

RotaScope[™]

Vertical Hanging Scope Drying Cabinet



FEATURES:

- Endoscope capacity = 9 (suits most flexible scopes)
- X-ray or standard pass through options
- HEPA Filtered Air Drying Independent air supply via Shared Air Box (for up to 2 cabinets); or
- Remote Air Generator for multiple cabinets
- Vacuum channel drying reduces hook-up cross contamination
- Small footprint: 600mm(w) x 600mm(d) x 2335mm(h)
- Hygienic acrylic cabinet construction
- Interlocking RFID door locks
- Airflow, temperature, pressure and humidity monitoring and reporting as per EN I 6442 Standards
- RFID Scope Data Monitoring and Display:
 - o Countdown timers for each scope.
 - Electronic data backup and integration to other software packages via CSV or MySQL.
 - Live view of cabinets via software
- Data management system allows printing of labels to report scope status, cabinet cleaning status, error status
- Discrete lighting indicates cabinet hygiene status and prompts when cleaning or service is required
- Scope validation label with 'Expiry Date and Time' information for Washer to Patient validation
- Stainless steel hooks and vacuum hose kits supplied (nine sets including scope connectors)
- 12 168 hours storage time configurable



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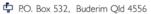
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NOTICE AND DECLARATION

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Distributor Details:

Product designed and manufactured by Smartline Machinery Pty. Ltd. PO Box 532, Buderim, Qld 4556 Australia



PREFACE

Products made by Smartline Machinery Pty Ltd are designed to meet specific needs in the healthcare industry and we manufacture in Australia under ISO 9001 quality system standards. Before our products leave the factory they undergo quality assurance testing to ensure that they meet our quality standards. Should you experience problems with this product, please contact us for support or repairs.

This User Manual covers the installation, general use and maintenance of the RotaScope™ Scope Drying Cabinet designed and supplied by Smartline Machinery or approved distributors.

In countries outside Australia, our products are supported by local distributors which are always ready to help you. See Distributor details on Page 5.

If the local distributor is unable to assist you, forward your support requests to Smartline Machinery at tech@smartlinemachinery.com

This product has been designed to dry and store up to nine flexible Endoscopes. The construction and assembly is configured to do so reliably and effectively in conjunction with European and Australian Standards and Guidelines.

Number of Scopes stored per cabinet: 9 Endoscopes. Capable of storing Gastroscopes, Colonoscopes, Bronchoscopes, Duodenoscopes, EUS Scopes, Enteroscopes, ENT Scopes and more of most brands.

EN 16442 COMPLIANCE REQUIREMENTS

Continuous monitored air-drying cabinets complying with European Standard EN 16442:2015 – for drying Thermoliable Endoscopes. Globally this standard currently represents the highest documented level indicating best practice of Scope storage at time of publication of this document.

EN16442 requires the cabinet to monitor, report and print various parameters including airflow status indication, cabinet pressure, temperature, humidity, door open parameters and power outages.

All events are logged in the Data Management System for log retrieval and reporting

Maintenance: It is an operational requirement to have an up-to-date Maintenance Contract in place.

Validation: To maintain the accuracy of the environment monitoring equipment, the system needs to be recalibrated and checked annually by an approved service agent. A Certificate of Compliance will be issued upon each annual recalibration. A Validation Contract is separate to a Maintenance Contract, and is also an operational requirement.

RotaScope[™] Cabinets meet current 2017 GENCA Guidelines and Position Statement March 2017 and are Compliant with EN16442.

Australia: According to the GENCA Position Statement, March 2017, all cabinets must comply with EN16442 by December 2020.

This product is TGA listed – Article ARTG 140018. According to GESA/GENCA/ACIPC August 2017, "Statement 7a, "All endoscopic instruments, except those in sterile packaging, should be stored in TGA-approved forced air drying cabinets". And Statement 7b, "Endoscopes stored in TGA-approved forced-air drying cabinets may be used for a period of up to 7 days without reprocessing, unless otherwise stated by the manufacturer.



RotaScope[™]

CABINET OVERVIEW

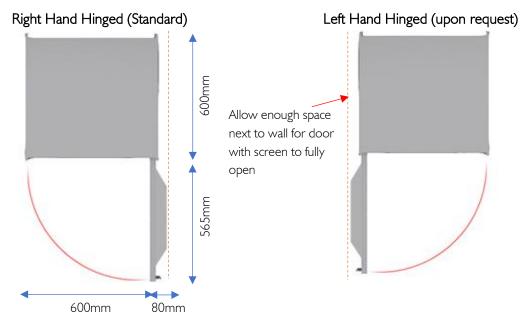


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Door Opening Directions and Door Style Selection

RotaScope $^{\text{TM}}$ Cabinets come standard with doors hinged on the right. If there is a requirement that doors be hinged on the left, this needs to be shown in the room layout drawings and be noted on all documentation. It is very important that this information is detailed in the quoting stage, as although it is possible for the doors to be changed onsite, the client will incur additional charges if changes were not requested in the original specification.



Right Hand Hinged (Standard)

Left Hand Hinged (upon request)

INTERLOCKING

If the selected RotaScope $^{\text{\tiny M}}$ Cabinet is of the pass-through variety, the standard door locking mechanism will prevent both doors from being open at the same time. This interlocking function will therefore prevent air from passing between the cleaning and procedure rooms.

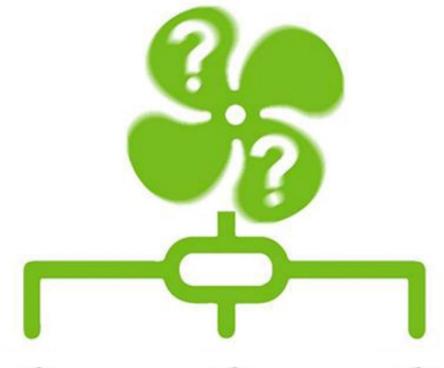
STORING VERTICALLY

By hanging scopes vertically, the detrimental memory effect produced by coiling scopes is reduced significantly.



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AIR OPTIONS







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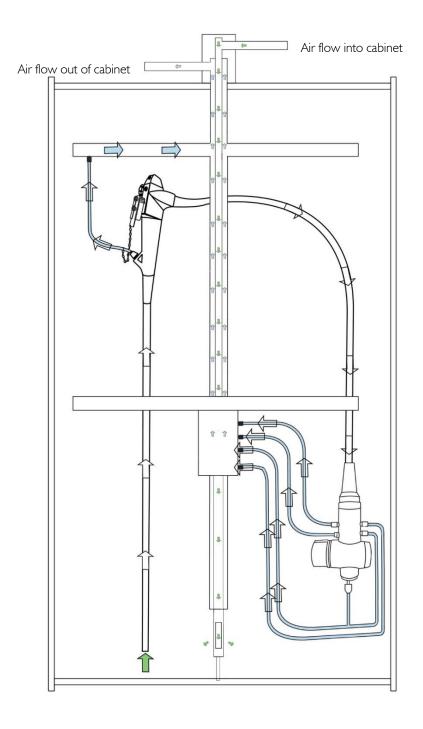
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BENEFITS OF SHARED AIR SYSTEM

The cabinet will provide an environment fit for drying qualified scopes stored inside.

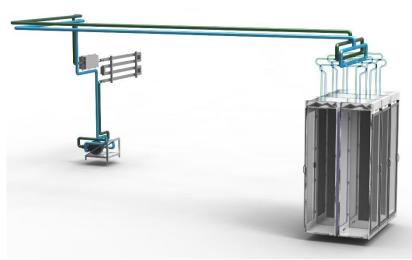
Air Flow Schematic





There are two options for the air generation for the RotaScope[™] Cabinet. Both options are an inexpensive air supply and do NOT connect to the hospital, medical grade, air supply. Low servicing costs of filters (annually) and pumps (bi-annually) creates a cost-effective solution to airflow.

1. Remote Air System (Multiple Cabinets Use – Each site needs independent evaluation)

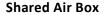


The Remote Air System can service 1 -7 cabinets and will require air ducting from the pump system (Remote Air Generator) to the cabinets. The largest pump will require a 3-Phase power source.

2. Shared Air Box

The Shared Air Box can be positioned on top of a RotaScope $^{\text{TM}}$ Cabinet if the ceiling height is 2700mm. If the ceiling is lower than this, it will have to be wall mounted using the SAB Wall Mounting Kit (09.SC-SB -WMK).

If a wall mount kit is used, there is a possibility that a 5-10 metre hose extension kit will be required to connect the SAB to the RotaScope $^{\text{TM}}$ Cabinet. Similarly, a hose extension kit may be required to connect air to the secondary RotaScope $^{\text{TM}}$ Cabinet if positioned up to 10m away from the primary cabinet that holds the SAB.



