you start a re-processing cycle.

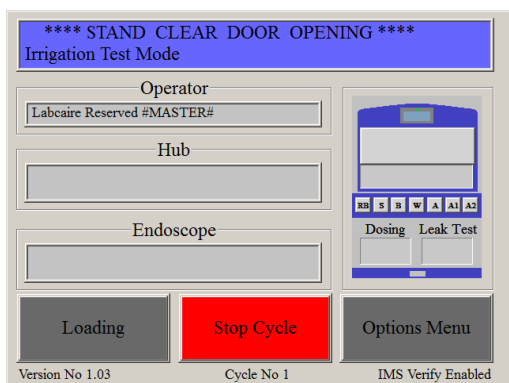
To use the RAPIDAER machine:

The operator needs to follow the instructions in the blue box at the top of the screen.



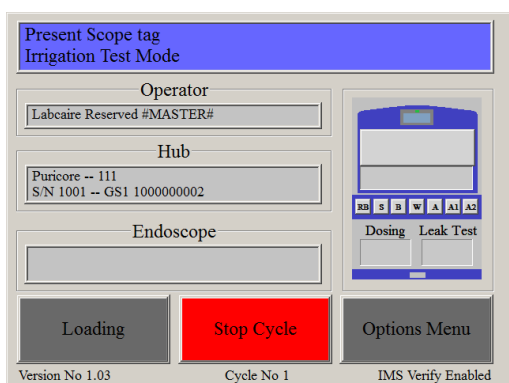
Present the Operator ID TAG to the TAG Reader. This identifies the operator as an approved user.

If the foot switch or load scope button is pressed then the operator will be asked to tag in or log on before proceeding.



NB: the operator DATA box now has the user ID displayed. This will be recorded for all information regarding this cleaning cycle.

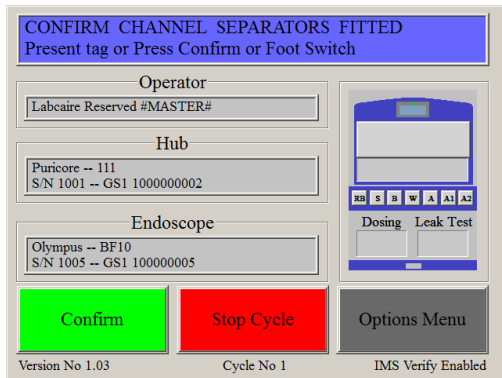
Present the operator ID tag or use the foot switch to open the door. Load the basket and endoscope in to the chamber and the use the tag reader wand to identify the hub.



The DATA boxes now have the user ID and the hub ID

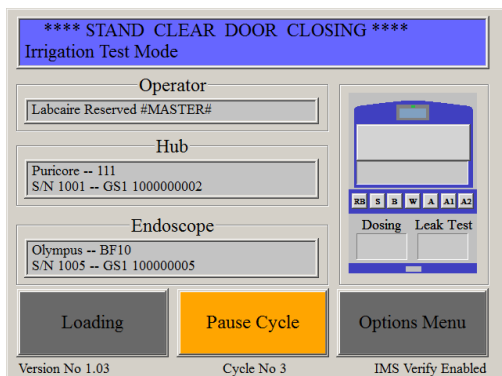
Use the tag reader wand to identify the endoscope.

The DATA boxes now have the user ID, the hub ID and the endoscope ID.



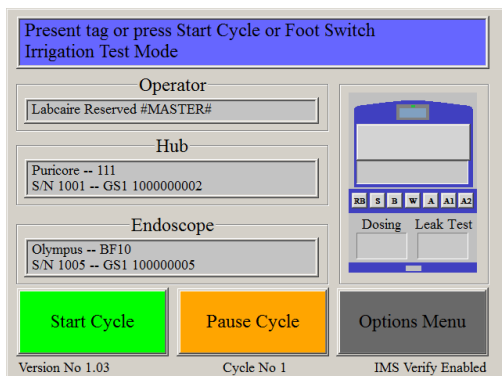
The operator will be asked to confirm if the channel separators have been fitted.

If separators are not required, still select Confirm.



On confirming the channel separators are fitted the door will close automatically.

Pause Cancel will allow the cycle to be stopped and return to the beginning of the load sequence.



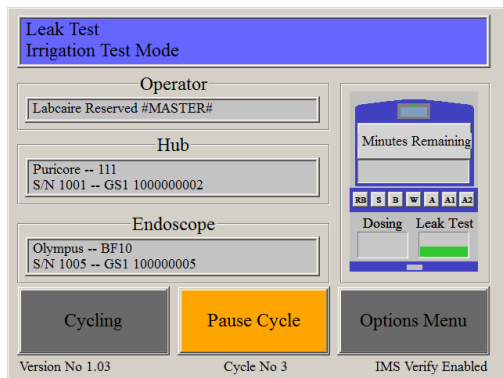
Press the green "START CYCLE" button on the left side of the touch screen, present the user tag to the tag reader or press the foot switch to start the cycle.

If a scope is loaded without presenting the Tag to the Tag Reader, the RAPIDAER machine will not let the software continue to the next stage.

This is achieved by means of the door not closing, until the endoscope Tag is presented to the Tag Reader.

Only then; will RAPIDAER allow you to continue to perform a wash cycle.

The RAPIDAER machine will automatically proceed with the leak test & cleaning cycles.



Firstly RAPIDAER performs an initial Leak Test.

At the same time it will prepare for the wash cycle.



The phase of the cycle is displayed in the blue box at the top of the screen

The duration of the cycle is displayed in minutes

The time remaining will count down in whole minutes

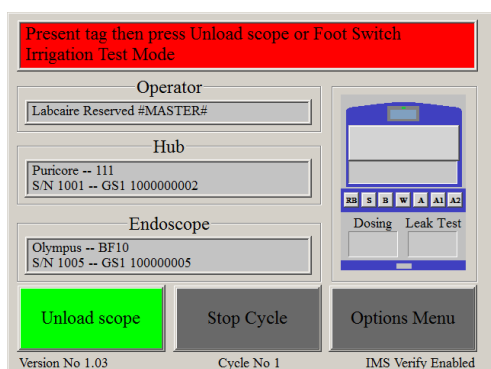
The final sequence of the cycle is the air purge which flushes the rinse water out the scope channels.

At the end of the process cycle RAPIDAER will inform you if the scope has passed or failed.

A failure will usually be indicated at the relevant point during the process cycle.

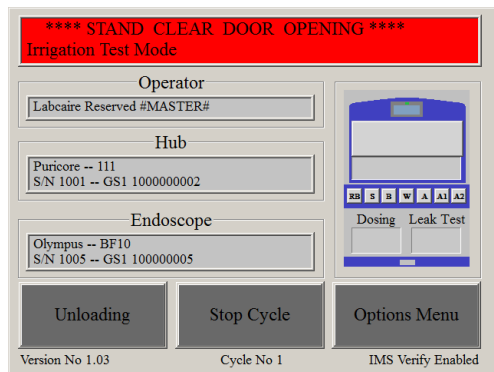
NB: Coloured buttons are active, press them to activate the function. Grey buttons are de-activated or display information only.

SCOPE PASS UNLOAD PROCESS



The Unload operator must use their ID tag to identify themselves to the RAPIDAER machine on the unload side.

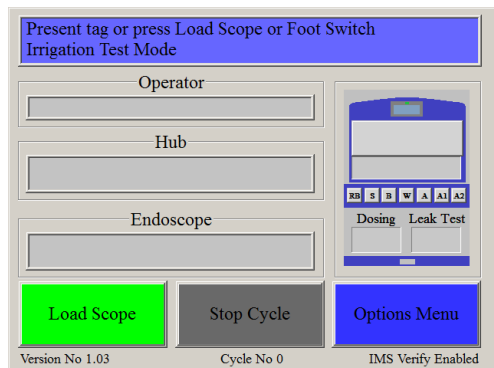
When the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.



The Un-load operator's ID will be recorded on the computer, and this information will be included on the print out, which appears on the clean side for the passed cycle.

When the door is open, remove the basket and endoscope.

Remove the cycle printout from the printer.



Close the door by using the operator ID tag or foot switch.

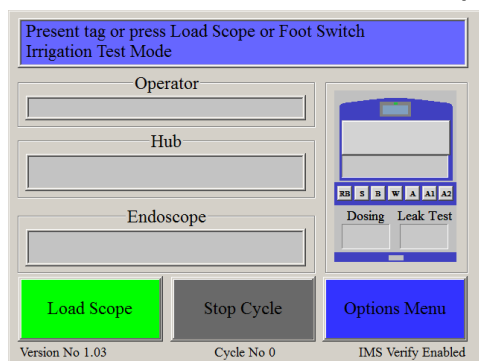
When the door is closed, the RAPIDAER returns to the HOME PAGE ready for loading to commence the next cycle.

Any scope that fails to pass all the criteria can only be removed from the "dirty side" Load side of the RAPIDAER machine.

The operator must present their Tag to the Tag reader to unload.

SCOPE FAIL UNLOAD PROCESS

The process to remove the endoscope from a failed cycle is the same as for a pass cycle except the Unload operator must use their ID tag to identify themselves on the load 'dirty' side of the machine.



Once the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.

The cycle printout will be given on the load 'dirty' side of the machine.

When the door is open, remove the basket and endoscope.

Close the door by using the operator ID tag or foot switch.

RAPIDAER will return to the HOME PAGE ready for loading to commence the next cycle.

Unload the endoscope from the basket and assess the problem from the data given before reprocessing the endoscope.



OPTIONS MENU

The options button allows various functions to be carried out by the user and for an administrator to use the 'Hospital Protocol' section to add endoscopes, operators and hubs to the data base.

Press the 'Options menu' button on the right hand side of the home page.

The 'Log In' screen will be displayed. Either present the operator tag to the tag reader or enter your user ID and PIN as covered on page 16

Options Menus

User Menu

Administration Menu

SELF DISINFECT:

The thermal self disinfect can be set to come on at a predetermined time so the process is completed before the machine is required for reprocessing the endoscopes used that day.

There is also a 'Start Now' button on this screen, so a self disinfect process can be started when ever required



OPENING DOORS:

To open a door when prompted to by the screen instruction, you will be required to present your operator TAG to the RAPIDAER machine or use the foot switch. The door will unlock and open automatically.

Should you wish to open the access door at other times, or if the operator is not in possession of their TAG. Then the operator will be required to access the OPTIONS menu in order to open the door.

To do this, the operator must first. Select the OPTIONS button on the HOME PAGE This will then take you to the options selection screen.

HOME PAGE - Press the OPTIONS button to select:

LOG ON - The operator should use either their ID tag or enter ID number and PIN.

Press the OPEN DOOR button.

The door will 'unlock', so that it can be opened.

RETRIEVING A SCOPE:

Should the operator need to retrieve a scope from the RAPIDAER machine, other than in the normal sequence of a wash cycle; then this can be achieved by the following steps.

Scope Failed message - Press the abort button.

Press the "Options" Button

OPTIONS" Log on Screen - Present TAG to the tag reader or Enter user ID number & PIN

Then press Log On to proceed

OPTIONS Menu

Press the "OPEN DOOR" button
This will open the Dirty Side door only.



OPENING THE CHEMICAL STORAGE DRAWER:

To access the chemicals, the operator must first press the GREEN OPTIONS button on the RAPIDAER computer screen. This will then take you to the options selection screen.

Press the OPTIONS button to select:

LOG ON OPTIONS MENU by the operator either using their ID TAG or manually not entering their ID number and PIN.

Now press the “OPEN CHEMICAL CHAMBER” button.

The drawer will unlock, and the operator can manually pull the door open.

NB: the air extract fan will operate to contain and remove any odours via the carbon filter.

Select the chemical to be added, detergent, Base or Activator by touching the screen to highlight the chemical to be changed.

Pass the chemical bottle, with the label side facing the tag reader, across the bottle tag reader and the new bottle batch number will appear in the new

chemical boxes. Press OK to confirm the data.

Put the chemical bottle in the drawer and then change the lid over to the pick up lid in the unit.

IF the tag reader or the bottle label does not activate the new number correctly the the number can be added manually.

Press the Batch number area by the 'new' section.

A screen will appear that allows the new batch number to be entered.

Similarly select the serial number and enter this in the same way.

Finally add the expiry date for the chemical in the date boxes.

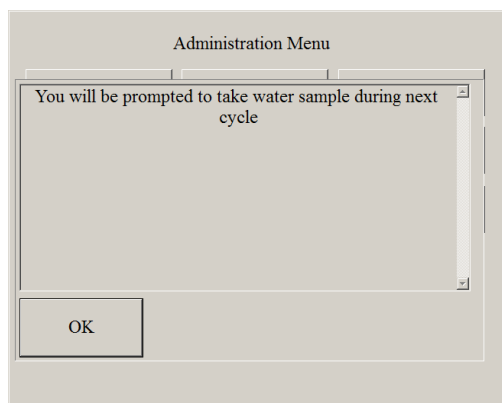


ACTIVATE FLUSH SYSTEM ROUTINE:

This facility flushes all the complete system and dosing pots so that they are at the correct status for a new cycle to be started. This facility should be used when the wash cycle has been interrupted and RAPIDAER is out of synchronisation.

WATER SAMPLE

This option can be selected to allow a prompt to be given when the last rinse is being done and the water sample should be taken.

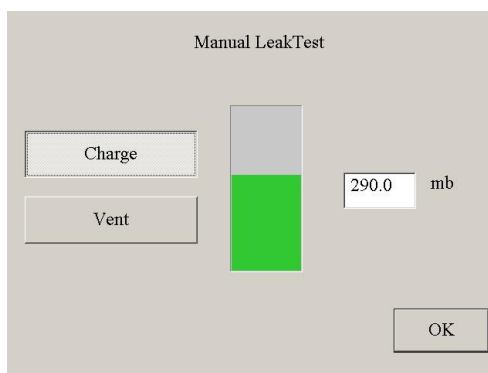


Select OK and the cycle will emit an alarm when the final rinse stage is reached in the next cycle.

ENGINEERING.

This button is not displayed in the normal user mode, it only becomes active when the engineer has a special USB key in the machine.

LEAK TEST:



In the event of a leak test failure, a manual leak test can be carried out in the machine. This will pressurise the scope to the required 290 mbar and by watching the screen any leak can be detected by the slow decrease of the pressure reading.



SET TIME

The date and time can be changed to the local time at the location of the unit.

Select the time and date on the UP/DOWN arrows and press save to confirm the new date and/or time.

PRINT CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

This function is in the Hospital Protocols for personnel with ADMIN access.

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

This function is in the Hospital Protocols for personnel with ADMIN access

HOSPITAL PROTOCOLS

These screens can only be accessed by users that have been given 'ADMIN' rights during the set up of the user's tag.

An operator with user access only will not be allowed to access the "Hospital Protocol" menus.

Functions within Hospital Protocols

Add a NEW operator/user
 EDIT an existing operator's details
 Assign a NEW scope ID
 EDIT an existing scope ID
 Add a NEW connector hub
 EDIT a connector hub
 Print a last cycle ticket
 Print a cycle report
 Print the last self disinfect cycle ticket
 Copy files



ADD A NEW USER

Press the “New Operator” button on the Screen

The operator ID is sequentially assigned by RapidAER automatically.
Every Operator will have a unique ID number.

To enter an operator name:
Touch the white text box

Touch screen type writer pad.

Input the new operator's name.

Then press OK.

The name will now appear in the white text box.

To enter the user PIN
Touch the White text box .

Touch screen number pad:
Type in the 4 digit PIN for the new operator according to your SOP.
(standard operating procedure) Then press OK!

The PIN will not be displayed on the screen
Only a symbolic representation, this is for security reasons.

It is recommended that you keep a record of the PIN elsewhere.

To assign a TAG, present the new TAG to the tag reader.



All the operator details are now installed and linked to the ID TAG.

Next assign access rights and press the 'Inactive' box to make the operator 'Active'.

Access Rights

To assign the new operators access capabilities; Press the relevant Description to tick the boxes.

Then press OK:

Access Rights:

For basic machine operation access:- tick the User box

For access to set up new scopes, users or hubs or copy data files:- tick the Admin box.

The Admin access automatically gives an operator user rights to run a cycle.

The New Operator is now installed into the RapidAER computer.

EDIT AN EXISTING USER'S DETAILS

Press the "Edit User" button on Screen

Select the operator to be edited by touching the operators name on the screen.

Then press edit operator

The operator details will be displayed.

Select and modify their Access Rights, or re-assign a new Tag.

Then press OK.

The edit function is now complete.



ADD A NEW CONNECTION HUB ID

Press the 'Add Hub' button on the Menu screen

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

The complete hub list will appear

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

Select the hub to be added

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be added

Press OK

Max Flows

Suction 1800

Biopsy 0

Water 0

Air 0

Aux 1 0

Aux 2 1800

RB Min Pres 0

Make CANCEL

Model RAH008

Dept

Serial No

GS1

Tag

Adding Hub Type RAH008

OK Cancel

To add the information touch the white box adjacent to 'Dept'.

Endoscopy

q w e r t y u i o p

a s d f g h j k l

z x c v b n m

Number Space Delete

Shift - \

Clear . @

Enter Department

OK Cancel

Type in the department name and Press OK



Max Flows		Make
Suction	1800	CANTEL
Biopsy	0	Model RAH008
Water	0	Dept Endoscopy
Air	0	Serial No
Aux 1	0	GS1
Aux 2	1800	Tag
RB Min Pres	0	Adding Hub Type RAH008
		OK Cancel

Next add the serial number that is on the new hub serial number plate. (Each hub has its own serial number so individual hubs of the same type number can be identified.)

Max Flows		Make
Suction	1800	CANTEL
Biopsy	0	Model RAH008
Water	0	Dept Endoscopy
Air	0	Serial No 012345
Aux 1	0	GS1 334
Aux 2	1800	Tag
RB Min Pres	0	Adding Hub Type RAH008
		OK Cancel

Complete the data by selecting each box and typing in the data.

Finally present the tag fixed onto the hub to the tag reader to add this data.

Press OK to save the new hub data.

NOTE The max. Flow values on the right side of the screen give the disconnect alarm and cannot be altered. Any changes that are required to these flows must be made by a Cantel Medical engineer after testing the hub with the respective endoscope.

This new connector hub can now be used in the RapidAER machine.

EDIT AN EXISTING HUB ID

Press the 'Edit Hub' button on the screen. This allows a hub to be edited and assigned to another department or for a hub to be deleted from the hub list in the RapidAER computer.

RA002 S/N 1008	Delete
RA017 S/N 1011	
RA020 S/N 1012	
RA022 S/N 1013	
RA038 S/N DSFS	
Select Hub to Edit	OK Cancel

The list of connection hubs that have been stored in your RapidAER machine will be displayed

A hub can now be edited or deleted



Select the hub by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be edited

Press OK if hub to be edited

The Hub information page will appear.

Now make your alterations as per the “add new hub” procedures, selecting any of the data that has a white box and changing as necessary.

Then press OK to Save the new data.

If the hub is no longer to be used then the delete button can be selected after the hub has been selected in the hub list displayed in the edit scope process as above.

Select ‘Yes’ and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

To exit this process then press ‘Cancel’

ADD A NEW ENDOSCOPE ID

Press the “Add Scope” button on the Menu Screen

The Scope Information page will appear. Now fill-in the boxes in sequence.

Press the “Make” box on the touch screen



Olympus									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number			Space			Delete			
Shift	-	\	Enter Manufacturer						
Clear	.	@	OK			Cancel			

The key pad will appear.

Enter the manufacturer of the scope eg. Olympus, Pentax , Storz etc

Then press the OK button to enter the data.

Min Flows		Make	Olympus
Suction	100	Model	
Biopsy	100	Dept	
Water	50	Serial No	
Air	50	GS1	
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK Cancel	

Press the “Model” box on the touch screen

Gastroscope									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number			Space			Delete			
Shift	-	\	Enter Model						
Clear	.	@	OK			Cancel			

The key pad will appear.

Enter the model of the scope eg. Gastroscope, Broncoscope etc

Then press the OK button to enter the data.

Continue to add the Department, Serial number, GS1 number if known in the same way as the Make and Model, typing in the data and pressing OK after each entry.

Min Flows		Make	Olympus
Suction	100	Model	Gastroscope
Biopsy	100	Dept	Endoscopy
Water	50	Serial No	GIF1246789
Air	50	GS1	F234
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK Cancel	

To complete the new endoscope entry present the scope tag to the tag reader to assign that tag to the data entered.

The tag data will be entered in the tag box.

Press OK to save the data to the RapidAER data base.

This new scope can now be re-processed using the RapidAER machine.



EDIT AN EXISTING SCOPE ID

Press the 'Edit Scope' button on the screen. This allows a tag to be edited and assigned to another scope or for a scope to be deleted from the endoscope list in the RapidAER computer.

The list of scopes that have been allocated by the user which are stored in your RapidAER machine will be displayed

A scope can now be edited or deleted

Select the scope by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the scope that is to be edited

Press OK if scope to be edited

The Scope information page will appear.

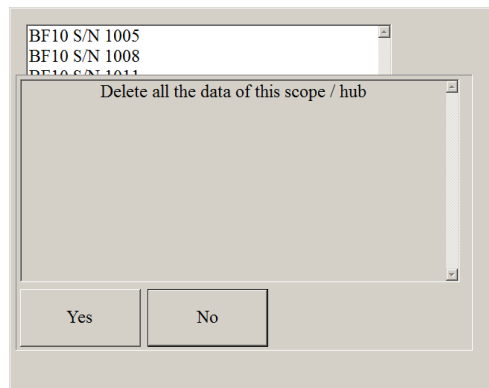
Now make your alterations as per the "add new scope" procedures, selecting any of the data and changing as necessary.

Then press OK to Save the new data.

Whenever this scope is re-processed in the RapidAER machine the new details will be logged and recorded.



If the endoscope is no longer to be reprocessed then the delete button can be selected after the endoscope has been selected in the endoscope list displayed in the edit scope process as above.



Select 'Yes' and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

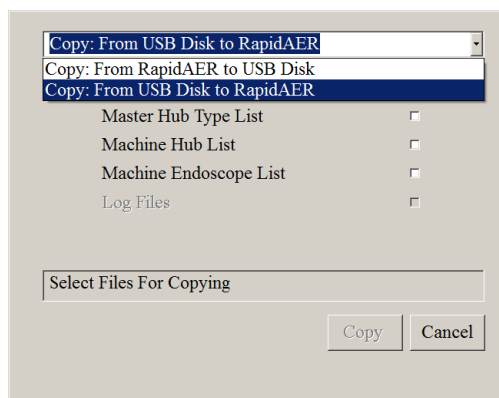
To exit this process then press 'Cancel'

Select 'No' and the screen returns to the scope list with endoscope still visible.

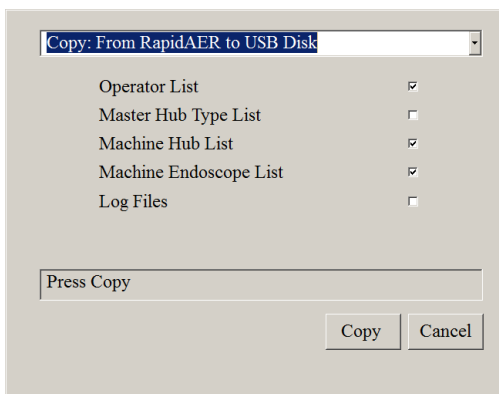
To exit this process then press 'Cancel'

COPY FILES

This button allows files to be copied onto the RapidAER computer or copied from the RapidAER computer. This allows the operator, endoscope, and department hub lists to be copied from machine to machine so data only has to be entered once.



From the arrow along side the top box select if files are to be copied onto the RapidAER from a USB key or whether files are to be copied from the RapidAER onto a USB key.



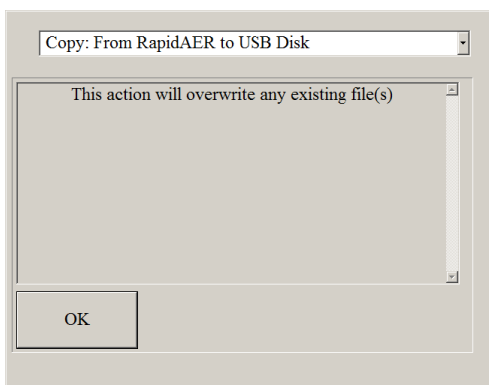
So to copy files from machine to machine after adding new operators, endoscopes or hubs

Select From RapidAER to USB disc

Tick the files to be copied – Operator list, machine hub list or machine endoscope list

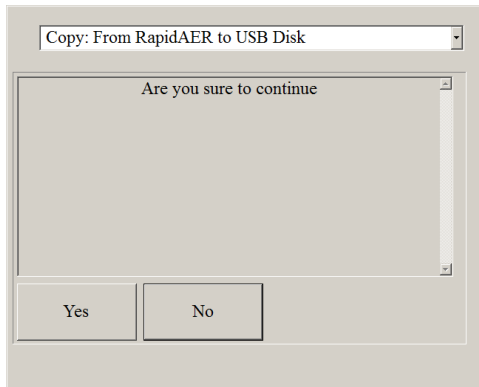
Note: Log Files can only be copied from the RapidAER to the USB Drive

Press 'Copy'

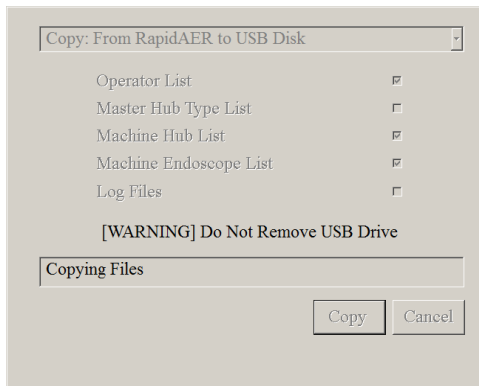


A message will appear to alert the operator that any files on the USB disc with the same name will be overwritten.

Select OK to acknowledge the message

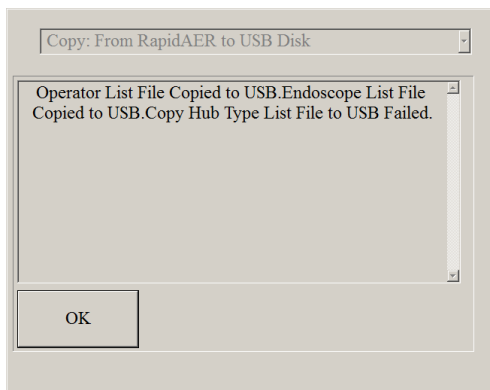


Press 'Yes' to continue the transfer or 'No' to exit



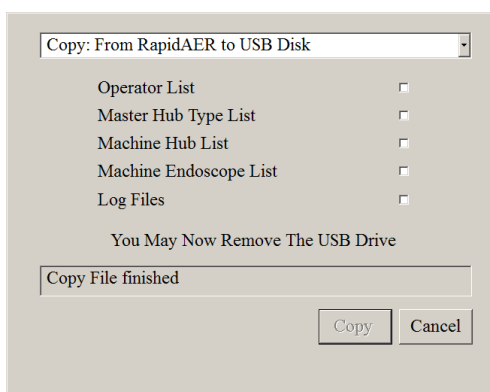
The files are now being copied.

Do not remove the USB drive



The screen indicates that the files have been copied or that a list has failed to copy.

Press OK



The final screen informs the operator that the copy file instruction is complete and the USB drive can be removed.

Press cancel to exit

To copy the files from the USB Drive to the next RapidaER machine, insert the USB drive in the slot adjacent to the screen on the dirty side of the machine. Go to Hospital Protocols and select 'Copy Files' follow the same process as above but initially select 'Copy: From USB Disk to RapidaER'



LOG FILES

These can be selected to be copied onto the USB drive as the above process and they can then be downloaded onto a hospital computer for analysis.

PRINT CYCLE REPORT

This will print a detailed report of the cycle that has just been completed. For more information see Printouts.

PRINT LAST CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

AUDIBLE ALARMS

INFORMATION ALARM:

When the RAPIDAER machine has completed the endoscope cleaning cycle, it will emit a single beep audible alarm, to indicate that the machine is ready for unloading

WARNING ALARMS:

When ever there is a visual warning alarm on the computer screen, the RAPIDAER machine will also emit a continuous audible alarm.

To stop this audible alarm, the operator needs to accept / acknowledge the visual alarm on the computer screen, by responding to the computer instruction or prompt.

POWER INTERRUPTION:

If the power source to the RAPIDAER is interrupted, the volt free contacts will enable a remote signal to indicate an alarm.

If the power supply to RAPIDAER is interrupted, then the RAPIDAER machine will need to be manually switched on, using the green button, on the front of the machine.



However if the RAPIDAER machine was performing a wash cycle when the power was interrupted; then, when the power is re-connected, the RAPIDAER machine will emit an audible alarm, linked with the wash cycle fail indication on the computer screen.

REMOTE ALARMS:

When ever there is a major alarm on the RAPIDAER machine, that would require immediate attention, eg: water leakage, power failure, self disinfect chemical bottles empty. Then the alarm will be duplicated via the volt free contacts, which will active either a visual or audible alarm in a remote location of the hospitals choosing. Eg: estate dept, BMS room, RAPIDAER managers office.



DATA SYSTEMS

The RAPIDAER AER machine has data storage and retrieval options for various types of data.

LOG DATA:

This is the cycle log record for every wash cycle and scope that has been processed in the RAPIDAER AER machine.

This data can be downloaded on to a USB key for achieving or the machine can be networked and the data transferred every cycle.

IMS:

(Independent Monitoring System)

This is a separate measuring system to confirm that the wash cycle parameters are within the tolerance that is required.

There are two levels of data retrieval obtainable through this system.

Level 1:- Process cycle history in an excel.csv spread sheet format.

Level 2:- the Full IMS data screen which will require the Cantel Medical IMS.net software package

Operator Data:

This is a history of every operator (present and previous) that has had access to the RAPIDAER machine.

Connector Hub Data:

This is a record of every connector hub present & previous that has been ID logged into the RAPIDAER AER machine, including the hub number, serial number and TAG ID.

Endoscope Data:

This is a record of every scope present & previous that has been ID logged into the RAPIDAER AER machine, including the make, model, serial number and TAG ID.



DATA STORAGE:

The RAPIDAER onboard computer has the capacity to store a large volume of information.

The memory allocated to cycle DATA storage will be able to store 250,000 wash cycles of information.

The information stored is formatted on an excel spread sheet, so that DATA retrieval is user friendly in both operator programme knowledge, and also in computer software compatibility.

The DATA storage format contains a heading with:

- The Department identification,
- The RAPIDAER machine serial number,
- The software version number.

DATA Storage Topic Headings:

- Date:
- Time:
- Pass / fail
- SD date
- SD time
- SD No:
- Operator ID
- Operator Name
- Un-load Operator ID
- Un-load Operator Name
- Contact time (seconds)
- Scope ID
- Manufacturer
- Model
- Serial Number
- Department
- Leak Test
- Raiser Bridge
- Channels Irrigated
- Comments
- Cycle Name
- Leak Test
- Number of Faults
- Reason Code
- Reason.



PRINTOUTS

The RAPIDAER provides a “hard copy” printout for the process that has been performed. This is in addition to the DATA being stored on the RAPIDAER computer which can be retrieval via a USB key or by direct connection to a Track and Trace system.

There are five label printout configurations:

Cycle Complete	= When a wash cycle has been completed.
Cycle terminated	= When a wash cycle has automatically stopped.
Cycle terminated	= When a wash cycle has been manually stopped
Test Label	= Engineer access only
Detailed Process Report	= RAPIDAER Hospital Protocol access required

The printers are located on the front of the machine:

On a pass through machine there will be a print out on the “clean side” (un-load side) for a ‘pass’ cycle and on the ‘dirty side’ (loading side) for a ‘failed’ cycle.

Below are example labels that depict the type of information that will be presented on the printouts



CYCLE COMPLETE 'PASS' PRINTOUT

(-----)	
(-----)	
(--Wash Cycle Pass --)	Cycle Pass/ Fail identification
(-----)	
(Cantel RapidAER)	
(Serial No RA0009)	RapidAER serial number
(-----)	
(Start 09h 44m)	Cycle start time:
(End 10h 02m)	Cycle finish time:
(Date 20-10-2014)	Date
(-----)	
(Cycle No. 52)	Unique sequential cycle number
(-----)	
(Load Operator 1)	
(Name Paul)	Loading operator identification
(-----)	
(Unload Operator 1)	
(Name Paul)	Un-Loading operator identification
(-----)	
(--Hub-----)	
(Cantel A3 Testroom)	Connection Hub used for the process
(Serial No 1)	
(GS1 1)	
(-----)	
(--Endoscope--)	
(Olympus Gastroscope)	Scope ID – including Make & Model
(Serial No GIFH260)	Serial No & GS1 No
(GS1 1)	
(-----)	
(IMS Verify Enabled)	IMS Status
(-----)	
(Control Pass)	Status of IMS & Control system at end of cycle
(IMS Verify Pass)	Pass confirmation
(-----)	
(Contact Time 5minutes)	Disinfectant Contact Time
(-----)	
(Last SD 20-10-2014 at 06h 00m)	RapidAER self disinfect information.
(-----)	
(Suction Av Flow 2185ml)	
(Biopsy Av Flow 1775ml)	
(Water Av Flow 120ml)	Average Flows in each of the channels during the
(Air Av Flow 85ml)	process including Raiser Bridge & Leak Test
(Aux 1 Av Flow 400ml)	Pressures
(Aux 2 Av Flow 900ml)	
(RB Av Pres 3850mb)	
(Leak Test Av Pres 300mb)	
(-----)	
(---Conductivity---)	
(Detergent 764µs)	Conductivity of each phase of the cycle
(Disinfectant 1150 µs)	
(Final Rinse 35 µs)	
(-----)	
(---Temperature---)	
(Detergent 25.1 deg)	Temperature of each phase of the cycle
(Disinfectant 26.1 deg)	
(Final Rinse 24.9 deg)	
(-----)	
(Chemical Batch/serial No)	
(Detergent D412/1134)	Chemical Batch / Serial numbers of each of the
(Part B B3321/889)	chemicals used for the process
(Part A A6543/996)	
(-----)	



CYCLE COMPLETE 'FAIL' PRINTOUT

There are two types of 'Fail' cycle and this is when the control or IMS system do the cycle checks and one or more parameters are outside the range allowed. The second failure is a manual abort by an operator. An example of each is given below.

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       10h 40m    )
( End         11h 02m    )
( Date        20-10-2014 )
(-----)
( Cycle No.   53         )
(-----)
( Load Operator 1      )
( Name         Paul     )
(-----)
( Unload Operator 1     )
( Name         Paul     )
(-----)
(  ---Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled   )
(-----)
( Control      Fail      )
( IMS Verify   Fail      )
(-----)
( Fault: 9044 Manual Abort (dis wash) )
( Fault: 9045 IMS: RB Flow duration   )
( Fault: 9024 IMS Aux 1 Low flow (0)   )
(           (dis wash)                )
( Fault: 9049 IMS conductivity        )
(           (dis wash)                )
(-----)
```

Cycle Pass/ Fail identification

RapidAER serial number

Cycle start time:

Cycle finish time:

Date

Unique sequential cycle number

Loading operator identification

Un-Loading operator identification

Connection Hub used for the process

Scope ID – including Make & Model
Serial No & GS1 No

IMS Status

Status of IMS & Control system at end
of cycle

Fault codes – reason for failure

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       11h 24m    )
( End         11h 42m    )
( Date        20-10-2014 )
(-----)
( Cycle No.   54         )
(-----)
( Load Operator 1      )
( Name         Paul     )
(-----)
( Unload Operator 1     )
( Name         Paul     )
(-----)
(  ---Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled   )
(-----)
( Control      Pass      )
( IMS Verify   Fail      )
(-----)
( Fault: 9048 IMS Irr temp 180.1 C    )
(           (Leak Test)                )
( Fault: 9048 IMS Irr temp 600.6 C    )
(           (Gross Wash)                )
( Fault: 9048 IMS Irr temp 600.6 C    )
(           (DetWash)                    )
( Fault: 9048 IMS Irr temp 600.6 C    )
(           (DetRinse)                   )
( Fault: 3035 IMS Irrigation temp     )
(           sensor fault (6006)        )
(-----)
```



CYCLE PRINTOUTS FOR SELF DISINFECT

There are two printouts for Self Disinfect Cycle Pass and Cycle Fail. Examples are both are shown below.

```
(-----)
(-----)
(  -Self Disinfect Passed--  )
(-----)
( Cantel      RapidAER      )
( Serial No   RA0009       )
(-----)
( Start       07h 29m      )
( End         08h 31m      )
( Date        20-10-2014   )
(-----)
( Cycle No.   11           )
(-----)
( Operator    1             )
( Name        Paul         )
(-----)
( Unload Operator 1       )
( Name        Paul         )
(-----)
( IMS Verify   Enabled     )
(-----)
( Control      Pass        )
( IMS Verify    Pass       )
(-----)
( Temp Stage 1  86.1deg    )
( Temp Stage 1  85.1deg    )
( Temp Stage 1  85.5deg    )
( Contact Time  10         )
(-----)
```

```
(-----)
(-----)
(  -Self Disinfect Failed ----  )
(-----)
( Cantel      RapidAER      )
( Serial No   RA0009       )
(-----)
( Start       07h 59m      )
( End         09h 14m      )
( Date        21-10-2014   )
(-----)
( Cycle No.   7            )
(-----)
( Operator    1             )
( Name        Paul         )
(-----)
( Unload Operator 1       )
( Name        Paul         )
(-----)
( IMS Verify   Enabled     )
(-----)
( Control      Fail        )
( IMS Verify    Fail       )
(-----)
( Fault: 9053 Spray system running )
( with empty sump (Recirc stage 2) )
( Fault: 9048 IMS Circ temp 64.5 C )
( (Recirc stage 2) )
( Fault: 9048 IMS Temp Su 63.7 C )
( (Recirc stage 2) )
(-----)
```



CHANGING PRINTER PAPER:

The printer is located as shown in the “Find your way around RAPIDAER” diagrams



The printers are located on the right hand side just below the chamber on both sides of the machine.