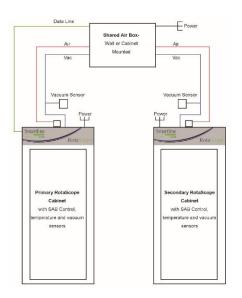


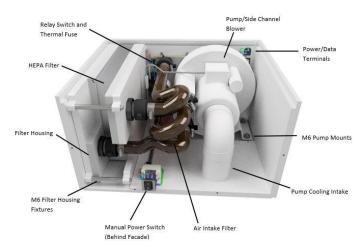


Single cabinet install schematic

Shared Air BoxWall or Cabinet Mounted Vacuum Sensor Power Power Power Power Power Power Rota wth SAB Connoi, temperature and vacuum sensors

Double cabinet install schematic





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-Note: Top and Front plate, not shown.

The Shared Air Box (09.SAB) will generate HEPA Filtered air and vacuum for up to two cabinets.

The Shared Air Box is located with the cabinets (no plumbing or construction work required)

The ongoing costs of this product is low, and it only requires basic servicing.



The following table details replacement parts:

QUANTITY OF CABINETS (One system can service two cabinets)

FILTER REPLACEMENT

PUMP REPLACEMENT

Year	I Cabinet	2 Cabinets	3 Cabinets	4 Cabinets	5 Cabinets
ı	lx	lx	2x	2x	3x Filters
2	lx	lx	2x	2x	3x
3	lx	lx	2x	2x	3x
4	lx	lx	2x	2x	3x
5	lx	lx	2x	2x	3x
		l.			
ı	N/A	N/A	N/A	N/A	N/A
2	lx	lx	2x	2x	3x Pumps
3	N/A	N/A	N/A	N/A	N/A
4	lx	lx	2x	2x	3x
5	N/A	N/A	N/A	N/A	N/A

BENEFITS OF VACUUM THROUGH CHANNELS

The RotaScope™ Cabinet uses vacuum which ensures enough airflow passes through each endoscope channel to assist with drying the internal surfaces. The clean HEPA Filtered air is passed into the cabinet and across each scope, the air is pulled through the distil tip of the scope and returns through the various hook-up manifolds.



RotaScope

CABINET SPECIFICATIONS







CABINET CONDITIONS

Cabinet Mounted Touch Screen Interface



Sensor Status Key

= Value out of range



= Scope Storage details (Expired in RED)

The RotaScope[™] Environmental Monitor measures and records the following cabinet conditions:

- Temperature
- Humidity
- Air (Cabinet Pressure)
- Vacuum
- Door Status
- Shared Air Box Temp
- Routine Cleaning Status Clean Due
- CONTROL SAB and Alarm Status
- Scope Location Button Detailed Storage Info

The air system automatically maintains a positive pressure within each cabinet. Having a positively pressured cabinet, minimises external airflow (cleaning room / theatre air) into the cabinet. All the Environmental Conditions are measured and recorded by the Data Management System as required to meet EN I 6442 Standards. If a deviant reading level is received (in the Warning or Alarm values of these conditions), the following will occur:

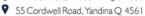
An automatically generated printout identifies actions for Cabinet Clean Completed and Alarms



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Cabinet lighting will change colour (each fault has an assigned colour, see: Warnings and Alarms section)

Cabinet Mounted Touch Screen Control Screen



Sensor Status Key

= Alarm Acknowledge Button

= SAB on/off

Cabinet Mounted Touch Scope Storage Details Screen





SPECIFICATIONS TABLE

Topic	Answer	Notes
List of endoscopes that can be stored in	See: Approved Scope List.	Endoscope accessories (e.g. valves) can be
the storage cabinet;		stored inside the storage cabinet but it is not
		the intention of the storage cabinet to
		maintain the microbiological quality of these
		accessories.
Storage temperature band	10 – 40degC	
Maximum storage time	168hrs	7 days maximum storage
Drying function	N/A	Cabinet is not equipped with a drying function
Drying temperature band	N/A	Not Applicable as cabinet does not use
		elevated temperatures to dry load.
Time required to dry the endoscopes (if applicable)	3 Hours (MAX)	Dryness may be achieved in less than 3 hours
Channel aeration	Tested at IQ, OQ and PQ Intervals (Install	Testing with use of Smartline Medical Aeration
	and Annual PQ)	Testing Device inline between scope channel
		and vacuum manifold to check air circulation
		through different channels.
		Manifold Test with Oxyview
Automated channel flushing control	N/A	Automated channel flushing NOT used
Air Flow circulation diagram	See: USER Manuals	See: Benefits of Shared Air System
-		RotaScope:Page 10
		SlidaScope: Page 10
Cabinet Flow Rate (Ports at Manifold)	>1.0 l/m	Minimum detectable flow rate is .5 l/m
Cabinet Flow Rate (Total)	200 l/m	10x Air Exchanges p/h
		Minimum detectable flow rate is 20 l/m
Total Vacuum Flow Rate Per Cabinet	170l/m	
Cabinet Pressure Band	-1- 27pa	Differential Pressure (above 27Pa is possible
		but not recorded.
Endoscopes that one or more channels	N/A	Currently there are no endoscopes that can be
is below the detection limit		stored in the cabinet that have a flow rate that
		is below the detectable flow rate of 1 l/min.
Air Quality	99.99% @0.3µm Filtration Rate (HEPA	Third party air is not used by the storage
	Filtered Supply Via SAB)	cabinet. A Shared Air Box draws required air
		from the surrounding environment of which it
		is situated and therefore standard office
		working conditions need to be provided at all
		times. Room temperature range 10 C° to 30 C°,
		relative humidity between 40% and 70%,
		environmental room pressure greater than 102 kPa.
Humidity Band	3.0 – 90.0 %RH	N. U.
Oil Content	N/A	Compressed air not used
Air Quality Testing Frequency	Annually – Service and PQ	HEPA Filter replaced Annually

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Cabinet Cleanliness Level	N/A	A specific cleanliness level is not claimed – Clinical Clean at commissioning/handover is required by HSO required
Cabinet Cleaning Limits	<168hrs	Weekly cleaning required for cabinet and accessories (Vacuum Hose Kits)
Cabinet Cleaning IFU	See: User Manual	See: Maintenance and Cleaning RotaScope: Page 47 SlidaScope: Page 48
Accessory Cleaning IFU	See: Vacuum Hose Kit IFU Document	
Microbiological Alert Levels - Airborne	See: PQ Contract <50 CFU Acceptable >50CFU = Failure >1CFU must be identified >1CFU Identified as Pathogenic = Failure	Testing carried out as part of Annual PQ in accordance with AS4187 and EN16442
Microbiological Alert Levels - Surfaces	See: PQ Contract <25 CFU Acceptable >25CFU = Failure >1CFU must be identified >1CFU Identified as Pathogenic = Failure	Testing carried out as part of Annual PQ in accordance with AS4187 and EN16442
Preventative Maintenance	See: Service Agreement and/or User Manual	See: PQ – Performance Qualification RotaScope: Page 52 SlidaScope: Page 51 Annual Preventative Maintenance of Cabinets and Shared Air Systems are Recommended – To be done by a Smartline Medical Accredited Service Technician
Selectable storage cabinet cycles	Out of Cabinet Time – 3hrs Non-alcohol Cycle – 12hrs Alcohol Cycle – 168hrs See: Staff Training Manual	See: Wash Validation of Scopes
Transferring Endoscopes	See: User Manual	See: Storing/Hanging A Scope RotaScope: Page 22 SlidaScope: Page 22
IFU for Power Outage	See: User Manual	After a power outage a cabinet will illuminate purple and a label will be printed with associated information. See: Cabinet Reporting Conditions & Power Outages RotaScope: Page 46 & 54 SlidaScope: Page 45 & 53
Model Numbers and Serial Numbers	See: Cabinet	See: Compliance Page 53
Environmental Conditions		Standard office working conditions need to be provided at all times. Room temperature range 10 C° to 30 C°, relative humidity between 40% and 70%,