To access the paper roll,
Press the GREEN button on the top of the printer and the paper holder falls open.



To input a new paper roll, simply place the replacement paper roll into the printer as shown with the feed off section to the top, pull some paper forward, to create a tongue.



Push the paper holder closed, and tear off the excess paper against the serrated edge.

RAPIDAER printer is now ready for use.



To feed paper forward from the roll, press the button on the RIGHT.



ESSENTIAL OPERATING PRACTICES.

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

To ensure endoscopes are correctly disinfected it is important the following points are observed.

1. The machine thermal self-disinfection is carried out each day, before use.
2. The disinfectant contact parameter times are pre-programmed into the machine. The soak times must be determined by the manufacturer of the disinfectant and the Hospital Infection Control Department.
(Please refer to the tables in the "Disinfectant Types" section)
3. The manufacturer's instructions on the manual pre-cleaning, machine cleaning and disinfection of endoscopes must be followed at all times. The efficiency of the process depends on an efficient pre-clean and brushing through of the internal channels prior to disinfection.
4. It is most important that the endoscope internal channels are disinfected. The quality of the rinse water should be monitored at routine intervals.
5. The RAPIDAER must not be positioned within a risk area of anaesthetic equipment.

HOSPITAL PROTOCOLS:

Within the HOSPITAL PROTOCOL Menu, the user access protected CYCLE & SELF DISINFECT Menus allows for the defining of the following operational criteria:

RAPIDAER Hospital Protocol Menu
<i>Set & Edit Operator ID</i>
<i>Set & Edit Connection Hub ID</i>
<i>Set & Edit Endoscope ID</i>
<i>Copy Files</i>
<i>Reprint last cycle data</i>
<i>Reprint last self Disinfect cycle data</i>
<i>Print a detailed cycle report</i>



DISINFECTANT WARNINGS:

Disinfectants are hazardous substances and controlled by COSHH Regulations. Manufacturers must supply Safety Hazard Data Sheets to cover the use of their products.

The following Points should also be considered for use in this application.

1. Personal protection equipment should be worn when handling disinfectants or endoscopes. Suitable gloves, eye / face protection and apron.
2. The opening of disinfectants and closing of empty containers should be carried out, inside a suitable ventilated area.
3. The hospital should establish a procedure for safe storage, handling and disposal of disinfectant containers.
4. The hospital should establish a procedure for accidental spillage.
5. The RAPIDAER will provide a safe system for transfer of disinfectant to the chamber, during processing and disposal of used disinfectant. However, attention should be given to the room environment (ventilation) etc. see installation drawings. Correct ventilation will minimise problems if a spillage occurs.
6. The carbon filter should be changed every year to keep emissions below exposure limits.
7. Any disinfection contact should be washed off immediately and referred for medical attention.



DISINFECTANT TYPES:

The machine is compatible with two Peracetic Acid, single use disinfectants, for use on endoscopes, but the following points must be observed (see table below).

- A. The manufacturer of the Endoscope should be contacted for advice on chemical compatibility. Warrantees may only be valid on approved disinfectants.
- B. The Hospital Protocol and disinfection soak time should be approved by the disinfectant manufacturer and the Hospital Infection Control Department.
- C. Disinfectants activated with powders should not be used in RAPIDAER.
- D. Silicone based de-foamers should not be used in RAPIDAER.

DISINFECTANT NAME	DISINFECTANT TYPE	CARBON FILTER TYPE
Rapicide PA	single use peracetic acid	ACI
Purisept	single use peracetic acid	ACI

DISINFECTANT CONTACT TIME PARAMETERS		
disinfectant name	specific scopes	contact time
Rapicide	all	5 minutes
Purisept	all	5 minutes



DISINFECTION OF SCOPES:

CONNECTION OF ENDOSCOPES TO IRRIGATION CHANNELS:

Connection of the Endoscope to the irrigation lines is a critical procedure and as such great care must be taken to ensure correct connection. Connector hubs are available from Cantel Medical (UK) Ltd for each of the main types of the endoscope.

These connectors ensure that each channel is separated fully and therefore irrigated completely. Liquid is pumped into the endoscope from the light source end and passes completely through the length of the endoscope in a single motion.

It is essential that all channels are securely connected to prevent a cycle failure occurring.

RAPIDAER will remind the operator as part of the sequential screen prompts to check that channel separators have been installed.

NB: Certain scopes need to be sterilised after washing in an AER (Automated Endoscope Re-processor). The RAPIDAER AER should not be used as a replacement for sterilisation.

ENDOSCOPE STORAGE AFTER DISINFECTION PROCESS

Note:

Following the automatic disinfection cycle, the endoscope should be dried prior to long term storage, and can be hung directly into a Puricore Endoscope Drying Cabinet where the drying process will be carried out automatically, using dry compressed air, prior to longer storage of the endoscope in the clean environment of the cabinet. Alternatively the endoscope should be dried according to the endoscope manufacturer's protocol.



EU REGULATIONS:

Medical Devices Directive 93/42/EEC

Chemical Washer Disinfectors are a Class 2b medical device and the design, manufacture, installation and service are controlled under this directive. See Compliance for details of Puricore's accreditation.

Chemical Hazards - COSHH Regulations

Disinfectants are hazardous chemicals and it is necessary to perform a risk assessment covering all stages of use. The manufacturer of the disinfectant will supply Safety Hazard Data Sheets for their products.

See section on Disinfectant Types and Disinfectant Warnings.

The RAPIDAER should be tested at least every fourteen months to comply with this regulation.

BIOLOGICAL HAZARDS:

There is a risk to staff and patients from endoscopic procedures. The hospital should have its own procedures to control risk at each stage of the process.

TRAINING:

All staff using the RAPIDAER should be fully trained and certified on the use of the equipment.

Puricore Clinical Nurse Advisors will provide training sessions at each RAPIDAER installation, for the training and certification of operators and management staff.

Please contact Puricore for further details of training and availability.

VALIDATION:

The Autoscope RAPIDAER is manufactured to comply with BS EN 15883 Pt 1 & Pt 4, CFPP 01-06 and SHTM 2030. It should be fully validated according to table C1 of the BS EN 15883 Pt 1 & Pt 4 at the time of installation, followed by quarterly and annual re-validations.

COMPLIANCE:

Medical Devices Directive 93/42/EEC

Puricore International Ltd is approved to ISO 13485:2003 to design, manufacture and install chemical washer disinfectors.

Puricore International Ltd is approved to ISO 9001/EN46001 to service chemical washer disinfectors.

CE Marking

CE marking is applied to medical devices under Medical Devices Directive 93/42/EEC.



DECLARATION OF CONFORMITY



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Medical Device Directive Essential Requirements Checklist Declaration of Conformity

Description of Device
Product(s):

RapidAER

Assessment of Product based upon:

Certification of Quality System

Certificate No: LRQ 0954199/A
Issued by: LRQA

Date: 01/12/11

Essential Requirements Checklist

Prepared by: Regulatory Affairs

Date: 10/02/14

Technical File

Prepared by: Regulatory Affairs
Document number

Date: 10/02/14
2G-011

Product Classification:

Determine product classification based upon the requirements in MDD and Medical Devices Regulations 2002:

☐ Class I ☒ Class IIb ☐ Class III

Approvals:

Based on a review of the above documents, we hereby declare that the above products comply with the following EC directives:

- Medical Devices Directive 93/42/EEC as amended by 2007/47/EC
- Electro Magnetic Compatibility Directive 2004/108/EC
- Low Voltage Directive 2006/95/EC
- Machinery Directive 2006/42/EC
- Waste Electrical and Electronic Equipment Directive 2002/95/EC
- BS EN ISO 15883-1:2009
- BS EN ISO 15883-4:2009

Approved By: Neil Blewitt
Managing Director

Signature: _____

Date: _____

8th July 2014



Recommended actions to be taken for

“PERACETIC ACID” SPILLAGE

1. Evacuate the area.
2. Seal off the area to non-essential staff.
3. Put on protective clothing outside the affected area (boots, gown, apron, nitrile gloves, respirator face mask, goggles – NOT visors,).
4. On entry into the affected area – open all available windows (ie ventilate area) BUT DO NOT leave a door open into a corridor.
5. If it is a concentrate solution, absorb the excess with an inert material such as sand.
6. Put the contaminated sand into the disposal bag and seal tightly. Place this into a second disposal bag and seal tightly again. Contact your disposal company to collect it.
7. If it is a diluted solution or a small volume of concentrate, Dilute the solution with copious amounts of water and flush to drain.
8. Wash the floor area thoroughly with water.
9. Clean off boot soles before leaving the area.
10. Change any clothing that may have come into contact with the chemicals.



CONSUMABLES:

Description	Part No	Delivery lead time
1. Air Extract Carbon Filter	IS-LA 7014	5 Days
2. Printer Rolls (Pack of 20)	IS 795732	5 Days
3. Mediclean Plus Detergent (2 x 5 litre bottles)	900540	5 Days
4. Rapicide Disinfectant Part A	900530	5 Days
Rapicide Disinfectant Part B	900531	5 Days
5. Autowipes Disinfectant Wipes (6 x 200 wipe drums)	900505	5 Days



GENERAL CARE:

RAPIDAER is manufactured in the UK from quality materials, however any machine benefits from care and attention.

The exterior of RAPIDAER is manufactured from epoxy powder coated steel and polyurethane moulded panels. The use of abrasive cleaning agents should always be avoided. It is recommended that a warm soapy solution, or mild, diluted cleaning disinfectant is used.

The process chamber is manufactured from stainless steel with a smooth mirror finish. Gouges and scratches will enable biofilm and thus promote bug growth. Care should be taken at all times not to damage the surface finish of your process chamber.

ACTIVATED CARBON AIR FILTRATION

When the chemical drawer is opened, the airflow fan will operate creating a negative pressure in the drawer which helps prevent any fumes from escaping towards the operator.

The exhaust air from the chemical drawer is filtered at the point of discharge from the bottom of the machine, through an activated carbon filter.

This filter should be tested at each service visit, and should be changed at least every 12 months, or sooner if required.

This filter is located in the base of the RAPIDAER machine, together with the air flow fan.

NB: The carbon filter must be changed every 12 months.

NB:
TO ENSURE THAT THE AIR AND CARBON FILTERS ARE FITTED CORRECTLY,
THEY SHOULD ALWAYS BE INSTALLED BY A QUALIFIED ENGINEER.



ROUTINE MAINTENANCE:

RAPIDAER should be regularly maintained. Once the new equipment has been installed, commissioned and certified by a qualified Test Person (TP), you should adhere to the recommended service intervals.

Engineer visits = 2 per year at six monthly intervals, these consist of:

1 annual ~ Regular service every 52 weeks.

1 six monthly ~ Routine engineer inspections, every 26 weeks:

In between engineer visits, it is the responsibility of the user to ensure that the RAPIDAER machine is kept in the correct working status.

Regular water samples should be tested, and the water filters changed as required. The frequency for changing the wall mounted water filters will be site dependant, and will vary according to the supply water quality.



MACHINE SELF DISINFECTION:

The reason for self disinfect is to prevent the development of biofilm and micro-organisms, whilst the machine is not processing scopes

The self disinfect cycle is a thermal process, and will happen automatically during the night at the preselected time. There is also a self disinfect button in the options menu should it be necessary to carry out a self disinfect cycle at any other time.

The self disinfect process will be disabled when the RAPIDAER machine is used for any purpose whatsoever, or is not left in the start screen at the end of the day.

If the RAPIDAER is not used following the completion of the self disinfect protocol, it will repeat the above procedure the next night at the selected time.

Note:

It is important to ensure that no endoscope has been left in the machine at the end of the day and the start screen is displayed.

NB: during installation, some customers will require that all test results are returned prior to the RAPIDAER AER machine being used with endoscopes.

This will preclude the user training from taking place until these results are collated, which could take several weeks.

During such a period as this, the RAPIDAER machine will be set up to run self disinfect schedules over night to maintain the cleanliness of the machine.



CHEMICAL STORAGE DRAWER:

The chemical drawer is located on the dirty side (Load side) of the RAPIDAER machine.

Handles are fitted to allow you to open the chamber drawer.

You should always clean up any spillages caused during the changing or loading of Chemical bottles immediately.

CHANGING CHEMICALS:

When a chemical storage bottle is empty, the RAPIDAER computer screen will show a pop up warning box to tell the operator that a chemical bottle needs to be changed.

There will also be an audible alarm sounding, and the wash cycle “if in progress” will pause.

To change the bottles: First open the storage drawer , undo the cap and remove from the bottle.

Lift out the empty bottle. Ensure the replacement bottle is the same chemical.

Scan the data on the RFID tag on the front label of the new bottle, this will insert the lot number of the chemical, the expiry date and the serial number of the bottle.

Loosen the cap on the bottle with a bottle spanner and then put the bottle in the drawer.

Remove the cap on the bottle and replace with the pick-up cap.

Do the cap up tightly and closed the chemical drawer.

If a wash cycle was in progress when the bottle was changed, the operator should press the continue button in the pop up window to continue with the wash cycle.



DOOR LOCK – MANUAL OVERRIDE:

The door is actuated and held in position by air pressure and an electrical door lock, so no access can be gained during a cycle.

In the event of a power failure, the air pressure vessel will automatically empty, the door lock will release to the open position and thus the door can be manually pushed open to access any endoscope that may be in the chamber.



WATER SAMPLE PROTOCOL

RAPIDAER IS SAMPLED DURING THE FINAL RINSE AS THE SAMPLE PORT IS IN THE FEED TO THE CHAMBER. THE SAMPLE TAKEN SHOULD BE A MINIMUM OF 250MLS

1. PREPARE NECESSARY EQUIPMENT NEEDED I.E.: STERILE GLOVES, STERILE WATER SAMPLING BOTTLE, ALCOHOL WIPES AND RELEVANT LABORATORY FORM.
2. PREPARE RAPIDAER SAMPLE PORT BY RUNNING OFF 20MLS OF DISINFECTANT DURING THE DISINFECTANT PHASE OF THE CYCLE. WEARING PPE (MASK AND GLOVES), REMOVE THE BLUE PROTECTOR FROM THE END OF THE SAMPLE PORT, OPEN THE SCREW KNOB, ALLOW THE DISINFECTANT TO RUN OUT AND THEN CLOSE THE SAMPLE KNOB. DISCARD THE DISINFECTANT DOWN THE DRAIN AND RINSE CONTAINER.
3. WIPE DOWN WORK AREA WITH ALCOHOL WIPE, AND OPEN PACKET OF STERILE GLOVES. IN ADDITION, OPEN ANOTHER ALCOHOL WIPE AND DROP ONTO GLOVES. TAKE LID OFF SAMPLE CONTAINER.
4. WASH HANDS WITH HIBISCRUB OR EQUIVALENT E.G.: BETADINE SCRUB.
5. PUT ON GLOVES USING ASEPTIC TECHNIQUE AND KEEP HANDS ABOVE WAIST LEVEL AND AWAY FROM THE BODY
6. WHEN THE FINAL RINSE IS STARTED, TAKE AN ALCOHOL WIPE AND WIPE THE SAMPLE OUTLET .
7. DURING THIS RINSE, OPEN THE SAMPLE KNOB AND ALLOW AT LEAST 50MLS TO RUN INTO A WASTE CONTAINERS, THEN TAKE THE STERILE BOTTLE AND PLACE GENTLY UNDER THE SAMPLE OUTLET AND FILL THE SAMPLE BOTTLE. CLOSE THE SAMPLE KNOB AND FIT THE BLUE PROTECTOR.
8. PLACE LID ON BOTTLE, AND DRY THE OUTSIDE.
9. FILL IN THE LABEL AND ATTACH TO THE BOTTLE.
10. FILL OUT THE APPROPRIATE FORM GIVING DETAILS OF SAMPLE SOURCE, TIME AND DATE ETC. AND SEND AS SOON AS POSSIBLE TO THE LABORATORY.
11. FILL OUT THE RAPIDAER WEEKLY VALIDATION TEST LOG, WITH THE RELEVANT DETAILS.

ASEPTIC TECHNIQUE MUST BE USED WHEN OBTAINING A WATER SAMPLE



WHERE TO FIND THE WATER SAMPLING PORT.

The special water sample port is located on the left hand side just below the chamber on the loading side of the chamber.

Water Sampling Port

Water sampling in the RAPIDAER offers the user the facility to collect water from the point of application, as close to the contact with the scope as possible.

The water and Chemicals that pass through the pipework holding the sample point is the same as the irrigation feed to the scope channels.



The sample port has a blue cover which should always be replaced to help keep the fitting clean. You can fill this with alcohol when replacing it, after taking a water sample.



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MEDIVATORS® RAPIDAER



Operators Manual

Issue 01 – September 2014



Language Version
Original Instructions in English.



0088

CE Marking certifies that this equipment conforms to the following EEC directives:

Medical device directive 93/42/EEC

Low Voltage Equipment – 72/23/EEC

CE marking directive 93/68 EEC

Electromagnetic Compatibility – 89/336/EEC



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INTRODUCTION:

RAPIDAER DESCRIPTION:

The Medivators® range of automated endoscope re-processors, cover a wide range of capabilities to suit your particular requirements. RAPIDAER is the latest in the range, which now offers the user full pass through compliance to meet the requirements of BS EN 15883 Parts 1 & 4, SHTM2030 & CFPP01-06.

The RAPIDAER is a single chamber machine processing a single multiple channel endoscope per cycle in an easy to load basket. The machine has the same unparalleled external scope cleaning performance and integral individual channel cleaning facility as the Autoscope Isis providing a fully compliant re-processing performance.

Included in the automated wash cycle time of approx.17 minutes, is the automated leak test facility, and continuous channel monitoring. DATA records include operator, endoscope, and wash cycle information, together with the unique identification of the connection manifold being cross referenced against the endoscope channels of the endoscope.

PROCESS CYCLE

The normal re-processing cycle is in 7 stages.

1. Leak Test
2. Gross Wash and lumen patency check
3. Detergent wash
4. Detergent Rinse,
5. Disinfectant Clean,
6. Disinfectant Rinse.
7. Air flush

The operator also has the option to perform a "Manual Leak Test" with the door open, prior to the wash cycle



UNDERSTANDING RAPIDAER:

RAPIDAER is a fully compliant self contained pass-through endoscope reprocessing machine.

Designed to re-process one endoscope in each cycle, RAPIDAER offers a full cycle process with-in 17 - 18 minutes of pressing the start button. *(subject to a 5 minute disinfectant contact time and the incoming water temperature)*

Likewise loading the scopes is quick and efficient, by the use of the scope carrier basket design. Scopes can pre-loaded into their carrier baskets ready to be loaded in to the RAPIDAER machine, as soon as the re-processed scope is removed.

PASS THROUGH TECHNOLOGY:

RAPIDAER offers a compact footprint design that can be easily delivered and installed with access through standard size doorways. The pass through function of RAPIDAER allows the owner to split the re-processing task into separate areas, either in the same room, or separate rooms, by incorporating RAPIDAER into a dividing wall.

“Dirty Side” for loading used scopes & un-loading scopes that don’t complete their re-processing cycle.

“Clean Side” for unloading re-processed scopes only.

TRACE ABILITY:

RAPIDAER incorporates all the information that you require:
Operators have to log onto the machine, by use of a Tag, or ID & PIN for both loading & un-loading

The connection manifold and the endoscopes have to be logged onto the machine by use of a Tag, which identifies the channel configuration for irrigation and checks the hub and the manifold have the same channel connections.

Any access to the user configuration and set-up options, requires a log in, either by use of a TAG, or “ID & PIN”.

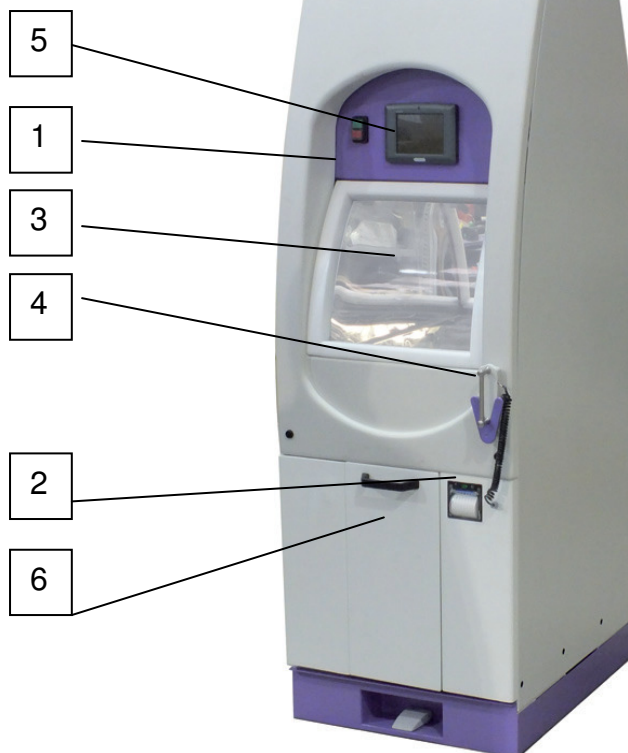
All information is captured in the RAPIDAER computer memory, and can be transferred when required via a USB data storage device, or the unit can be linked directly to a traceability system.

A printout is produced as part of each cycle, with the option for a comprehensive print out:- detailed report.



FIND YOUR WAY AROUND RAPIDAER: "DIRTY SIDE" SCOPE LOADING SIDE

1. ON / OFF switches
2. Printer (optional on this side)
3. Process Chamber
4. Tag Reader
5. Control Panel touch screen (onboard computer)
6. Chemical storage chamber



"CLEAN SIDE" SCOPE UN-LOADING SIDE

The clean side has

- Emergency stop Button
- Printer
- Access to Process Chamber
- Tag Reader
- Control Panel Read out for cycle status



ON/ OFF SWITCHES:

The On/Off switches are located on the top left of the load side (dirty side) of the RAPIDAER adjacent to the control panel.

GREEN is ON
RED is OFF



EMERGENCY STOP BUTTON: (CLEAN SIDE ONLY)

There is an emergency stop button on the top left of the unload side (clean side) of RAPIDAER.



TAG READER:

The TAG readers are on both sides of the RAPIDAER machine, and are positioned to give the best possible ergonomic interaction with the operator and scope carrier baskets during loading and unloading.



CHEMICAL CHAMBER:

The Chemical chamber is on the Dirty Scope, load side of the machine.



RAPIDAER CONNECTIONS:

ELECTRICAL CONNECTIONS:

RAPIDAER will be connected to a 32 amp, 50Hz, 240 V single phase supply.

The connection point for each RAPIDAER machine should have an isolator switch located close to one side of the RAPIDAER machine, (pass through installations)

If an engineer is working on the RAPIDAER machined he may require to disconnect the power supply and lock this isolator for health and safety requirements.



SUPPLY WATER:

The incoming water supply to the RAPIDAER should be from an RO plant. The RO is connected to the machine at the top where there is an aseptic sampling point and isolation tap. The machine will use 44 litres per cycle.

WASTE WATER:

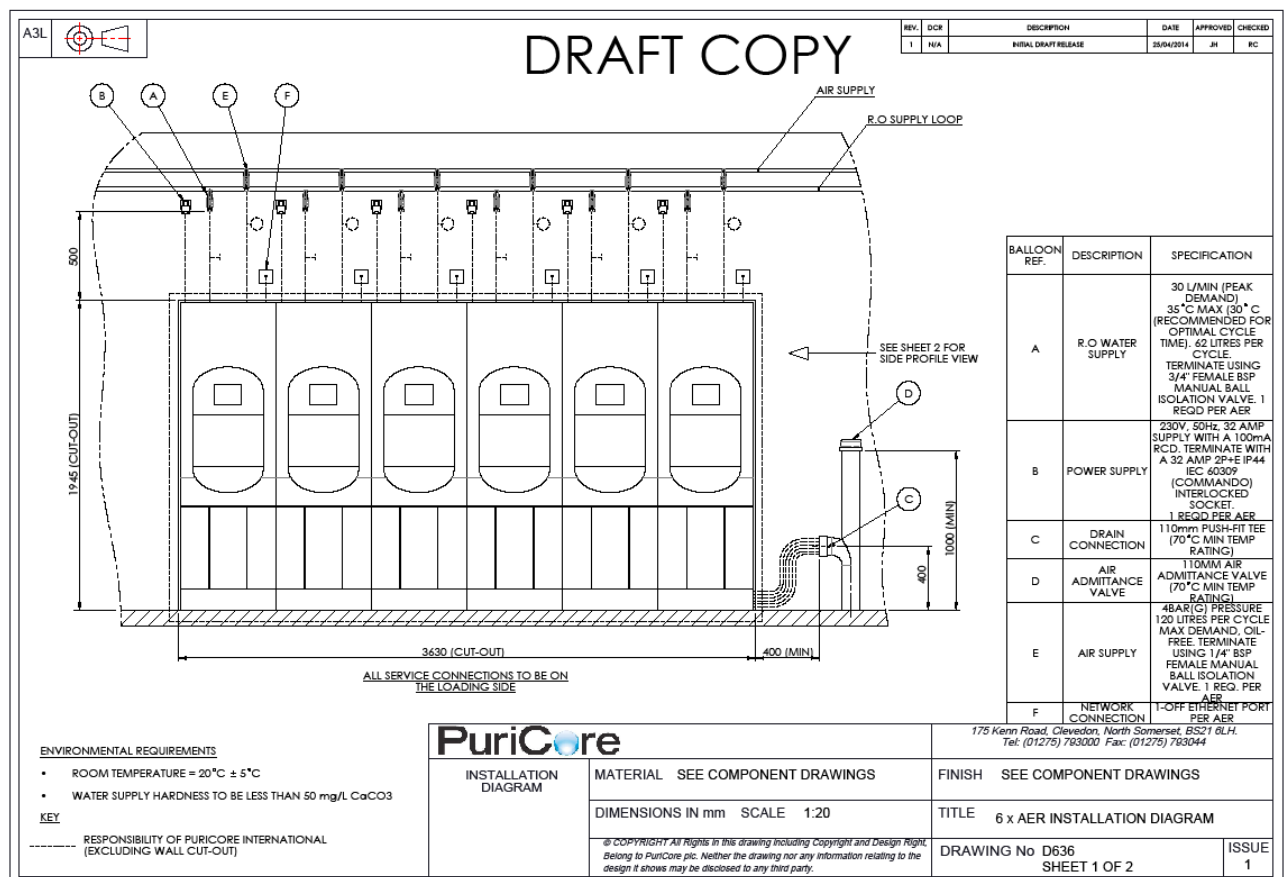
Waste water from the RAPIDAER should flow directly to a standard vented drain.

Always ensure that the water supply is turn on before using the RAPIDAER machine.

AIR PURGE SUPPLY:

A medical grade air supply should be connected to the top of the machine with an line gauge to allow operators to see the air pressure that is being supplied.

CONNECTION DIAGRAM





SPECIFICATION

Model	RapidAER
Dimensions	600mm (w) x 800mm (d) x 1930mm (h)
Processing Time	17 minutes
Disinfectant	Rapicide PA two part, single shot, Peracetic acid based disinfectant
Detergent	Mediclean Plus alkaline single shot detergent
Power Requirements	230v, 50hz, 32 amp supply
Class 1 equipment	Protective Earth required
Connection to supply	IEC 60309 industrial coupler
Water Requirements	64 litres per processed scope
Construction	Steel frame, Polycarbonate doors, Plastic cover panels.
Noise Level	<58 dBA
Weight	240Kg
Process Capacity	1 large flexible endoscope per cycle
Environmental Operation Conditions	
Operating Temperature Range	Ambient (0-40 °C)
Humidity	20%- 90%



OPERATOR - RAPIDAER INTERFACE

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

The operator has various options on how to interface with the RAPIDAER machine.

For ease of use, speed and efficiency the RAPIDAER machine is configured to operate using a TAG system.

There are three types of TAGS:

The Operator TAG:- which contains all the relevant data about the operative.

The Scope TAG:- which contains all the relevant data about the endoscope.

The Connection Manifold TAG – which contains all the details about endoscope connection

(All of these are covered in more detail on the following pages).

The TAGS are pre-programmed by the RAPIDAER manager with all the relevant details. The TAG system allows the operator to follow the prompts / instructions on the computer screen, and by presenting the TAG to the tag reader, the RAPIDAER machine will progress onto the next step in the process.

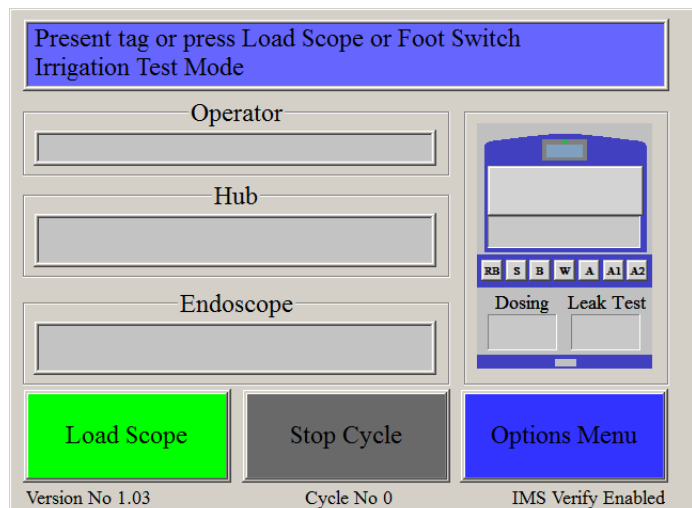
However, should the operator not have their TAG for whatever reason, RAPIDAER also has the option to allow access through the computer touch screen.

Each operator will also have an identification number and a PIN, these can be used to identify the operator to the RAPIDAER manually.

The operator will also be required to use the computer touch screen during the endoscope loading process. The buttons that are active and can be pressed to select an option or confirm a question, are always coloured in green.

The only other button that can be pressed is the Pause button, active once the cycle has started.

To operate a touch screen button, the operator should gently, but firmly press their finger on the button on the computer screen.





RAPIDAER CONTROL PANELS:

DIRTY SIDE (LOAD SIDE) CONTROL TOUCH SCREEN



CLEAN SIDE (UN-LOAD SIDE) CONTROL PANEL





OPERATOR ID

PERSONAL IDENTIFICATION NUMBER (PIN)

Under the “Hospital protocols” section of the RAPIDAER control functions, you are required to choose a PIN and sequential ID number for each operator or manager who has access to your RAPIDAER machine.

The PIN should be a confidential identification known only to the assignee, and the RAPIDAER manager.

It is recommended that a secure log or record of the PIN’s should be kept by the hospital (RAPIDAER manager) to cover for the event of an operator losing their TAG, and forgetting their PIN.

It doesn’t matter if operators choose a PIN that someone else already has, because it has to be used with their unique sign on ID number.

Once an ID & PIN and a TAG have been assigned to a user’s log on, the operator does not need to use their PIN because all the necessary information is stored on the operator TAG.

The operators ID & PIN will be required if a TAG is lost or stolen; so that the operator can access the RAPIDAER machine manually. The ID & PIN are also needed to re-assign a new TAG for the operator.

Please refer to the following section on TAG’s , for lost or damaged TAG’s



OPERATOR ID TAG:



Fig: Tag 1

Each operator that is assigned to your Autoscope RAPIDAER machine, should be allocated a unique personal TAG.

The operator ID TAG provides several functions:

- 1) Identifies the operator.
- 2) Automatically logs the operator into the RAPIDAER machine.
- 3) Automatically confirms the operator's access level status.
- 4) The TAG is required to open the RAPIDAER doors for both loading & unloading.
- 5) If a tag is lost or stolen. The RAPIDAER Manager should assign a new tag to the operator, this will disable the lost TAG.

SCOPE ID TAG:



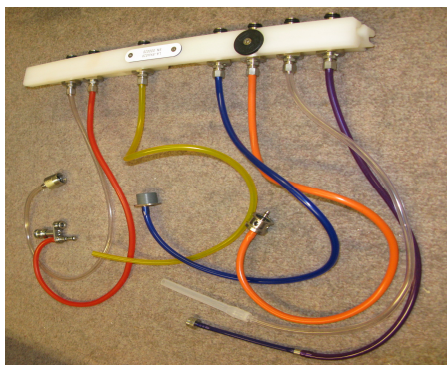
Fig : Tag 2

Each Scope that will be re-processed in the RAPIDAER requires a unique identification TAG rated to IP68.

This will identify the scope to the RAPIDAER machine, automatically confirming the parameters for cleaning and testing etc.

The TAG will also allow the endoscope to be tracked within the DATA storage and printouts.

CONNECTION HUBS



THE CONNECTOR HUB.

This is used with each scope that is installed into the carrier basket. There are a large number of hubs with connections dedicated to number of channels in that particular family of endoscopes. The hubs vary dependant on manufacturer and the individual connectors required to fit the individual channels.



CONNECTOR HUBS ID TAG



The connector hub tag is similar to endoscope ID tag and is rated to IP68. The information stored on the tag allows for the number of channel that are connected to be verified against the number on channels on the endoscope tag and then during the process these connections are monitored.

NOTE: All accessories used with the RapidAER, and to connect the endoscopes must comply to Cantel Medical's specification.

PRE-LOADING A SCOPE:

PREPARING THE SCOPE BASKET:

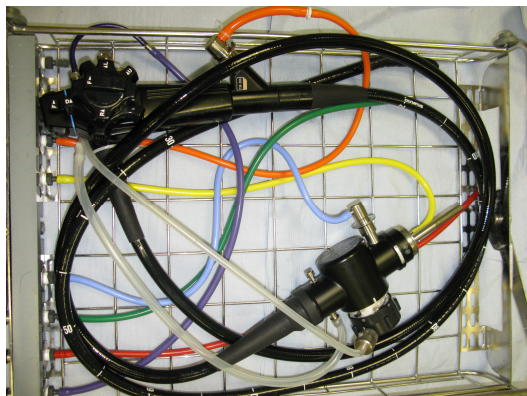
The RAPIDAER machine uses a scope carrier basket to house the scope in the machine. The basket is pre-loaded with the scope on a worktop, and placed into the RAPIDAER when ready.

On completion of the wash cycle, the scope is removed in its basket, so that another scope basket can be loaded and washed whilst the previous scope is removed from the basket.

The carrier basket can then be returned to the load side, for re-loading with more scopes.

Take an empty basket and then select the correct hub for the endoscope to be reprocessed. Each type of endoscope will have a specific connection manifold with the correct number of channel connectors suitable for that family of endoscopes.

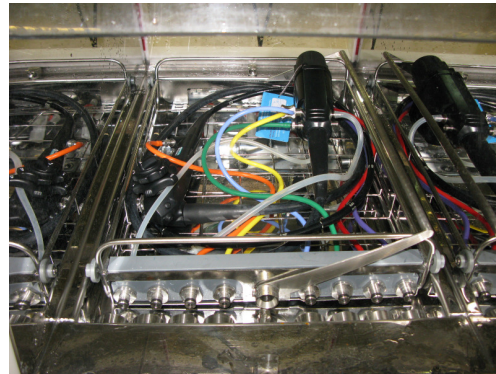
The manifold is slid into the end of the basket, the scope is then placed in the basket and the connections made to the scope.





LOADING THE SCOPE INTO THE RAPIDAER MACHINE

Open the RAPIDAER load door, using the operator tag or foot pedal.



Place the end of the basket on the side guides and slide the basket forward into the chamber until it rests totally in the base area.



Pull the basket back towards the front of the machine to locate the connectors into the irrigation ports on the inside front face of the chamber. When located, lock in position by moving the locking arm across the basket.

When the scope is loaded securely, Check the computer screen, and answer the question regarding channel separators, before closing the door,

UN-LOADING A SCOPE FROM THE RAPIDAER MACHINE:

To unload a scope, it is the reverse of the load operation.

When the computer instructs that the unload door can be opened, the operator should present their TAG to identify the unload operator and then retag or use the foot switch to open the clean side door.

Move the locking arm across to unlock the connections and then slide the basket upwards and remove through the clean door.

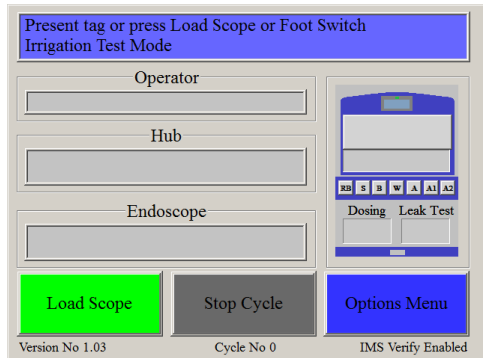
Close the door using the tag or foot switch.

The RAPIDAER machine will not proceed to the next step until the door has been closed properly.



How to “LOG ON” RAPIDAER

RAPIDAER functions via the onboard touch screen computer. The following steps show how to LOG ON to RAPIDAER using the touch screen.