Correcting, resetting and acting on	See: User Manual	See: Cabinet Conditions
faults		RotaScope: Page 16
		SlidaScope: Page 16
Over and under pressure stabilisation	Instant	Cabinet Air pressure requires no time for
band		stabilisation
SAB Over Temp,	Instant	Alarm:
.,		Subtracts time from OoCCauses SAB to Shutdown
		Self-rectifying – attempts to run again after 2 minutes.
		Note: Alarm Acknowledge required at Cabinet interface for normal operating function (Yellow Cabinet Lighting) however, OoC will only count down whilst the pump is not running.
Cabinet Temperature, Humidity, Air Pressure, Vacuum and Door Alarms	3 Minutes	Warning Mode: Yellow warning light for first three minutes Alarm:
		Subtracts time from OoC
		Self-rectifying Alarm, once cabinet reads in normal status, the cabinet will return to green and OoC will cease counting down.
Clean Alarm	24hr Warning (Blue Light)	Alarm:
		Subtracts time from OoC Requires Cabinet Clean Function to rectify alarm
Storage Expiry	Instant	Visible:
- , ,		00:00 On Door Screen
		"Re-Process Scope" on Label
OoC Expiry	Instant	Visible:
		00:00 On Door Screen
		"Re-Process Scope" on Label
Endoscope Channel Condition Prior to	See: Automated Endoscope Reprocessor	The verification that all channels allow the
Storage	(AER) IFU or Manual Cleaning Regime	passage of air before the device is loaded into
		the storage cabinet is required when a scope
		has been cleaned and disinfected using a
		manual cleaning procedure. For each cabinet,
		one endoscope is to undergo an aeration test
		(bubble test) as per manufactures instructions
		during annual Performance Qualification. In
		the case where the endoscope is cleaned and
		disinfected using a validated processing
		procedure (washers compliant with EN ISO
		15883-4:2009) this verification is included
		through channel monitoring however,
		extensive air flushing of all channels is
		recommended before placing the endoscope in





		the cabinet to purge any water left inside endoscope channels from the washers. The absence of purge of internal channels of endoscopes at the end of a washing/disinfection procedure could impact the storage cabinet efficiency. It is reminded to
		users that it is important to conform to manufacturer's recommendations and instructions.
		NOTE: In accordance with EN16442
Cabinet Dimensions (Height x Width x Depth)	2335 x 600 x 600mm	
Cabinet Weight Metric	104 kg	
Scope Holding Capacity	9	
Min ceiling height requirement metric	2400mm	
Height (bottom edge) GPO & Data points	2245mm	
Power USA	110V – Cabinet	Cabinet Only 2 A @240v
Power Other regions	240V 50-60Hz	Data 12V
Shipping Crate (Height x Width x Depth)	2420 x 770 x 900mm (195kg)	Certified Treated Timber
SHARED AIR BOX		
Shared Air Box Dimensions (Height x Width x Depth)	334 x 600 x 500mm	
Power USA	110V/60Hz 20A Cabinet	Actual 3.1A@240V
Power Other regions	240V/50Hz 10A	Data: 12V
SAB Product Weight Metric	51 kg	
Room Operating Temperatures Range	>10 to 40°C	
Max Room Humidity - air intake	<70% RH	
Environment	Indoor use only	
Airflow capacity	350 I/m Max pump capacity	-200l/m 1x cabinet 120 l/m 2x cabinets
Thermal protection: Fuse and Measured	80 °C: Thermal Fuse in SAB Housing	76 °C: Electronic Regulated
Shipping Crate (Height x Width x Depth)	750 x 750 x 570mm (95kg)	Certified Treated Timber
Cabinet Materials per	Glass, Anodised Aluminium, Acrylic,	Conforms to AS4187 and EN16442 and is
AS4187 and EN16442	Stainless Steel, Silicone, and PVC labelling	tested SEE: EN16442 test results - Biotech-Germande (France) 2017/2018

Electronic and Compliance Testing

EMC 60601-1 and 60601-2 Complete and independently accredited 2018

EN16442:2015 Complete and accredited to 31 days Storage via international test house Biotech-Germande (France) 2018

Quality Assurance and Manufacture Approvals





ISO-9001 Quality Assurance – 2018 Audited and current

TGA-approval article number

ARTG 140018 - Current 2018



RotaScope™ with Shared Air Box fitted on top

Dimensions: 600mm W x 600mm D x 2335mm mm H Cabinet (2665mm H with Shared Air Box Fitted)

NOTE: Bulkhead also $600 \times 500 \times 330$ mm



RotaScope™

OPERATION INSTRUCTIONS



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BEFORE STORAGE

NOTE: If you do not air purge the internal channels of the endoscopes after the washing/disinfection procedure, retained moisture could impact on the storage cabinet efficiency. Users are reminded that it is important to conform to manufacturer's recommendations and instructions.

The verification that all channels allow the passage of air before the device is loaded into the storage cabinet is required.

In the case where the endoscope is cleaned and disinfected using a validated processing procedure (washers compliant with EN ISO 15883-4:2009) this verification is included through channel monitoring, however, extensive air flushing of all channels is recommended before placing the endoscope in the cabinet to purge any water left inside endoscope channels from the washers. Scopes should have channels blown dry with medical air from handpiece ports including biopsy channel and thumb ports for *suction* and *air/water*.

Endoscopes should be transferred into storage/ drying cabinet as soon as possible after endoscope has completed all of it set cleaning phases. Take care to not touch any part of the endoscope on surfaces that may cause a cross contamination onto the endoscope.

HANGING A SCOPE

- 1. WHO Operator Tag presented to Cabinet Door Mounted Wand
- 2. Open the RotaScope™ Cabinet door
- 3. WHAT Use Cabinet Door Mounted Wand to swipe Scope Tag
- 4. WHERE Use Cabinet Door Mounted Wand to swipe desired Storage Location (Position Number)
- 5. System will announce Scope "Stored"
- 6. The RotaScope[™] Cabinet centre post assembly can be rotated in either direction to expose vacant hooks to the most convenient position for hanging or removing scopes.
- 7. Pick up the scope by the upper control body (preferably with your right hand) so that the control knobs are to the left of the hand piece, the video connector cable is away from you & the distal cord is towards you.
- 8. Use your other hand to control the distal cord & video connector cable.
- 9. Present the scope to the top hook & rest the upper control body into the hook.
- 10. Guide the video connector cable into the innermost channel of the centre disc then guide the distal cord into the outermost channel.
- 11. Continue with attaching the vacuum hoses
- 12. Hoses are connected to either the lower manifold or top connecting arms with push in & turn clockwise "Luer Lock" fittings.
- 13. As soon as the Scope(s) have been correctly hung (and connected if applicable) close the door & keep the door closed at all times whenever possible.
- 14. Feed the scope cables out of the guide slot with one hand and then lift the scope out of the top hook with the other hand, attach vacuum blockers to all unused luer lock fittings that are not attached via the connectors to the scope channels (Both top and bottom manifold).
- 15. Removal of a Scope is the reverse of the procedure to hang them Steps 1-4
- 16. System will announce Scope "Removed"

Some staff may experience difficulty with reaching scopes when putting them into or out of the cabinet as the top hook assembly may be positioned quite high for longer Scopes, it is advisable that an appropriate step stool be available. After the door has been opened, a step stool, may be used to assist with access. It is important to limit the amount of time that the door is opened wherever possible.











ADJUSTING TOP AND CENTRE DISC HEIGHTS

If the standard working height of the top or centre disc does not suit, the following steps will detail how to adjust this:

- 1. Remove all endoscopes from the cabinet
- 2. Use the supplied Allen key to loosen shaft collar (while supporting the weight of the disc)
- 3. Move the disc to desired position
- 4. Tighten shaft collar back up using Allen key



CONNECTING VACUUM TO A SCOPE:

There are usually four channels that need to be connected to vacuum, these are shown below:

To connect to the RotaScope $^{\text{TM}}$ cabinet the cleaning adaptors that are supplied with the scopes need to be used and differ between the endoscope brands.

NOTE: To meet EN I 6442 requirements the scope channels and external surfaces of the scope will need to be purged and blown off using medical grade air to remove excessive moisture prior to loading into the cabinet for continuous drying. Extra attention must be paid to remove all water droplets from in between control knobs on handpiece.

There are usually four channels that need to be connected to vacuum, these are shown below:

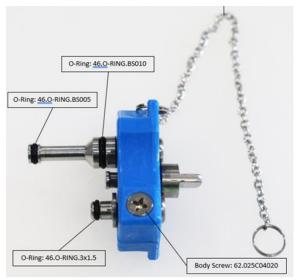
To connect to the RotaScope $^{\mathsf{TM}}$ Cabinet the cleaning adaptors that are supplied with the scopes need to be used and differ between the endoscope brands.