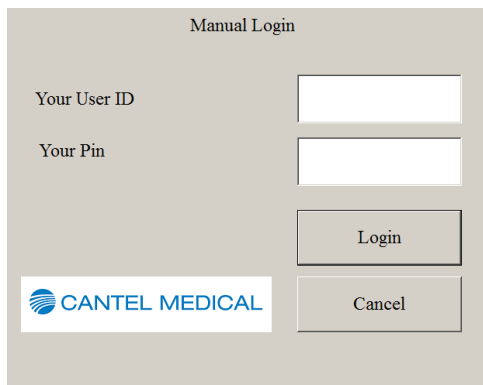
RAPIDAER Home screen

When at rest, the RAPIDAER will display the Home Screen.

In order to access the operating system, present the operator TAG to the reader.

Alternatively, touch the green box as indicated.

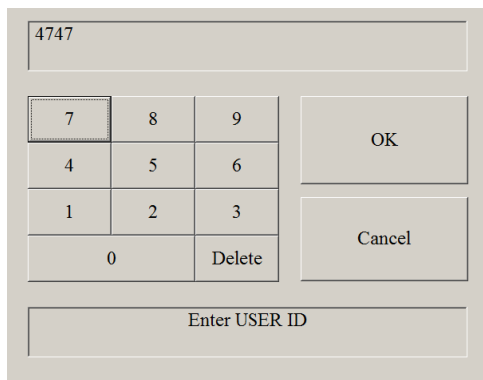
If the TAG is used, the door can then be opened by using the operator tag again or pressing the foot switch, and the RAPIDAER will ask for the Scope ID.



If the green box is pressed, the computer will proceed to the LOG ON screen

LOG ON screen

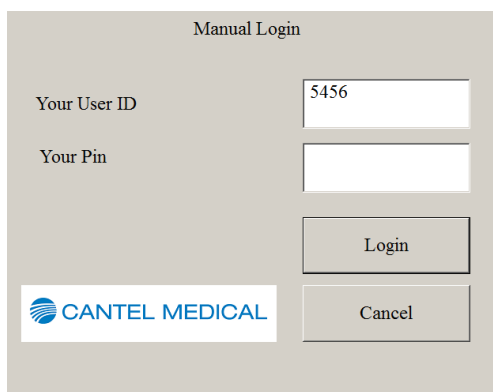
Touch the user ID box to input the users 4 digit reference number via the Key Pad screen



The numerical Key pad screen

Enter the user 4 digit ID number

Press OK to accept



Enter PIN

Touch the PIN box to activate the numerical keypad



7	8	9	OK
4	5	6	
1	2	3	Cancel
0	Delete		

Enter User Pin

The numerical Key pad screen

Enter the user 4 digit PIN

Press OK to accept


Manual Login

Your User ID

Your Pin

Login

Cancel

 CANTEL MEDICAL

Now press LOG ON

The door will open and the RAPIDAER will ask for the hub and scope ID

All the information displayed on the screen will be stored in the Data Log:
ie: User ID, name, PIN, TAG, including dates & times.



AUTOMATIC RE-PROCESS CYCLE

The normal re-processing cycle for either a one or two scope process is in 7 stages.

1. Leak Test
2. Gross Wash and Lumen Patency
3. Detergent wash
4. Rinse
5. Disinfectant Clean
6. Disinfectant Rinse
7. Air flush

The Computer display on the Load side of the RAPIDAER machine is the main user interface. Most of the wash cycle sequence can be performed by the use of the Operator TAG, Manifold TAG and the Endoscope TAG. Additional operator input is by pressing buttons on the touch screen.

The touch screen buttons are all indicated when they are active and are mostly located across the bottom of the computer screen.

The computer screen display prompts and instructs the operator on the physical actions to be taken during the load and un-load sequences.

During the wash cycle process, the computer screen displays the stage of the cycle that is being performed. This information is repeated on the unload side, scrolling display.

Other information displayed on the screen includes:

The load operator for each scope
The hub identification
The endoscope identification
The PAUSE cycle button.



CYCLE SEQUENCE

The following information will be displayed at each stage of the cycle in the purple information box on the computer “dirty side” (Load side), and will also be scrolling across the, Machine Status Display, on the “clean side” (Un-Load side)

SCOPE LOAD SEQUENCE

- 1) RAPIDAER Ready Tag or Log On
- 2) Load Operator ID recorded
- 3) Load basket
- 4) Present Hub Tag
- 5) Hub ID recorded
- 6) Present Endoscope TAG
- 7) Endoscope ID recorded
- 8) Close door
- 9) Fitted Channel Separators?
- 10) Press Start

WASH CYCLE SEQUENCE

- 11) Leak Test and detergent dose measured
- 12) Gross Wash & Lumen patency check
- 13) Dose Detergent, Detergent Wash (Solution will be heated if water temperature lower than required)
- 14) Detergent Rinse
- 15) Dose Disinfectant solutions
- 16) Disinfectant contact (Solution will be heated if water temperature lower than required)
- 17) Disinfectant Rinse
- 18) Air Purge

SCOPE UNLOAD SEQUENCE

- 19) Present operatorTAG to open door
- 20) Un-load operator ID recorded
- 21) Unload & close door
- 22) Rotating to unload position 2
- 23) RAPIDAER READY (Tag or Log On)



USING THE RAPIDAER MACHINE

To start an automatic cycle, simply perform the following procedures.

SWITCHING THE RAPIDAER MACHINE ON.

First ensure that the power supply is switched on at the isolator. This should be located on the wall, close to the machine.

Then ensure that the water supply is turned on.

It is also important to take regular water samples to ensure that the supply RO water is clean.



Then press the GREEN start button.

This is located on the Top Left Hand Side of RAPIDAER, on the Load Side of the machine.

When the start button is pressed the computer will display the initialising screen. Once the RAPIDAER computer has booted up all the required configurations, the touch screen will display the Home Page

The Main Computer screen will stay on the Home Page, until a re-processing cycle is started.



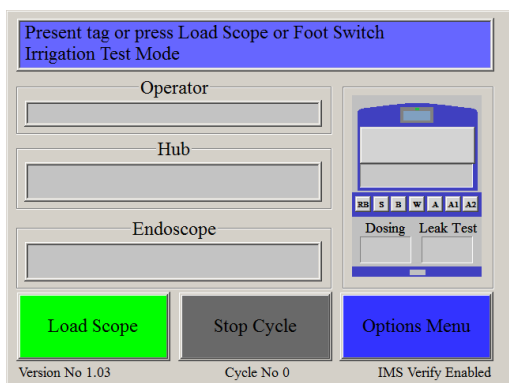
USING THE RAPIDAER MACHINE – RUNNING A CYCLE:

On switch on the RAPIDAER computer will load the standard home screen

The Main Computer screen will stay on the Home Page, until you start a re-processing cycle.

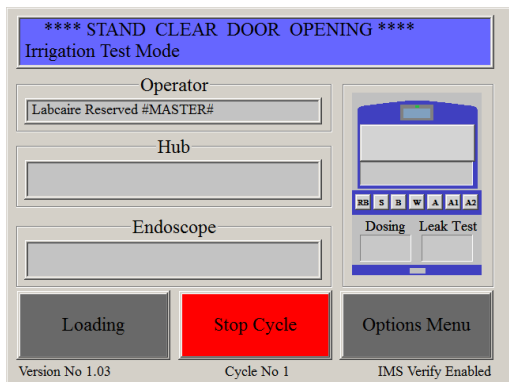
To use the RAPIDAER machine:

The operator needs to follow the instructions in the blue box at the top of the screen.



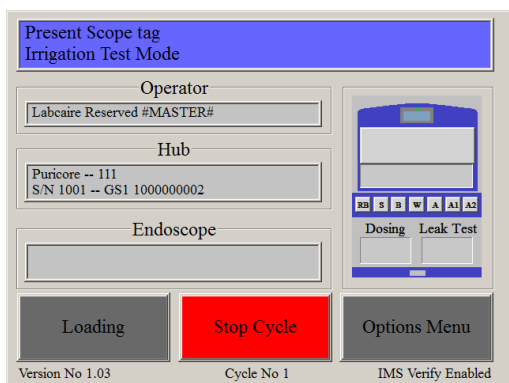
Present the Operator ID TAG to the TAG Reader. This identifies the operator as an approved user.

If the foot switch or load scope button is pressed then the operator will be asked to tag in or log on before proceeding.



NB: the operator DATA box now has the user ID displayed. This will be recorded for all information regarding this cleaning cycle.

Present the operator ID tag or use the foot switch to open the door. Load the basket and endoscope in to the chamber and the use the tag reader wand to identify the hub.



The DATA boxes now have the user ID and the hub ID

Use the tag reader wand to identify the endoscope.

The DATA boxes now have the user ID, the hub ID and the endoscope ID.



CONFIRM CHANNEL SEPARATORS FITTED
Present tag or Press Confirm or Foot Switch

Operator
Labcaire Reserved #MASTER#

Hub
Puricare -- 111
S/N 1001 -- GS1 1000000002

Endoscope
Olympus -- BF10
S/N 1005 -- GS1 1000000005

Confirm **Stop Cycle** Options Menu

Version No 1.03 Cycle No 1 IMS Verify Enabled

The operator will be asked to confirm if the channel separators have been fitted.

If separators are not required, still select Confirm.

****** STAND CLEAR DOOR CLOSING ******
Irrigation Test Mode

Operator
Labcaire Reserved #MASTER#

Hub
Puricare -- 111
S/N 1001 -- GS1 1000000002

Endoscope
Olympus -- BF10
S/N 1005 -- GS1 1000000005

Loading **Pause Cycle** Options Menu

Version No 1.03 Cycle No 3 IMS Verify Enabled

On confirming the channel separators are fitted the door will close automatically.

Pause Cancel will allow the cycle to be stopped and return to the beginning of the load sequence.

Present tag or press Start Cycle or Foot Switch
Irrigation Test Mode

Operator
Labcaire Reserved #MASTER#

Hub
Puricare -- 111
S/N 1001 -- GS1 1000000002

Endoscope
Olympus -- BF10
S/N 1005 -- GS1 1000000005

Start Cycle **Pause Cycle** Options Menu

Version No 1.03 Cycle No 1 IMS Verify Enabled

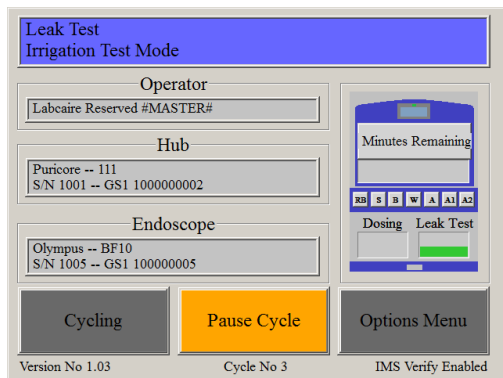
Press the green "START CYCLE" button on the left side of the touch screen, present the user tag to the tag reader or press the foot switch to start the cycle.

If a scope is loaded without presenting the Tag to the Tag Reader, the RAPIDAER machine will not let the software continue to the next stage.

This is achieved by means of the door not closing, until the endoscope Tag is presented to the Tag Reader.

Only then; will RAPIDAER allow you to continue to perform a wash cycle.

The RAPIDAER machine will automatically proceed with the leak test & cleaning cycles.



Firstly RAPIDAER performs an initial Leak Test.

At the same time it will prepare for the wash cycle.



The phase of the cycle is displayed in the blue box at the top of the screen

The duration of the cycle is displayed in minutes

The time remaining will count down in whole minutes

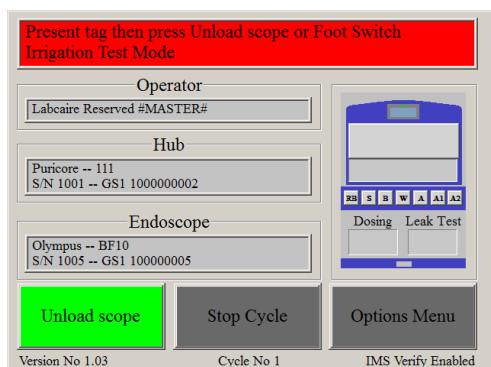
The final sequence of the cycle is the air purge which flushes the rinse water out the scope channels.

At the end of the process cycle RAPIDAER will inform you if the scope has passed or failed.

A failure will usually be indicated at the relevant point during the process cycle.

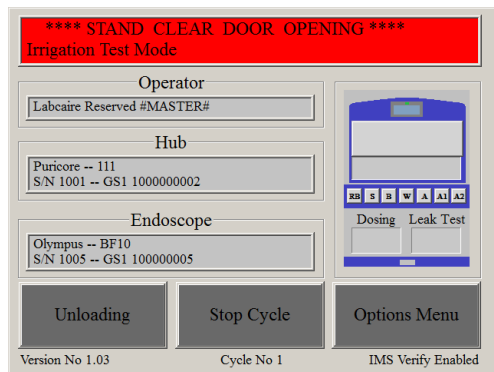
NB: Coloured buttons are active, press them to activate the function. Grey buttons are de-activated or display information only.

SCOPE PASS UNLOAD PROCESS



The Unload operator must use their ID tag to identify themselves to the RAPIDAER machine on the unload side.

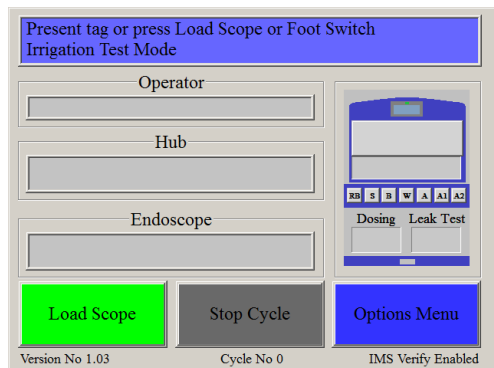
When the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.



The Un-load operator's ID will be recorded on the computer, and this information will be included on the print out, which appears on the clean side for the passed cycle.

When the door is open, remove the basket and endoscope.

Remove the cycle printout from the printer.



Close the door by using the operator ID tag or foot switch.

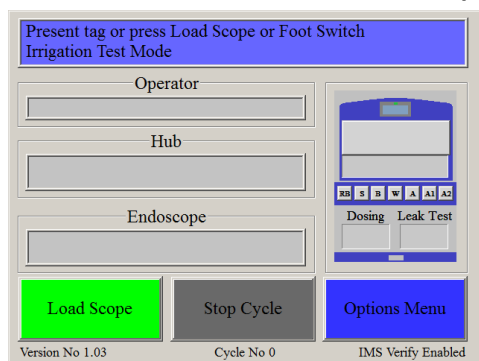
When the door is closed, the RAPIDAER returns to the HOME PAGE ready for loading to commence the next cycle.

Any scope that fails to pass all the criteria can only be removed from the "dirty side" Load side of the RAPIDAER machine.

The operator must present their Tag to the Tag reader to unload.

SCOPE FAIL UNLOAD PROCESS

The process to remove the endoscope from a failed cycle is the same as for a pass cycle except the Unload operator must use their ID tag to identify themselves on the load 'dirty' side of the machine.



Once the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.

The cycle printout will be given on the load 'dirty' side of the machine.

When the door is open, remove the basket and endoscope.

Close the door by using the operator ID tag or foot switch.

RAPIDAER will return to the HOME PAGE ready for loading to commence the next cycle.

Unload the endoscope from the basket and assess the problem from the data given before reprocessing the endoscope.



OPTIONS MENU

The options button allows various functions to be carried out by the user and for an administrator to use the 'Hospital Protocol' section to add endoscopes, operators and hubs to the data base.

Press the 'Options menu' button on the right hand side of the home page.

The 'Log In' screen will be displayed. Either present the operator tag to the tag reader or enter your user ID and PIN as covered on page 16

Options Menus

User Menu

Administration Menu

SELF DISINFECT:

The thermal self disinfect can be set to come on at a predetermined time so the process is completed before the machine is required for reprocessing the endoscopes used that day.

There is also a 'Start Now' button on this screen, so a self disinfect process can be started when ever required



OPENING DOORS:

To open a door when prompted to by the screen instruction, you will be required to present your operator TAG to the RAPIDAER machine or use the foot switch. The door will unlock and open automatically.

Should you wish to open the access door at other times, or if the operator is not in possession of their TAG. Then the operator will be required to access the OPTIONS menu in order to open the door.

To do this, the operator must first. Select the OPTIONS button on the HOME PAGE This will then take you to the options selection screen.

HOME PAGE - Press the OPTIONS button to select:

LOG ON - The operator should use either their ID tag or enter ID number and PIN.

Press the OPEN DOOR button.

The door will 'unlock', so that it can be opened.

RETRIEVING A SCOPE:

Should the operator need to retrieve a scope from the RAPIDAER machine, other than in the normal sequence of a wash cycle; then this can be achieved by the following steps.

Scope Failed message - Press the abort button.

Press the "Options" Button

OPTIONS" Log on Screen - Present TAG to the tag reader or Enter user ID number & PIN

Then press Log On to proceed

OPTIONS Menu

Press the "OPEN DOOR" button
This will open the Dirty Side door only.



OPENING THE CHEMICAL STORAGE DRAWER:

To access the chemicals, the operator must first press the GREEN OPTIONS button on the RAPIDAER computer screen. This will then take you to the options selection screen.

Press the OPTIONS button to select:

LOG ON OPTIONS MENU by the operator either using their ID TAG or manually not entering their ID number and PIN.

Now press the “OPEN CHEMICAL CHAMBER” button.

The drawer will unlock, and the operator can manually pull the door open.

NB: the air extract fan will operate to contain and remove any odours via the carbon filter.

Select the chemical to be added, detergent, Base or Activator by touching the screen to highlight the chemical to be changed.

Pass the chemical bottle, with the label side facing the tag reader, across the bottle tag reader and the new bottle batch number will appear in the new

chemical boxes. Press OK to confirm the data.

Put the chemical bottle in the drawer and then change the lid over to the pick up lid in the unit.

IF the tag reader or the bottle label does not activate the new number correctly the the number can be added manually.

Press the Batch number area by the 'new' section.

A screen will appear that allows the new batch number to be entered.

Similarly select the serial number and enter this in the same way.

Finally add the expiry date for the chemical in the date boxes.

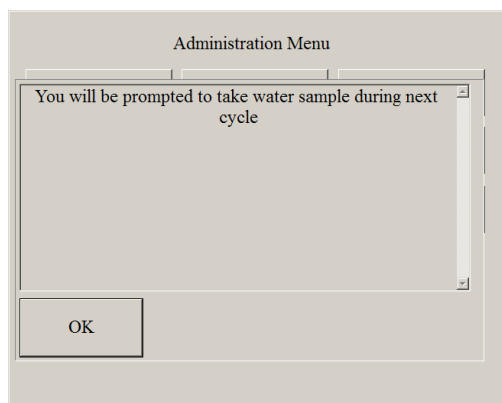


ACTIVATE FLUSH SYSTEM ROUTINE:

This facility flushes all the complete system and dosing pots so that they are at the correct status for a new cycle to be started. This facility should be used when the wash cycle has been interrupted and RAPIDAER is out of synchronisation.

WATER SAMPLE

This option can be selected to allow a prompt to be given when the last rinse is being done and the water sample should be taken.

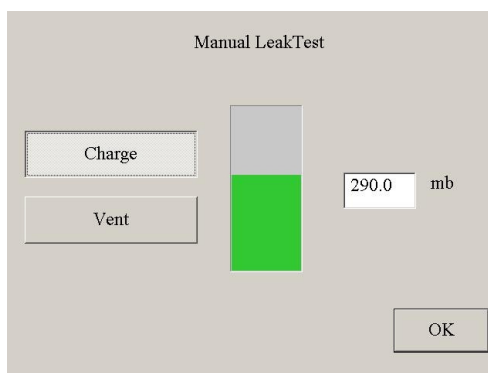


Select OK and the cycle will emit an alarm when the final rinse stage is reached in the next cycle.

ENGINEERING.

This button is not displayed in the normal user mode, it only becomes active when the engineer has a special USB key in the machine.

LEAK TEST:



In the event of a leak test failure, a manual leak test can be carried out in the machine. This will pressurise the scope to the required 290 mbar and by watching the screen any leak can be detected by the slow decrease of the pressure reading.



SET TIME

The date and time can be changed to the local time at the location of the unit.

Select the time and date on the UP/DOWN arrows and press save to confirm the new date and/or time.

PRINT CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

This function is in the Hospital Protocols for personnel with ADMIN access.

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

This function is in the Hospital Protocols for personnel with ADMIN access

HOSPITAL PROTOCOLS

These screens can only be accessed by users that have been given 'ADMIN' rights during the set up of the user's tag.

An operator with user access only will not be allowed to access the "Hospital Protocol" menus.

Functions within Hospital Protocols

Add a NEW operator/user
 EDIT an existing operator's details
 Assign a NEW scope ID
 EDIT an existing scope ID
 Add a NEW connector hub
 EDIT a connector hub
 Print a last cycle ticket
 Print a cycle report
 Print the last self disinfect cycle ticket
 Copy files



ADD A NEW USER

Press the “New Operator” button on the Screen

The operator ID is sequentially assigned by RapidAER automatically.
Every Operator will have a unique ID number.

To enter an operator name:
Touch the white text box

Touch screen type writer pad.

Input the new operator’s name.

Then press OK.

The name will now appear in the white text box.

To enter the user PIN
Touch the White text box .

Touch screen number pad:
Type in the 4 digit PIN for the new operator according to your SOP.
(standard operating procedure) Then press OK!

The PIN will not be displayed on the screen
Only a symbolic representation, this is for security reasons.

It is recommended that you keep a record of the PIN elsewhere.

To assign a TAG, present the new TAG to the tag reader.



All the operator details are now installed and linked to the ID TAG.

Next assign access rights and press the 'Inactive' box to make the operator 'Active'.

Access Rights

To assign the new operators access capabilities; Press the relevant Description to tick the boxes.

Then press OK:

Access Rights:

For basic machine operation access:- tick the User box

For access to set up new scopes, users or hubs or copy data files:- tick the Admin box.

The Admin access automatically gives an operator user rights to run a cycle.

The New Operator is now installed into the RapidAER computer.

EDIT AN EXISTING USER'S DETAILS

Press the "Edit User" button on Screen

Select the operator to be edited by touching the operators name on the screen.

Then press edit operator

The operator details will be displayed.

Select and modify their Access Rights, or re-assign a new Tag.

Then press OK.

The edit function is now complete.



ADD A NEW CONNECTION HUB ID

Press the 'Add Hub' button on the Menu screen

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

The complete hub list will appear

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

Select the hub to be added

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be added

Press OK

Max Flows

Suction 1800

Biopsy 0

Water 0

Air 0

Aux 1 0

Aux 2 1800

RB Min Pres 0

Make CANCEL

Model RAH008

Dept

Serial No

GS1

Tag

Adding Hub Type RAH008

OK Cancel

To add the information touch the white box adjacent to 'Dept'.

Endoscopy

q w e r t y u i o p

a s d f g h j k l

z x c v b n m

Number Space Delete

Shift - \

Clear . @

Enter Department

OK Cancel

Type in the department name and Press OK



Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	
Air	0	GS1	
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Next add the serial number that is on the new hub serial number plate. (Each hub has its own serial number so individual hubs of the same type number can be identified.)

Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	012345
Air	0	GS1	334
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Complete the data by selecting each box and typing in the data.

Finally present the tag fixed onto the hub to the tag reader to add this data.

Press OK to save the new hub data.

NOTE The max. Flow values on the right side of the screen give the disconnect alarm and cannot be altered. Any changes that are required to these flows must be made by a Cantel Medical engineer after testing the hub with the respective endoscope.

This new connector hub can now be used in the RapidAER machine.

EDIT AN EXISTING HUB ID

Press the 'Edit Hub' button on the screen. This allows a hub to be edited and assigned to another department or for a hub to be deleted from the hub list in the RapidAER computer.

RA002 S/N 1008 RA017 S/N 1011 RA020 S/N 1012 RA022 S/N 1013 RA038 S/N DSFS	<input type="button" value="Delete"/>
<input type="button" value="Select Hub to Edit"/>	<input type="button" value="OK"/> <input type="button" value="Cancel"/>

The list of connection hubs that have been stored in your RapidAER machine will be displayed

A hub can now be edited or deleted



Select the hub by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be edited

Press OK if hub to be edited

The Hub information page will appear.

Now make your alterations as per the “add new hub” procedures, selecting any of the data that has a white box and changing as necessary.

Then press OK to Save the new data.

If the hub is no longer to be used then the delete button can be selected after the hub has been selected in the hub list displayed in the edit scope process as above.

Select ‘Yes’ and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

To exit this process then press ‘Cancel’

ADD A NEW ENDOSCOPE ID

Press the “Add Scope” button on the Menu Screen

The Scope Information page will appear. Now fill-in the boxes in sequence.

Press the “Make” box on the touch screen



Olympus									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number			Space			Delete			
Shift	-	\	Enter Manufacturer						
Clear	.	@	OK			Cancel			

The key pad will appear.
Enter the manufacturer of the scope eg. Olympus, Pentax , Storz etc

Then press the OK button to enter the data.

Min Flows		Make	Olympus
Suction	100	Model	
Biopsy	100	Dept	
Water	50	Serial No	
Air	50	GS1	
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK Cancel	

Press the “Model” box on the touch screen

Gastroscope									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number			Space			Delete			
Shift	-	\	Enter Model						
Clear	.	@	OK			Cancel			

The key pad will appear.
Enter the model of the scope eg. Gastroscope, Broncoscope etc

Then press the OK button to enter the data.

Continue to add the Department, Serial number, GS1 number if known in the same way as the Make and Model, typing in the data and pressing OK after each entry.

Min Flows		Make	Olympus
Suction	100	Model	Gastroscope
Biopsy	100	Dept	Endoscopy
Water	50	Serial No	GIF1246789
Air	50	GS1	F234
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK Cancel	

To complete the new endoscope entry
present the scope tag to the tag reader to assign
that tag to the data entered.

The tag data will be entered in the tag box.

Press OK to save the data to the RapidAER data base.

This new scope can now be re-processed using the RapidAER machine.



EDIT AN EXISTING SCOPE ID

Press the 'Edit Scope' button on the screen. This allows a tag to be edited and assigned to another scope or for a scope to be deleted from the endoscope list in the RapidAER computer.

The list of scopes that have been allocated by the user which are stored in your RapidAER machine will be displayed

A scope can now be edited or deleted

Select the scope by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the scope that is to be edited

Press OK if scope to be edited

The Scope information page will appear.

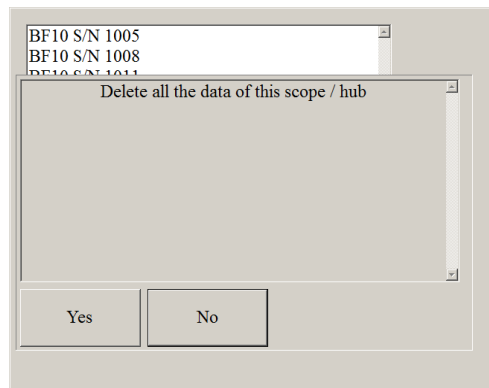
Now make your alterations as per the "add new scope" procedures, selecting any of the data and changing as necessary.

Then press OK to Save the new data.

Whenever this scope is re-processed in the RapidAER machine the new details will be logged and recorded.



If the endoscope is no longer to be reprocessed then the delete button can be selected after the endoscope has been selected in the endoscope list displayed in the edit scope process as above.



Select 'Yes' and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

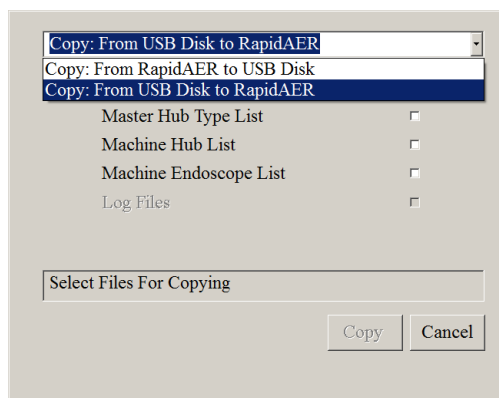
To exit this process then press 'Cancel'

Select 'No' and the screen returns to the scope list with endoscope still visible.

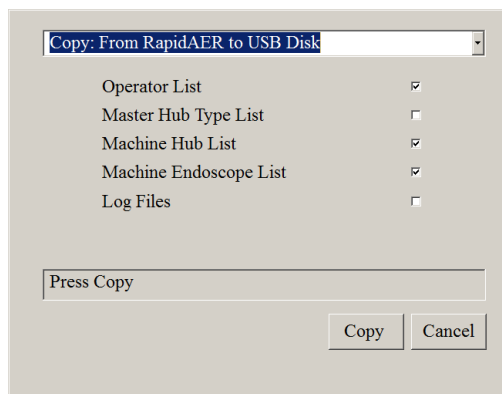
To exit this process then press 'Cancel'

COPY FILES

This button allows files to be copied onto the RapidAER computer or copied from the RapidAER computer. This allows the operator, endoscope, and department hub lists to be copied from machine to machine so data only has to be entered once.



From the arrow along side the top box select if files are to be copied onto the RapidAER from a USB key or whether files are to be copied from the RapidAER onto a USB key.



So to copy files from machine to machine after adding new operators, endoscopes or hubs

Select From RapidAER to USB disc

Tick the files to be copied – Operator list, machine hub list or machine endoscope list

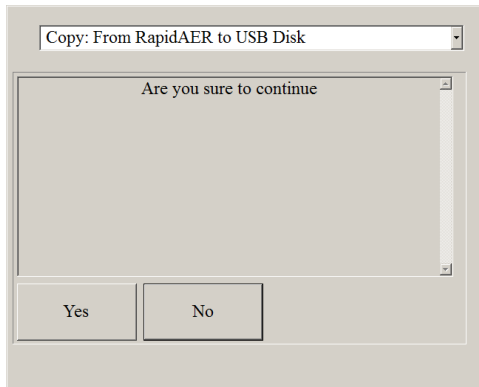
Note: Log Files can only be copied from the RapidAER to the USB Drive

Press 'Copy'

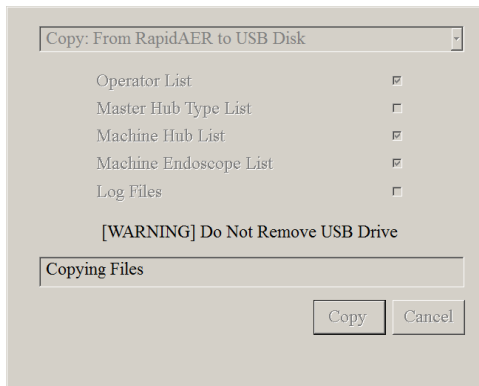


A message will appear to alert the operator that any files on the USB disc with the same name will be overwritten.

Select OK to acknowledge the message

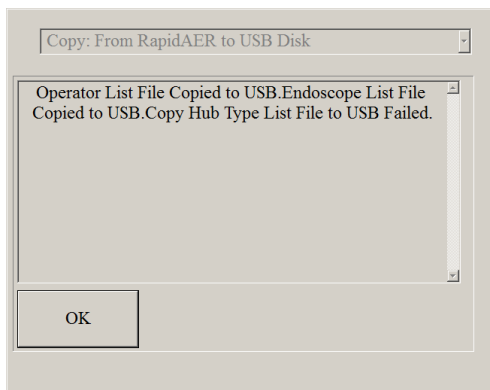


Press 'Yes' to continue the transfer or 'No' to exit



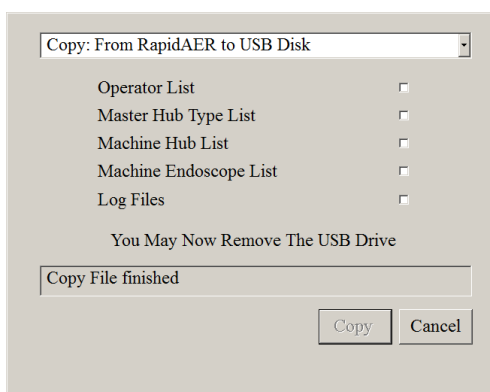
The files are now being copied.

Do not remove the USB drive



The screen indicates that the files have been copied or that a list has failed to copy.

Press OK



The final screen informs the operator that the copy file instruction is complete and the USB drive can be removed.

Press cancel to exit

To copy the files from the USB Drive to the next RapidaER machine, insert the USB drive in the slot adjacent to the screen on the dirty side of the machine. Go to Hospital Protocols and select 'Copy Files' follow the same process as above but initially select 'Copy: From USB Disk to RapidaER'



LOG FILES

These can be selected to be copied onto the USB drive as the above process and they can then be downloaded onto a hospital computer for analysis.

PRINT CYCLE REPORT

This will print a detailed report of the cycle that has just been completed. For more information see Printouts.

PRINT LAST CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

AUDIBLE ALARMS

INFORMATION ALARM:

When the RAPIDAER machine has completed the endoscope cleaning cycle, it will emit a single beep audible alarm, to indicate that the machine is ready for unloading

WARNING ALARMS:

When ever there is a visual warning alarm on the computer screen, the RAPIDAER machine will also emit a continuous audible alarm.

To stop this audible alarm, the operator needs to accept / acknowledge the visual alarm on the computer screen, by responding to the computer instruction or prompt.

POWER INTERRUPTION:

If the power source to the RAPIDAER is interrupted, the volt free contacts will enable a remote signal to indicate an alarm.

If the power supply to RAPIDAER is interrupted, then the RAPIDAER machine will need to be manually switched on, using the green button, on the front of the machine.



However if the RAPIDAER machine was performing a wash cycle when the power was interrupted; then, when the power is re-connected, the RAPIDAER machine will emit an audible alarm, linked with the wash cycle fail indication on the computer screen.

REMOTE ALARMS:

When ever there is a major alarm on the RAPIDAER machine, that would require immediate attention, eg: water leakage, power failure, self disinfect chemical bottles empty. Then the alarm will be duplicated via the volt free contacts, which will active either a visual or audible alarm in a remote location of the hospitals choosing. Eg: estate dept, BMS room, RAPIDAER managers office.



DATA SYSTEMS

The RAPIDAER AER machine has data storage and retrieval options for various types of data.

LOG DATA:

This is the cycle log record for every wash cycle and scope that has been processed in the RAPIDAER AER machine.

This data can be downloaded on to a USB key for achieving or the machine can be networked and the data transferred every cycle.

IMS:

(Independent Monitoring System)

This is a separate measuring system to confirm that the wash cycle parameters are within the tolerance that is required.

There are two levels of data retrieval obtainable through this system.

Level 1:- Process cycle history in an excel.csv spread sheet format.

Level 2:- the Full IMS data screen which will require the Cantel Medical IMS.net software package

Operator Data:

This is a history of every operator (present and previous) that has had access to the RAPIDAER machine.

Connector Hub Data:

This is a record of every connector hub present & previous that has been ID logged into the RAPIDAER AER machine, including the hub number, serial number and TAG ID.

Endoscope Data:

This is a record of every scope present & previous that has been ID logged into the RAPIDAER AER machine, including the make, model, serial number and TAG ID.



DATA STORAGE:

The RAPIDAER onboard computer has the capacity to store a large volume of information.

The memory allocated to cycle DATA storage will be able to store 250,000 wash cycles of information.

The information stored is formatted on an excel spread sheet, so that DATA retrieval is user friendly in both operator programme knowledge, and also in computer software compatibility.

The DATA storage format contains a heading with:

- The Department identification,
- The RAPIDAER machine serial number,
- The software version number.

DATA Storage Topic Headings:

- Date:
- Time:
- Pass / fail
- SD date
- SD time
- SD No:
- Operator ID
- Operator Name
- Un-load Operator ID
- Un-load Operator Name
- Contact time (seconds)
- Scope ID
- Manufacturer
- Model
- Serial Number
- Department
- Leak Test
- Raiser Bridge
- Channels Irrigated
- Comments
- Cycle Name
- Leak Test
- Number of Faults
- Reason Code
- Reason.



PRINTOUTS

The RAPIDAER provides a “hard copy” printout for the process that has been performed. This is in addition to the DATA being stored on the RAPIDAER computer which can be retrieval via a USB key or by direct connection to a Track and Trace system.

There are five label printout configurations:

- Cycle Complete = When a wash cycle has been completed.
- Cycle terminated = When a wash cycle has automatically stopped.
- Cycle terminated = When a wash cycle has been manually stopped
- Test Label = Engineer access only
- Detailed Process Report = RAPIDAER Hospital Protocol access required

The printers are located on the front of the machine:

On a pass through machine there will be a print out on the “clean side” (un-load side) for a ‘pass’ cycle and on the ‘dirty side’ (loading side) for a ‘failed’ cycle.

Below are example labels that depict the type of information that will be presented on the printouts



CYCLE COMPLETE 'PASS' PRINTOUT

(-----)	
(-----)	
(--Wash Cycle Pass --)	Cycle Pass/ Fail identification
(-----)	
(Cantel RapidAER)	
(Serial No RA0009)	RapidAER serial number
(-----)	
(Start 09h 44m)	Cycle start time:
(End 10h 02m)	Cycle finish time:
(Date 20-10-2014)	Date
(-----)	
(Cycle No. 52)	Unique sequential cycle number
(-----)	
(Load Operator 1)	
(Name Paul)	Loading operator identification
(-----)	
(Unload Operator 1)	
(Name Paul)	Un-Loading operator identification
(-----)	
(--Hub-----)	
(Cantel A3 Testroom)	Connection Hub used for the process
(Serial No 1)	
(GS1 1)	
(-----)	
(--Endoscope--)	
(Olympus Gastroscope)	Scope ID – including Make & Model
(Serial No GIFH260)	Serial No & GS1 No
(GS1 1)	
(-----)	
(IMS Verify Enabled)	IMS Status
(-----)	
(Control Pass)	Status of IMS & Control system at end of cycle
(IMS Verify Pass)	Pass confirmation
(-----)	
(Contact Time 5minutes)	Disinfectant Contact Time
(-----)	
(Last SD 20-10-2014 at 06h 00m)	RapidAER self disinfect information.
(-----)	
(Suction Av Flow 2185ml)	
(Biopsy Av Flow 1775ml)	
(Water Av Flow 120ml)	Average Flows in each of the channels during the
(Air Av Flow 85ml)	process including Raiser Bridge & Leak Test
(Aux 1 Av Flow 400ml)	Pressures
(Aux 2 Av Flow 900ml)	
(RB Av Pres 3850mb)	
(Leak Test Av Pres 300mb)	
(-----)	
(---Conductivity---)	
(Detergent 764µs)	Conductivity of each phase of the cycle
(Disinfectant 1150 µs)	
(Final Rinse 35 µs)	
(-----)	
(---Temperature---)	
(Detergent 25.1 deg)	Temperature of each phase of the cycle
(Disinfectant 26.1 deg)	
(Final Rinse 24.9 deg)	
(-----)	
(Chemical Batch/serial No)	
(Detergent D412/1134)	Chemical Batch / Serial numbers of each of the
(Part B B3321/889)	chemicals used for the process
(Part A A6543/996)	
(-----)	



CYCLE COMPLETE 'FAIL' PRINTOUT

There are two types of 'Fail' cycle and this is when the control or IMS system do the cycle checks and one or more parameters are outside the range allowed. The second failure is a manual abort by an operator. An example of each is given below.

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       10h 40m     )
( End         11h 02m     )
( Date        20-10-2014  )
(-----)
( Cycle No.   53          )
(-----)
( Load Operator 1      )
( Name         Paul      )
(-----)
( Unload Operator 1     )
( Name         Paul      )
(-----)
(  --Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled    )
(-----)
( Control      Fail       )
( IMS Verify   Fail       )
(-----)
( Fault: 9044 Manual Abort (dis wash) )
( Fault: 9045 IMS: RB Flow duration   )
( Fault: 9024 IMS Aux 1 Low flow (0)  )
(                               (dis wash) )
( Fault: 9049 IMS conductivity       )
(                               (dis wash) )
(-----)
```

Cycle Pass/ Fail identification

RapidAER serial number

Cycle start time:

Cycle finish time:

Date

Unique sequential cycle number

Loading operator identification

Un-Loading operator identification

Connection Hub used for the process

Scope ID – including Make & Model
Serial No & GS1 No

IMS Status

Status of IMS & Control system at end
of cycle

Fault codes – reason for failure

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       11h 24m     )
( End         11h 42m     )
( Date        20-10-2014  )
(-----)
( Cycle No.   54          )
(-----)
( Load Operator 1      )
( Name         Paul      )
(-----)
( Unload Operator 1     )
( Name         Paul      )
(-----)
(  --Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled    )
(-----)
( Control      Pass       )
( IMS Verify   Fail       )
(-----)
( Fault: 9048 IMS Irr temp 180.1 C    )
(                               (Leak Test) )
( Fault: 9048 IMS Irr temp 600.6 C    )
(                               (Gross Wash) )
( Fault: 9048 IMS Irr temp 600.6 C    )
(                               (DetWash) )
( Fault: 9048 IMS Irr temp 600.6 C    )
(                               (DetRinse) )
( Fault: 3035 IMS Irrigation temp     )
(                               sensor fault (6006) )
(-----)
```



CYCLE PRINTOUTS FOR SELF DISINFECT

There are two printouts for Self Disinfect Cycle Pass and Cycle Fail. Examples are both are shown below.

```
(-----)
(-----)
( -Self Disinfect Passed-- )
(-----)
( Cantel      RapidAER )
( Serial No   RA0009   )
(-----)
( Start       07h 29m   )
( End         08h 31m   )
( Date        20-10-2014 )
(-----)
( Cycle No.    11       )
(-----)
( Operator     1         )
( Name         Paul      )
(-----)
( Unload Operator 1 )
( Name         Paul      )
(-----)
( IMS Verify   Enabled   )
(-----)
( Control      Pass      )
( IMS Verify   Pass      )
(-----)
( Temp Stage 1  86.1deg   )
( Temp Stage 1  85.1deg   )
( Temp Stage 1  85.5deg   )
( Contact Time  10        )
(-----)
```

```
(-----)
(-----)
( -Self Disinfect Failed ---- )
(-----)
( Cantel      RapidAER )
( Serial No   RA0009   )
(-----)
( Start       07h 59m   )
( End         09h 14m   )
( Date        21-10-2014 )
(-----)
( Cycle No.     7       )
(-----)
( Operator     1         )
( Name         Paul      )
(-----)
( Unload Operator 1 )
( Name         Paul      )
(-----)
( IMS Verify   Enabled   )
(-----)
( Control      Fail      )
( IMS Verify   Fail      )
(-----)
( Fault: 9053 Spray system running )
( with empty sump (Recirc stage 2) )
( Fault: 9048 IMS Circ temp 64.5 C )
( (Recirc stage 2) )
( Fault: 9048 IMS Temp Su 63.7 C )
( (Recirc stage 2) )
(-----)
```




CHANGING PRINTER PAPER:

The printer is located as shown in the “Find your way around RAPIDAER” diagrams



The printers are located on the right hand side just below the chamber on both sides of the machine.



To access the paper roll,
Press the GREEN button on the top of the printer and the paper holder falls open.



To input a new paper roll, simply place the replacement paper roll into the printer as shown with the feed off section to the top, pull some paper forward, to create a tongue.



Push the paper holder closed, and tear off the excess paper against the serrated edge.

RAPIDAER printer is now ready for use.



To feed paper forward from the roll, press the button on the RIGHT.



ESSENTIAL OPERATING PRACTICES.

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

To ensure endoscopes are correctly disinfected it is important the following points are observed.

1. The machine thermal self-disinfection is carried out each day, before use.
2. The disinfectant contact parameter times are pre-programmed into the machine. The soak times must be determined by the manufacturer of the disinfectant and the Hospital Infection Control Department.
(Please refer to the tables in the "Disinfectant Types" section)
3. The manufacturer's instructions on the manual pre-cleaning, machine cleaning and disinfection of endoscopes must be followed at all times. The efficiency of the process depends on an efficient pre-clean and brushing through of the internal channels prior to disinfection.
4. It is most important that the endoscope internal channels are disinfected. The quality of the rinse water should be monitored at routine intervals.
5. The RAPIDAER must not be positioned within a risk area of anaesthetic equipment.

HOSPITAL PROTOCOLS:

Within the HOSPITAL PROTOCOL Menu, the user access protected CYCLE & SELF DISINFECT Menus allows for the defining of the following operational criteria:

RAPIDAER Hospital Protocol Menu
<i>Set & Edit Operator ID</i>
<i>Set & Edit Connection Hub ID</i>
<i>Set & Edit Endoscope ID</i>
<i>Copy Files</i>
<i>Reprint last cycle data</i>
<i>Reprint last self Disinfect cycle data</i>
<i>Print a detailed cycle report</i>



DISINFECTANT WARNINGS:

Disinfectants are hazardous substances and controlled by COSHH Regulations. Manufacturers must supply Safety Hazard Data Sheets to cover the use of their products.

The following Points should also be considered for use in this application.

1. Personal protection equipment should be worn when handling disinfectants or endoscopes. Suitable gloves, eye / face protection and apron.
2. The opening of disinfectants and closing of empty containers should be carried out, inside a suitable ventilated area.
3. The hospital should establish a procedure for safe storage, handling and disposal of disinfectant containers.
4. The hospital should establish a procedure for accidental spillage.
5. The RAPIDAER will provide a safe system for transfer of disinfectant to the chamber, during processing and disposal of used disinfectant. However, attention should be given to the room environment (ventilation) etc. see installation drawings. Correct ventilation will minimise problems if a spillage occurs.
6. The carbon filter should be changed every year to keep emissions below exposure limits.
7. Any disinfection contact should be washed off immediately and referred for medical attention.



DISINFECTANT TYPES:

The machine is compatible with two Peracetic Acid, single use disinfectants, for use on endoscopes, but the following points must be observed (see table below).

- A. The manufacturer of the Endoscope should be contacted for advice on chemical compatibility. Warrantees may only be valid on approved disinfectants.
- B. The Hospital Protocol and disinfection soak time should be approved by the disinfectant manufacturer and the Hospital Infection Control Department.
- C. Disinfectants activated with powders should not be used in RAPIDAER.
- D. Silicone based de-foamers should not be used in RAPIDAER.

DISINFECTANT NAME	DISINFECTANT TYPE	CARBON FILTER TYPE
Rapicide PA	single use peracetic acid	ACI
Purisept	single use peracetic acid	ACI

DISINFECTANT CONTACT TIME PARAMETERS		
disinfectant name	specific scopes	contact time
Rapicide	all	5 minutes
Purisept	all	5 minutes



DISINFECTION OF SCOPES:

CONNECTION OF ENDOSCOPES TO IRRIGATION CHANNELS:

Connection of the Endoscope to the irrigation lines is a critical procedure and as such great care must be taken to ensure correct connection. Connector hubs are available from Cantel Medical (UK) Ltd for each of the main types of the endoscope.

These connectors ensure that each channel is separated fully and therefore irrigated completely. Liquid is pumped into the endoscope from the light source end and passes completely through the length of the endoscope in a single motion.

It is essential that all channels are securely connected to prevent a cycle failure occurring.

RAPIDAER will remind the operator as part of the sequential screen prompts to check that channel separators have been installed.

NB: Certain scopes need to be sterilised after washing in an AER (Automated Endoscope Re-processor). The RAPIDAER AER should not be used as a replacement for sterilisation.

ENDOSCOPE STORAGE AFTER DISINFECTION PROCESS

Note:

Following the automatic disinfection cycle, the endoscope should be dried prior to long term storage, and can be hung directly into a Puricore Endoscope Drying Cabinet where the drying process will be carried out automatically, using dry compressed air, prior to longer storage of the endoscope in the clean environment of the cabinet. Alternatively the endoscope should be dried according to the endoscope manufacturer's protocol.



EU REGULATIONS:

Medical Devices Directive 93/42/EEC

Chemical Washer Disinfectors are a Class 2b medical device and the design, manufacture, installation and service are controlled under this directive. See Compliance for details of Puricore's accreditation.

Chemical Hazards - COSHH Regulations

Disinfectants are hazardous chemicals and it is necessary to perform a risk assessment covering all stages of use. The manufacturer of the disinfectant will supply Safety Hazard Data Sheets for their products.

See section on Disinfectant Types and Disinfectant Warnings.

The RAPIDAER should be tested at least every fourteen months to comply with this regulation.

BIOLOGICAL HAZARDS:

There is a risk to staff and patients from endoscopic procedures. The hospital should have its own procedures to control risk at each stage of the process.

TRAINING:

All staff using the RAPIDAER should be fully trained and certified on the use of the equipment.

Puricore Clinical Nurse Advisors will provide training sessions at each RAPIDAER installation, for the training and certification of operators and management staff.

Please contact Puricore for further details of training and availability.

VALIDATION:

The Autoscope RAPIDAER is manufactured to comply with BS EN 15883 Pt 1 & Pt 4, CFPP 01-06 and SHTM 2030. It should be fully validated according to table C1 of the BS EN 15883 Pt 1 & Pt 4 at the time of installation, followed by quarterly and annual re-validations.

COMPLIANCE:

Medical Devices Directive 93/42/EEC

Puricore International Ltd is approved to ISO 13485:2003 to design, manufacture and install chemical washer disinfectors.

Puricore International Ltd is approved to ISO 9001/EN46001 to service chemical washer disinfectors.

CE Marking

CE marking is applied to medical devices under Medical Devices Directive 93/42/EEC.



DECLARATION OF CONFORMITY



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Medical Device Directive Essential Requirements Checklist Declaration of Conformity

Description of Device
Product(s):

RapidAER

Assessment of Product based upon:

Certification of Quality System

Certificate No: LRQ 0954199/A
Issued by: LRQA

Date: 01/12/11

Essential Requirements Checklist

Prepared by: Regulatory Affairs

Date: 10/02/14

Technical File

Prepared by: Regulatory Affairs
Document number

Date: 10/02/14
2G-011

Product Classification:

Determine product classification based upon the requirements in MDD and
Medical Devices Regulations 2002:

☐ Class I ☒ Class IIb ☐ Class III

Approvals:

Based on a review of the above documents, we hereby declare that the above products comply with the
following EC directives:

- Medical Devices Directive 93/42/EEC as amended by 2007/47/EC
- Electro Magnetic Compatibility Directive 2004/108/EC
- Low Voltage Directive 2006/95/EC
- Machinery Directive 2006/42/EC
- Waste Electrical and Electronic Equipment Directive 2002/95/EC
- BS EN ISO 15883-1:2009
- BS EN ISO 15883-4:2009

Approved By: Neil Blewitt
Managing Director

Signature: _____

Date: _____

8th July 2014



Recommended actions to be taken for

"PERACETIC ACID" SPILLAGE

1. Evacuate the area.
2. Seal off the area to non-essential staff.
3. Put on protective clothing outside the affected area (boots, gown, apron, nitrile gloves, respirator face mask, goggles – NOT visors,).
4. On entry into the affected area – open all available windows (ie ventilate area) BUT DO NOT leave a door open into a corridor.
5. If it is a concentrate solution, absorb the excess with an inert material such as sand.
6. Put the contaminated sand into the disposal bag and seal tightly. Place this into a second disposal bag and seal tightly again. Contact your disposal company to collect it.
7. If it is a diluted solution or a small volume of concentrate, Dilute the solution with copious amounts of water and flush to drain.
8. Wash the floor area thoroughly with water.
9. Clean off boot soles before leaving the area.
10. Change any clothing that may have come into contact with the chemicals.



CONSUMABLES:

Description	Part No	Delivery lead time
1. Air Extract Carbon Filter	IS-LA 7014	5 Days
2. Printer Rolls (Pack of 20)	IS 795732	5 Days
3. Mediclean Plus Detergent (2 x 5 litre bottles)	900540	5 Days
4. Rapicide Disinfectant Part A	900530	5 Days
Rapicide Disinfectant Part B	900531	5 Days
5. Autowipes Disinfectant Wipes (6 x 200 wipe drums)	900505	5 Days



GENERAL CARE:

RAPIDAER is manufactured in the UK from quality materials, however any machine benefits from care and attention.

The exterior of RAPIDAER is manufactured from epoxy powder coated steel and polyurethane moulded panels. The use of abrasive cleaning agents should always be avoided. It is recommended that a warm soapy solution, or mild, diluted cleaning disinfectant is used.

The process chamber is manufactured from stainless steel with a smooth mirror finish. Gouges and scratches will enable biofilm and thus promote bug growth. Care should be taken at all times not to damage the surface finish of your process chamber.

ACTIVATED CARBON AIR FILTRATION

When the chemical drawer is opened, the airflow fan will operate creating a negative pressure in the drawer which helps prevent any fumes from escaping towards the operator.

The exhaust air from the chemical drawer is filtered at the point of discharge from the bottom of the machine, through an activated carbon filter.

This filter should be tested at each service visit, and should be changed at least every 12 months, or sooner if required.

This filter is located in the base of the RAPIDAER machine, together with the air flow fan.

NB: The carbon filter must be changed every 12 months.

NB:
TO ENSURE THAT THE AIR AND CARBON FILTERS ARE FITTED CORRECTLY,
THEY SHOULD ALWAYS BE INSTALLED BY A QUALIFIED ENGINEER.



ROUTINE MAINTENANCE:

RAPIDAER should be regularly maintained. Once the new equipment has been installed, commissioned and certified by a qualified Test Person (TP), you should adhere to the recommended service intervals.

Engineer visits = 2 per year at six monthly intervals, these consist of:

1 annual ~ Regular service every 52 weeks.

1 six monthly ~ Routine engineer inspections, every 26 weeks:

In between engineer visits, it is the responsibility of the user to ensure that the RAPIDAER machine is kept in the correct working status.

Regular water samples should be tested, and the water filters changed as required. The frequency for changing the wall mounted water filters will be site dependant, and will vary according to the supply water quality.



MACHINE SELF DISINFECTION:

The reason for self disinfect is to prevent the development of biofilm and micro-organisms, whilst the machine is not processing scopes

The self disinfect cycle is a thermal process, and will happen automatically during the night at the preselected time. There is also a self disinfect button in the options menu should it be necessary to carry out a self disinfect cycle at any other time.

The self disinfect process will be disabled when the RAPIDAER machine is used for any purpose whatsoever, or is not left in the start screen at the end of the day.

If the RAPIDAER is not used following the completion of the self disinfect protocol, it will repeat the above procedure the next night at the selected time.

Note:

It is important to ensure that no endoscope has been left in the machine at the end of the day and the start screen is displayed.

NB: during installation, some customers will require that all test results are returned prior to the RAPIDAER AER machine being used with endoscopes.

This will preclude the user training from taking place until these results are collated, which could take several weeks.

During such a period as this, the RAPIDAER machine will be set up to run self disinfect schedules over night to maintain the cleanliness of the machine.



CHEMICAL STORAGE DRAWER:

The chemical drawer is located on the dirty side (Load side) of the RAPIDAER machine.

Handles are fitted to allow you to open the chamber drawer.

You should always clean up any spillages caused during the changing or loading of Chemical bottles immediately.

CHANGING CHEMICALS:

When a chemical storage bottle is empty, the RAPIDAER computer screen will show a pop up warning box to tell the operator that a chemical bottle needs to be changed.

There will also be an audible alarm sounding, and the wash cycle “if in progress” will pause.

To change the bottles: First open the storage drawer , undo the cap and remove from the bottle.

Lift out the empty bottle. Ensure the replacement bottle is the same chemical.

Scan the data on the RFID tag on the front label of the new bottle, this will insert the lot number of the chemical, the expiry date and the serial number of the bottle.

Loosen the cap on the bottle with a bottle spanner and then put the bottle in the drawer.

Remove the cap on the bottle and replace with the pick-up cap.

Do the cap up tightly and closed the chemical drawer.

If a wash cycle was in progress when the bottle was changed, the operator should press the continue button in the pop up window to continue with the wash cycle.



DOOR LOCK – MANUAL OVERRIDE:

The door is actuated and held in position by air pressure and an electrical door lock, so no access can be gained during a cycle.

In the event of a power failure, the air pressure vessel will automatically empty, the door lock will release to the open position and thus the door can be manually pushed open to access any endoscope that may be in the chamber.



WATER SAMPLE PROTOCOL

RAPIDAER IS SAMPLED DURING THE FINAL RINSE AS THE SAMPLE PORT IS IN THE FEED TO THE CHAMBER. THE SAMPLE TAKEN SHOULD BE A MINIMUM OF 250MLS

1. PREPARE NECESSARY EQUIPMENT NEEDED I.E.: STERILE GLOVES, STERILE WATER SAMPLING BOTTLE, ALCOHOL WIPES AND RELEVANT LABORATORY FORM.
2. PREPARE RAPIDAER SAMPLE PORT BY RUNNING OFF 20MLS OF DISINFECTANT DURING THE DISINFECTANT PHASE OF THE CYCLE. WEARING PPE (MASK AND GLOVES), REMOVE THE BLUE PROTECTOR FROM THE END OF THE SAMPLE PORT, OPEN THE SCREW KNOB, ALLOW THE DISINFECTANT TO RUN OUT AND THEN CLOSE THE SAMPLE KNOB. DISCARD THE DISINFECTANT DOWN THE DRAIN AND RINSE CONTAINER.
3. WIPE DOWN WORK AREA WITH ALCOHOL WIPE, AND OPEN PACKET OF STERILE GLOVES. IN ADDITION, OPEN ANOTHER ALCOHOL WIPE AND DROP ONTO GLOVES. TAKE LID OFF SAMPLE CONTAINER.
4. WASH HANDS WITH HIBISCRUB OR EQUIVALENT E.G.: BETADINE SCRUB.
5. PUT ON GLOVES USING ASEPTIC TECHNIQUE AND KEEP HANDS ABOVE WAIST LEVEL AND AWAY FROM THE BODY
6. WHEN THE FINAL RINSE IS STARTED, TAKE AN ALCOHOL WIPE AND WIPE THE SAMPLE OUTLET .
7. DURING THIS RINSE, OPEN THE SAMPLE KNOB AND ALLOW AT LEAST 50MLS TO RUN INTO A WASTE CONTAINERS, THEN TAKE THE STERILE BOTTLE AND PLACE GENTLY UNDER THE SAMPLE OUTLET AND FILL THE SAMPLE BOTTLE. CLOSE THE SAMPLE KNOB AND FIT THE BLUE PROTECTOR.
8. PLACE LID ON BOTTLE, AND DRY THE OUTSIDE.
9. FILL IN THE LABEL AND ATTACH TO THE BOTTLE.
10. FILL OUT THE APPROPRIATE FORM GIVING DETAILS OF SAMPLE SOURCE, TIME AND DATE ETC. AND SEND AS SOON AS POSSIBLE TO THE LABORATORY.
11. FILL OUT THE RAPIDAER WEEKLY VALIDATION TEST LOG, WITH THE RELEVANT DETAILS.

ASEPTIC TECHNIQUE MUST BE USED WHEN OBTAINING A WATER SAMPLE



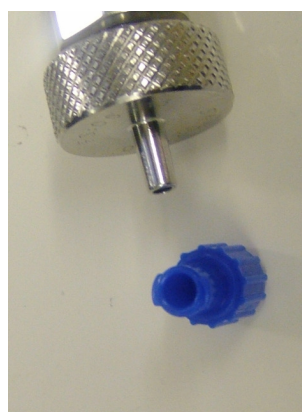
WHERE TO FIND THE WATER SAMPLING PORT.

The special water sample port is located on the left hand side just below the chamber on the loading side of the chamber.

Water Sampling Port

Water sampling in the RAPIDAER offers the user the facility to collect water from the point of application, as close to the contact with the scope as possible.

The water and Chemicals that pass through the pipework holding the sample point is the same as the irrigation feed to the scope channels.



The sample port has a blue cover which should always be replaced to help keep the fitting clean. You can fill this with alcohol when replacing it, after taking a water sample.



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MEDIVATORS® RAPIDAER



Operators Manual

Issue 01 – September 2014



Language Version
Original Instructions in English.



0088

CE Marking certifies that this equipment conforms to the following EEC directives:
Medical device directive 93/42/EEC
Low Voltage Equipment – 72/23/EEC
CE marking directive 93/68 EEC
Electromagnetic Compatibility – 89/336/EEC



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INTRODUCTION:

RAPIDAER DESCRIPTION:

The Medivators® range of automated endoscope re-processors, cover a wide range of capabilities to suit your particular requirements. RAPIDAER is the latest in the range, which now offers the user full pass through compliance to meet the requirements of BS EN 15883 Parts 1 & 4, SHTM2030 & CFPP01-06.

The RAPIDAER is a single chamber machine processing a single multiple channel endoscope per cycle in an easy to load basket. The machine has the same unparalleled external scope cleaning performance and integral individual channel cleaning facility as the Autoscope Isis providing a fully compliant re-processing performance.

Included in the automated wash cycle time of approx.17 minutes, is the automated leak test facility, and continuous channel monitoring. DATA records include operator, endoscope, and wash cycle information, together with the unique identification of the connection manifold being cross referenced against the endoscope channels of the endoscope.

PROCESS CYCLE

The normal re-processing cycle is in 7 stages.

1. Leak Test
2. Gross Wash and lumen patency check
3. Detergent wash
4. Detergent Rinse,
5. Disinfectant Clean,
6. Disinfectant Rinse.
7. Air flush

The operator also has the option to perform a "Manual Leak Test" with the door open, prior to the wash cycle



UNDERSTANDING RAPIDAER:

RAPIDAER is a fully compliant self contained pass-through endoscope reprocessing machine.

Designed to re-process one endoscope in each cycle, RAPIDAER offers a full cycle process with-in 17 - 18 minutes of pressing the start button. *(subject to a 5 minute disinfectant contact time and the incoming water temperature)*

Likewise loading the scopes is quick and efficient, by the use of the scope carrier basket design. Scopes can pre-loaded into their carrier baskets ready to be loaded in to the RAPIDAER machine, as soon as the re-processed scope is removed.

PASS THROUGH TECHNOLOGY:

RAPIDAER offers a compact footprint design that can be easily delivered and installed with access through standard size doorways. The pass through function of RAPIDAER allows the owner to split the re-processing task into separate areas, either in the same room, or separate rooms, by incorporating RAPIDAER into a dividing wall.

“Dirty Side” for loading used scopes & un-loading scopes that don’t complete their re-processing cycle.

“Clean Side” for unloading re-processed scopes only.

TRACE ABILITY:

RAPIDAER incorporates all the information that you require:
Operators have to log onto the machine, by use of a Tag, or ID & PIN for both loading & un-loading

The connection manifold and the endoscopes have to be logged onto the machine by use of a Tag, which identifies the channel configuration for irrigation and checks the hub and the manifold have the same channel connections.

Any access to the user configuration and set-up options, requires a log in, either by use of a TAG, or “ID & PIN”.

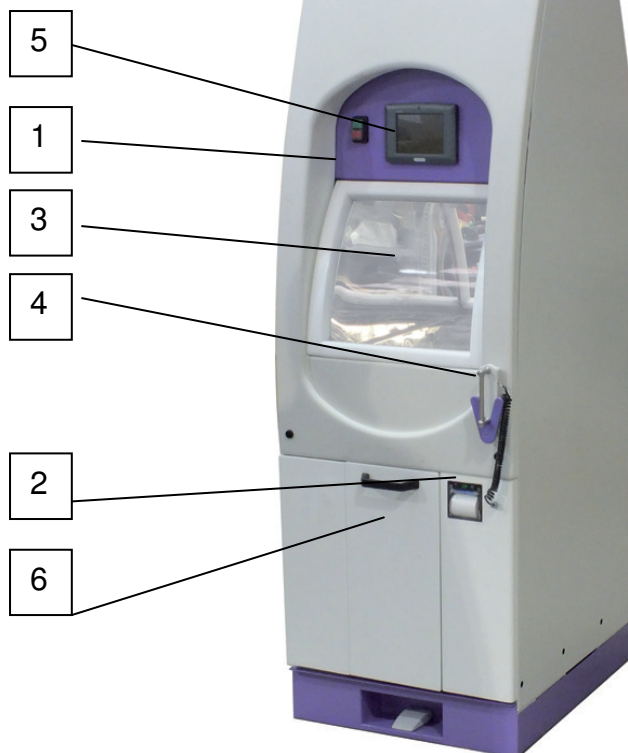
All information is captured in the RAPIDAER computer memory, and can be transferred when required via a USB data storage device, or the unit can be linked directly to a traceability system.

A printout is produced as part of each cycle, with the option for a comprehensive print out:- detailed report.



FIND YOUR WAY AROUND RAPIDAER: "DIRTY SIDE" SCOPE LOADING SIDE

1. ON / OFF switches
2. Printer (optional on this side)
3. Process Chamber
4. Tag Reader
5. Control Panel touch screen (onboard computer)
6. Chemical storage chamber



"CLEAN SIDE" SCOPE UN-LOADING SIDE

The clean side has

- Emergency stop Button
- Printer
- Access to Process Chamber
- Tag Reader
- Control Panel Read out for cycle status



ON/ OFF SWITCHES:

The On/Off switches are located on the top left of the load side (dirty side) of the RAPIDAER adjacent to the control panel.

GREEN is ON
RED is OFF



EMERGENCY STOP BUTTON: (CLEAN SIDE ONLY)

There is an emergency stop button on the top left of the unload side (clean side) of RAPIDAER.



TAG READER:

The TAG readers are on both sides of the RAPIDAER machine, and are positioned to give the best possible ergonomic interaction with the operator and scope carrier baskets during loading and unloading.



CHEMICAL CHAMBER:

The Chemical chamber is on the Dirty Scope, load side of the machine.



RAPIDAER CONNECTIONS:

ELECTRICAL CONNECTIONS:

RAPIDAER will be connected to a 32 amp, 50Hz, 240 V single phase supply.

The connection point for each RAPIDAER machine should have an isolator switch located close to one side of the RAPIDAER machine, (pass through installations)

If an engineer is working on the RAPIDAER machined he may require to disconnect the power supply and lock this isolator for health and safety requirements.



SUPPLY WATER:

The incoming water supply to the RAPIDAER should be from an RO plant. The RO is connected to the machine at the top where there is an aseptic sampling point and isolation tap. The machine will use 44 litres per cycle.

WASTE WATER:

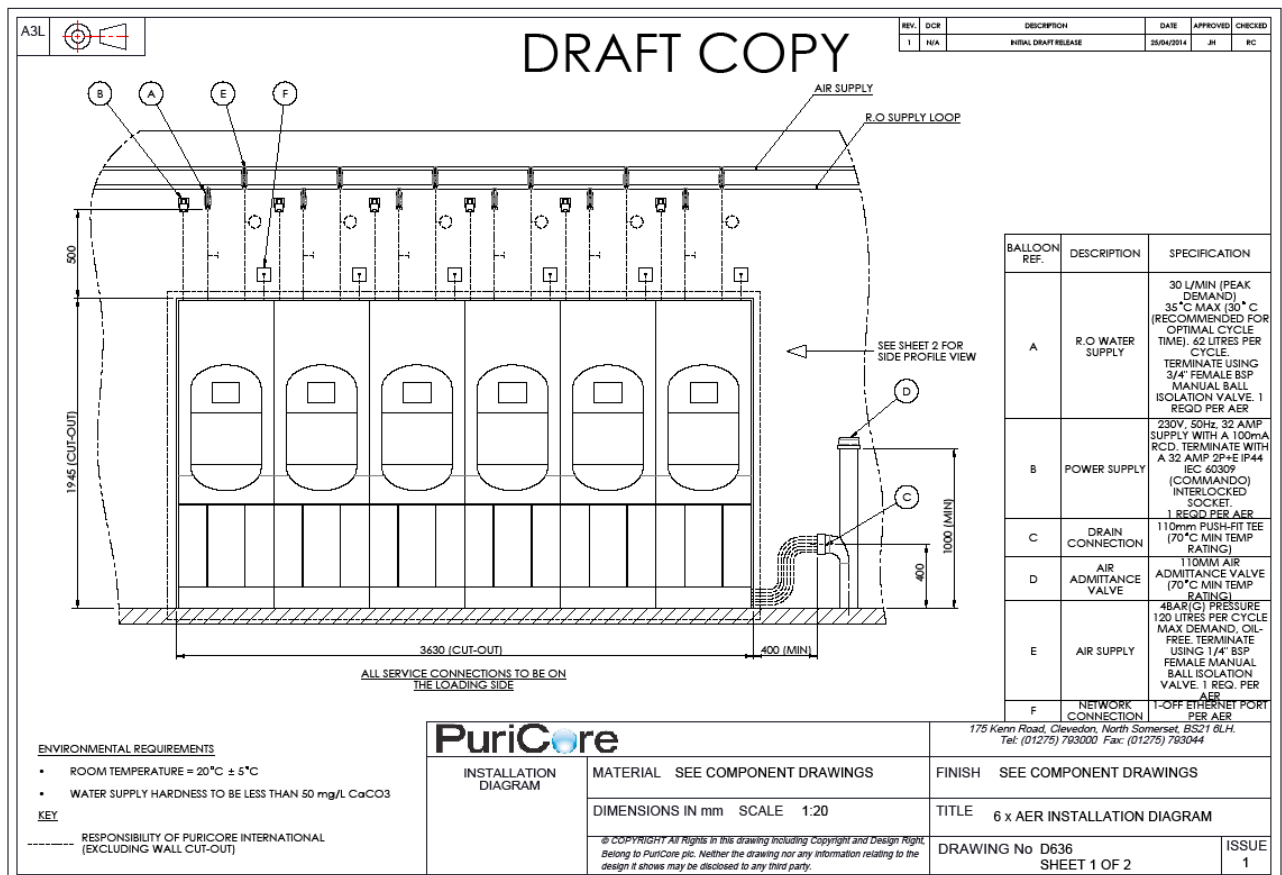
Waste water from the RAPIDAER should flow directly to a standard vented drain.

Always ensure that the water supply is turn on before using the RAPIDAER machine.

AIR PURGE SUPPLY:

A medical grade air supply should be connected to the top of the machine with an line gauge to allow operators to see the air pressure that is being supplied.

CONNECTION DIAGRAM





SPECIFICATION

Model	RapidAER
Dimensions	600mm (w) x 800mm (d) x 1930mm (h)
Processing Time	17 minutes
Disinfectant	Rapicide PA two part, single shot, Peracetic acid based disinfectant
Detergent	Mediclean Plus alkaline single shot detergent
Power Requirements	230v, 50hz, 32 amp supply
Class 1 equipment	Protective Earth required
Connection to supply	IEC 60309 industrial coupler
Water Requirements	64 litres per processed scope
Construction	Steel frame, Polycarbonate doors, Plastic cover panels.
Noise Level	<58 dBA
Weight	240Kg
Process Capacity	1 large flexible endoscope per cycle
Environmental Operation Conditions	
Operating Temperature Range	Ambient (0-40 °C)
Humidity	20%- 90%



OPERATOR - RAPIDAER INTERFACE

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

The operator has various options on how to interface with the RAPIDAER machine.

For ease of use, speed and efficiency the RAPIDAER machine is configured to operate using a TAG system.

There are three types of TAGS:

The Operator TAG:- which contains all the relevant data about the operative.

The Scope TAG:- which contains all the relevant data about the endoscope.

The Connection Manifold TAG – which contains all the details about endoscope connection

(All of these are covered in more detail on the following pages).

The TAGS are pre-programmed by the RAPIDAER manager with all the relevant details. The TAG system allows the operator to follow the prompts / instructions on the computer screen, and by presenting the TAG to the tag reader, the RAPIDAER machine will progress onto the next step in the process.

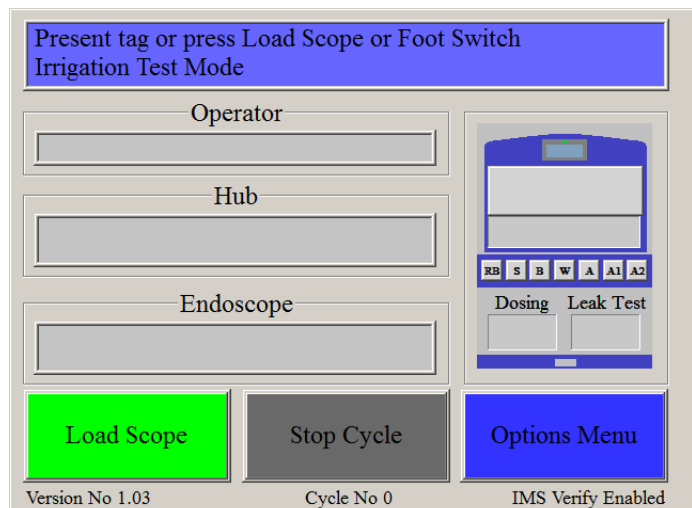
However, should the operator not have their TAG for whatever reason, RAPIDAER also has the option to allow access through the computer touch screen.

Each operator will also have an identification number and a PIN, these can be used to identify the operator to the RAPIDAER manually.

The operator will also be required to use the computer touch screen during the endoscope loading process. The buttons that are active and can be pressed to select an option or confirm a question, are always coloured in green.

The only other button that can be pressed is the Pause button, active once the cycle has started.

To operate a touch screen button, the operator should gently, but firmly press their finger on the button on the computer screen.





RAPIDAER CONTROL PANELS:

DIRTY SIDE (LOAD SIDE) CONTROL TOUCH SCREEN



CLEAN SIDE (UN-LOAD SIDE) CONTROL PANEL





OPERATOR ID

PERSONAL IDENTIFICATION NUMBER (PIN)

Under the “Hospital protocols” section of the RAPIDAER control functions, you are required to choose a PIN and sequential ID number for each operator or manager who has access to your RAPIDAER machine.

The PIN should be a confidential identification known only to the assignee, and the RAPIDAER manager.

It is recommended that a secure log or record of the PIN’s should be kept by the hospital (RAPIDAER manager) to cover for the event of an operator losing their TAG, and forgetting their PIN.

It doesn’t matter if operators choose a PIN that someone else already has, because it has to be used with their unique sign on ID number.

Once an ID & PIN and a TAG have been assigned to a user’s log on, the operator does not need to use their PIN because all the necessary information is stored on the operator TAG.

The operators ID & PIN will be required if a TAG is lost or stolen; so that the operator can access the RAPIDAER machine manually. The ID & PIN are also needed to re-assign a new TAG for the operator.

Please refer to the following section on TAG’s , for lost or damaged TAG’s



OPERATOR ID TAG:



Fig: Tag 1

Each operator that is assigned to your Autoscope RAPIDAER machine, should be allocated a unique personal TAG.

The operator ID TAG provides several functions:

- 1) Identifies the operator.
- 2) Automatically logs the operator into the RAPIDAER machine.
- 3) Automatically confirms the operator's access level status.
- 4) The TAG is required to open the RAPIDAER doors for both loading & unloading.
- 5) If a tag is lost or stolen. The RAPIDAER Manager should assign a new tag to the operator, this will disable the lost TAG.

SCOPE ID TAG:



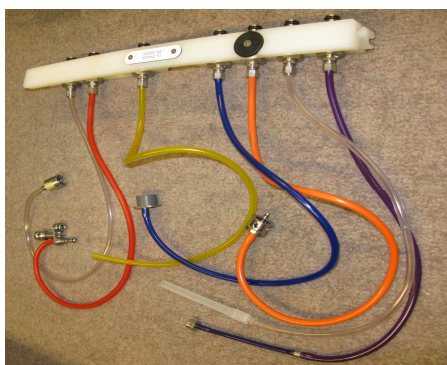
Fig : Tag 2

Each Scope that will be re-processed in the RAPIDAER requires a unique identification TAG rated to IP68.