Auxilliary Connector Hose Suction Connection Hose Leave This End Open 47.VHW-1-AC-4 - Auxilliary Connector Hose 47.VHC-1-6 - Connection Hose 9 per Kit 9 per Kit **Biopsy Valve Hose Air Water Connection Hose** 47.VHB-1-BV14-4 - Biopsy Valve Hose 9 per Kit 47.VHM-AW - Air/Water Channel Connection Hose **Bronchoscope Biopsy Valve Hose Bronchoscope Port Hose** 47.VHB-1-BV17-4 - Bronch Biopsy Valve Hose 47.VHC-1-BPP-6 - Bronchial Port Hose



All other ports must be blocked to ensure a continuous airflow through the channels using channel separators as shown below:

Channel Separator 47.VHB-CS





*IMPORTANT: O-rings must be regularly inspected for wear.



Minimum and maximum temperatures for sterilization of channel separator O-Rings is -40 to 125 C. Washing the O-Rings for prolonged periods over 115 C may cause them to swell, leading to damage to the surface that makes connection and disconnection to endoscopes unworkable. It is recommended O-Rings are replaced at the annual service or prior where visual damage to O-Rings occurs.

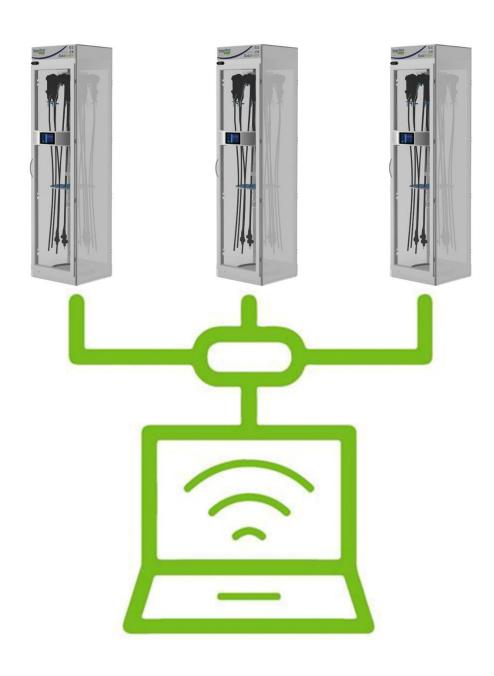


Endoscope ports should also be monitored for signs of damage such as sharp edges that could scour the O-Ring surface leading to deterioration and difficulty fitting and removing the channel separators.



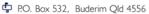
RotaScope

DATA SYSTEM



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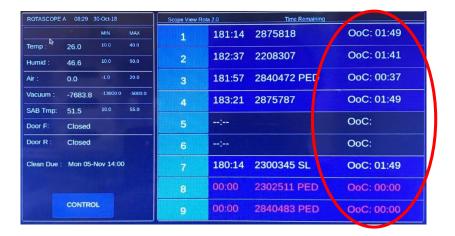
DATA SYSTEM OVERVIEW

The RotaScope Data System functions on Linux and RFID Tags, the concept functions on the concept of **WHO, WHAT** and **WHERE**, with **WHEN** being automatically captured by the Data System.

- 1. WHO = Operator Tag
- 2. WHAT = Scope Tag
- 3. WHERE = Device Tag
- Washer Information
 - WHO Operator that washed the scope in the AER
 - o WHAT Which Scope
 - WHERE Where it was washed (Washer/AER Chamber)
 - Into the AER
 - Out of the AER
- Storage Information
 - o WHO Operator that stored the scope in the Cabinet
 - WHAT Which Scope
 - WHERE Where is was stored (Cabinet and Location)
 - Into the Cabinet
 - Out of the Cabinet

COUNT DOWN TIMERS

A reduction in reprocessing costs can be obtained through improved efficiencies via the Data Starter Kit to each RotaScope $^{\text{TM}}$ cabinet site. Utilising the oldest stored scope first, will reduce department reprocessing costs.





SCOPE AND STAFF TAGS

SCOPE TAG - FITS ONTO UMBILICAL CORD







SCOPE MANAGER

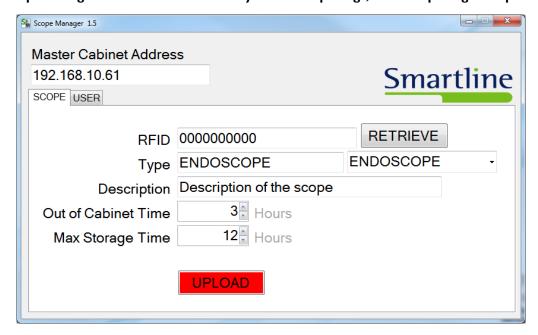
The Scope Manager Software is used to link RFID Tag Information to the Data System. This unit runs off USB and with a PC and software (Scope Manager $^{\text{IM}}$). The Scope Manager is used to link storage time and scope names to Scope Tags, it is also used to link operator names to Operator Tags.







BELOW: Scope Manager Software - Used to easily create Scope Tags, Loan Scope Tags or Operator Tags



WASHER STATION

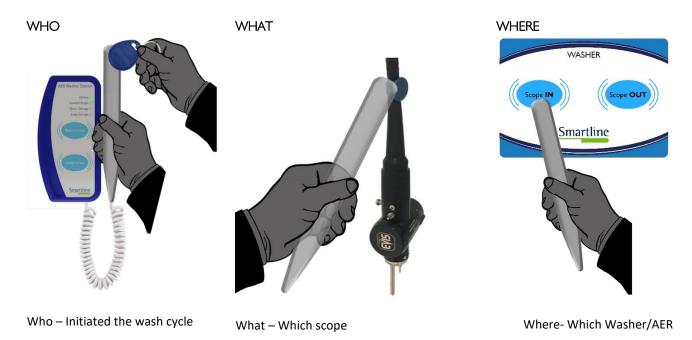


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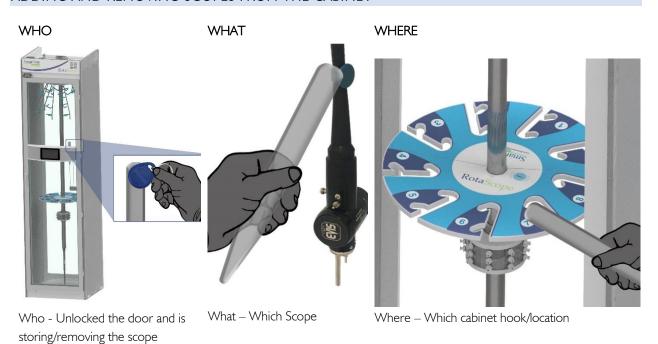
Fig 2 – Washer Area



SEQUENCE FOR WASHING SCOPE: WHO, WHAT, WHERE



ADDING AND REMOVING SCOPES FROM THE CABINET



PRINTER STATION





Present Scope Tag to Printer





SCOPE STORAGE RECORD

SCOPE TYPE: ENDOSCOPE SCOPE NAME: scope 4 LOADED TO: ROTASCOPE 1:1 LOADED TIME: 11:46:58 Jan-06 20 LOADED BY: Door TAG REMOVAL TIME 11:47:09 Jan-06 20

REMOVED BY: Richard2 STORED FOR: 0.0 HOURS

OOC EXPIRES: 14:46:52 Jan-06 20

REPLACING LABELS

2.3 LOADING LABELS OR TAGS

2.3.1 Loading Roll media

1. With the power supply off, pull the cover open/close latches (1) on both sides of the printer toward you to unlock the top cover, and then open the top cover (2).

Note: Make sure that the cover rests firmly so that it will not fall forward and injure your hands.

2. While holding the media guide slide lever, adjust the width of the media holder 1 to match the media size.





3. Load the media onto the media holder.



 After pulling out the media, pass the media through the media guides and place the leading edge of the media on top of the platen roller. Note:

Make sure the printed side of the media is facing



Printed side should face upwards



LAPTOP KIT



Laptop Kit Inclusions:

Computer and

Processor

1.1 gigahertz (GHz), 64-bit dual-core processor

Operating System Windows 10

Display 1366 x 768p

Memory (RAM) 4 gigabyte (GB) RAM (64-bit)

Auxiliary parts Tag reader, Loan Scope tags, Wireless mini USB adaptor

PC OPERATING SYSTEMS

The Scope Manager Software is to be installed on a Laptop or PC (with Wi-Fi). This is an integral part of the system and using a Smartline Medical "Laptop Kit" is preferred.