This will identify the scope to the RAPIDAER machine, automatically confirming the parameters for cleaning and testing etc.

The TAG will also allow the endoscope to be tracked within the DATA storage and printouts.

CONNECTION HUBS



THE CONNECTOR HUB.

This is used with each scope that is installed into the carrier basket. There are a large number of hubs with connections dedicated to number of channels in that particular family of endoscopes. The hubs vary dependant on manufacturer and the individual connectors required to fit the individual channels.



CONNECTOR HUBS ID TAG



The connector hub tag is similar to endoscope ID tag and is rated to IP68. The information stored on the tag allows for the number of channel that are connected to be verified against the number on channels on the endoscope tag and then during the process these connections are monitored.

NOTE: All accessories used with the RapidAER, and to connect the endoscopes must comply to Cantel Medical's specification.

PRE-LOADING A SCOPE:

PREPARING THE SCOPE BASKET:

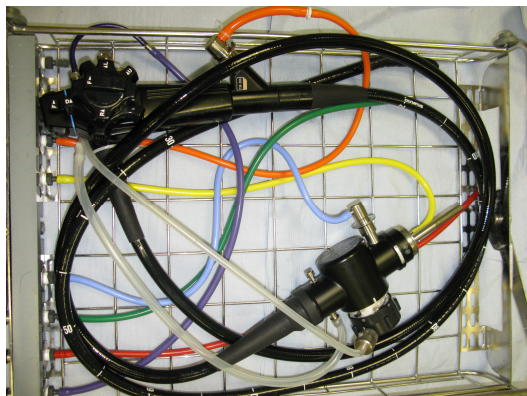
The RAPIDAER machine uses a scope carrier basket to house the scope in the machine. The basket is pre-loaded with the scope on a worktop, and placed into the RAPIDAER when ready.

On completion of the wash cycle, the scope is removed in its basket, so that another scope basket can be loaded and washed whilst the previous scope is removed from the basket.

The carrier basket can then be returned to the load side, for re-loading with more scopes.

Take an empty basket and then select the correct hub for the endoscope to be reprocessed. Each type of endoscope will have a specific connection manifold with the correct number of channel connectors suitable for that family of endoscopes.

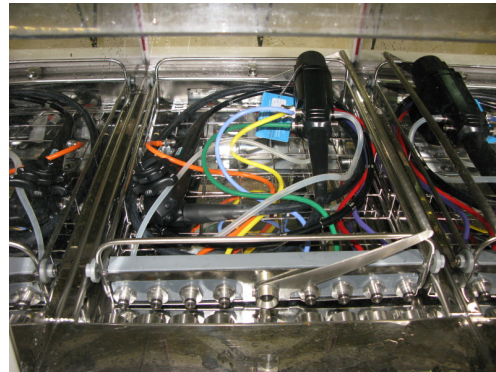
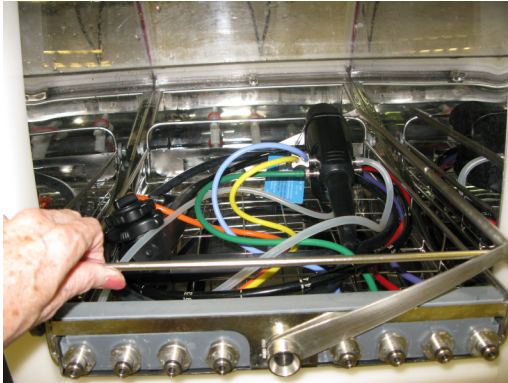
The manifold is slid into the end of the basket, the scope is then placed in the basket and the connections made to the scope.



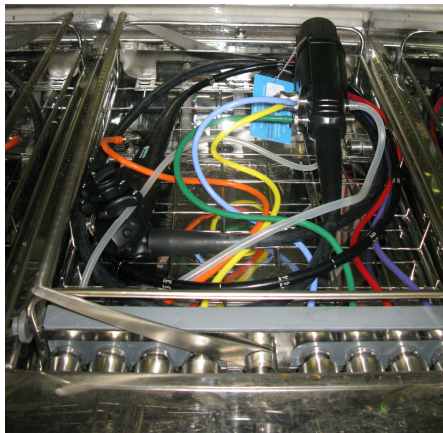


LOADING THE SCOPE INTO THE RAPIDAER MACHINE

Open the RAPIDAER load door, using the operator tag or foot pedal.



Place the end of the basket on the side guides and slide the basket forward into the chamber until it rests totally in the base area.



Pull the basket back towards the front of the machine to locate the connectors into the irrigation ports on the inside front face of the chamber. When located, lock in position by moving the locking arm across the basket.

When the scope is loaded securely, Check the computer screen, and answer the question regarding channel separators, before closing the door,

UN-LOADING A SCOPE FROM THE RAPIDAER MACHINE:

To unload a scope, it is the reverse of the load operation.

When the computer instructs that the unload door can be opened, the operator should present their TAG to identify the unload operator and then retag or use the foot switch to open the clean side door.

Move the locking arm across to unlock the connections and then slide the basket upwards and remove through the clean door.

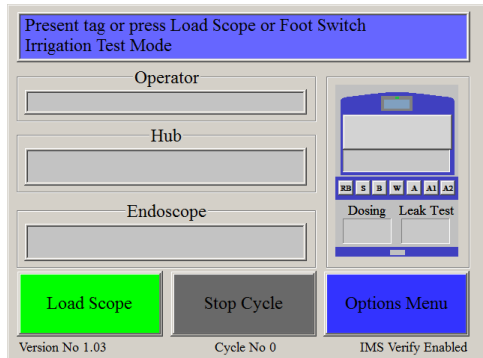
Close the door using the tag or foot switch.

The RAPIDAER machine will not proceed to the next step until the door has been closed properly.



How to “LOG ON” RAPIDAER

RAPIDAER functions via the onboard touch screen computer. The following steps show how to LOG ON to RAPIDAER using the touch screen.



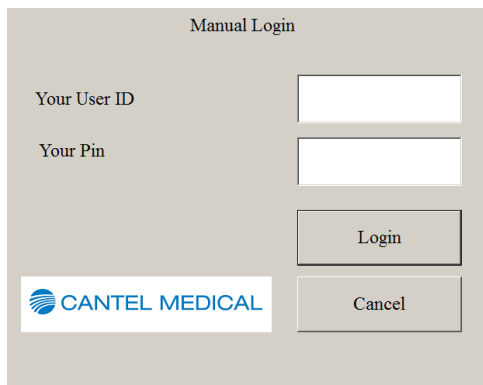
RAPIDAER Home screen

When at rest, the RAPIDAER will display the Home Screen.

In order to access the operating system, present the operator TAG to the reader.

Alternatively, touch the green box as indicated.

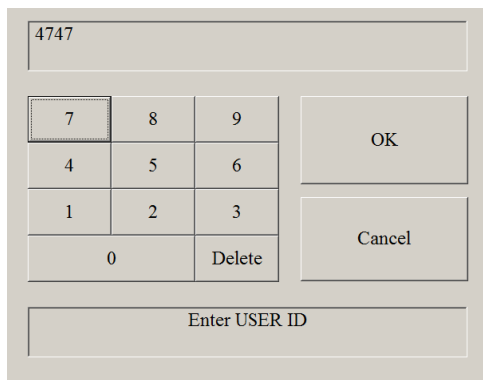
If the TAG is used, the door can then be opened by using the operator tag again or pressing the foot switch, and the RAPIDAER will ask for the Scope ID.



If the green box is pressed, the computer will proceed to the LOG ON screen

LOG ON screen

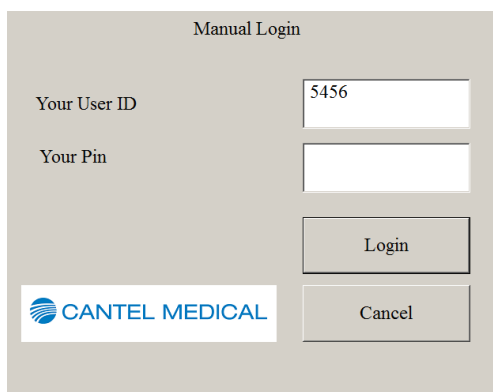
Touch the user ID box to input the users 4 digit reference number via the Key Pad screen



The numerical Key pad screen

Enter the user 4 digit ID number

Press OK to accept



Enter PIN

Touch the PIN box to activate the numerical keypad



7	8	9	OK
4	5	6	
1	2	3	Cancel
0	Delete		

Enter User Pin

The numerical Key pad screen

Enter the user 4 digit PIN

Press OK to accept


Manual Login

Your User ID

Your Pin

Login

Cancel

 CANTEL MEDICAL

Now press LOG ON

The door will open and the RAPIDAER will ask for the hub and scope ID

All the information displayed on the screen will be stored in the Data Log:
 ie: User ID, name, PIN, TAG, including dates & times.



AUTOMATIC RE-PROCESS CYCLE

The normal re-processing cycle for either a one or two scope process is in 7 stages.

1. Leak Test
2. Gross Wash and Lumen Patency
3. Detergent wash
4. Rinse
5. Disinfectant Clean
6. Disinfectant Rinse
7. Air flush

The Computer display on the Load side of the RAPIDAER machine is the main user interface. Most of the wash cycle sequence can be performed by the use of the Operator TAG, Manifold TAG and the Endoscope TAG. Additional operator input is by pressing buttons on the touch screen.

The touch screen buttons are all indicated when they are active and are mostly located across the bottom of the computer screen.

The computer screen display prompts and instructs the operator on the physical actions to be taken during the load and un-load sequences.

During the wash cycle process, the computer screen displays the stage of the cycle that is being performed. This information is repeated on the unload side, scrolling display.

Other information displayed on the screen includes:

The load operator for each scope
The hub identification
The endoscope identification
The PAUSE cycle button.



CYCLE SEQUENCE

The following information will be displayed at each stage of the cycle in the purple information box on the computer “dirty side” (Load side), and will also be scrolling across the, Machine Status Display, on the “clean side” (Un-Load side)

SCOPE LOAD SEQUENCE

- 1) RAPIDAER Ready Tag or Log On
- 2) Load Operator ID recorded
- 3) Load basket
- 4) Present Hub Tag
- 5) Hub ID recorded
- 6) Present Endoscope TAG
- 7) Endoscope ID recorded
- 8) Close door
- 9) Fitted Channel Separators?
- 10) Press Start

WASH CYCLE SEQUENCE

- 11) Leak Test and detergent dose measured
- 12) Gross Wash & Lumen patency check
- 13) Dose Detergent, Detergent Wash (Solution will be heated if water temperature lower than required)
- 14) Detergent Rinse
- 15) Dose Disinfectant solutions
- 16) Disinfectant contact (Solution will be heated if water temperature lower than required)
- 17) Disinfectant Rinse
- 18) Air Purge

SCOPE UNLOAD SEQUENCE

- 19) Present operatorTAG to open door
- 20) Un-load operator ID recorded
- 21) Unload & close door
- 22) Rotating to unload position 2
- 23) RAPIDAER READY (Tag or Log On)



USING THE RAPIDAER MACHINE

To start an automatic cycle, simply perform the following procedures.

SWITCHING THE RAPIDAER MACHINE ON.

First ensure that the power supply is switched on at the isolator. This should be located on the wall, close to the machine.

Then ensure that the water supply is turned on.

It is also important to take regular water samples to ensure that the supply RO water is clean.



Then press the GREEN start button.

This is located on the Top Left Hand Side of RAPIDAER, on the Load Side of the machine.

When the start button is pressed the computer will display the initialising screen. Once the RAPIDAER computer has booted up all the required configurations, the touch screen will display the Home Page

The Main Computer screen will stay on the Home Page, until a re-processing cycle is started.



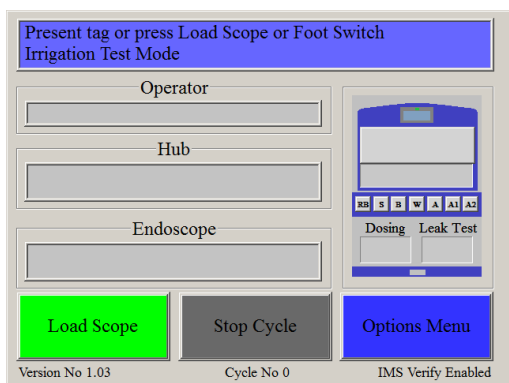
USING THE RAPIDAER MACHINE – RUNNING A CYCLE:

On switch on the RAPIDAER computer will load the standard home screen

The Main Computer screen will stay on the Home Page, until you start a re-processing cycle.

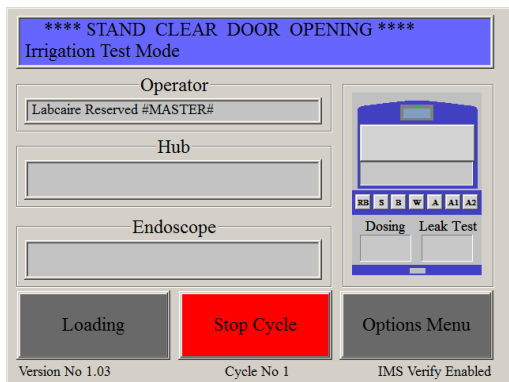
To use the RAPIDAER machine:

The operator needs to follow the instructions in the blue box at the top of the screen.



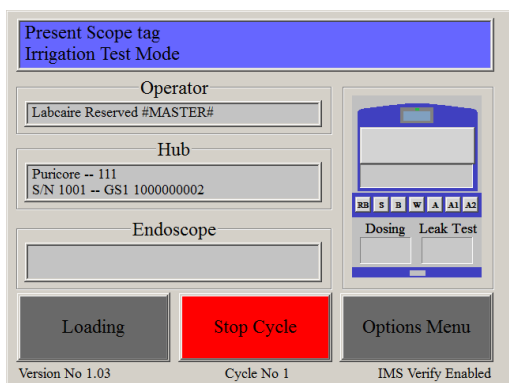
Present the Operator ID TAG to the TAG Reader. This identifies the operator as an approved user.

If the foot switch or load scope button is pressed then the operator will be asked to tag in or log on before proceeding.



NB: the operator DATA box now has the user ID displayed. This will be recorded for all information regarding this cleaning cycle.

Present the operator ID tag or use the foot switch to open the door. Load the basket and endoscope in to the chamber and the use the tag reader wand to identify the hub.



The DATA boxes now have the user ID and the hub ID

Use the tag reader wand to identify the endoscope.

The DATA boxes now have the user ID, the hub ID and the endoscope ID.



CONFIRM CHANNEL SEPARATORS FITTED
Present tag or Press Confirm or Foot Switch

Operator
Labcaire Reserved #MASTER#

Hub
Puricare -- 111
S/N 1001 -- GS1 1000000002

Endoscope
Olympus -- BF10
S/N 1005 -- GS1 1000000005

Confirm **Stop Cycle** Options Menu

Version No 1.03 Cycle No 1 IMS Verify Enabled

The operator will be asked to confirm if the channel separators have been fitted.

If separators are not required, still select Confirm.

****** STAND CLEAR DOOR CLOSING ******
Irrigation Test Mode

Operator
Labcaire Reserved #MASTER#

Hub
Puricare -- 111
S/N 1001 -- GS1 1000000002

Endoscope
Olympus -- BF10
S/N 1005 -- GS1 1000000005

Loading **Pause Cycle** Options Menu

Version No 1.03 Cycle No 3 IMS Verify Enabled

On confirming the channel separators are fitted the door will close automatically.

Pause Cancel will allow the cycle to be stopped and return to the beginning of the load sequence.

Present tag or press Start Cycle or Foot Switch
Irrigation Test Mode

Operator
Labcaire Reserved #MASTER#

Hub
Puricare -- 111
S/N 1001 -- GS1 1000000002

Endoscope
Olympus -- BF10
S/N 1005 -- GS1 1000000005

Start Cycle **Pause Cycle** Options Menu

Version No 1.03 Cycle No 1 IMS Verify Enabled

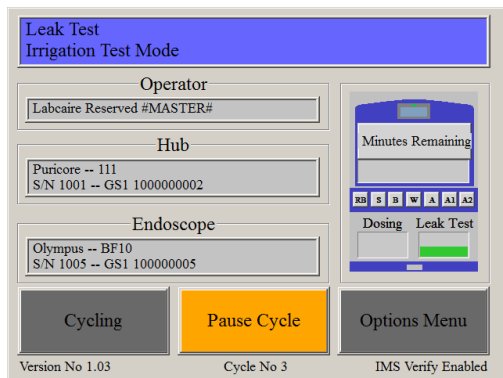
Press the green "START CYCLE" button on the left side of the touch screen, present the user tag to the tag reader or press the foot switch to start the cycle.

If a scope is loaded without presenting the Tag to the Tag Reader, the RAPIDAER machine will not let the software continue to the next stage.

This is achieved by means of the door not closing, until the endoscope Tag is presented to the Tag Reader.

Only then; will RAPIDAER allow you to continue to perform a wash cycle.

The RAPIDAER machine will automatically proceed with the leak test & cleaning cycles.



Firstly RAPIDAER performs an initial Leak Test.

At the same time it will prepare for the wash cycle.



The phase of the cycle is displayed in the blue box at the top of the screen

The duration of the cycle is displayed in minutes

The time remaining will count down in whole minutes

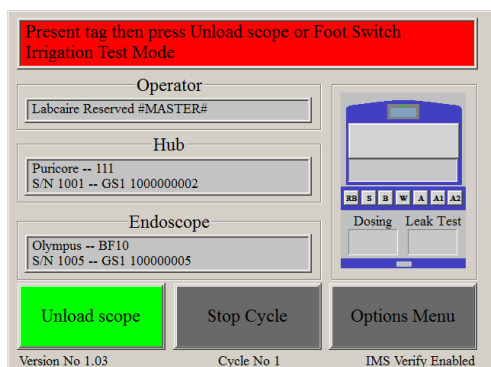
The final sequence of the cycle is the air purge which flushes the rinse water out the scope channels.

At the end of the process cycle RAPIDAER will inform you if the scope has passed or failed.

A failure will usually be indicated at the relevant point during the process cycle.

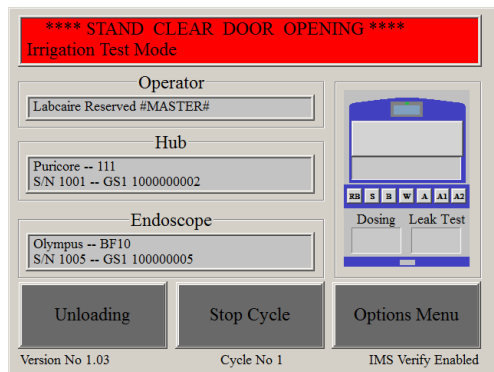
NB: Coloured buttons are active, press them to activate the function. Grey buttons are de-activated or display information only.

SCOPE PASS UNLOAD PROCESS



The Unload operator must use their ID tag to identify themselves to the RAPIDAER machine on the unload side.

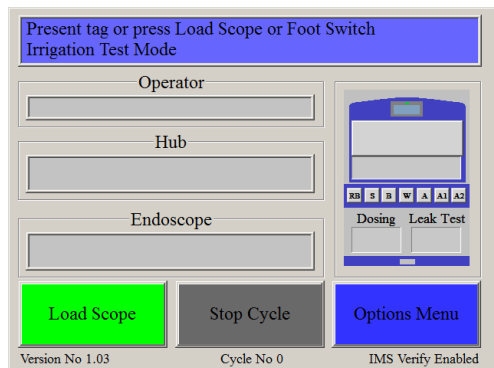
When the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.



The Un-load operator's ID will be recorded on the computer, and this information will be included on the print out, which appears on the clean side for the passed cycle.

When the door is open, remove the basket and endoscope.

Remove the cycle printout from the printer.



Close the door by using the operator ID tag or foot switch.

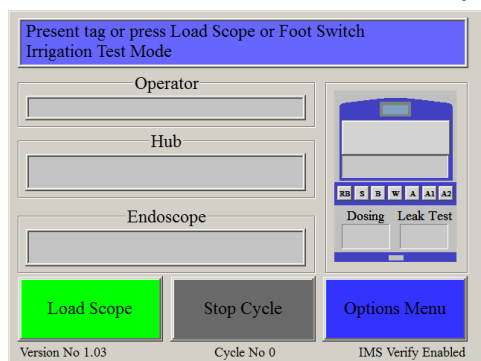
When the door is closed, the RAPIDAER returns to the HOME PAGE ready for loading to commence the next cycle.

Any scope that fails to pass all the criteria can only be removed from the "dirty side" Load side of the RAPIDAER machine.

The operator must present their Tag to the Tag reader to unload.

SCOPE FAIL UNLOAD PROCESS

The process to remove the endoscope from a failed cycle is the same as for a pass cycle except the Unload operator must use their ID tag to identify themselves on the load 'dirty' side of the machine.



Once the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.

The cycle printout will be given on the load 'dirty' side of the machine.

When the door is open, remove the basket and endoscope.

Close the door by using the operator ID tag or foot switch.

RAPIDAER will return to the HOME PAGE ready for loading to commence the next cycle.

Unload the endoscope from the basket and assess the problem from the data given before reprocessing the endoscope.



OPTIONS MENU

The options button allows various functions to be carried out by the user and for an administrator to use the 'Hospital Protocol' section to add endoscopes, operators and hubs to the data base.

Press the 'Options menu' button on the right hand side of the home page.

The 'Log In' screen will be displayed. Either present the operator tag to the tag reader or enter your user ID and PIN as covered on page 16

Options Menus

User Menu

Administration Menu

SELF DISINFECT:

The thermal self disinfect can be set to come on at a predetermined time so the process is completed before the machine is required for reprocessing the endoscopes used that day.

There is also a 'Start Now' button on this screen, so a self disinfect process can be started when ever required



OPENING DOORS:

To open a door when prompted to by the screen instruction, you will be required to present your operator TAG to the RAPIDAER machine or use the foot switch. The door will unlock and open automatically.

Should you wish to open the access door at other times, or if the operator is not in possession of their TAG. Then the operator will be required to access the OPTIONS menu in order to open the door.

To do this, the operator must first. Select the OPTIONS button on the HOME PAGE This will then take you to the options selection screen.

HOME PAGE - Press the OPTIONS button to select:

LOG ON - The operator should use either their ID tag or enter ID number and PIN.

Press the OPEN DOOR button.

The door will 'unlock', so that it can be opened.

RETRIEVING A SCOPE:

Should the operator need to retrieve a scope from the RAPIDAER machine, other than in the normal sequence of a wash cycle; then this can be achieved by the following steps.

Scope Failed message - Press the abort button.

Press the "Options" Button

OPTIONS" Log on Screen - Present TAG to the tag reader or Enter user ID number & PIN

Then press Log On to proceed

OPTIONS Menu

Press the "OPEN DOOR" button
This will open the Dirty Side door only.



OPENING THE CHEMICAL STORAGE DRAWER:

To access the chemicals, the operator must first press the GREEN OPTIONS button on the RAPIDAER computer screen. This will then take you to the options selection screen.

Press the OPTIONS button to select:

LOG ON OPTIONS MENU by the operator either using their ID TAG or manually not entering their ID number and PIN.

Now press the “OPEN CHEMICAL CHAMBER” button.

The drawer will unlock, and the operator can manually pull the door open.

NB: the air extract fan will operate to contain and remove any odours via the carbon filter.

Select the chemical to be added, detergent, Base or Activator by touching the screen to highlight the chemical to be changed.

Pass the chemical bottle, with the label side facing the tag reader, across the bottle tag reader and the new bottle batch number will appear in the new

chemical boxes. Press OK to confirm the data.

Put the chemical bottle in the drawer and then change the lid over to the pick up lid in the unit.

IF the tag reader or the bottle label does not activate the new number correctly the the number can be added manually.

Press the Batch number area by the 'new' section.

A screen will appear that allows the new batch number to be entered.

Similarly select the serial number and enter this in the same way.

Finally add the expiry date for the chemical in the date boxes.

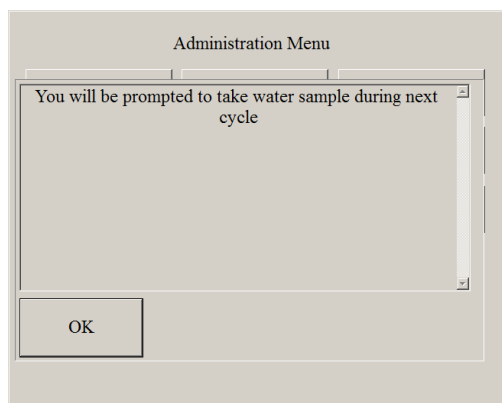


ACTIVATE FLUSH SYSTEM ROUTINE:

This facility flushes all the complete system and dosing pots so that they are at the correct status for a new cycle to be started. This facility should be used when the wash cycle has been interrupted and RAPIDAER is out of synchronisation.

WATER SAMPLE

This option can be selected to allow a prompt to be given when the last rinse is being done and the water sample should be taken.

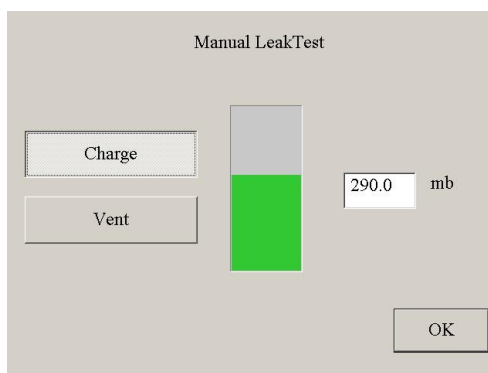


Select OK and the cycle will emit an alarm when the final rinse stage is reached in the next cycle.

ENGINEERING.

This button is not displayed in the normal user mode, it only becomes active when the engineer has a special USB key in the machine.

LEAK TEST:



In the event of a leak test failure, a manual leak test can be carried out in the machine. This will pressurise the scope to the required 290 mbar and by watching the screen any leak can be detected by the slow decrease of the pressure reading.



SET TIME

The date and time can be changed to the local time at the location of the unit.

Select the time and date on the UP/DOWN arrows and press save to confirm the new date and/or time.

PRINT CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

This function is in the Hospital Protocols for personnel with ADMIN access.

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

This function is in the Hospital Protocols for personnel with ADMIN access

HOSPITAL PROTOCOLS

These screens can only be accessed by users that have been given 'ADMIN' rights during the set up of the user's tag.

An operator with user access only will not be allowed to access the "Hospital Protocol" menus.

Functions within Hospital Protocols

Add a NEW operator/user
 EDIT an existing operator's details
 Assign a NEW scope ID
 EDIT an existing scope ID
 Add a NEW connector hub
 EDIT a connector hub
 Print a last cycle ticket
 Print a cycle report
 Print the last self disinfect cycle ticket
 Copy files



ADD A NEW USER

Press the “New Operator” button on the Screen

Name	<input type="checkbox"/> Inactive
<input type="text"/>	
Tag	
<input type="text"/>	
Operator	
<input type="text" value="0008"/>	<input type="checkbox"/> Admin
Pin	<input type="checkbox"/> User
<input type="text"/>	
<input type="button" value="Adding User 0008"/>	
<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

The operator ID is sequentially assigned by RapidAER automatically.
Every Operator will have a unique ID number.

To enter an operator name:
Touch the white text box

Roger Black									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		

Number	Space		Delete
Shift	- \	Enter User Name	
	~		
Clear	. @	OK	Cancel

Touch screen type writer pad.

Input the new operator's name.

Then press OK.

<div>Name</div> <div>Roger Black</div>	<div>Inactive</div>
<div>Tag</div> <div></div>	
<div>Operator</div> <div>0008</div>	<div>Admin</div> <div><input type="checkbox"/></div>
<div>Pin</div> <div></div>	<div>User</div> <div><input type="checkbox"/></div>
<div>Adding User 0008</div>	<div><div>OK</div><div>Cancel</div></div>

The name will now appear in the white text box.

To enter the user PIN
Touch the White text box .

------	--	--

7	8	9	OK
4	5	6	
1	2	3	
0		Delete	Cancel

Enter User Pin

Touch screen number pad:
Type in the 4 digit PIN for the new operator
according to your SOP.
(standard operating procedure) Then press OK!

The PIN will not be displayed on the screen
Only a symbolic representation, this is for security
reasons.

It is recommended that you keep a record of the PIN elsewhere.

To assign a TAG, present the new TAG to the tag reader.



All the operator details are now installed and linked to the ID TAG.

Next assign access rights and press the 'Inactive' box to make the operator 'Active'.

Access Rights

To assign the new operators access capabilities; Press the relevant Description to tick the boxes.

Then press OK:

Access Rights:

For basic machine operation access:- tick the User box

For access to set up new scopes, users or hubs or copy data files:- tick the Admin box.

The Admin access automatically gives an operator user rights to run a cycle.

The New Operator is now installed into the RapidAER computer.

EDIT AN EXISTING USER'S DETAILS

Press the "Edit User" button on Screen

Select the operator to be edited by touching the operators name on the screen.

Then press edit operator

The operator details will be displayed.

Select and modify their Access Rights, or re-assign a new Tag.

Then press OK.

The edit function is now complete.



ADD A NEW CONNECTION HUB ID

Press the 'Add Hub' button on the Menu screen

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

The complete hub list will appear

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

Select the hub to be added

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be added

Press OK

Max Flows

Suction 1800

Biopsy 0

Water 0

Air 0

Aux 1 0

Aux 2 1800

RB Min Pres 0

Make CANCEL

Model RAH008

Dept

Serial No

GS1

Tag

Adding Hub Type RAH008

OK Cancel

To add the information touch the white box adjacent to 'Dept'.

Endoscopy

q w e r t y u i o p

a s d f g h j k l

z x c v b n m

Number Space Delete

Shift - \

Clear . @

Enter Department

OK Cancel

Type in the department name and Press OK



Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	
Air	0	GS1	
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Next add the serial number that is on the new hub serial number plate. (Each hub has its own serial number so individual hubs of the same type number can be identified.)

Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	012345
Air	0	GS1	334
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Complete the data by selecting each box and typing in the data.

Finally present the tag fixed onto the hub to the tag reader to add this data.

Press OK to save the new hub data.

NOTE The max. Flow values on the right side of the screen give the disconnect alarm and cannot be altered. Any changes that are required to these flows must be made by a Cantel Medical engineer after testing the hub with the respective endoscope.

This new connector hub can now be used in the RapidAER machine.

EDIT AN EXISTING HUB ID

Press the 'Edit Hub' button on the screen. This allows a hub to be edited and assigned to another department or for a hub to be deleted from the hub list in the RapidAER computer.

RA002 S/N 1008 RA017 S/N 1011 RA020 S/N 1012 RA022 S/N 1013 RA038 S/N DSFS	<input type="button" value="Delete"/>
<input type="button" value="Select Hub to Edit"/>	<input type="button" value="OK"/> <input type="button" value="Cancel"/>

The list of connection hubs that have been stored in your RapidAER machine will be displayed

A hub can now be edited or deleted



Select the hub by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be edited

Press OK if hub to be edited

The Hub information page will appear.

Now make your alterations as per the “add new hub” procedures, selecting any of the data that has a white box and changing as necessary.

Then press OK to Save the new data.

If the hub is no longer to be used then the delete button can be selected after the hub has been selected in the hub list displayed in the edit scope process as above.

Select ‘Yes’ and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

To exit this process then press ‘Cancel’

ADD A NEW ENDOSCOPE ID

Press the “Add Scope” button on the Menu Screen

The Scope Information page will appear. Now fill-in the boxes in sequence.

Press the “Make” box on the touch screen



Olympus									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number		Space		Delete					
Shift	-	\	Enter Manufacturer						
Clear	.	@	OK		Cancel				

The key pad will appear.

Enter the manufacturer of the scope eg. Olympus, Pentax , Storz etc

Then press the OK button to enter the data.

Min Flows		Make	Olympus
Suction	100	Model	
Biopsy	100	Dept	
Water	50	Serial No	
Air	50	GS1	
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK	Cancel

Press the “Model” box on the touch screen

Gastroscope									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number		Space		Delete					
Shift	-	\	Enter Model						
Clear	.	@	OK		Cancel				

The key pad will appear.

Enter the model of the scope eg. Gastroscope, Broncoscope etc

Then press the OK button to enter the data.

Continue to add the Department, Serial number, GS1 number if known in the same way as the Make and Model, typing in the data and pressing OK after each entry.

Min Flows		Make	Olympus
Suction	100	Model	Gastroscope
Biopsy	100	Dept	Endoscopy
Water	50	Serial No	GIF1246789
Air	50	GS1	F234
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK	Cancel

To complete the new endoscope entry present the scope tag to the tag reader to assign that tag to the data entered.

The tag data will be entered in the tag box.

Press OK to save the data to the RapidAER data base.

This new scope can now be re-processed using the RapidAER machine.



EDIT AN EXISTING SCOPE ID

Press the 'Edit Scope' button on the screen. This allows a tag to be edited and assigned to another scope or for a scope to be deleted from the endoscope list in the RapidAER computer.

The list of scopes that have been allocated by the user which are stored in your RapidAER machine will be displayed

A scope can now be edited or deleted

Select the scope by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the scope that is to be edited

Press OK if scope to be edited

The Scope information page will appear.

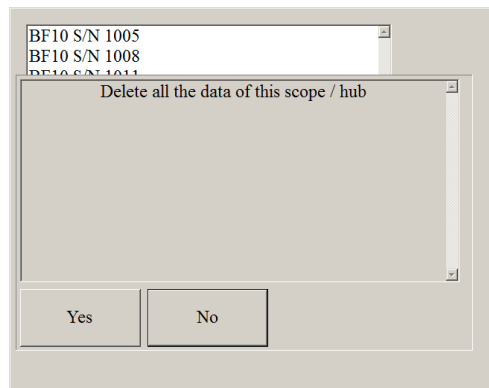
Now make your alterations as per the "add new scope" procedures, selecting any of the data and changing as necessary.

Then press OK to Save the new data.

Whenever this scope is re-processed in the RapidAER machine the new details will be logged and recorded.



If the endoscope is no longer to be reprocessed then the delete button can be selected after the endoscope has been selected in the endoscope list displayed in the edit scope process as above.



Select 'Yes' and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

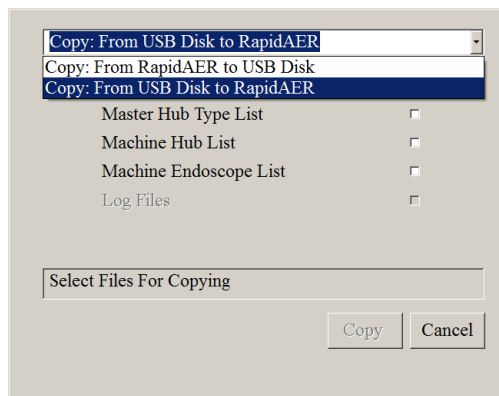
To exit this process then press 'Cancel'

Select 'No' and the screen returns to the scope list with endoscope still visible.

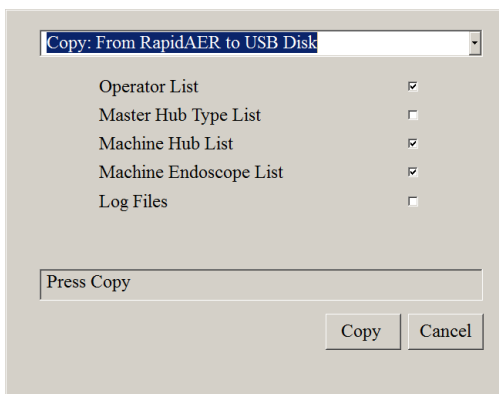
To exit this process then press 'Cancel'

COPY FILES

This button allows files to be copied onto the RapidAER computer or copied from the RapidAER computer. This allows the operator, endoscope, and department hub lists to be copied from machine to machine so data only has to be entered once.



From the arrow along side the top box select if files are to be copied onto the RapidAER from a USB key or whether files are to be copied from the RapidAER onto a USB key.



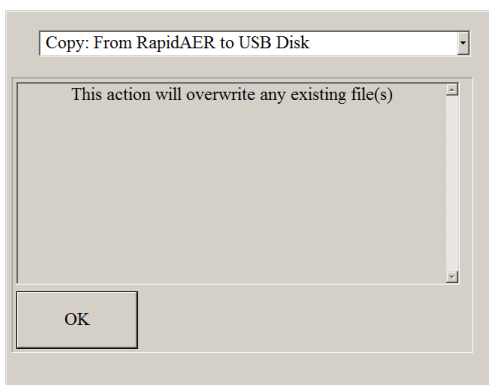
So to copy files from machine to machine after adding new operators, endoscopes or hubs

Select From RapidAER to USB disc

Tick the files to be copied – Operator list, machine hub list or machine endoscope list

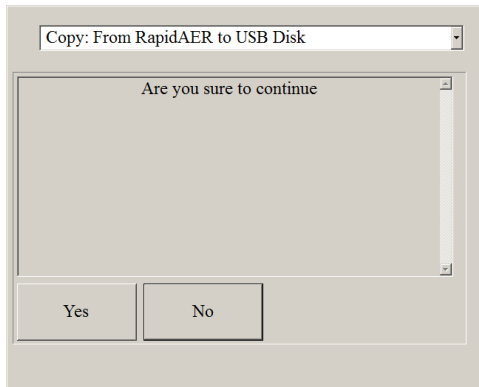
Note: Log Files can only be copied from the RapidAER to the USB Drive

Press 'Copy'

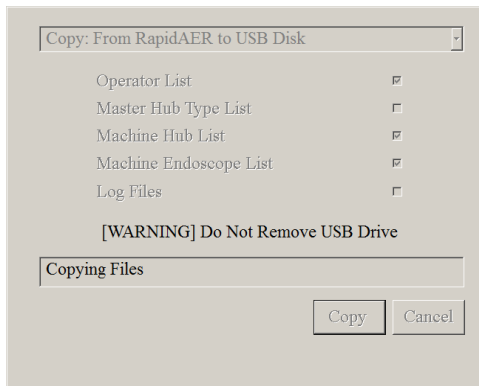


A message will appear to alert the operator that any files on the USB disc with the same name will be overwritten.

Select OK to acknowledge the message

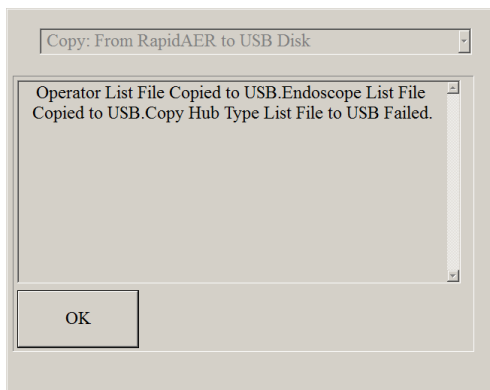


Press 'Yes' to continue the transfer or 'No' to exit



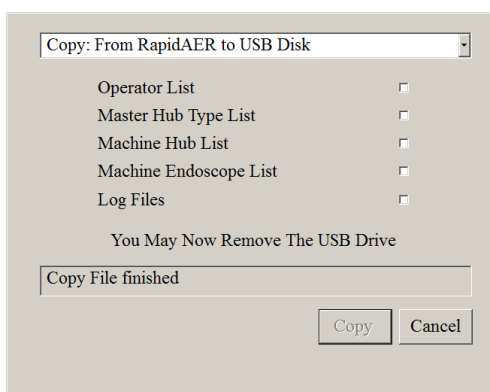
The files are now being copied.

Do not remove the USB drive



The screen indicates that the files have been copied or that a list has failed to copy.

Press OK



The final screen informs the operator that the copy file instruction is complete and the USB drive can be removed.

Press cancel to exit

To copy the files from the USB Drive to the next RapidaER machine, insert the USB drive in the slot adjacent to the screen on the dirty side of the machine. Go to Hospital Protocols and select 'Copy Files' follow the same process as above but initially select 'Copy: From USB Disk to RapidaER'



LOG FILES

These can be selected to be copied onto the USB drive as the above process and they can then be downloaded onto a hospital computer for analysis.

PRINT CYCLE REPORT

This will print a detailed report of the cycle that has just been completed. For more information see Printouts.

PRINT LAST CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

AUDIBLE ALARMS

INFORMATION ALARM:

When the RAPIDAER machine has completed the endoscope cleaning cycle, it will emit a single beep audible alarm, to indicate that the machine is ready for unloading

WARNING ALARMS:

When ever there is a visual warning alarm on the computer screen, the RAPIDAER machine will also emit a continuous audible alarm.

To stop this audible alarm, the operator needs to accept / acknowledge the visual alarm on the computer screen, by responding to the computer instruction or prompt.

POWER INTERRUPTION:

If the power source to the RAPIDAER is interrupted, the volt free contacts will enable a remote signal to indicate an alarm.

If the power supply to RAPIDAER is interrupted, then the RAPIDAER machine will need to be manually switched on, using the green button, on the front of the machine.



However if the RAPIDAER machine was performing a wash cycle when the power was interrupted; then, when the power is re-connected, the RAPIDAER machine will emit an audible alarm, linked with the wash cycle fail indication on the computer screen.

REMOTE ALARMS:

When ever there is a major alarm on the RAPIDAER machine, that would require immediate attention, eg: water leakage, power failure, self disinfect chemical bottles empty. Then the alarm will be duplicated via the volt free contacts, which will active either a visual or audible alarm in a remote location of the hospitals choosing. Eg: estate dept, BMS room, RAPIDAER managers office.



DATA SYSTEMS

The RAPIDAER AER machine has data storage and retrieval options for various types of data.

LOG DATA:

This is the cycle log record for every wash cycle and scope that has been processed in the RAPIDAER AER machine.

This data can be downloaded on to a USB key for achieving or the machine can be networked and the data transferred every cycle.

IMS:

(Independent Monitoring System)

This is a separate measuring system to confirm that the wash cycle parameters are within the tolerance that is required.

There are two levels of data retrieval obtainable through this system.

Level 1:- Process cycle history in an excel.csv spread sheet format.

Level 2:- the Full IMS data screen which will require the Cantel Medical IMS.net software package

Operator Data:

This is a history of every operator (present and previous) that has had access to the RAPIDAER machine.

Connector Hub Data:

This is a record of every connector hub present & previous that has been ID logged into the RAPIDAER AER machine, including the hub number, serial number and TAG ID.

Endoscope Data:

This is a record of every scope present & previous that has been ID logged into the RAPIDAER AER machine, including the make, model, serial number and TAG ID.



DATA STORAGE:

The RAPIDAER onboard computer has the capacity to store a large volume of information.

The memory allocated to cycle DATA storage will be able to store 250,000 wash cycles of information.

The information stored is formatted on an excel spread sheet, so that DATA retrieval is user friendly in both operator programme knowledge, and also in computer software compatibility.

The DATA storage format contains a heading with:

- The Department identification,
- The RAPIDAER machine serial number,
- The software version number.

DATA Storage Topic Headings:

- Date:
- Time:
- Pass / fail
- SD date
- SD time
- SD No:
- Operator ID
- Operator Name
- Un-load Operator ID
- Un-load Operator Name
- Contact time (seconds)
- Scope ID
- Manufacturer
- Model
- Serial Number
- Department
- Leak Test
- Raiser Bridge
- Channels Irrigated
- Comments
- Cycle Name
- Leak Test
- Number of Faults
- Reason Code
- Reason.



PRINTOUTS

The RAPIDAER provides a “hard copy” printout for the process that has been performed. This is in addition to the DATA being stored on the RAPIDAER computer which can be retrieval via a USB key or by direct connection to a Track and Trace system.

There are five label printout configurations:

Cycle Complete	= When a wash cycle has been completed.
Cycle terminated	= When a wash cycle has automatically stopped.
Cycle terminated	= When a wash cycle has been manually stopped
Test Label	= Engineer access only
Detailed Process Report	= RAPIDAER Hospital Protocol access required

The printers are located on the front of the machine:

On a pass through machine there will be a print out on the “clean side” (un-load side) for a ‘pass’ cycle and on the ‘dirty side’ (loading side) for a ‘failed’ cycle.

Below are example labels that depict the type of information that will be presented on the printouts



CYCLE COMPLETE 'PASS' PRINTOUT

(-----)	
(-----)	
(--Wash Cycle Pass --)	Cycle Pass/ Fail identification
(-----)	
(Cantel RapidAER)	
(Serial No RA0009)	RapidAER serial number
(-----)	
(Start 09h 44m)	Cycle start time:
(End 10h 02m)	Cycle finish time:
(Date 20-10-2014)	Date
(-----)	
(Cycle No. 52)	Unique sequential cycle number
(-----)	
(Load Operator 1)	
(Name Paul)	Loading operator identification
(-----)	
(Unload Operator 1)	
(Name Paul)	Un-Loading operator identification
(-----)	
(--Hub-----)	
(Cantel A3 Testroom)	
(Serial No 1)	Connection Hub used for the process
(GS1 1)	
(-----)	
(--Endoscope--)	
(Olympus Gastroscope)	
(Serial No GIFH260)	Scope ID – including Make & Model
(GS1 1)	Serial No & GS1 No
(-----)	
(IMS Verify Enabled)	IMS Status
(-----)	
(Control Pass)	Status of IMS & Control system at end of cycle
(IMS Verify Pass)	Pass confirmation
(-----)	
(Contact Time 5minutes)	Disinfectant Contact Time
(-----)	
(Last SD 20-10-2014 at 06h 00m)	RapidAER self disinfect information.
(-----)	
(Suction Av Flow 2185ml)	
(Biopsy Av Flow 1775ml)	
(Water Av Flow 120ml)	Average Flows in each of the channels during the
(Air Av Flow 85ml)	process including Raiser Bridge & Leak Test
(Aux 1 Av Flow 400ml)	Pressures
(Aux 2 Av Flow 900ml)	
(RB Av Pres 3850mb)	
(Leak Test Av Pres 300mb)	
(-----)	
(---Conductivity---)	
(Detergent 764µs)	Conductivity of each phase of the cycle
(Disinfectant 1150 µs)	
(Final Rinse 35 µs)	
(-----)	
(---Temperature---)	
(Detergent 25.1 deg)	
(Disinfectant 26.1 deg)	Temperature of each phase of the cycle
(Final Rinse 24.9 deg)	
(-----)	
(Chemical Batch/serial No)	
(Detergent D412/1134)	Chemical Batch / Serial numbers of each of the
(Part B B3321/889)	chemicals used for the process
(Part A A6543/996)	
(-----)	



CYCLE COMPLETE 'FAIL' PRINTOUT

There are two types of 'Fail' cycle and this is when the control or IMS system do the cycle checks and one or more parameters are outside the range allowed. The second failure is a manual abort by an operator. An example of each is given below.

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       10h 40m     )
( End         11h 02m     )
( Date        20-10-2014  )
(-----)
( Cycle No.   53          )
(-----)
( Load Operator 1      )
( Name         Paul      )
(-----)
( Unload Operator 1     )
( Name         Paul      )
(-----)
(  ---Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled    )
(-----)
( Control      Fail       )
( IMS Verify   Fail       )
(-----)
( Fault: 9044 Manual Abort (dis wash) )
( Fault: 9045 IMS: RB Flow duration   )
( Fault: 9024 IMS Aux 1 Low flow (0)   )
(           (dis wash)                )
( Fault: 9049 IMS conductivity        )
(           (dis wash)                )
(-----)
```

Cycle Pass/ Fail identification

RapidAER serial number

Cycle start time:

Cycle finish time:

Date

Unique sequential cycle number

Loading operator identification

Un-Loading operator identification

Connection Hub used for the process

Scope ID – including Make & Model
Serial No & GS1 No

IMS Status

Status of IMS & Control system at end
of cycle

Fault codes – reason for failure

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       11h 24m     )
( End         11h 42m     )
( Date        20-10-2014  )
(-----)
( Cycle No.   54          )
(-----)
( Load Operator 1      )
( Name         Paul      )
(-----)
( Unload Operator 1     )
( Name         Paul      )
(-----)
(  ---Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled    )
(-----)
( Control      Pass       )
( IMS Verify   Fail       )
(-----)
( Fault: 9048 IMS Irr temp 180.1 C     )
(           (Leak Test)                )
( Fault: 9048 IMS Irr temp 600.6 C     )
(           (Gross Wash)               )
( Fault: 9048 IMS Irr temp 600.6 C     )
(           (DetWash)                  )
( Fault: 9048 IMS Irr temp 600.6 C     )
(           (DetRinse)                 )
( Fault: 3035 IMS Irrigation temp      )
(           sensor fault (6006)        )
(-----)
```



CYCLE PRINTOUTS FOR SELF DISINFECT

There are two printouts for Self Disinfect Cycle Pass and Cycle Fail. Examples are both are shown below.

```
(-----)
(-----)
(  -Self Disinfect Passed--  )
(-----)
( Cantel      RapidAER      )
( Serial No   RA0009       )
(-----)
( Start       07h 29m      )
( End         08h 31m      )
( Date        20-10-2014   )
(-----)
( Cycle No.   11           )
(-----)
( Operator    1             )
( Name        Paul         )
(-----)
( Unload Operator 1       )
( Name        Paul         )
(-----)
( IMS Verify   Enabled     )
(-----)
( Control      Pass        )
( IMS Verify   Pass        )
(-----)
( Temp Stage 1 86.1deg     )
( Temp Stage 1 85.1deg     )
( Temp Stage 1 85.5deg     )
( Contact Time 10          )
(-----)
```

```
(-----)
(-----)
(  -Self Disinfect Failed ----  )
(-----)
( Cantel      RapidAER      )
( Serial No   RA0009       )
(-----)
( Start       07h 59m      )
( End         09h 14m      )
( Date        21-10-2014   )
(-----)
( Cycle No.    7           )
(-----)
( Operator    1             )
( Name        Paul         )
(-----)
( Unload Operator 1       )
( Name        Paul         )
(-----)
( IMS Verify   Enabled     )
(-----)
( Control      Fail        )
( IMS Verify   Fail        )
(-----)
( Fault: 9053 Spray system running )
( with empty sump (Recirc stage 2) )
( Fault: 9048 IMS Circ temp 64.5 C )
( (Recirc stage 2) )
( Fault: 9048 IMS Temp Su 63.7 C )
( (Recirc stage 2) )
(-----)
```



CHANGING PRINTER PAPER:

The printer is located as shown in the “Find your way around RAPIDAER” diagrams



The printers are located on the right hand side just below the chamber on both sides of the machine.



To access the paper roll,
Press the GREEN button on the top of the printer and the paper holder falls open.



To input a new paper roll, simply place the replacement paper roll into the printer as shown with the feed off section to the top, pull some paper forward, to create a tongue.



Push the paper holder closed, and tear off the excess paper against the serrated edge.

RAPIDAER printer is now ready for use.



To feed paper forward from the roll, press the button on the RIGHT.



ESSENTIAL OPERATING PRACTICES.

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

To ensure endoscopes are correctly disinfected it is important the following points are observed.

1. The machine thermal self-disinfection is carried out each day, before use.
2. The disinfectant contact parameter times are pre-programmed into the machine. The soak times must be determined by the manufacturer of the disinfectant and the Hospital Infection Control Department.
(Please refer to the tables in the "Disinfectant Types" section)
3. The manufacturer's instructions on the manual pre-cleaning, machine cleaning and disinfection of endoscopes must be followed at all times. The efficiency of the process depends on an efficient pre-clean and brushing through of the internal channels prior to disinfection.
4. It is most important that the endoscope internal channels are disinfected. The quality of the rinse water should be monitored at routine intervals.
5. The RAPIDAER must not be positioned within a risk area of anaesthetic equipment.

HOSPITAL PROTOCOLS:

Within the HOSPITAL PROTOCOL Menu, the user access protected CYCLE & SELF DISINFECT Menus allows for the defining of the following operational criteria:

RAPIDAER Hospital Protocol Menu
<i>Set & Edit Operator ID</i>
<i>Set & Edit Connection Hub ID</i>
<i>Set & Edit Endoscope ID</i>
<i>Copy Files</i>
<i>Reprint last cycle data</i>
<i>Reprint last self Disinfect cycle data</i>
<i>Print a detailed cycle report</i>



DISINFECTANT WARNINGS:

Disinfectants are hazardous substances and controlled by COSHH Regulations. Manufacturers must supply Safety Hazard Data Sheets to cover the use of their products.

The following Points should also be considered for use in this application.

1. Personal protection equipment should be worn when handling disinfectants or endoscopes. Suitable gloves, eye / face protection and apron.
2. The opening of disinfectants and closing of empty containers should be carried out, inside a suitable ventilated area.
3. The hospital should establish a procedure for safe storage, handling and disposal of disinfectant containers.
4. The hospital should establish a procedure for accidental spillage.
5. The RAPIDAER will provide a safe system for transfer of disinfectant to the chamber, during processing and disposal of used disinfectant. However, attention should be given to the room environment (ventilation) etc. see installation drawings. Correct ventilation will minimise problems if a spillage occurs.
6. The carbon filter should be changed every year to keep emissions below exposure limits.
7. Any disinfection contact should be washed off immediately and referred for medical attention.



DISINFECTANT TYPES:

The machine is compatible with two Peracetic Acid, single use disinfectants, for use on endoscopes, but the following points must be observed (see table below).

- A. The manufacturer of the Endoscope should be contacted for advice on chemical compatibility. Warrantees may only be valid on approved disinfectants.
- B. The Hospital Protocol and disinfection soak time should be approved by the disinfectant manufacturer and the Hospital Infection Control Department.
- C. Disinfectants activated with powders should not be used in RAPIDAER.
- D. Silicone based de-foamers should not be used in RAPIDAER.

DISINFECTANT NAME	DISINFECTANT TYPE	CARBON FILTER TYPE
Rapicide PA	single use peracetic acid	ACI
Purisept	single use peracetic acid	ACI

DISINFECTANT CONTACT TIME PARAMETERS		
disinfectant name	specific scopes	contact time
Rapicide	all	5 minutes
Purisept	all	5 minutes



DISINFECTION OF SCOPES:

CONNECTION OF ENDOSCOPES TO IRRIGATION CHANNELS:

Connection of the Endoscope to the irrigation lines is a critical procedure and as such great care must be taken to ensure correct connection. Connector hubs are available from Cantel Medical (UK) Ltd for each of the main types of the endoscope.

These connectors ensure that each channel is separated fully and therefore irrigated completely. Liquid is pumped into the endoscope from the light source end and passes completely through the length of the endoscope in a single motion.

It is essential that all channels are securely connected to prevent a cycle failure occurring.

RAPIDAER will remind the operator as part of the sequential screen prompts to check that channel separators have been installed.

NB: Certain scopes need to be sterilised after washing in an AER (Automated Endoscope Re-processor). The RAPIDAER AER should not be used as a replacement for sterilisation.

ENDOSCOPE STORAGE AFTER DISINFECTION PROCESS

Note:

Following the automatic disinfection cycle, the endoscope should be dried prior to long term storage, and can be hung directly into a Puricore Endoscope Drying Cabinet where the drying process will be carried out automatically, using dry compressed air, prior to longer storage of the endoscope in the clean environment of the cabinet. Alternatively the endoscope should be dried according to the endoscope manufacturer's protocol.



EU REGULATIONS:

Medical Devices Directive 93/42/EEC

Chemical Washer Disinfectors are a Class 2b medical device and the design, manufacture, installation and service are controlled under this directive. See Compliance for details of Puricore's accreditation.

Chemical Hazards - COSHH Regulations

Disinfectants are hazardous chemicals and it is necessary to perform a risk assessment covering all stages of use. The manufacturer of the disinfectant will supply Safety Hazard Data Sheets for their products.

See section on Disinfectant Types and Disinfectant Warnings.

The RAPIDAER should be tested at least every fourteen months to comply with this regulation.

BIOLOGICAL HAZARDS:

There is a risk to staff and patients from endoscopic procedures. The hospital should have its own procedures to control risk at each stage of the process.

TRAINING:

All staff using the RAPIDAER should be fully trained and certified on the use of the equipment.

Puricore Clinical Nurse Advisors will provide training sessions at each RAPIDAER installation, for the training and certification of operators and management staff.

Please contact Puricore for further details of training and availability.

VALIDATION:

The Autoscope RAPIDAER is manufactured to comply with BS EN 15883 Pt 1 & Pt 4, CFPP 01-06 and SHTM 2030. It should be fully validated according to table C1 of the BS EN 15883 Pt 1 & Pt 4 at the time of installation, followed by quarterly and annual re-validations.

COMPLIANCE:

Medical Devices Directive 93/42/EEC

Puricore International Ltd is approved to ISO 13485:2003 to design, manufacture and install chemical washer disinfectors.

Puricore International Ltd is approved to ISO 9001/EN46001 to service chemical washer disinfectors.

CE Marking

CE marking is applied to medical devices under Medical Devices Directive 93/42/EEC.



DECLARATION OF CONFORMITY



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Medical Device Directive Essential Requirements Checklist Declaration of Conformity

Description of Device
Product(s):

RapidAER

Assessment of Product based upon:

Certification of Quality System

Certificate No: LRQ 0954199/A
Issued by: LRQA

Date: 01/12/11

Essential Requirements Checklist

Prepared by: Regulatory Affairs

Date: 10/02/14

Technical File

Prepared by: Regulatory Affairs
Document number

Date: 10/02/14
2G-011

Product Classification:

Determine product classification based upon the requirements in MDD and Medical Devices Regulations 2002:

☐ Class I ☒ Class IIb ☐ Class III

Approvals:

Based on a review of the above documents, we hereby declare that the above products comply with the following EC directives:

- Medical Devices Directive 93/42/EEC as amended by 2007/47/EC
- Electro Magnetic Compatibility Directive 2004/108/EC
- Low Voltage Directive 2006/95/EC
- Machinery Directive 2006/42/EC
- Waste Electrical and Electronic Equipment Directive 2002/95/EC
- BS EN ISO 15883-1:2009
- BS EN ISO 15883-4:2009

Approved By: Neil Blewitt
Managing Director

Signature: _____

Date: _____

8th July 2014



Recommended actions to be taken for

"PERACETIC ACID" SPILLAGE

1. Evacuate the area.
2. Seal off the area to non-essential staff.
3. Put on protective clothing outside the affected area (boots, gown, apron, nitrile gloves, respirator face mask, goggles – NOT visors,).
4. On entry into the affected area – open all available windows (ie ventilate area) BUT DO NOT leave a door open into a corridor.
5. If it is a concentrate solution, absorb the excess with an inert material such as sand.
6. Put the contaminated sand into the disposal bag and seal tightly. Place this into a second disposal bag and seal tightly again. Contact your disposal company to collect it.
7. If it is a diluted solution or a small volume of concentrate, Dilute the solution with copious amounts of water and flush to drain.
8. Wash the floor area thoroughly with water.
9. Clean off boot soles before leaving the area.
10. Change any clothing that may have come into contact with the chemicals.



CONSUMABLES:

Description	Part No	Delivery lead time
1. Air Extract Carbon Filter	IS-LA 7014	5 Days
2. Printer Rolls (Pack of 20)	IS 795732	5 Days
3. Mediclean Plus Detergent (2 x 5 litre bottles)	900540	5 Days
4. Rapicide Disinfectant Part A	900530	5 Days
Rapicide Disinfectant Part B	900531	5 Days
5. Autowipes Disinfectant Wipes (6 x 200 wipe drums)	900505	5 Days



GENERAL CARE:

RAPIDAER is manufactured in the UK from quality materials, however any machine benefits from care and attention.

The exterior of RAPIDAER is manufactured from epoxy powder coated steel and polyurethane moulded panels. The use of abrasive cleaning agents should always be avoided. It is recommended that a warm soapy solution, or mild, diluted cleaning disinfectant is used.

The process chamber is manufactured from stainless steel with a smooth mirror finish. Gouges and scratches will enable biofilm and thus promote bug growth. Care should be taken at all times not to damage the surface finish of your process chamber.

ACTIVATED CARBON AIR FILTRATION

When the chemical drawer is opened, the airflow fan will operate creating a negative pressure in the drawer which helps prevent any fumes from escaping towards the operator.

The exhaust air from the chemical drawer is filtered at the point of discharge from the bottom of the machine, through an activated carbon filter.

This filter should be tested at each service visit, and should be changed at least every 12 months, or sooner if required.

This filter is located in the base of the RAPIDAER machine, together with the air flow fan.

NB: The carbon filter must be changed every 12 months.

NB:
TO ENSURE THAT THE AIR AND CARBON FILTERS ARE FITTED CORRECTLY,
THEY SHOULD ALWAYS BE INSTALLED BY A QUALIFIED ENGINEER.



ROUTINE MAINTENANCE:

RAPIDAER should be regularly maintained. Once the new equipment has been installed, commissioned and certified by a qualified Test Person (TP), you should adhere to the recommended service intervals.

Engineer visits = 2 per year at six monthly intervals, these consist of:

1 annual ~ Regular service every 52 weeks.

1 six monthly ~ Routine engineer inspections, every 26 weeks:

In between engineer visits, it is the responsibility of the user to ensure that the RAPIDAER machine is kept in the correct working status.

Regular water samples should be tested, and the water filters changed as required. The frequency for changing the wall mounted water filters will be site dependant, and will vary according to the supply water quality.



MACHINE SELF DISINFECTION:

The reason for self disinfect is to prevent the development of biofilm and micro-organisms, whilst the machine is not processing scopes

The self disinfect cycle is a thermal process, and will happen automatically during the night at the preselected time. There is also a self disinfect button in the options menu should it be necessary to carry out a self disinfect cycle at any other time.

The self disinfect process will be disabled when the RAPIDAER machine is used for any purpose whatsoever, or is not left in the start screen at the end of the day.

If the RAPIDAER is not used following the completion of the self disinfect protocol, it will repeat the above procedure the next night at the selected time.

Note:

It is important to ensure that no endoscope has been left in the machine at the end of the day and the start screen is displayed.

NB: during installation, some customers will require that all test results are returned prior to the RAPIDAER AER machine being used with endoscopes.

This will preclude the user training from taking place until these results are collated, which could take several weeks.

During such a period as this, the RAPIDAER machine will be set up to run self disinfect schedules over night to maintain the cleanliness of the machine.



CHEMICAL STORAGE DRAWER:

The chemical drawer is located on the dirty side (Load side) of the RAPIDAER machine.

Handles are fitted to allow you to open the chamber drawer.

You should always clean up any spillages caused during the changing or loading of Chemical bottles immediately.

CHANGING CHEMICALS:

When a chemical storage bottle is empty, the RAPIDAER computer screen will show a pop up warning box to tell the operator that a chemical bottle needs to be changed.

There will also be an audible alarm sounding, and the wash cycle “if in progress” will pause.

To change the bottles: First open the storage drawer , undo the cap and remove from the bottle.

Lift out the empty bottle. Ensure the replacement bottle is the same chemical.

Scan the data on the RFID tag on the front label of the new bottle, this will insert the lot number of the chemical, the expiry date and the serial number of the bottle.

Loosen the cap on the bottle with a bottle spanner and then put the bottle in the drawer.

Remove the cap on the bottle and replace with the pick-up cap.

Do the cap up tightly and closed the chemical drawer.

If a wash cycle was in progress when the bottle was changed, the operator should press the continue button in the pop up window to continue with the wash cycle.



DOOR LOCK – MANUAL OVERRIDE:

The door is actuated and held in position by air pressure and an electrical door lock, so no access can be gained during a cycle.

In the event of a power failure, the air pressure vessel will automatically empty, the door lock will release to the open position and thus the door can be manually pushed open to access any endoscope that may be in the chamber.



WATER SAMPLE PROTOCOL

RAPIDAER IS SAMPLED DURING THE FINAL RINSE AS THE SAMPLE PORT IS IN THE FEED TO THE CHAMBER. THE SAMPLE TAKEN SHOULD BE A MINIMUM OF 250MLS

1. PREPARE NECESSARY EQUIPMENT NEEDED I.E.: STERILE GLOVES, STERILE WATER SAMPLING BOTTLE, ALCOHOL WIPES AND RELEVANT LABORATORY FORM.
2. PREPARE RAPIDAER SAMPLE PORT BY RUNNING OFF 20MLS OF DISINFECTANT DURING THE DISINFECTANT PHASE OF THE CYCLE. WEARING PPE (MASK AND GLOVES), REMOVE THE BLUE PROTECTOR FROM THE END OF THE SAMPLE PORT, OPEN THE SCREW KNOB, ALLOW THE DISINFECTANT TO RUN OUT AND THEN CLOSE THE SAMPLE KNOB. DISCARD THE DISINFECTANT DOWN THE DRAIN AND RINSE CONTAINER.
3. WIPE DOWN WORK AREA WITH ALCOHOL WIPE, AND OPEN PACKET OF STERILE GLOVES. IN ADDITION, OPEN ANOTHER ALCOHOL WIPE AND DROP ONTO GLOVES. TAKE LID OFF SAMPLE CONTAINER.
4. WASH HANDS WITH HIBISCRUB OR EQUIVALENT E.G.: BETADINE SCRUB.
5. PUT ON GLOVES USING ASEPTIC TECHNIQUE AND KEEP HANDS ABOVE WAIST LEVEL AND AWAY FROM THE BODY
6. WHEN THE FINAL RINSE IS STARTED, TAKE AN ALCOHOL WIPE AND WIPE THE SAMPLE OUTLET .
7. DURING THIS RINSE, OPEN THE SAMPLE KNOB AND ALLOW AT LEAST 50MLS TO RUN INTO A WASTE CONTAINERS, THEN TAKE THE STERILE BOTTLE AND PLACE GENTLY UNDER THE SAMPLE OUTLET AND FILL THE SAMPLE BOTTLE. CLOSE THE SAMPLE KNOB AND FIT THE BLUE PROTECTOR.
8. PLACE LID ON BOTTLE, AND DRY THE OUTSIDE.
9. FILL IN THE LABEL AND ATTACH TO THE BOTTLE.
10. FILL OUT THE APPROPRIATE FORM GIVING DETAILS OF SAMPLE SOURCE, TIME AND DATE ETC. AND SEND AS SOON AS POSSIBLE TO THE LABORATORY.
11. FILL OUT THE RAPIDAER WEEKLY VALIDATION TEST LOG, WITH THE RELEVANT DETAILS.

ASEPTIC TECHNIQUE MUST BE USED WHEN OBTAINING A WATER SAMPLE



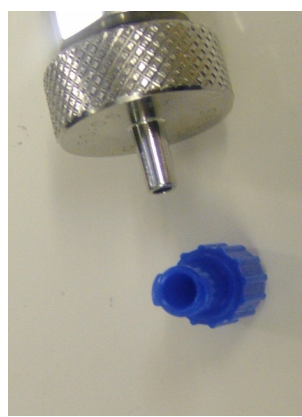
WHERE TO FIND THE WATER SAMPLING PORT.

The special water sample port is located on the left hand side just below the chamber on the loading side of the chamber.

Water Sampling Port

Water sampling in the RAPIDAER offers the user the facility to collect water from the point of application, as close to the contact with the scope as possible.

The water and Chemicals that pass through the pipework holding the sample point is the same as the irrigation feed to the scope channels.



The sample port has a blue cover which should always be replaced to help keep the fitting clean. You can fill this with alcohol when replacing it, after taking a water sample.



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MEDIVATORS® RAPIDAER



Operators Manual

Issue 01 – September 2014



Language Version
Original Instructions in English.



0088

CE Marking certifies that this equipment conforms to the following EEC directives:
Medical device directive 93/42/EEC
Low Voltage Equipment – 72/23/EEC
CE marking directive 93/68 EEC
Electromagnetic Compatibility – 89/336/EEC



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INTRODUCTION:

RAPIDAER DESCRIPTION:

The Medivators® range of automated endoscope re-processors, cover a wide range of capabilities to suit your particular requirements. RAPIDAER is the latest in the range, which now offers the user full pass through compliance to meet the requirements of BS EN 15883 Parts 1 & 4, SHTM2030 & CFPP01-06.

The RAPIDAER is a single chamber machine processing a single multiple channel endoscope per cycle in an easy to load basket. The machine has the same unparalleled external scope cleaning performance and integral individual channel cleaning facility as the Autoscope Isis providing a fully compliant re-processing performance.

Included in the automated wash cycle time of approx.17 minutes, is the automated leak test facility, and continuous channel monitoring. DATA records include operator, endoscope, and wash cycle information, together with the unique identification of the connection manifold being cross referenced against the endoscope channels of the endoscope.

PROCESS CYCLE

The normal re-processing cycle is in 7 stages.

1. Leak Test
2. Gross Wash and lumen patency check
3. Detergent wash
4. Detergent Rinse,
5. Disinfectant Clean,
6. Disinfectant Rinse.
7. Air flush

The operator also has the option to perform a "Manual Leak Test" with the door open, prior to the wash cycle



UNDERSTANDING RAPIDAER:

RAPIDAER is a fully compliant self contained pass-through endoscope reprocessing machine.

Designed to re-process one endoscope in each cycle, RAPIDAER offers a full cycle process with-in 17 - 18 minutes of pressing the start button. *(subject to a 5 minute disinfectant contact time and the incoming water temperature)*

Likewise loading the scopes is quick and efficient, by the use of the scope carrier basket design. Scopes can pre-loaded into their carrier baskets ready to be loaded in to the RAPIDAER machine, as soon as the re-processed scope is removed.

PASS THROUGH TECHNOLOGY:

RAPIDAER offers a compact footprint design that can be easily delivered and installed with access through standard size doorways. The pass through function of RAPIDAER allows the owner to split the re-processing task into separate areas, either in the same room, or separate rooms, by incorporating RAPIDAER into a dividing wall.

“Dirty Side” for loading used scopes & un-loading scopes that don’t complete their re-processing cycle.

“Clean Side” for unloading re-processed scopes only.

TRACE ABILITY:

RAPIDAER incorporates all the information that you require:
Operators have to log onto the machine, by use of a Tag, or ID & PIN for both loading & un-loading

The connection manifold and the endoscopes have to be logged onto the machine by use of a Tag, which identifies the channel configuration for irrigation and checks the hub and the manifold have the same channel connections.

Any access to the user configuration and set-up options, requires a log in, either by use of a TAG, or “ID & PIN”.

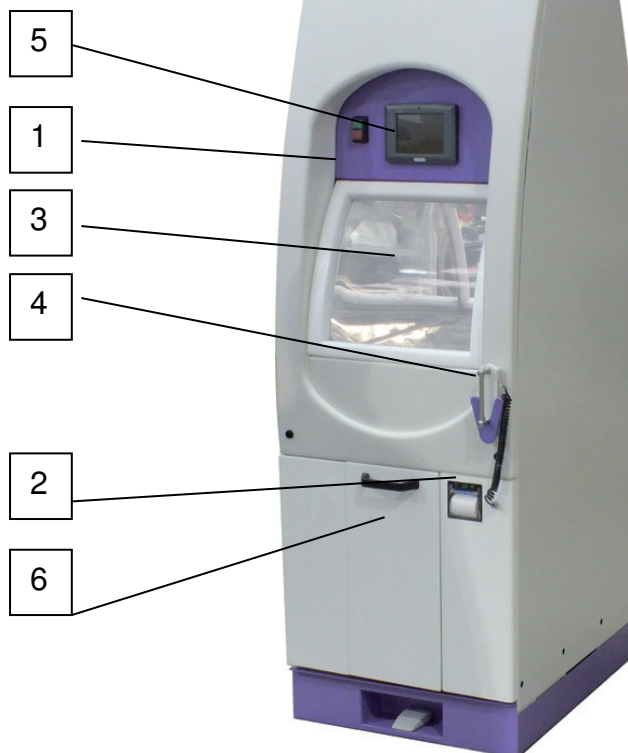
All information is captured in the RAPIDAER computer memory, and can be transferred when required via a USB data storage device, or the unit can be linked directly to a traceability system.

A printout is produced as part of each cycle, with the option for a comprehensive print out:- detailed report.



FIND YOUR WAY AROUND RAPIDAER: "DIRTY SIDE" SCOPE LOADING SIDE

1. ON / OFF switches
2. Printer (optional on this side)
3. Process Chamber
4. Tag Reader
5. Control Panel touch screen (onboard computer)
6. Chemical storage chamber



"CLEAN SIDE" SCOPE UN-LOADING SIDE

The clean side has

- Emergency stop Button
- Printer
- Access to Process Chamber
- Tag Reader
- Control Panel Read out for cycle status



ON/ OFF SWITCHES:

The On/Off switches are located on the top left of the load side (dirty side) of the RAPIDAER adjacent to the control panel.

GREEN is ON
RED is OFF



EMERGENCY STOP BUTTON: (CLEAN SIDE ONLY)

There is an emergency stop button on the top left of the unload side (clean side) of RAPIDAER.



TAG READER:

The TAG readers are on both sides of the RAPIDAER machine, and are positioned to give the best possible ergonomic interaction with the operator and scope carrier baskets during loading and unloading.



CHEMICAL CHAMBER:

The Chemical chamber is on the Dirty Scope, load side of the machine.



RAPIDAER CONNECTIONS:

ELECTRICAL CONNECTIONS:

RAPIDAER will be connected to a 32 amp, 50Hz, 240 V single phase supply.

The connection point for each RAPIDAER machine should have an isolator switch located close to one side of the RAPIDAER machine, (pass through installations)

If an engineer is working on the RAPIDAER machined he may require to disconnect the power supply and lock this isolator for health and safety requirements.



SUPPLY WATER:

The incoming water supply to the RAPIDAER should be from an RO plant. The RO is connected to the machine at the top where there is an aseptic sampling point and isolation tap. The machine will use 44 litres per cycle.