SOFTWARE - INSTALLED ONTO LAPTOP

Scope Manager



- Installed onto Laptop
- For setting up RFID tags
- Complete executable installer file

Tag Reader



- Supplied with Laptop Kit
- For reading tags and using with Scope Manager to set up tags

Team Viewer



• Enables remote access to the site Laptop

VNC Viewer



- Access to cabinet screen/control
- Via the shortcut on the laptop



The laptop's desktop background



POSITIONS OF COMPONENTS AND CABLE DISTANCES

Details of the required cable lengths can be identified if the quantities and locations of the components are shown on a set of room layout drawings. By measuring and determining the path the cables run between components, the job can be quoted and ordered easily, and will result in a seamless and easy installation.

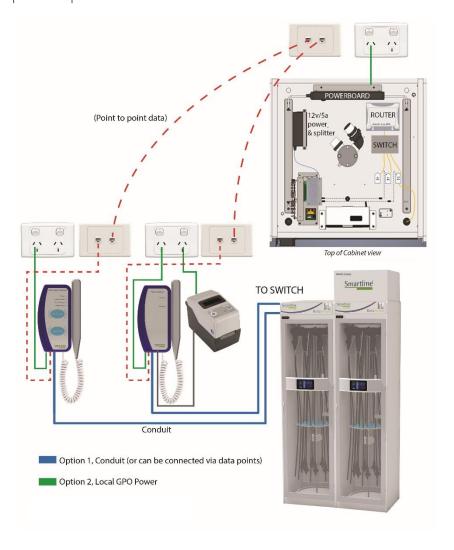
CLOSED NETWORK - TCP/IP

The Data System runs on an independent LAN (Local Area Network), separate from the hospitals own data network. This closed system reduces the additional traffic on the Hospital's IT system and allows the department to completely control the inclusions, as well as arrange and rearrange the components used.

When data needs to be run between rooms, a cable needs to be installed (Cat6 / Ethernet cables and wall sockets).

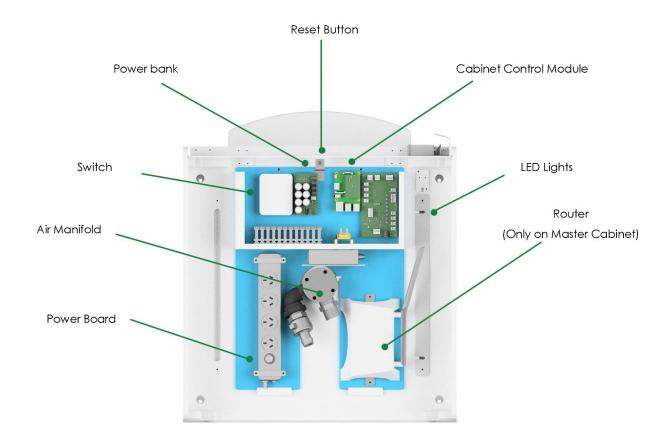
Details of integrating the system onto the hospital network need to be discussed on a case-by-case basis.

A simplified data and power setup can be seen below:





CABINET RESET BUTTON





PRINTING LABELS

To improve endoscope tracking and traceability, a sticker label printer can instantly display the last use time and processing details. The images below show the three labels that can be generated:

After Storage (2x Labels)	To print this record: Remove scope from cabinet using Who, What, Where sequence, and present Scope Tag to Printer Station Wand	SCOPE WASH RECORD SCOPE TYPE: ENDOSCOPE SCOPE NAME: scope 4 WASHER: AER 1 LOADED BY: Richard2 REMOVAL TIME: 11:46:52 Jan-06 20 REMOVED BY: Richard2 MAX STORAGE: 168 HOURS OOC EXPIRES: 14:46:52 Jan-06 20 (Along with:) SCOPE STORAGE RECORD SCOPE TYPE: ENDOSCOPE SCOPE NAME: scope 4 LOADED TIME: 11:46:58 Jan-06 20 LOADED BY: Door TAG REMOVAL TIME 11:47:09 Jan-06 20 REMOVAL TIME 11:47:09 Jan-06 20 REMOVED BY: Richard2 STORED FOR: 0.0 HOURS OOC EXPIRES: 14:46:52 Jan-06 20
After Clean	To print this record: Once scope is removed from AER, this label prints	CABINET CLEAN RECORD Cabinet: ROTASCOPE 1 Date: 08:07:52 Jan-06 20 User: RICHARD www.smartlinemachinery.com
Incorrect Scope Removal	To print this record: If a scope is removed from cabinet without the correct process being followed, the Incorrect Scope Removal label will print for your records.	INCORRECT SCOPE REMOVAL SCOPE TYPE: ENDOSCOPE SCOPE NAME: Scope 4 AER / WASHER: AER 1 WASHED AT: 14:46:58 Dec-16 19 AER OPERATOR: RICHARD STORED IN: REMOVAL TIME: SIGN: www.smartlinemachinery.com

NOTE: These printed labels can add to the efficiencies of the department with a standard and consistent point of reference for the storage and wash details. If Scope status is unconfirmed, a printout can be done to validate the Scope quickly.



RotaScope

installation requirements



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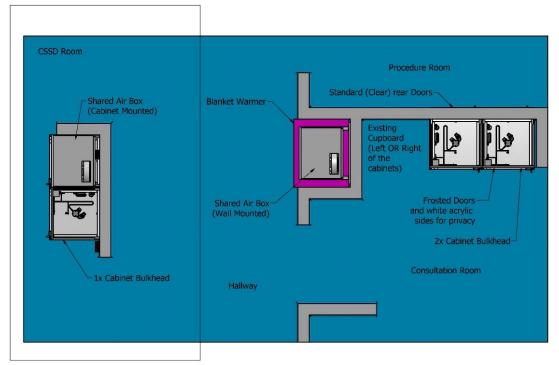
INFORMATION TO GATHER

Prior to your order being processed there is a range of things to consider and clarify with the customer. **Refer to form F227** for required information.

ROOM LAYOUTS, CEILING HEIGHTS AND WALL CONSTRUCTION

The cabinets and components can be drawn in by obtaining the room layout drawings from the engineering department or creating your own. This drawing will become the most important reference for the job process.

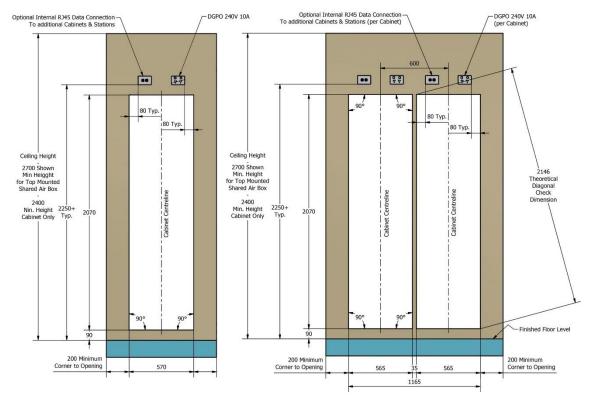
Plan View Example



All doors Hinged on the Right (unless otherwise specified)



Front View Opening and Power & Data Points Example



NOTES;

NOTES;
Cabinet has 575mm (F to R) x 600mm (L to R) Footprint.
Floor to Wall Coving behind Cabinet no greater than R15.
No Cornice above Cabinet if ceiling height is below 2750mm.
Wall Opening Tolerances as shown.
Minimum Wall Thickness = 95mm
Maximum Wall Thickness = 135mm (Standard Frames)
Cabinet Frames to sult thicker wall available upon application.
Sults Wall Mounted Rear Door Pass Through Variants



BULKHEAD

If the ceiling height is 2700mm and there is no SAB mounted on top of the cabinet, a bulkhead should be added to the job. The hospital/builder can arrange to have a bulkhead built onsite to suit but if so, they must have a gas strut hatch at the front for access and servicing.

Cabinet with an Acrylic Bulkhead





ACCESS AND ROUTE FOR INSTALL

Prior to each installation, it is very important to confirm access to the location of the cabinets. Mapping the complete route to be sure that a cabinet can be moved through the department / hospital without obstacles / impediments is necessary, to ensure the installation can be completed within the allocated timeframe.

LIFTS / STAIRWELLS

As the RotaScope $^{\text{TM}}$ Cabinet is of significant size, access on site can be of concern on occasion. Lifts being used for access must be at least 2500mm in any one direction, and if not, it will have to be confirmed that the stairwell is an acceptable alternative route.

INSTALL DATES, WORK HOURS

On occasion, capital equipment installation and work with pass-through RotaScope $^{\text{TM}}$ Cabinets must be completed during particular hours e.g. between lists or when department is not in use. Early establishment of the customer needs in this regard will assist Smartline Machinery with planning and logistics and should be discussed at the point of sale.

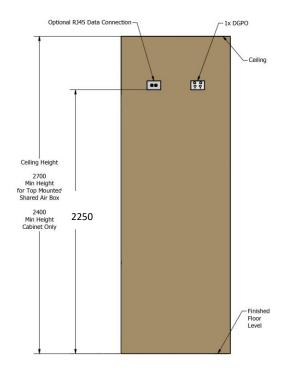
**All the above points are outlined, and data is collected within the F227 form.

POWER NEEDS

One double GPO must be installed per cabinet in the position shown below:

NOTE: For details on pass-through wall opening where more than one cabinet is to be installed, refer to wall opening drawings.

Power and Data Point Positions



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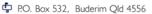
RotaScope

STAFF TRAINING AND EDUCATION



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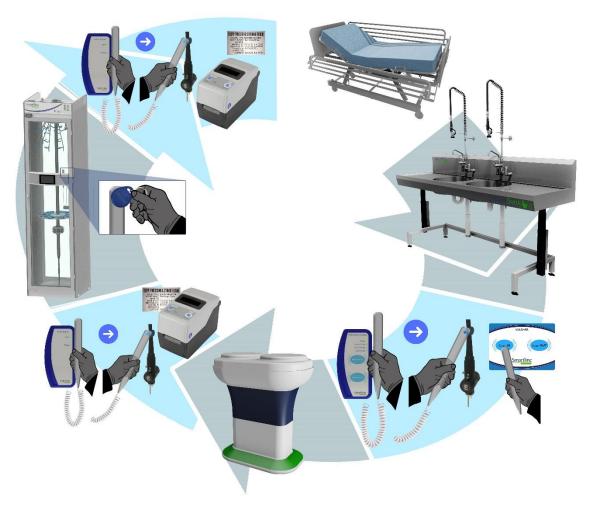






STANDARD WORKFLOW

The following flow chart includes the RotaScope $^{\text{m}}$ wash-use workflow. This diagram may cover some steps that are not required for every installation.



The typical endoscope workflow is as follows:

- 1. End of procedure (bedside wipe down)
- 2. Manual wash and leak test
- 3. Scan Scope into AER washer
- 4. AER wash (automated endoscope re-processor)
- 5. Scan scope out of AER washer
- 6. Print receipt (scope processing record)
- 7. Storage in RotaScope™ Cabinet (in & out)
- 8. Print receipt (scope processing and storage record)
- 9. Start of procedure (bedside)

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CABINET REPORTING CONDITIONS

The RotaScope ™ Environmental Monitor measures and records the following cabinet conditions:

- Temperature
- Vacuum
- Humidity
- Pressure
- Routine Cleaning Status
- Power outages

The system automatically maintains a positive pressure within each cabinet. By having a positively pressured cabinet, external air (cleaning room / theatre) will not flow into the cabinet.

All the Environmental Conditions are measured and recorded by the Data Management System as required to meet the EN I 6442 standards. Upon a reading level in the Warning or Alarm values of these conditions the following will occur:

- An automatically generated printout identifies the issue (where applicable)
- Screen display will turn red to highlight issue
- Cabinet lighting will change colour (each fault has an assigned colour)



Red = Alarm



Yellow = Warning



White = Door Open



Magenta = Power Outage



Green = Neutral / Normal Operation

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Blue = Clean Due



IN-SERVICE TRAINING FOR SITE

At the commencement of an installation, the department manager and key staff will require 'In-service' training.

The time and date of this training needs to be discussed prior to installation, however, cannot be done before the site is functioning- i.e. power, data and endoscopes available.

If the cabinets are being installed on a construction site and/or for contractors, in-service training may need to be carried out in two stages:

Stage I – Before handover and to the nominated parties of the contractors

Stage 2 – After site handover and to the operators / department staff

If this is the case, Hospital / Department may be required to be quoted separately. This is due to the fact that all purchases of the contractors will need to be signed off prior to handover and usually happens before completion of the build.

ADDITIONAL TRAINING AND SETUP

A representative will guide the implementation of the Data System at a high level i.e. set up:

- Hose Kits How to connect a scope
- Operator Tags How to program RFID Operator Tags
- Scope Tags How to program RFID Scope Tags



RotaScope

MAINTENANCE AND CLEANING



Follow these cleaning processes to ensure a decontaminated environment before using the cabinet for storing any endoscopes.

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VACUUM HOSES – CLEANING IFU

Hose kits and ESC connectors are to be disinfected every 7 days or upon disconnection from a valid stored endoscope if time since last disinfection exceeds 7 days. Hoses and ESC connectors should be inspected for any damage or degradation of the items that would diminish the items ability to perform at its full capacity.

Before attaching the airline to the scopes or the cabinet we recommend sterilizing the hoses and lines in an autoclave washer.

CLEANING

In accordance with EN16442 cabinet cleaning cycle is seven days, the cabinet will illuminate in blue when the clean is 24 hours from due.

Cabinet interior & exterior surfaces to be cleaned using soft, clean cloths & non-abrasive cleaning/disinfecting products that do not contain ammonia or alcohol. Any abrasive cleaning product or cloth/scourers will permanently mark the surface & potentially allow bacteria to grow within the fine surface scratches.

Do not allow electrical or electronic components, where fitted, to become wet or splashed with water or other fluids. Any fluids issuing from recently attached scopes should immediately be wiped up.

INTERNAL SURFACES

Cleaning of the RotaScope™ cabinet should be carried out regularly in accordance with hospital procedures.

Clean from top to bottom, and hardest to reach section to easiest to reach section of the cabinet. The recommended cleaning technique is to wipe all interior surfaces with a non-alcoholic disinfectant wipe. (Please avoid cleaners containing ammonia or alcohol, as it will cause damage to the cabinet surfaces).

The Top Hanger Assembly is made from stainless steel & any contact points have silicone tubing sleeves to eliminate rub marks or scratches on the scopes. These may be cleaned with the same materials as the cabinet.

Any fluids inadvertently spilled or dripped onto the cabinet floor are to be wiped up immediately.

EXTERIOR SURFACES

Depending on the type of external environment in which the cabinet is located, you could follow the directions for cleaning interior surfaces or simply wipe all surfaces down with a mild detergent and soft cloth. Please avoid cleaners containing ammonia or alcohol, as it will cause damage to the cabinet surfaces.



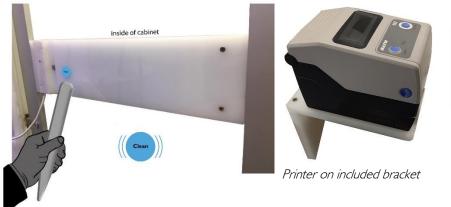
CLEANING DATA VALIDATION

The Clean Due time is a **reminder** of the scheduled cleaning day. The internal cabinet light will turn Blue at 7am of the day of cleaning (as a reminder). The cabinet should be cleaned within 24 hours of the Blue light reminder. *It is also acceptable to clean *before* the scheduled day.



Once cabinet is cleaned, operator should validate the clean by scanning USER tag, then CLEAN spot inside the cabinet. Cabinet will announce "Cleaned". A Cabinet Cleaning Record will automatically be printed and the cabinet light will return to neutral. If this clean process is not performed within 24 hours of the Clean reminder, the cabinet will turn RED and assumed 'contaminated'.

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SAFETY

SAFE OPERATING PROCEDURE

- RotaScope™ Cabinets MUST BE positioned on a stable, level floor.
- Cabinet power cable must be securely plugged into a standard GPO & switched 'On'. Note that not all variants require power for each unit.
- Inspect door components of the equipment prior to use as well as daily inspection to also be performed on rear door where fitted.
 - o Inspect the door components i.e.: handle, hinges, and locking mechanism (where fitted) for functionality, "wear and tear" or damage.
 - o Is the door easy to open and shut?
 - o Are there any obstructions in front of, or near the door to prevent it from opening?
 - o Do the cabinet interior lamps illuminate when the door is opened & extinguish when the door is closed?
- Inspect the centre post assembly prior to use and on a daily basis.
 - o Are the scope hanger hooks positioned correctly & firmly retained in their holder?
 - o Does each scope hook have silicone sleeves on the scope contact points?
 - o Are the silicone sleeves in good condition & order?
 - o Does the centre post assembly rotate freely? (Note that some variants allow the centre post assembly to rotate only though one revolution in either direction).
 - o Inspect that each occupied scope hook has no more than one scope attached.
- Inspect the silicone connection hoses & luer fittings for "wear & tear" or damage
- Are the silicone connection hoses connected to the centre post luer fittings?
- Are the silicone connection hoses connected to the cleaning adaptors or scopes as per instruction diagrams?
- Are the instruction diagrams located within convenient view?
- Is the power cable securely plugged in & power turned 'On'?
- Inspect all data system components power cables are securely plugged in & power switched 'On'.
- Inspect all data system components, accessories & connection cables for functionality, 'wear & tear' or damage.
- Inspect the centre disc displays for normal function.
- If any inspection fails, please advise your supervisor as soon as possible.