WASTE WATER:

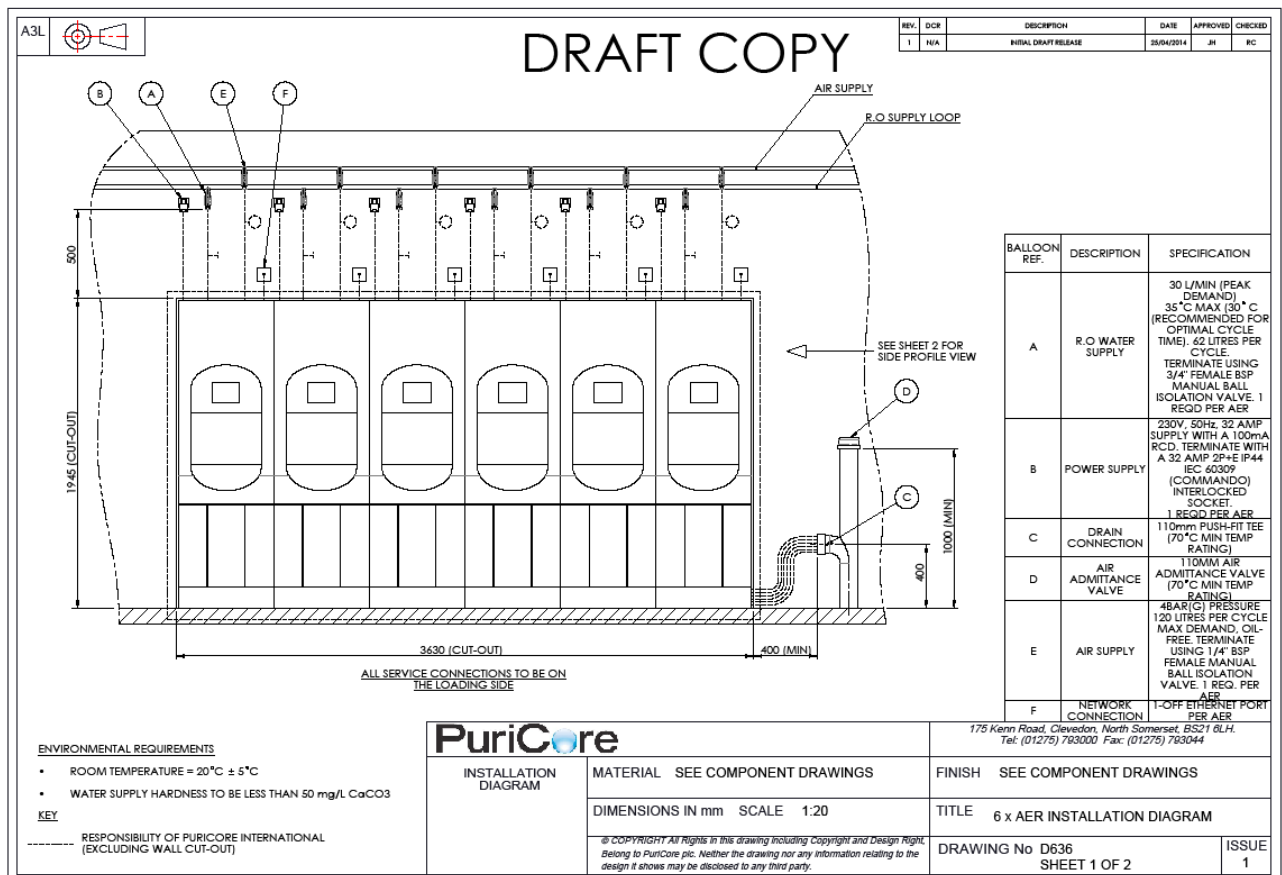
Waste water from the RAPIDAER should flow directly to a standard vented drain.

Always ensure that the water supply is turn on before using the RAPIDAER machine.

AIR PURGE SUPPLY:

A medical grade air supply should be connected to the top of the machine with an line gauge to allow operators to see the air pressure that is being supplied.

CONNECTION DIAGRAM





SPECIFICATION

Model	RapidAER
Dimensions	600mm (w) x 800mm (d) x 1930mm (h)
Processing Time	17 minutes
Disinfectant	Rapicide PA two part, single shot, Peracetic acid based disinfectant
Detergent	Mediclean Plus alkaline single shot detergent
Power Requirements	230v, 50hz, 32 amp supply
Class 1 equipment	Protective Earth required
Connection to supply	IEC 60309 industrial coupler
Water Requirements	64 litres per processed scope
Construction	Steel frame, Polycarbonate doors, Plastic cover panels.
Noise Level	<58 dBA
Weight	240Kg
Process Capacity	1 large flexible endoscope per cycle
Environmental Operation Conditions	
Operating Temperature Range	Ambient (0-40 °C)
Humidity	20%- 90%



OPERATOR - RAPIDAER INTERFACE

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

The operator has various options on how to interface with the RAPIDAER machine.

For ease of use, speed and efficiency the RAPIDAER machine is configured to operate using a TAG system.

There are three types of TAGS:

The Operator TAG:- which contains all the relevant data about the operative.

The Scope TAG:- which contains all the relevant data about the endoscope.

The Connection Manifold TAG – which contains all the details about endoscope connection

(All of these are covered in more detail on the following pages).

The TAGS are pre-programmed by the RAPIDAER manager with all the relevant details. The TAG system allows the operator to follow the prompts / instructions on the computer screen, and by presenting the TAG to the tag reader, the RAPIDAER machine will progress onto the next step in the process.

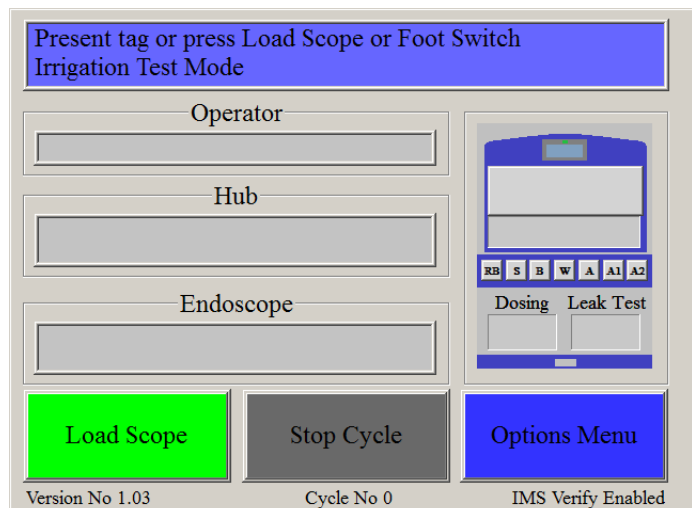
However, should the operator not have their TAG for whatever reason, RAPIDAER also has the option to allow access through the computer touch screen.

Each operator will also have an identification number and a PIN, these can be used to identify the operator to the RAPIDAER manually.

The operator will also be required to use the computer touch screen during the endoscope loading process. The buttons that are active and can be pressed to select an option or confirm a question, are always coloured in green.

The only other button that can be pressed is the Pause button, active once the cycle has started.

To operate a touch screen button, the operator should gently, but firmly press their finger on the button on the computer screen.





RAPIDAER CONTROL PANELS:

DIRTY SIDE (LOAD SIDE) CONTROL TOUCH SCREEN



CLEAN SIDE (UN-LOAD SIDE) CONTROL PANEL





OPERATOR ID

PERSONAL IDENTIFICATION NUMBER (PIN)

Under the “Hospital protocols” section of the RAPIDAER control functions, you are required to choose a PIN and sequential ID number for each operator or manager who has access to your RAPIDAER machine.

The PIN should be a confidential identification known only to the assignee, and the RAPIDAER manager.

It is recommended that a secure log or record of the PIN’s should be kept by the hospital (RAPIDAER manager) to cover for the event of an operator losing their TAG, and forgetting their PIN.

It doesn’t matter if operators choose a PIN that someone else already has, because it has to be used with their unique sign on ID number.

Once an ID & PIN and a TAG have been assigned to a user’s log on, the operator does not need to use their PIN because all the necessary information is stored on the operator TAG.

The operators ID & PIN will be required if a TAG is lost or stolen; so that the operator can access the RAPIDAER machine manually. The ID & PIN are also needed to re-assign a new TAG for the operator.

Please refer to the following section on TAG’s , for lost or damaged TAG’s



OPERATOR ID TAG:



Fig: Tag 1

Each operator that is assigned to your Autoscope RAPIDAER machine, should be allocated a unique personal TAG.

The operator ID TAG provides several functions:

- 1) Identifies the operator.
- 2) Automatically logs the operator into the RAPIDAER machine.
- 3) Automatically confirms the operator's access level status.
- 4) The TAG is required to open the RAPIDAER doors for both loading & unloading.
- 5) If a tag is lost or stolen. The RAPIDAER Manager should assign a new tag to the operator, this will disable the lost TAG.

SCOPE ID TAG:



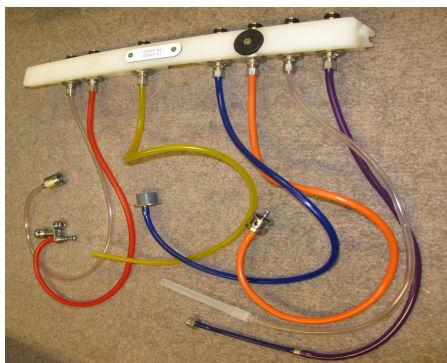
Fig : Tag 2

Each Scope that will be re-processed in the RAPIDAER requires a unique identification TAG rated to IP68.

This will identify the scope to the RAPIDAER machine, automatically confirming the parameters for cleaning and testing etc.

The TAG will also allow the endoscope to be tracked within the DATA storage and printouts.

CONNECTION HUBS



THE CONNECTOR HUB.

This is used with each scope that is installed into the carrier basket. There are a large number of hubs with connections dedicated to number of channels in that particular family of endoscopes. The hubs vary dependant on manufacturer and the individual connectors required to fit the individual channels.



CONNECTOR HUBS ID TAG



The connector hub tag is similar to endoscope ID tag and is rated to IP68. The information stored on the tag allows for the number of channel that are connected to be verified against the number on channels on the endoscope tag and then during the process these connections are monitored.

NOTE: All accessories used with the RapidAER, and to connect the endoscopes must comply to Cantel Medical's specification.

PRE-LOADING A SCOPE:

PREPARING THE SCOPE BASKET:

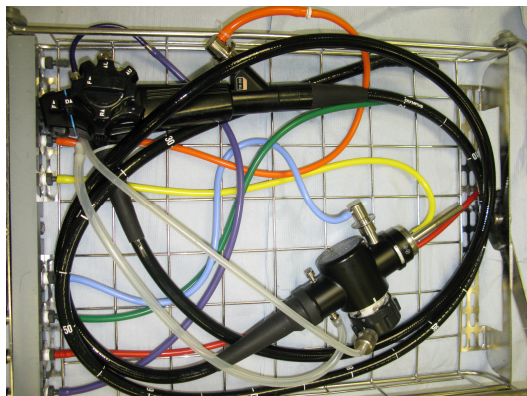
The RAPIDAER machine uses a scope carrier basket to house the scope in the machine. The basket is pre-loaded with the scope on a worktop, and placed into the RAPIDAER when ready.

On completion of the wash cycle, the scope is removed in its basket, so that another scope basket can be loaded and washed whilst the previous scope is removed from the basket.

The carrier basket can then be returned to the load side, for re-loading with more scopes.

Take an empty basket and then select the correct hub for the endoscope to be reprocessed. Each type of endoscope will have a specific connection manifold with the correct number of channel connectors suitable for that family of endoscopes.

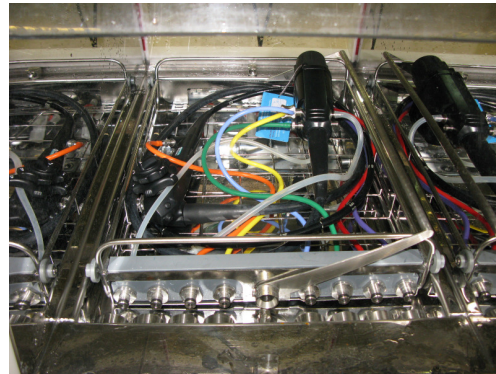
The manifold is slid into the end of the basket, the scope is then placed in the basket and the connections made to the scope.





LOADING THE SCOPE INTO THE RAPIDAER MACHINE

Open the RAPIDAER load door, using the operator tag or foot pedal.



Place the end of the basket on the side guides and slide the basket forward into the chamber until it rests totally in the base area.



Pull the basket back towards the front of the machine to locate the connectors into the irrigation ports on the inside front face of the chamber. When located, lock in position by moving the locking arm across the basket.

When the scope is loaded securely, Check the computer screen, and answer the question regarding channel separators, before closing the door,

UN-LOADING A SCOPE FROM THE RAPIDAER MACHINE:

To unload a scope, it is the reverse of the load operation.

When the computer instructs that the unload door can be opened, the operator should present their TAG to identify the unload operator and then retag or use the foot switch to open the clean side door.

Move the locking arm across to unlock the connections and then slide the basket upwards and remove through the clean door.

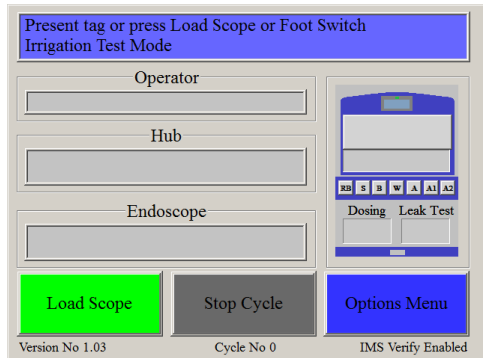
Close the door using the tag or foot switch.

The RAPIDAER machine will not proceed to the next step until the door has been closed properly.



How to “LOG ON” RAPIDAER

RAPIDAER functions via the onboard touch screen computer. The following steps show how to LOG ON to RAPIDAER using the touch screen.



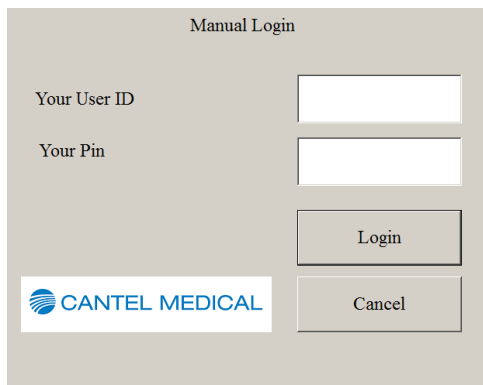
RAPIDAER Home screen

When at rest, the RAPIDAER will display the Home Screen.

In order to access the operating system, present the operator TAG to the reader.

Alternatively, touch the green box as indicated.

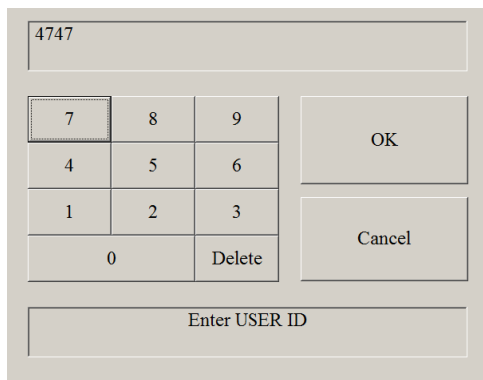
If the TAG is used, the door can then be opened by using the operator tag again or pressing the foot switch, and the RAPIDAER will ask for the Scope ID.



If the green box is pressed, the computer will proceed to the LOG ON screen

LOG ON screen

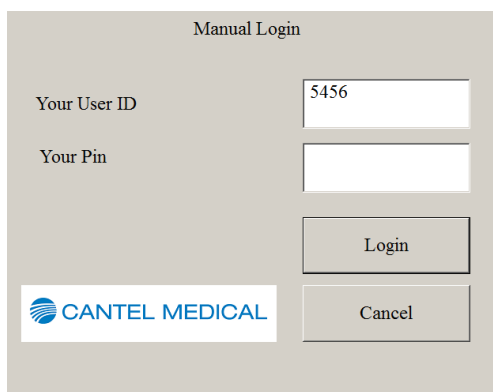
Touch the user ID box to input the users 4 digit reference number via the Key Pad screen



The numerical Key pad screen

Enter the user 4 digit ID number

Press OK to accept



Enter PIN

Touch the PIN box to activate the numerical keypad



7	8	9	OK
4	5	6	
1	2	3	Cancel
0	Delete		

Enter User Pin

The numerical Key pad screen

Enter the user 4 digit PIN

Press OK to accept


Manual Login

Your User ID

Your Pin

Login

Cancel

 CANTEL MEDICAL

Now press LOG ON

The door will open and the RAPIDAER will ask for the hub and scope ID

All the information displayed on the screen will be stored in the Data Log:
 ie: User ID, name, PIN, TAG, including dates & times.



AUTOMATIC RE-PROCESS CYCLE

The normal re-processing cycle for either a one or two scope process is in 7 stages.

1. Leak Test
2. Gross Wash and Lumen Patency
3. Detergent wash
4. Rinse
5. Disinfectant Clean
6. Disinfectant Rinse
7. Air flush

The Computer display on the Load side of the RAPIDAER machine is the main user interface. Most of the wash cycle sequence can be performed by the use of the Operator TAG, Manifold TAG and the Endoscope TAG. Additional operator input is by pressing buttons on the touch screen.

The touch screen buttons are all indicated when they are active and are mostly located across the bottom of the computer screen.

The computer screen display prompts and instructs the operator on the physical actions to be taken during the load and un-load sequences.

During the wash cycle process, the computer screen displays the stage of the cycle that is being performed. This information is repeated on the unload side, scrolling display.

Other information displayed on the screen includes:

The load operator for each scope
The hub identification
The endoscope identification
The PAUSE cycle button.



CYCLE SEQUENCE

The following information will be displayed at each stage of the cycle in the purple information box on the computer “dirty side” (Load side), and will also be scrolling across the, Machine Status Display, on the “clean side” (Un-Load side)

SCOPE LOAD SEQUENCE

- 1) RAPIDAER Ready Tag or Log On
- 2) Load Operator ID recorded
- 3) Load basket
- 4) Present Hub Tag
- 5) Hub ID recorded
- 6) Present Endoscope TAG
- 7) Endoscope ID recorded
- 8) Close door
- 9) Fitted Channel Separators?
- 10) Press Start

WASH CYCLE SEQUENCE

- 11) Leak Test and detergent dose measured
- 12) Gross Wash & Lumen patency check
- 13) Dose Detergent, Detergent Wash (Solution will be heated if water temperature lower than required)
- 14) Detergent Rinse
- 15) Dose Disinfectant solutions
- 16) Disinfectant contact (Solution will be heated if water temperature lower than required)
- 17) Disinfectant Rinse
- 18) Air Purge

SCOPE UNLOAD SEQUENCE

- 19) Present operatorTAG to open door
- 20) Un-load operator ID recorded
- 21) Unload & close door
- 22) Rotating to unload position 2
- 23) RAPIDAER READY (Tag or Log On)



USING THE RAPIDAER MACHINE

To start an automatic cycle, simply perform the following procedures.

SWITCHING THE RAPIDAER MACHINE ON.

First ensure that the power supply is switched on at the isolator. This should be located on the wall, close to the machine.

Then ensure that the water supply is turned on.

It is also important to take regular water samples to ensure that the supply RO water is clean.



Then press the GREEN start button.

This is located on the Top Left Hand Side of RAPIDAER, on the Load Side of the machine.

When the start button is pressed the computer will display the initialising screen. Once the RAPIDAER computer has booted up all the required configurations, the touch screen will display the Home Page

The Main Computer screen will stay on the Home Page, until a re-processing cycle is started.



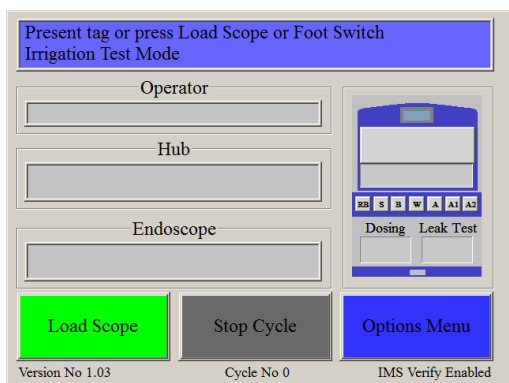
USING THE RAPIDAER MACHINE – RUNNING A CYCLE:

On switch on the RAPIDAER computer will load the standard home screen

The Main Computer screen will stay on the Home Page, until you start a re-processing cycle.

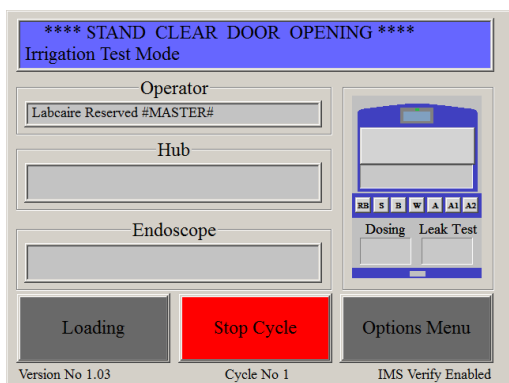
To use the RAPIDAER machine:

The operator needs to follow the instructions in the blue box at the top of the screen.



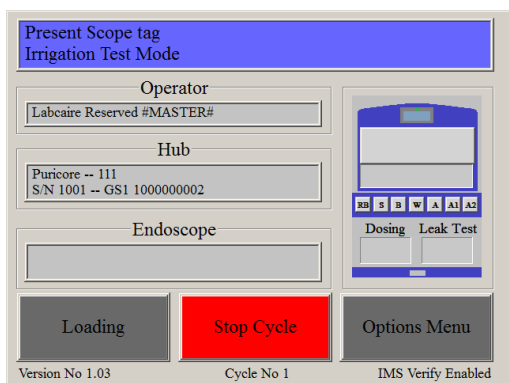
Present the Operator ID TAG to the TAG Reader. This identifies the operator as an approved user.

If the foot switch or load scope button is pressed then the operator will be asked to tag in or log on before proceeding.



NB: the operator DATA box now has the user ID displayed. This will be recorded for all information regarding this cleaning cycle.

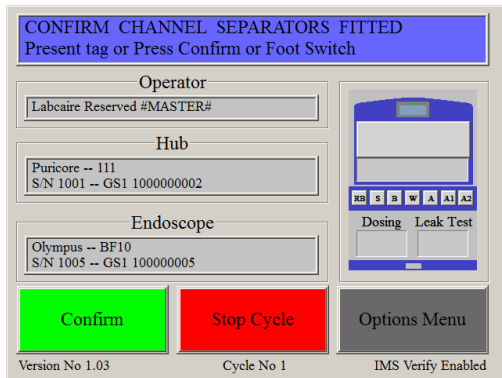
Present the operator ID tag or use the foot switch to open the door. Load the basket and endoscope in to the chamber and the use the tag reader wand to identify the hub.



The DATA boxes now have the user ID and the hub ID

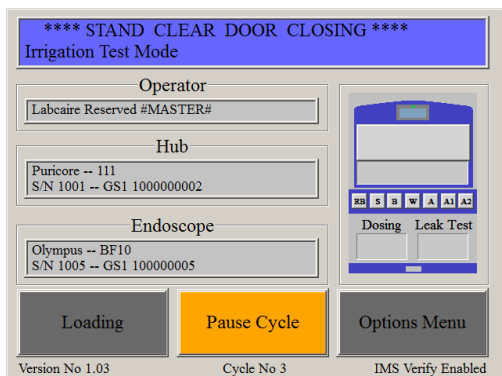
Use the tag reader wand to identify the endoscope.

The DATA boxes now have the user ID, the hub ID and the endoscope ID.



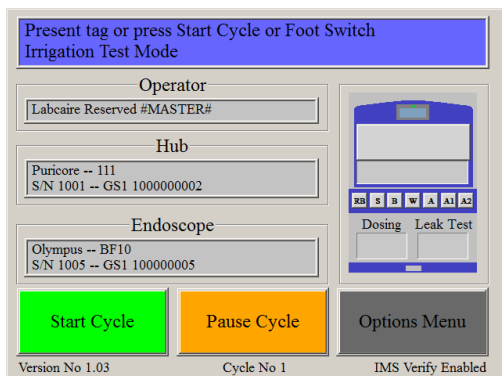
The operator will be asked to confirm if the channel separators have been fitted.

If separators are not required, still select Confirm.



On confirming the channel separators are fitted the door will close automatically.

Pause Cancel will allow the cycle to be stopped and return to the beginning of the load sequence.



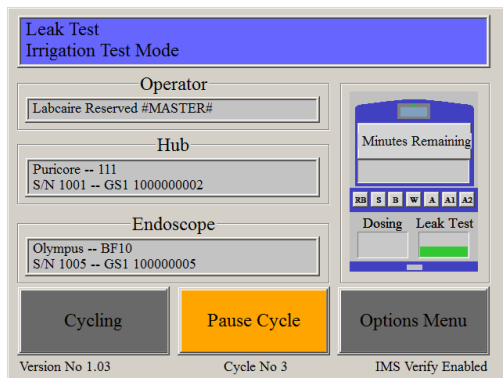
Press the green "START CYCLE" button on the left side of the touch screen, present the user tag to the tag reader or press the foot switch to start the cycle.

If a scope is loaded without presenting the Tag to the Tag Reader, the RAPIDAER machine will not let the software continue to the next stage.

This is achieved by means of the door not closing, until the endoscope Tag is presented to the Tag Reader.

Only then; will RAPIDAER allow you to continue to perform a wash cycle.

The RAPIDAER machine will automatically proceed with the leak test & cleaning cycles.



Firstly RAPIDAER performs an initial Leak Test.

At the same time it will prepare for the wash cycle.



The phase of the cycle is displayed in the blue box at the top of the screen

The duration of the cycle is displayed in minutes

The time remaining will count down in whole minutes

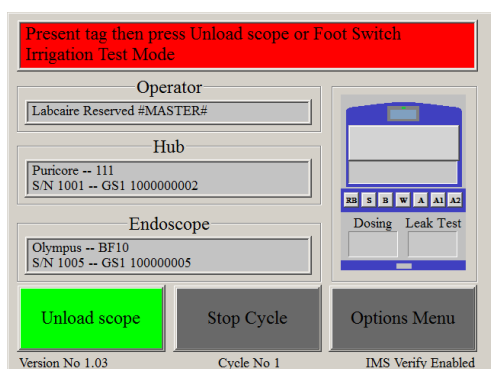
The final sequence of the cycle is the air purge which flushes the rinse water out the scope channels.

At the end of the process cycle RAPIDAER will inform you if the scope has passed or failed.

A failure will usually be indicated at the relevant point during the process cycle.

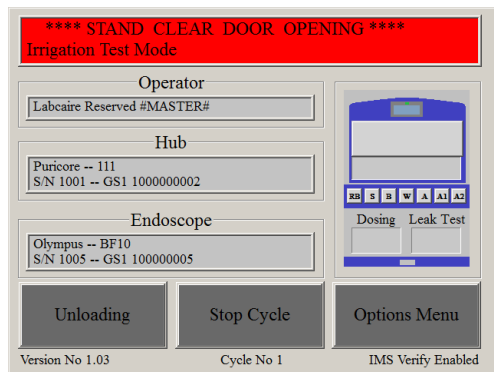
NB: Coloured buttons are active, press them to activate the function. Grey buttons are de-activated or display information only.

SCOPE PASS UNLOAD PROCESS



The Unload operator must use their ID tag to identify themselves to the RAPIDAER machine on the unload side.

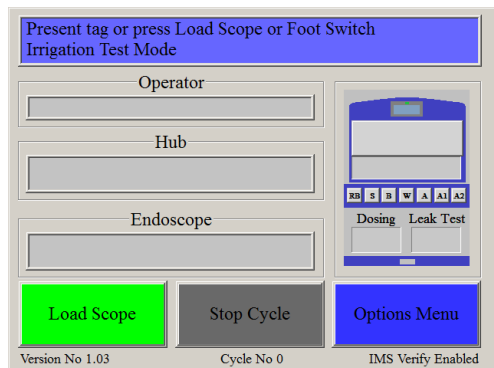
When the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.



The Un-load operator's ID will be recorded on the computer, and this information will be included on the print out, which appears on the clean side for the passed cycle.

When the door is open, remove the basket and endoscope.

Remove the cycle printout from the printer.



Close the door by using the operator ID tag or foot switch.

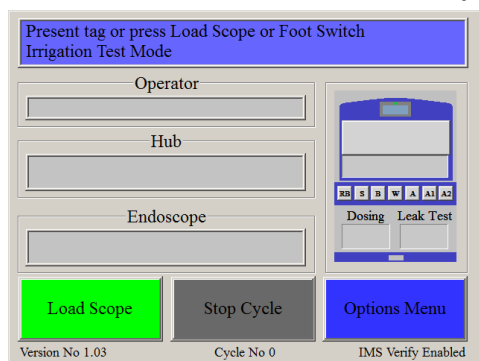
When the door is closed, the RAPIDAER returns to the HOME PAGE ready for loading to commence the next cycle.

Any scope that fails to pass all the criteria can only be removed from the "dirty side" Load side of the RAPIDAER machine.

The operator must present their Tag to the Tag reader to unload.

SCOPE FAIL UNLOAD PROCESS

The process to remove the endoscope from a failed cycle is the same as for a pass cycle except the Unload operator must use their ID tag to identify themselves on the load 'dirty' side of the machine.



Once the unload operator has presented their TAG, the unload door will unlock and the foot switch or using the operator tag again will open the door.

The cycle printout will be given on the load 'dirty' side of the machine.

When the door is open, remove the basket and endoscope.

Close the door by using the operator ID tag or foot switch.

RAPIDAER will return to the HOME PAGE ready for loading to commence the next cycle.

Unload the endoscope from the basket and assess the problem from the data given before reprocessing the endoscope.



OPTIONS MENU

The options button allows various functions to be carried out by the user and for an administrator to use the 'Hospital Protocol' section to add endoscopes, operators and hubs to the data base.

Press the 'Options menu' button on the right hand side of the home page.

The 'Log In' screen will be displayed. Either present the operator tag to the tag reader or enter your user ID and PIN as covered on page 16

Options Menus

User Menu

Administration Menu

SELF DISINFECT:

The thermal self disinfect can be set to come on at a predetermined time so the process is completed before the machine is required for reprocessing the endoscopes used that day.

There is also a 'Start Now' button on this screen, so a self disinfect process can be started when ever required



OPENING DOORS:

To open a door when prompted to by the screen instruction, you will be required to present your operator TAG to the RAPIDAER machine or use the foot switch. The door will unlock and open automatically.

Should you wish to open the access door at other times, or if the operator is not in possession of their TAG. Then the operator will be required to access the OPTIONS menu in order to open the door.

To do this, the operator must first. Select the OPTIONS button on the HOME PAGE This will then take you to the options selection screen.

HOME PAGE - Press the OPTIONS button to select:

LOG ON - The operator should use either their ID tag or enter ID number and PIN.

Press the OPEN DOOR button.

The door will 'unlock', so that it can be opened.

RETRIEVING A SCOPE:

Should the operator need to retrieve a scope from the RAPIDAER machine, other than in the normal sequence of a wash cycle; then this can be achieved by the following steps.

Scope Failed message - Press the abort button.

Press the "Options" Button

OPTIONS" Log on Screen - Present TAG to the tag reader or Enter user ID number & PIN

Then press Log On to proceed

OPTIONS Menu

Press the "OPEN DOOR" button
This will open the Dirty Side door only.



OPENING THE CHEMICAL STORAGE DRAWER:

To access the chemicals, the operator must first press the GREEN OPTIONS button on the RAPIDAER computer screen. This will then take you to the options selection screen.

Press the OPTIONS button to select:

LOG ON OPTIONS MENU by the operator either using their ID TAG or manually not entering their ID number and PIN.

Now press the “OPEN CHEMICAL CHAMBER” button.

The drawer will unlock, and the operator can manually pull the door open.

NB: the air extract fan will operate to contain and remove any odours via the carbon filter.

Select the chemical to be added, detergent, Base or Activator by touching the screen to highlight the chemical to be changed.

Pass the chemical bottle, with the label side facing the tag reader, across the bottle tag reader and the new bottle batch number will appear in the new

chemical boxes. Press OK to confirm the data.

Put the chemical bottle in the drawer and then change the lid over to the pick up lid in the unit.

IF the tag reader or the bottle label does not activate the new number correctly the the number can be added manually.

Press the Batch number area by the 'new' section.

A screen will appear that allows the new batch number to be entered.

Similarly select the serial number and enter this in the same way.

Finally add the expiry date for the chemical in the date boxes.

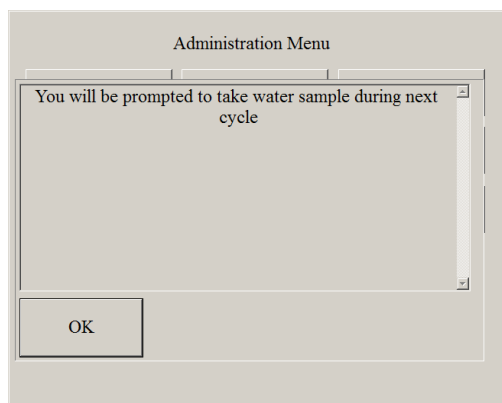


ACTIVATE FLUSH SYSTEM ROUTINE:

This facility flushes all the complete system and dosing pots so that they are at the correct status for a new cycle to be started. This facility should be used when the wash cycle has been interrupted and RAPIDAER is out of synchronisation.

WATER SAMPLE

This option can be selected to allow a prompt to be given when the last rinse is being done and the water sample should be taken.

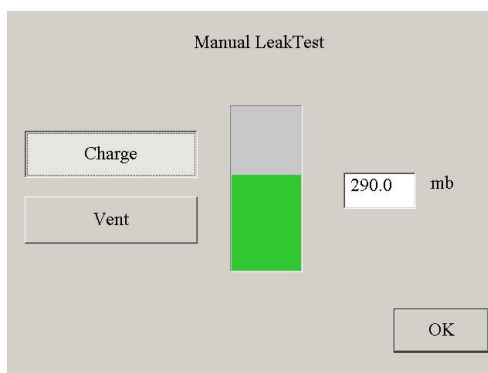


Select OK and the cycle will emit an alarm when the final rinse stage is reached in the next cycle.

ENGINEERING.

This button is not displayed in the normal user mode, it only becomes active when the engineer has a special USB key in the machine.

LEAK TEST:



In the event of a leak test failure, a manual leak test can be carried out in the machine. This will pressurise the scope to the required 290 mbar and by watching the screen any leak can be detected by the slow decrease of the pressure reading.



SET TIME

The date and time can be changed to the local time at the location of the unit.

Select the time and date on the UP/DOWN arrows and press save to confirm the new date and/or time.

PRINT CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

This function is in the Hospital Protocols for personnel with ADMIN access.

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

This function is in the Hospital Protocols for personnel with ADMIN access

HOSPITAL PROTOCOLS

These screens can only be accessed by users that have been given 'ADMIN' rights during the set up of the user's tag.

An operator with user access only will not be allowed to access the "Hospital Protocol" menus.

Functions within Hospital Protocols

Add a NEW operator/user
 EDIT an existing operator's details
 Assign a NEW scope ID
 EDIT an existing scope ID
 Add a NEW connector hub
 EDIT a connector hub
 Print a last cycle ticket
 Print a cycle report
 Print the last self disinfect cycle ticket
 Copy files



ADD A NEW USER

Press the “New Operator” button on the Screen

The operator ID is sequentially assigned by RapidAER automatically.
Every Operator will have a unique ID number.

To enter an operator name:
Touch the white text box

Touch screen type writer pad.

Input the new operator’s name.

Then press OK.

The name will now appear in the white text box.

To enter the user PIN
Touch the White text box .

Touch screen number pad:
Type in the 4 digit PIN for the new operator according to your SOP.
(standard operating procedure) Then press OK!

The PIN will not be displayed on the screen
Only a symbolic representation, this is for security reasons.

It is recommended that you keep a record of the PIN elsewhere.

To assign a TAG, present the new TAG to the tag reader.



All the operator details are now installed and linked to the ID TAG.

Next assign access rights and press the 'Inactive' box to make the operator 'Active'.

Access Rights

To assign the new operators access capabilities; Press the relevant Description to tick the boxes.

Then press OK:

Access Rights:

For basic machine operation access:- tick the User box

For access to set up new scopes, users or hubs or copy data files:- tick the Admin box.

The Admin access automatically gives an operator user rights to run a cycle.

The New Operator is now installed into the RapidAER computer.

EDIT AN EXISTING USER'S DETAILS

Press the "Edit User" button on Screen

Select the operator to be edited by touching the operators name on the screen.

Then press edit operator

The operator details will be displayed.

Select and modify their Access Rights, or re-assign a new Tag.

Then press OK.

The edit function is now complete.



ADD A NEW CONNECTION HUB ID

Press the 'Add Hub' button on the Menu screen

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

The complete hub list will appear

RAH001
RAH002
RAH003
RAH004
RAH005
RAH006
RAH007
RAH008
RAH009
RAH010
RAH011
RAH012
RAH013

Select Hub to Add

OK Cancel

Select the hub to be added

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be added

Press OK

Max Flows

Suction 1800

Biopsy 0

Water 0

Air 0

Aux 1 0

Aux 2 1800

RB Min Pres 0

Make CANCEL

Model RAH008

Dept

Serial No

GS1

Tag

Adding Hub Type RAH008

OK Cancel

To add the information touch the white box adjacent to 'Dept'.

Endoscopy

q w e r t y u i o p

a s d f g h j k l

z x c v b n m

Number Space Delete

Shift - \

Clear . @

Enter Department

OK Cancel

Type in the department name and Press OK



Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	
Air	0	GS1	
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Next add the serial number that is on the new hub serial number plate. (Each hub has its own serial number so individual hubs of the same type number can be identified.)

Max Flows		Make	CANTEL
Suction	1800	Model	RAH008
Biopsy	0	Dept	Endoscopy
Water	0	Serial No	012345
Air	0	GS1	334
Aux 1	0	Tag	
Aux 2	1800	Adding Hub Type RAH008	
RB Min Pres	0	<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Complete the data by selecting each box and typing in the data.

Finally present the tag fixed onto the hub to the tag reader to add this data.

Press OK to save the new hub data.

NOTE The max. Flow values on the right side of the screen give the disconnect alarm and cannot be altered. Any changes that are required to these flows must be made by a Cantel Medical engineer after testing the hub with the respective endoscope.

This new connector hub can now be used in the RapidAER machine.

EDIT AN EXISTING HUB ID

Press the 'Edit Hub' button on the screen. This allows a hub to be edited and assigned to another department or for a hub to be deleted from the hub list in the RapidAER computer.

RA002 S/N 1008 RA017 S/N 1011 RA020 S/N 1012 RA022 S/N 1013 RA038 S/N DSFS	<input type="button" value="Delete"/>
<input type="button" value="Select Hub to Edit"/>	<input type="button" value="OK"/> <input type="button" value="Cancel"/>

The list of connection hubs that have been stored in your RapidAER machine will be displayed

A hub can now be edited or deleted



Select the hub by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the hub that is to be edited

Press OK if hub to be edited

The Hub information page will appear.

Now make your alterations as per the “add new hub” procedures, selecting any of the data that has a white box and changing as necessary.

Then press OK to Save the new data.

If the hub is no longer to be used then the delete button can be selected after the hub has been selected in the hub list displayed in the edit scope process as above.

Select ‘Yes’ and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

To exit this process then press ‘Cancel’

ADD A NEW ENDOSCOPE ID

Press the “Add Scope” button on the Menu Screen

The Scope Information page will appear. Now fill-in the boxes in sequence.

Press the “Make” box on the touch screen



Olympus									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number		Space		Delete					
Shift	-	\	Enter Manufacturer						
Clear	.	@	OK		Cancel				

The key pad will appear.

Enter the manufacturer of the scope eg. Olympus, Pentax , Storz etc

Then press the OK button to enter the data.

Min Flows		Make	Olympus
Suction	100	Model	
Biopsy	100	Dept	
Water	50	Serial No	
Air	50	GS1	
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK	Cancel

Press the “Model” box on the touch screen

Gastroscope									
q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
	z	x	c	v	b	n	m		
Number		Space		Delete					
Shift	-	\	Enter Model						
Clear	.	@	OK		Cancel				

The key pad will appear.

Enter the model of the scope eg. Gastroscope, Broncoscope etc

Then press the OK button to enter the data.

Continue to add the Department, Serial number, GS1 number if known in the same way as the Make and Model, typing in the data and pressing OK after each entry.

Min Flows		Make	Olympus
Suction	100	Model	Gastroscope
Biopsy	100	Dept	Endoscopy
Water	50	Serial No	GIF1246789
Air	50	GS1	F234
Aux 1	50	Tag	
Aux 2	50	Adding Endoscope	
RB Diff %	30	OK	Cancel

To complete the new endoscope entry present the scope tag to the tag reader to assign that tag to the data entered.

The tag data will be entered in the tag box.

Press OK to save the data to the RapidAER data base.

This new scope can now be re-processed using the RapidAER machine.



EDIT AN EXISTING SCOPE ID

Press the 'Edit Scope' button on the screen. This allows a tag to be edited and assigned to another scope or for a scope to be deleted from the endoscope list in the RapidAER computer.

The list of scopes that have been allocated by the user which are stored in your RapidAER machine will be displayed

A scope can now be edited or deleted

Select the scope by pressing it on the touch screen

Scroll down, if necessary, using the up/ down arrows by the list until you find the scope that is to be edited

Press OK if scope to be edited

The Scope information page will appear.

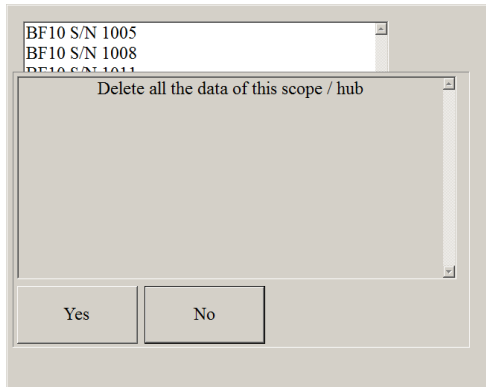
Now make your alterations as per the "add new scope" procedures, selecting any of the data and changing as necessary.

Then press OK to Save the new data.

Whenever this scope is re-processed in the RapidAER machine the new details will be logged and recorded.



If the endoscope is no longer to be reprocessed then the delete button can be selected after the endoscope has been selected in the endoscope list displayed in the edit scope process as above.



Select 'Yes' and the scope will be removed from the list. The screen returns to the scope list with endoscope removed.

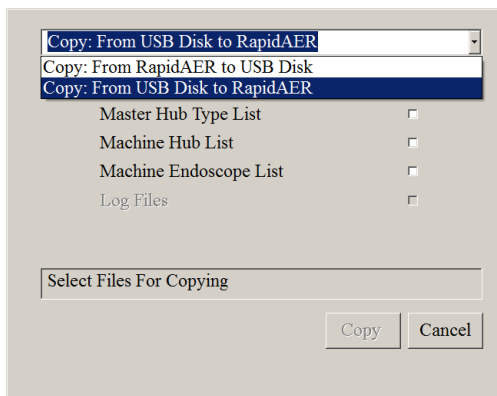
To exit this process then press 'Cancel'

Select 'No' and the screen returns to the scope list with endoscope still visible.

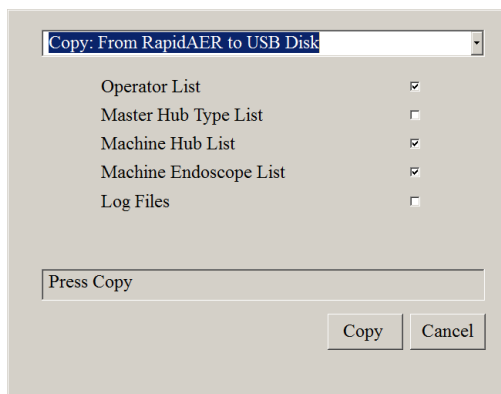
To exit this process then press 'Cancel'

COPY FILES

This button allows files to be copied onto the RapidAER computer or copied from the RapidAER computer. This allows the operator, endoscope, and department hub lists to be copied from machine to machine so data only has to be entered once.



From the arrow along side the top box select if files are to be copied onto the RapidAER from a USB key or whether files are to be copied from the RapidAER onto a USB key.



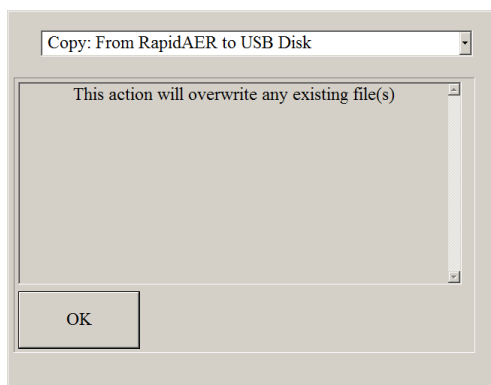
So to copy files from machine to machine after adding new operators, endoscopes or hubs

Select From RapidAER to USB disc

Tick the files to be copied – Operator list, machine hub list or machine endoscope list

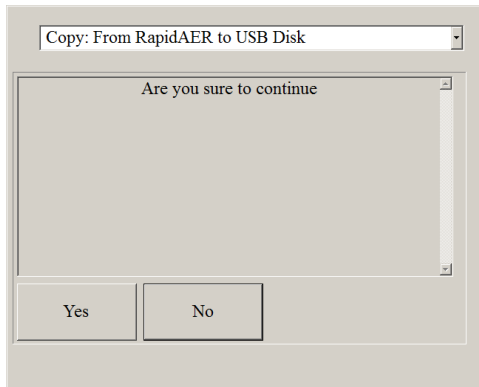
Note: Log Files can only be copied from the RapidAER to the USB Drive

Press 'Copy'

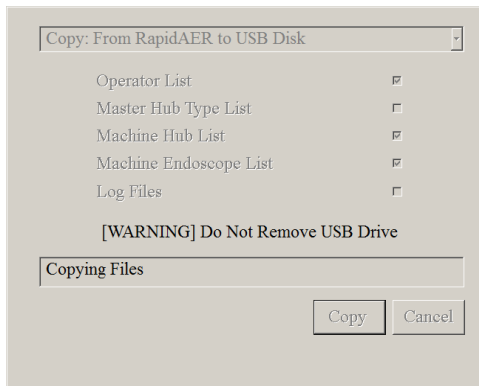


A message will appear to alert the operator that any files on the USB disc with the same name will be overwritten.

Select OK to acknowledge the message

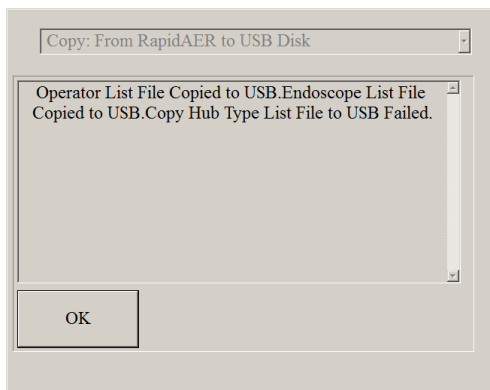


Press 'Yes' to continue the transfer or 'No' to exit



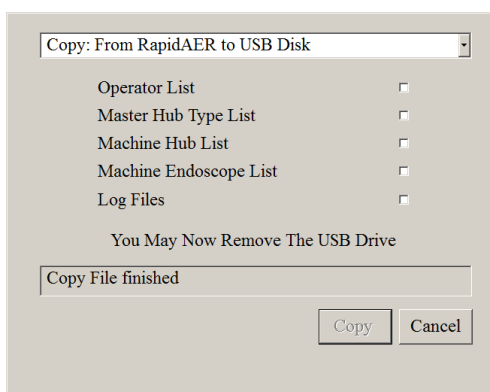
The files are now being copied.

Do not remove the USB drive



The screen indicates that the files have been copied or that a list has failed to copy.

Press OK



The final screen informs the operator that the copy file instruction is complete and the USB drive can be removed.

Press cancel to exit

To copy the files from the USB Drive to the next RapidaER machine, insert the USB drive in the slot adjacent to the screen on the dirty side of the machine. Go to Hospital Protocols and select 'Copy Files' follow the same process as above but initially select 'Copy: From USB Disk to RapidaER'



LOG FILES

These can be selected to be copied onto the USB drive as the above process and they can then be downloaded onto a hospital computer for analysis.

PRINT CYCLE REPORT

This will print a detailed report of the cycle that has just been completed. For more information see Printouts.

PRINT LAST CYCLE TICKET

This will reprint the cycle ticket from the previous cycle

PRINT SD TICKET

This will reprint the last self disinfect cycle record.

AUDIBLE ALARMS

INFORMATION ALARM:

When the RAPIDAER machine has completed the endoscope cleaning cycle, it will emit a single beep audible alarm, to indicate that the machine is ready for unloading

WARNING ALARMS:

When ever there is a visual warning alarm on the computer screen, the RAPIDAER machine will also emit a continuous audible alarm.

To stop this audible alarm, the operator needs to accept / acknowledge the visual alarm on the computer screen, by responding to the computer instruction or prompt.

POWER INTERRUPTION:

If the power source to the RAPIDAER is interrupted, the volt free contacts will enable a remote signal to indicate an alarm.

If the power supply to RAPIDAER is interrupted, then the RAPIDAER machine will need to be manually switched on, using the green button, on the front of the machine.



However if the RAPIDAER machine was performing a wash cycle when the power was interrupted; then, when the power is re-connected, the RAPIDAER machine will emit an audible alarm, linked with the wash cycle fail indication on the computer screen.

REMOTE ALARMS:

When ever there is a major alarm on the RAPIDAER machine, that would require immediate attention, eg: water leakage, power failure, self disinfect chemical bottles empty. Then the alarm will be duplicated via the volt free contacts, which will active either a visual or audible alarm in a remote location of the hospitals choosing. Eg: estate dept, BMS room, RAPIDAER managers office.



DATA SYSTEMS

The RAPIDAER AER machine has data storage and retrieval options for various types of data.

LOG DATA:

This is the cycle log record for every wash cycle and scope that has been processed in the RAPIDAER AER machine.

This data can be downloaded on to a USB key for achieving or the machine can be networked and the data transferred every cycle.

IMS:

(Independent Monitoring System)

This is a separate measuring system to confirm that the wash cycle parameters are within the tolerance that is required.

There are two levels of data retrieval obtainable through this system.

Level 1:- Process cycle history in an excel.csv spread sheet format.

Level 2:- the Full IMS data screen which will require the Cantel Medical IMS.net software package

Operator Data:

This is a history of every operator (present and previous) that has had access to the RAPIDAER machine.

Connector Hub Data:

This is a record of every connector hub present & previous that has been ID logged into the RAPIDAER AER machine, including the hub number, serial number and TAG ID.

Endoscope Data:

This is a record of every scope present & previous that has been ID logged into the RAPIDAER AER machine, including the make, model, serial number and TAG ID.



DATA STORAGE:

The RAPIDAER onboard computer has the capacity to store a large volume of information.

The memory allocated to cycle DATA storage will be able to store 250,000 wash cycles of information.

The information stored is formatted on an excel spread sheet, so that DATA retrieval is user friendly in both operator programme knowledge, and also in computer software compatibility.

The DATA storage format contains a heading with:

- The Department identification,
- The RAPIDAER machine serial number,
- The software version number.

DATA Storage Topic Headings:

- Date:
- Time:
- Pass / fail
- SD date
- SD time
- SD No:
- Operator ID
- Operator Name
- Un-load Operator ID
- Un-load Operator Name
- Contact time (seconds)
- Scope ID
- Manufacturer
- Model
- Serial Number
- Department
- Leak Test
- Raiser Bridge
- Channels Irrigated
- Comments
- Cycle Name
- Leak Test
- Number of Faults
- Reason Code
- Reason.



PRINTOUTS

The RAPIDAER provides a “hard copy” printout for the process that has been performed. This is in addition to the DATA being stored on the RAPIDAER computer which can be retrieval via a USB key or by direct connection to a Track and Trace system.

There are five label printout configurations:

Cycle Complete	= When a wash cycle has been completed.
Cycle terminated	= When a wash cycle has automatically stopped.
Cycle terminated	= When a wash cycle has been manually stopped
Test Label	= Engineer access only
Detailed Process Report	= RAPIDAER Hospital Protocol access required

The printers are located on the front of the machine:

On a pass through machine there will be a print out on the “clean side” (un-load side) for a ‘pass’ cycle and on the ‘dirty side’ (loading side) for a ‘failed’ cycle.

Below are example labels that depict the type of information that will be presented on the printouts



CYCLE COMPLETE 'PASS' PRINTOUT

(-----)	
(-----)	
(--Wash Cycle Pass --)	Cycle Pass/ Fail identification
(-----)	
(Cantel RapidAER)	
(Serial No RA0009)	RapidAER serial number
(-----)	
(Start 09h 44m)	Cycle start time:
(End 10h 02m)	Cycle finish time:
(Date 20-10-2014)	Date
(-----)	
(Cycle No. 52)	Unique sequential cycle number
(-----)	
(Load Operator 1)	
(Name Paul)	Loading operator identification
(-----)	
(Unload Operator 1)	
(Name Paul)	Un-Loading operator identification
(-----)	
(--Hub-----)	
(Cantel A3 Testroom)	Connection Hub used for the process
(Serial No 1)	
(GS1 1)	
(-----)	
(--Endoscope--)	
(Olympus Gastroscope)	Scope ID – including Make & Model
(Serial No GIFH260)	Serial No & GS1 No
(GS1 1)	
(-----)	
(IMS Verify Enabled)	IMS Status
(-----)	
(Control Pass)	Status of IMS & Control system at end of cycle
(IMS Verify Pass)	Pass confirmation
(-----)	
(Contact Time 5minutes)	Disinfectant Contact Time
(-----)	
(Last SD 20-10-2014 at 06h 00m)	RapidAER self disinfect information.
(-----)	
(Suction Av Flow 2185ml)	
(Biopsy Av Flow 1775ml)	
(Water Av Flow 120ml)	Average Flows in each of the channels during the
(Air Av Flow 85ml)	process including Raiser Bridge & Leak Test
(Aux 1 Av Flow 400ml)	Pressures
(Aux 2 Av Flow 900ml)	
(RB Av Pres 3850mb)	
(Leak Test Av Pres 300mb)	
(-----)	
(---Conductivity---)	
(Detergent 764µs)	Conductivity of each phase of the cycle
(Disinfectant 1150 µs)	
(Final Rinse 35 µs)	
(-----)	
(---Temperature---)	
(Detergent 25.1 deg)	Temperature of each phase of the cycle
(Disinfectant 26.1 deg)	
(Final Rinse 24.9 deg)	
(-----)	
(Chemical Batch/serial No)	
(Detergent D412/1134)	Chemical Batch / Serial numbers of each of the
(Part B B3321/889)	chemicals used for the process
(Part A A6543/996)	
(-----)	



CYCLE COMPLETE 'FAIL' PRINTOUT

There are two types of 'Fail' cycle and this is when the control or IMS system do the cycle checks and one or more parameters are outside the range allowed. The second failure is a manual abort by an operator. An example of each is given below.

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       10h 40m    )
( End         11h 02m    )
( Date        20-10-2014 )
(-----)
( Cycle No.   53         )
(-----)
( Load Operator 1      )
( Name         Paul     )
(-----)
( Unload Operator 1     )
( Name         Paul     )
(-----)
(  --Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled   )
(-----)
( Control      Fail      )
( IMS Verify   Fail      )
(-----)
( Fault: 9044 Manual Abort (dis wash) )
( Fault: 9045 IMS: RB Flow duration   )
( Fault: 9024 IMS Aux 1 Low flow (0)   )
(           (dis wash)                )
( Fault: 9049 IMS conductivity        )
(           (dis wash)                )
(-----)
```

Cycle Pass/ Fail identification

RapidAER serial number

Cycle start time:

Cycle finish time:

Date

Unique sequential cycle number

Loading operator identification

Un-Loading operator identification

Connection Hub used for the process

Scope ID – including Make & Model
Serial No & GS1 No

IMS Status

Status of IMS & Control system at end
of cycle

Fault codes – reason for failure

```
(-----)
(-----)
(  --Wash Cycle Failed--  )
(-----)
( Cantel      RapidAER    )
( Serial No   RA0009     )
(-----)
( Start       11h 24m    )
( End         11h 42m    )
( Date        20-10-2014 )
(-----)
( Cycle No.   54         )
(-----)
( Load Operator 1      )
( Name         Paul     )
(-----)
( Unload Operator 1     )
( Name         Paul     )
(-----)
(  --Hub-----  )
( Cantel      A3 Testroom )
( Serial No   1           )
( GS1         1           )
(-----)
(  --Endoscope--  )
( Olympus     Gastroscope )
( Serial No   GIFH260     )
( GS1         1           )
(-----)
( IMS Verify   Enabled   )
(-----)
( Control      Pass      )
( IMS Verify   Fail      )
(-----)
( Fault: 9048 IMS Irr temp 180.1 C    )
(           (Leak Test)              )
( Fault: 9048 IMS Irr temp 600.6 C    )
(           (Gross Wash)             )
( Fault: 9048 IMS Irr temp 600.6 C    )
(           (DetWash)                )
( Fault: 9048 IMS Irr temp 600.6 C    )
(           (DetRinse)               )
( Fault: 3035 IMS Irrigation temp     )
(           sensor fault (6006)      )
(-----)
```



CYCLE PRINTOUTS FOR SELF DISINFECT

There are two printouts for Self Disinfect Cycle Pass and Cycle Fail. Examples are both are shown below.

(-----)	
(-----)	
(-Self Disinfect Passed--)	
(-----)	
(Cantel	RapidAER)
(Serial No	RA0009)
(-----)	
(Start	07h 29m)
(End	08h 31m)
(Date	20-10-2014)
(-----)	
(Cycle No.	11)
(-----)	
(Operator	1)
(Name	Paul)
(-----)	
(Unload Operator	1)
(Name	Paul)
(-----)	
(IMS Verify	Enabled)
(-----)	
(Control	Pass)
(IMS Verify	Pass)
(-----)	
(Temp Stage 1	86.1deg)
(Temp Stage 1	85.1deg)
(Temp Stage 1	85.5deg)
(Contact Time	10)
(-----)	

(-----)	
(-----)	
(-Self Disinfect Failed ----)	
(-----)	
(Cantel	RapidAER)
(Serial No	RA0009)
(-----)	
(Start	07h 59m)
(End	09h 14m)
(Date	21-10-2014)
(-----)	
(Cycle No.	7)
(-----)	
(Operator	1)
(Name	Paul)
(-----)	
(Unload Operator	1)
(Name	Paul)
(-----)	
(IMS Verify	Enabled)
(-----)	
(Control	Fail)
(IMS Verify	Fail)
(-----)	
(Fault: 9053	Spray system running)
(with empty sump (Recirc stage 2))
((Fault: 9048	IMS Circ temp 64.5 C)
((Recirc stage 2))
(Fault: 9048	IMS Temp Su 63.7 C)
((Recirc stage 2))
(-----)	



CHANGING PRINTER PAPER:

The printer is located as shown in the “Find your way around RAPIDAER” diagrams



The printers are located on the right hand side just below the chamber on both sides of the machine.



To access the paper roll,
Press the GREEN button on the top of the printer and the paper holder falls open.



To input a new paper roll, simply place the replacement paper roll into the printer as shown with the feed off section to the top, pull some paper forward, to create a tongue.



Push the paper holder closed, and tear off the excess paper against the serrated edge.

RAPIDAER printer is now ready for use.



To feed paper forward from the roll, press the button on the RIGHT.



ESSENTIAL OPERATING PRACTICES.

NOTE: Only trained personnel should use the RapidAER, and should have read and understood the manual.

If the unit is not used in the correct manner, the cleaning and decontamination carried out by the unit may be impaired.

To ensure endoscopes are correctly disinfected it is important the following points are observed.

1. The machine thermal self-disinfection is carried out each day, before use.
2. The disinfectant contact parameter times are pre-programmed into the machine. The soak times must be determined by the manufacturer of the disinfectant and the Hospital Infection Control Department.
(Please refer to the tables in the "Disinfectant Types" section)
3. The manufacturer's instructions on the manual pre-cleaning, machine cleaning and disinfection of endoscopes must be followed at all times. The efficiency of the process depends on an efficient pre-clean and brushing through of the internal channels prior to disinfection.
4. It is most important that the endoscope internal channels are disinfected. The quality of the rinse water should be monitored at routine intervals.
5. The RAPIDAER must not be positioned within a risk area of anaesthetic equipment.

HOSPITAL PROTOCOLS:

Within the HOSPITAL PROTOCOL Menu, the user access protected CYCLE & SELF DISINFECT Menus allows for the defining of the following operational criteria:

RAPIDAER Hospital Protocol Menu
<i>Set & Edit Operator ID</i>
<i>Set & Edit Connection Hub ID</i>
<i>Set & Edit Endoscope ID</i>
<i>Copy Files</i>
<i>Reprint last cycle data</i>
<i>Reprint last self Disinfect cycle data</i>
<i>Print a detailed cycle report</i>



DISINFECTANT WARNINGS:

Disinfectants are hazardous substances and controlled by COSHH Regulations. Manufacturers must supply Safety Hazard Data Sheets to cover the use of their products.

The following Points should also be considered for use in this application.

1. Personal protection equipment should be worn when handling disinfectants or endoscopes. Suitable gloves, eye / face protection and apron.
2. The opening of disinfectants and closing of empty containers should be carried out, inside a suitable ventilated area.
3. The hospital should establish a procedure for safe storage, handling and disposal of disinfectant containers.
4. The hospital should establish a procedure for accidental spillage.
5. The RAPIDAER will provide a safe system for transfer of disinfectant to the chamber, during processing and disposal of used disinfectant. However, attention should be given to the room environment (ventilation) etc. see installation drawings. Correct ventilation will minimise problems if a spillage occurs.
6. The carbon filter should be changed every year to keep emissions below exposure limits.
7. Any disinfection contact should be washed off immediately and referred for medical attention.



DISINFECTANT TYPES:

The machine is compatible with two Peracetic Acid, single use disinfectants, for use on endoscopes, but the following points must be observed (see table below).

- A. The manufacturer of the Endoscope should be contacted for advice on chemical compatibility. Warranties may only be valid on approved disinfectants.
- B. The Hospital Protocol and disinfection soak time should be approved by the disinfectant manufacturer and the Hospital Infection Control Department.
- C. Disinfectants activated with powders should not be used in RAPIDAER.
- D. Silicone based de-foamers should not be used in RAPIDAER.

DISINFECTANT NAME	DISINFECTANT TYPE	CARBON FILTER TYPE
Rapicide PA	single use peracetic acid	ACI
Purisept	single use peracetic acid	ACI

DISINFECTANT CONTACT TIME PARAMETERS		
disinfectant name	specific scopes	contact time
Rapicide	all	5 minutes
Purisept	all	5 minutes



DISINFECTION OF SCOPES:

CONNECTION OF ENDOSCOPES TO IRRIGATION CHANNELS:

Connection of the Endoscope to the irrigation lines is a critical procedure and as such great care must be taken to ensure correct connection. Connector hubs are available from Cantel Medical (UK) Ltd for each of the main types of the endoscope.

These connectors ensure that each channel is separated fully and therefore irrigated completely. Liquid is pumped into the endoscope from the light source end and passes completely through the length of the endoscope in a single motion.

It is essential that all channels are securely connected to prevent a cycle failure occurring.

RAPIDAER will remind the operator as part of the sequential screen prompts to check that channel separators have been installed.

NB: Certain scopes need to be sterilised after washing in an AER (Automated Endoscope Re-processor). The RAPIDAER AER should not be used as a replacement for sterilisation.

ENDOSCOPE STORAGE AFTER DISINFECTION PROCESS

Note:

Following the automatic disinfection cycle, the endoscope should be dried prior to long term storage, and can be hung directly into a Puricore Endoscope Drying Cabinet where the drying process will be carried out automatically, using dry compressed air, prior to longer storage of the endoscope in the clean environment of the cabinet. Alternatively the endoscope should be dried according to the endoscope manufacturer's protocol.



EU REGULATIONS:

Medical Devices Directive 93/42/EEC

Chemical Washer Disinfectors are a Class 2b medical device and the design, manufacture, installation and service are controlled under this directive. See Compliance for details of Puricore's accreditation.

Chemical Hazards - COSHH Regulations

Disinfectants are hazardous chemicals and it is necessary to perform a risk assessment covering all stages of use. The manufacturer of the disinfectant will supply Safety Hazard Data Sheets for their products.

See section on Disinfectant Types and Disinfectant Warnings.

The RAPIDAER should be tested at least every fourteen months to comply with this regulation.

BIOLOGICAL HAZARDS:

There is a risk to staff and patients from endoscopic procedures. The hospital should have its own procedures to control risk at each stage of the process.

TRAINING:

All staff using the RAPIDAER should be fully trained and certified on the use of the equipment.

Puricore Clinical Nurse Advisors will provide training sessions at each RAPIDAER installation, for the training and certification of operators and management staff.

Please contact Puricore for further details of training and availability.

VALIDATION:

The Autoscope RAPIDAER is manufactured to comply with BS EN 15883 Pt 1 & Pt 4, CFPP 01-06 and SHTM 2030. It should be fully validated according to table C1 of the BS EN 15883 Pt 1 & Pt 4 at the time of installation, followed by quarterly and annual re-validations.

COMPLIANCE:

Medical Devices Directive 93/42/EEC

Puricore International Ltd is approved to ISO 13485:2003 to design, manufacture and install chemical washer disinfectors.

Puricore International Ltd is approved to ISO 9001/EN46001 to service chemical washer disinfectors.

CE Marking

CE marking is applied to medical devices under Medical Devices Directive 93/42/EEC.



DECLARATION OF CONFORMITY



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Medical Device Directive Essential Requirements Checklist Declaration of Conformity

Description of Device
Product(s):

RapidAER

Assessment of Product based upon:

Certification of Quality System

Certificate No: LRQ 0954199/A
Issued by: LRQA

Date: 01/12/11

Essential Requirements Checklist

Prepared by: Regulatory Affairs

Date: 10/02/14

Technical File

Prepared by: Regulatory Affairs
Document number

Date: 10/02/14
2G-011

Product Classification:

Determine product classification based upon the requirements in MDD and
Medical Devices Regulations 2002:

☐ Class I ☒ Class IIb ☐ Class III

Approvals:

Based on a review of the above documents, we hereby declare that the above products comply with the following EC directives:

- Medical Devices Directive 93/42/EEC as amended by 2007/47/EC
- Electro Magnetic Compatibility Directive 2004/108/EC
- Low Voltage Directive 2006/95/EC
- Machinery Directive 2006/42/EC
- Waste Electrical and Electronic Equipment Directive 2002/95/EC
- BS EN ISO 15883-1:2009
- BS EN ISO 15883-4:2009

Approved By: Neil Blewitt
Managing Director

Signature: _____

Date: _____

8th July 2014



Recommended actions to be taken for

"PERACETIC ACID" SPILLAGE

1. Evacuate the area.
2. Seal off the area to non-essential staff.
3. Put on protective clothing outside the affected area (boots, gown, apron, nitrile gloves, respirator face mask, goggles – NOT visors,).
4. On entry into the affected area – open all available windows (ie ventilate area) BUT DO NOT leave a door open into a corridor.
5. If it is a concentrate solution, absorb the excess with an inert material such as sand.
6. Put the contaminated sand into the disposal bag and seal tightly. Place this into a second disposal bag and seal tightly again. Contact your disposal company to collect it.
7. If it is a diluted solution or a small volume of concentrate, Dilute the solution with copious amounts of water and flush to drain.
8. Wash the floor area thoroughly with water.
9. Clean off boot soles before leaving the area.
10. Change any clothing that may have come into contact with the chemicals.



CONSUMABLES:

Description	Part No	Delivery lead time
1. Air Extract Carbon Filter	IS-LA 7014	5 Days
2. Printer Rolls (Pack of 20)	IS 795732	5 Days
3. Mediclean Plus Detergent (2 x 5 litre bottles)	900540	5 Days
4. Rapicide Disinfectant Part A	900530	5 Days
Rapicide Disinfectant Part B	900531	5 Days
5. Autowipes Disinfectant Wipes (6 x 200 wipe drums)	900505	5 Days



GENERAL CARE:

RAPIDAER is manufactured in the UK from quality materials, however any machine benefits from care and attention.

The exterior of RAPIDAER is manufactured from epoxy powder coated steel and polyurethane moulded panels. The use of abrasive cleaning agents should always be avoided. It is recommended that a warm soapy solution, or mild, diluted cleaning disinfectant is used.

The process chamber is manufactured from stainless steel with a smooth mirror finish. Gouges and scratches will enable biofilm and thus promote bug growth. Care should be taken at all times not to damage the surface finish of your process chamber.

ACTIVATED CARBON AIR FILTRATION

When the chemical drawer is opened, the airflow fan will operate creating a negative pressure in the drawer which helps prevent any fumes from escaping towards the operator.

The exhaust air from the chemical drawer is filtered at the point of discharge from the bottom of the machine, through an activated carbon filter.

This filter should be tested at each service visit, and should be changed at least every 12 months, or sooner if required.

This filter is located in the base of the RAPIDAER machine, together with the air flow fan.

NB: The carbon filter must be changed every 12 months.

NB:
TO ENSURE THAT THE AIR AND CARBON FILTERS ARE FITTED CORRECTLY,
THEY SHOULD ALWAYS BE INSTALLED BY A QUALIFIED ENGINEER.



ROUTINE MAINTENANCE:

RAPIDAER should be regularly maintained. Once the new equipment has been installed, commissioned and certified by a qualified Test Person (TP), you should adhere to the recommended service intervals.

Engineer visits = 2 per year at six monthly intervals, these consist of:

1 annual ~ Regular service every 52 weeks.

1 six monthly ~ Routine engineer inspections, every 26 weeks:

In between engineer visits, it is the responsibility of the user to ensure that the RAPIDAER machine is kept in the correct working status.

Regular water samples should be tested, and the water filters changed as required. The frequency for changing the wall mounted water filters will be site dependant, and will vary according to the supply water quality.



MACHINE SELF DISINFECTION:

The reason for self disinfect is to prevent the development of biofilm and micro-organisms, whilst the machine is not processing scopes

The self disinfect cycle is a thermal process, and will happen automatically during the night at the preselected time. There is also a self disinfect button in the options menu should it be necessary to carry out a self disinfect cycle at any other time.

The self disinfect process will be disabled when the RAPIDAER machine is used for any purpose whatsoever, or is not left in the start screen at the end of the day.

If the RAPIDAER is not used following the completion of the self disinfect protocol, it will repeat the above procedure the next night at the selected time.

Note:

It is important to ensure that no endoscope has been left in the machine at the end of the day and the start screen is displayed.

NB: during installation, some customers will require that all test results are returned prior to the RAPIDAER AER machine being used with endoscopes.

This will preclude the user training from taking place until these results are collated, which could take several weeks.

During such a period as this, the RAPIDAER machine will be set up to run self disinfect schedules over night to maintain the cleanliness of the machine.



CHEMICAL STORAGE DRAWER:

The chemical drawer is located on the dirty side (Load side) of the RAPIDAER machine.

Handles are fitted to allow you to open the chamber drawer.

You should always clean up any spillages caused during the changing or loading of Chemical bottles immediately.

CHANGING CHEMICALS:

When a chemical storage bottle is empty, the RAPIDAER computer screen will show a pop up warning box to tell the operator that a chemical bottle needs to be changed.

There will also be an audible alarm sounding, and the wash cycle “if in progress” will pause.

To change the bottles: First open the storage drawer , undo the cap and remove from the bottle.

Lift out the empty bottle. Ensure the replacement bottle is the same chemical.

Scan the data on the RFID tag on the front label of the new bottle, this will insert the lot number of the chemical, the expiry date and the serial number of the bottle.

Loosen the cap on the bottle with a bottle spanner and then put the bottle in the drawer.

Remove the cap on the bottle and replace with the pick-up cap.

Do the cap up tightly and closed the chemical drawer.

If a wash cycle was in progress when the bottle was changed, the operator should press the continue button in the pop up window to continue with the wash cycle.



DOOR LOCK – MANUAL OVERRIDE:

The door is actuated and held in position by air pressure and an electrical door lock, so no access can be gained during a cycle.

In the event of a power failure, the air pressure vessel will automatically empty, the door lock will release to the open position and thus the door can be manually pushed open to access any endoscope that may be in the chamber.



WATER SAMPLE PROTOCOL

RAPIDAER IS SAMPLED DURING THE FINAL RINSE AS THE SAMPLE PORT IS IN THE FEED TO THE CHAMBER. THE SAMPLE TAKEN SHOULD BE A MINIMUM OF 250MLS

1. PREPARE NECESSARY EQUIPMENT NEEDED I.E.: STERILE GLOVES, STERILE WATER SAMPLING BOTTLE, ALCOHOL WIPES AND RELEVANT LABORATORY FORM.
2. PREPARE RAPIDAER SAMPLE PORT BY RUNNING OFF 20MLS OF DISINFECTANT DURING THE DISINFECTANT PHASE OF THE CYCLE. WEARING PPE (MASK AND GLOVES), REMOVE THE BLUE PROTECTOR FROM THE END OF THE SAMPLE PORT, OPEN THE SCREW KNOB, ALLOW THE DISINFECTANT TO RUN OUT AND THEN CLOSE THE SAMPLE KNOB. DISCARD THE DISINFECTANT DOWN THE DRAIN AND RINSE CONTAINER.
3. WIPE DOWN WORK AREA WITH ALCOHOL WIPE, AND OPEN PACKET OF STERILE GLOVES. IN ADDITION, OPEN ANOTHER ALCOHOL WIPE AND DROP ONTO GLOVES. TAKE LID OFF SAMPLE CONTAINER.
4. WASH HANDS WITH HIBISCRUB OR EQUIVALENT E.G.: BETADINE SCRUB.
5. PUT ON GLOVES USING ASEPTIC TECHNIQUE AND KEEP HANDS ABOVE WAIST LEVEL AND AWAY FROM THE BODY
6. WHEN THE FINAL RINSE IS STARTED, TAKE AN ALCOHOL WIPE AND WIPE THE SAMPLE OUTLET .
7. DURING THIS RINSE, OPEN THE SAMPLE KNOB AND ALLOW AT LEAST 50MLS TO RUN INTO A WASTE CONTAINERS, THEN TAKE THE STERILE BOTTLE AND PLACE GENTLY UNDER THE SAMPLE OUTLET AND FILL THE SAMPLE BOTTLE. CLOSE THE SAMPLE KNOB AND FIT THE BLUE PROTECTOR.
8. PLACE LID ON BOTTLE, AND DRY THE OUTSIDE.
9. FILL IN THE LABEL AND ATTACH TO THE BOTTLE.
10. FILL OUT THE APPROPRIATE FORM GIVING DETAILS OF SAMPLE SOURCE, TIME AND DATE ETC. AND SEND AS SOON AS POSSIBLE TO THE LABORATORY.
11. FILL OUT THE RAPIDAER WEEKLY VALIDATION TEST LOG, WITH THE RELEVANT DETAILS.

ASEPTIC TECHNIQUE MUST BE USED WHEN OBTAINING A WATER SAMPLE



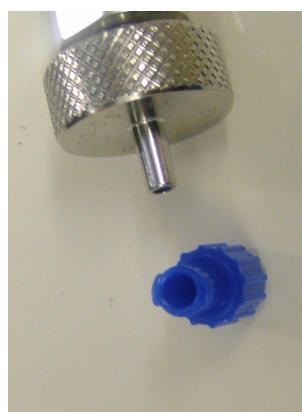
WHERE TO FIND THE WATER SAMPLING PORT.

The special water sample port is located on the left hand side just below the chamber on the loading side of the chamber.

Water Sampling Port

Water sampling in the RAPIDAER offers the user the facility to collect water from the point of application, as close to the contact with the scope as possible.

The water and Chemicals that pass through the pipework holding the sample point is the same as the irrigation feed to the scope channels.



The sample port has a blue cover which should always be replaced to help keep the fitting clean. You can fill this with alcohol when replacing it, after taking a water sample.



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