PRE-START CHECKS

• Ensure that the cabinet is connected to a certified GPO.

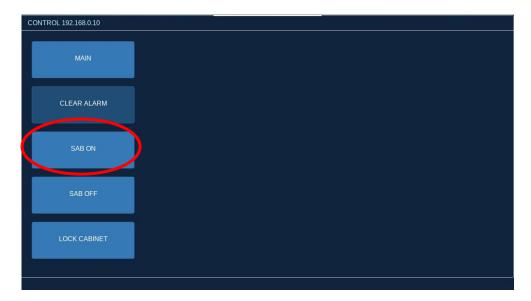
If Shared Air Box (SAB) is mounted on or near the cabinet in question, please check the following:

- Ensure that the SAB external wiring loom is plugged into the cabinet controller and the SAB.
- Ensure that the air and vacuum hoses are connected.
- Refer to installation drawings to ensure correct installation of the SAB.

TURNING ON THE CABINET

- ullet The SAB is controlled by the cabinet-mounted touch screen on the front of the RotaScope $^{\text{\tiny M}}$ cabinet.
- Press the SAB ON / SAB OFF on the Control Screen to start the SAB.
- Once the SAB is running the display will update with cabinet temperature, humidity, air, vacuum





MAINTENANCE CONTRACTS

To ensure you get the best performance out of your RotaScope™ Cabinets, it is an operational requirement to have a Maintenance Contract in place. These contracts are to be set up through the Maintenance Department. A Maintenance Contract is an annual service agreement covering replacement equipment e.g. filters and parts for the Shared Air Box and basic ongoing cabinet maintenance.

PQ - PERFORMANCE QUALIFICATION

AS/NZS4187:2014 Section 7.4 States: **Performance qualification shall be performed by the HSO.** PQ may be performed by suitable trained in-house personnel or a suitable experienced and qualified external contractor. PQ shall be undertaken in accordance with the applicable national or international standards.

PQ shall be performed-

- (a) Immediately after IQ and OQ for newly installed or relocated equipment;
- (b) When repairs are made, or a service is changed that might adversely impact the quality of the RMD (see Clause 10.5);
- (c) When existing equipment is modified to deliver a new process;
- (d) Using RMDs that are representative of the range of RMDs identified as the most difficult to process that are in use in the HSO. Refer to clause 5.2; and
- (e) When introducing new or modified RMD, packaging or loading configurations unless equivalence to a previously qualified reference load, RMD/product family, packaging or loading pattern has been demonstrated.

Requalification of the process shall be performed annually. Refer Clause 10.4.

Smartline does offer a performance Qualification Service for the RotaScope Cabinets in line with the requirements of AS/NZS4187:2014 and BS EN 16442:2015. Please email sales@smartlinemachinery.com or ring 07 5478 9977 for a PQ quote.



COMPLIANCE

A sample compliance sticker has been shown below. Please refer to your individual product for the compliance label that relates to your region.





RotaScope...

TROUBLESHOOTING





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PHYSICAL TESTS AND CHECKS

AIR FLOW CHECK

User to connect Oxyview In-line between scope channel and vacuum manifold to check air circulation through different channels.

Using Oxyview flow meter the minimum flow rate detectable is 1 l/min.

ENDOSCOPE CONDITION

The verification that all channels allow the passage of air before the device is loaded into the storage cabinet is required when a scope has been cleaned and disinfected using a manual cleaning procedure. The internal channels of the endoscope are to undergo an aeration test (bubble test) as per manufactures instructions.

In the case where the endoscope is cleaned and disinfected using a validated processing procedure (washers compliant with EN ISO 15883-4:2009) this verification is included through channel monitoring however, extensive air flushing of all channels is recommended before placing the endoscope in the cabinet to purge any water left inside endoscope channels from the washers.

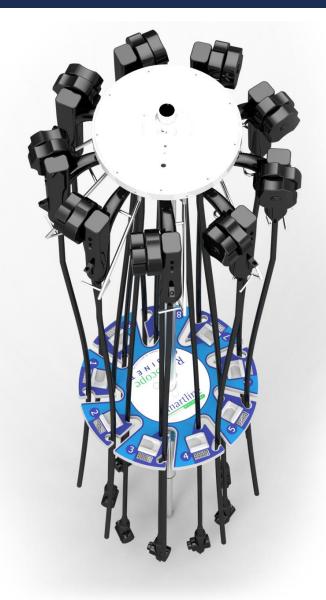
POWER OUTAGES

Restore power as quickly as possible to endoscope storage cabinet or transfer endoscope to a fully operation cabinet. Endoscope count down timer will count every minute that the endoscope is stored without power as a minute of Out of Cabinet time. Each endoscope has only 180 minutes of Out of Cabinet time per cleaning cycle. If endoscopes are stored without power for a time period that excess the Out of Cabinet time, endoscopes will have to go through the cleaning cycle again in full to be reprocessed in order to be used.



RotaScope

ANNEX A - VALIDATED SCOPES FOR STORAGE



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VALIDATED SCOPES OVERVIEW

Currently there are some endoscopes that can be stored in the cabinet that have a flow rate that is below the detectable flow rate of I I/min.

AUX, air & water channels have less than the minimum detectable flow rate of the Oxyview. The cabinets do not monitor individual channel flow rates, only vacuum air pressure is monitored in the manifold of the cabinets. Air flow device should be used to verify that air is flowing through the channels of the endoscope under test conditions only, not for normal operation use.

OLYMPUS COLONOSCOPES

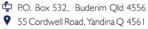
Name	Brand	Series	Туре
*+CF-H260AZI158	Olympus		Colonoscope
*+CF-H260AZL158	Olympus		Colonoscope
*CF-240AI49	Olympus		Colonoscope
*CF-240AL49	Olympus		Colonoscope
*CF-H180DI293	Olympus		Colonoscope
*CF-H180DL293	Olympus		Colonoscope
*CF-H260AI158	Olympus		Colonoscope
*CF-H260AL158	Olympus		Colonoscope
*CF-H260DI293	Olympus		Colonoscope
*CF-H260DL293	Olympus		Colonoscope
*CF-H290I297	Olympus		Colonoscope
*CF-H290L297	Olympus		Colonoscope
*CF-HQ290I297	Olympus		Colonoscope
*CF-HQ290L297	Olympus		Colonoscope
*CF-Q240AI49	Olympus		Colonoscope
*CF-Q240AL49	Olympus		Colonoscope
*CF-Q260AI158	Olympus		Colonoscope
*CF-Q260AL158	Olympus		Colonoscope
*PCF-160Al36	Olympus		Colonoscope
*PCF-160AL36	Olympus		Colonoscope
*PCF-H290I297	Olympus		Colonoscope
*PCF-H290L297	Olympus		Colonoscope
*PCF-P240AI49	Olympus		Colonoscope
*PCF-P240AL49	Olympus		Colonoscope
*PCF-Q260AI158	Olympus		Colonoscope
*PCF-Q260AL158	Olympus		Colonoscope
*PCF-Q260AZI293	Olympus		Colonoscope

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+CF-Q160ZI37	Olympus	Colonoscope
+CF-Q160ZL37	Olympus	Colonoscope
CF-100l11, 98	Olympus	Colonoscope
CF-100L11, 98	Olympus	Colonoscope
CF-100S98, 50	Olympus	Colonoscope
CF-100Ti14	Olympus	Colonoscope
CF-100TL14	Olympus	Colonoscope
CF-1301129	Olympus	Colonoscope
CF-130L129	Olympus	Colonoscope
CF-130S127, 129	Olympus	Colonoscope
CF-140I	Olympus	Colonoscope
CF-140L38, 105	Olympus	Colonoscope
CF-140S38	Olympus	Colonoscope
CF-160ZI	Olympus	Colonoscope
CF-160ZL	Olympus	Colonoscope
CF-200HL	Olympus	Colonoscope
CF-2001E CF-200S49	Olympus	Colonoscope
CF-240DI156	Olympus	Colonoscope
CF-240DL156 CF-240DL156	Olympus	Colonoscope
CF-240L136 CF-240I49	· ·	Colonoscope
CF-240149 CF-240L49	Olympus	•
CF-240L49 CF-2T160I	Olympus	Colonoscope
	Olympus	Colonoscope
CF-2T160L	Olympus	Colonoscope
CF-40I	Olympus	Colonoscope
CF-40L22, 34, 105	Olympus	Colonoscope
CF-FH260AZI	Olympus	Colonoscope
CF-FH260AZL	Olympus	Colonoscope
CF-H180AI	Olympus	Colonoscope
CF-H180AL	Olympus	Colonoscope
CF-H185I	Olympus	Colonoscope
CF-H185L	Olympus	Colonoscope
CF-H190I	Olympus	Colonoscope
CF-H190L2	Olympus	Colonoscope
CF-HQ190I	Olympus	Colonoscope
CF-HQ190L	Olympus	Colonoscope
CF-Q140I	Olympus	Colonoscope
CF-Q140L20, 38	Olympus	Colonoscope
CF-Q145I	Olympus	Colonoscope
CF-Q145L	Olympus	Colonoscope
CF-Q150I290	Olympus	Colonoscope

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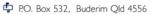
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MAN-0901 RotaScope VALID DATE: 01/2019 to 12/2020 Model: RotaScope G & Upgrades













PCF-PQ260L293	Olympus	Colonoscope
PCF-Q160AI	Olympus	Colonoscope
PCF-Q160AL	Olympus	Colonoscope
PCF-Q180AI205	Olympus	Colonoscope
PCF-Q180AL	Olympus	Colonoscope
PCF-Q260JI293	Olympus	Colonoscope
PCF-Q260JL293	Olympus	Colonoscope

Name Brand Series Type GF-UE140P Olympus Gastro GF-UE160 Olympus Gastro GF-UM240 Olympus Gastro GF-UMQ240 Olympus Gastro GF-UM2000 Olympus Gastro GIF-100 Olympus Gastro GIF-130 Olympus Gastro GIF-1458 Olympus Gastro GIF-145 Olympus Gastro GIF-160 Olympus Gastro GIF-1710098 Olympus Gastro GIF-17110098 Olympus Gastro GIF-17140 Olympus Gastro GIF-17160 Olympus Gastro GIF-17160 Olympus Gastro GIF-1710160 Olympus Gastro GIF-27160 Olympus Gastro GIF-27160 Olympus Gastro GIF-27160 Olympus Gastro GIF-27180 Olympus Gastro GIF-27160	OLYMPUS GASTROSCOPES		
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GIF-2TH180 Olympus Gastro GIF-E Olympus Gastro GIF-E3 Olympus Gastro GIF-FQ260 Olympus Gastro	GIF-2T200243	Olympus	Gastro
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GIF-FQ260 Olympus Gastro	GIF-E	Olympus	Gastro
· · · · · · · · · · · · · · · · · · ·	GIF-E3	Olympus	Gastro
GIF-FQ260Z Olympus Gastro	GIF-FQ260	Olympus	Gastro
	GIF-FQ260Z	Olympus	Gastro

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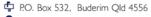
GIF-H180



Gastro

Olympus











GIF-H180J	Olympus	Gastro
GIF-H185	Olympus	Gastro
GIF-H190	Olympus	Gastro
GIF-H260158	Olympus	Gastro
GIF-H260Z293	Olympus	Gastro
GIF-H290297	Olympus	Gastro
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GIF-Q30122	Olympus	Gastro
GIF-Q4034	Olympus	Gastro
GIF-V2125	Olympus	Gastro
GIF-V43	Olympus	Gastro
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GIF-XT30	Olympus	Gastro

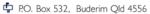
OLYMPUS DUODENOSCOPES

Name	Brand	Series	Туре
PJF-16	Olympus		Duodeno
PJF-160	Olympus		Duodeno
PJF-240	Olympus		Duodeno
TJF-140	Olympus		Duodeno

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TJF-140F	Olympus	Duodeno
TJF-140R	Olympus	Duodeno
TJF-145	Olympus	Duodeno
TJF-160F	Olympus	Duodeno
TJF-160R	Olympus	Duodeno
TJF-160VF	Olympus	Duodeno
TJF-160VR	Olympus	Duodeno
TJF-240	Olympus	Duodeno
TJF-260V	Olympus	Duodeno
JF-140	Olympus	Duodeno
JF-140F	Olympus	Duodeno
JF-1T40	Olympus	Duodeno
JF-240	Olympus	Duodeno

OLYMPUS	BRONCHOSCOPES

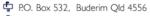
Name	Brand	Series	Туре
BF-30	Olympus		Bronco
BF-40	Olympus		Bronco
BF-140	Olympus		Bronco
BF-160	Olympus		Bronco
BF-180	Olympus		Bronco
BF-200	Olympus		Bronco
BF-240	Olympus		Bronco
BF-240AWY1	Olympus		Bronco
BF-260	Olympus		Bronco
BF-6C240	Olympus		Bronco
BF-6C260	Olympus		Bronco
BF-MP160	Olympus		Bronco
BF-MP160F	Olympus		Bronco
BF-MP60	Olympus		Bronco
BF-P30	Olympus		Bronco
BF-P40	Olympus		Bronco
BF-P60	Olympus		Bronco
BF-P150	Olympus		Bronco
BF-P160	Olympus		Bronco
BF-P180	Olympus		Bronco
BF-P190	Olympus		Bronco
BF-P200	Olympus		Bronco
BF-P240	Olympus		Bronco

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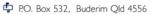
BF-P290	Olympus	Bronco
BF-Q180-AC	Olympus	Bronco
BF-Q190	Olympus	Bronco
BF-TE2	Olympus	Bronco
BF-XP160	Olympus	Bronco
BF-1T30	Olympus	Bronco
BF-1T30D	Olympus	Bronco
BF-1T40	Olympus	Bronco
BF-1T180	Olympus	Bronco
BF-1TQ180	Olympus	Bronco
BF-1T200	Olympus	Bronco
BF-1T240	Olympus	Bronco
BF-1T260	Olympus	Bronco
BF-Q180	Olympus	Bronco
BF-XT30	Olympus	Bronco
BF-F260	Olympus	Bronco
BF-H190	Olympus	Bronco
BF-XP190	Olympus	Bronco
BF-1TH190	Olympus	Bronco
BF-P260F	Olympus	Bronco
ENF-VT	Olympus	Bronco
ENF-VT2	Olympus	Bronco
LTF-160	Olympus	Bronco
LTF-240	Olympus	Bronco
MAF-TM	Olympus	Bronco

PENTAX SCOPES			
Name	Brand	Series	Туре
EC-3801F ^{76, 115}	Pentax	3800	Colonoscope
EC-3801F2 ^{76, 115}	Pentax	3800	Colonoscope
EC-3801M ^{76, 115}	Pentax	3800	Colonoscope
EC-3801M2 ^{76, 115}	Pentax	3800	Colonoscope
EC-3801S2 ^{76, 115}	Pentax	3800	Colonoscope
FC-38FW ¹¹¹	Pentax	W	Colonoscope
FC-38FW2 ^{111, 140}	Pentax	W	Colonoscope
FC-38MW ¹¹¹	Pentax	W	Colonoscope
FC-38MW2 ²⁸⁸	Pentax	W	Colonoscope
FC-38SW2 ¹⁴⁰	Pentax	W	Colonoscope

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FC-38FV ^{60, 66, 111}	Pentax	V	Colonoscope
EC-3830F ^{64, 67, 72}	Pentax	30	Colonoscope
EC-3830F2 ^{64, 67}	Pentax		Colonoscope
EC-3830M ^{64, 67, 72}	Pentax		Colonoscope
EC-3830M2 ^{64, 67, 72}	Pentax		Colonoscope
EC-3831F ¹⁴⁵	Pentax		Colonoscope
EC-3830FK	Pentax	30K	Colonoscope
EC-3831FK ¹²⁷	Pentax	30K	Colonoscope
EC-3840F	Pentax	40	Colonoscope
EC-3840FK	Pentax	40K	Colonoscope
EC-3840TFK	Pentax	40K	Colonoscope
EC-3470FK ¹⁶⁹	Pentax	70K	Colonoscope
EC-3470MK ¹⁶⁹	Pentax	70K	Colonoscope
EC-3870FK	Pentax	70K	Colonoscope
EC-3870MK ¹⁶⁹	Pentax	70K	Colonoscope
EC-3870FZK	Pentax	70K	Colonoscope
EC-3880FK	Pentax	80K	Colonoscope
EC-3880FK2	Pentax	80K	Colonoscope
EC-3880MK ¹⁶⁹	Pentax	80K	Colonoscope
EC-3880MK2	Pentax	80K	Colonoscope
EC-3885F ¹⁶⁹	Pentax	85	Colonoscope
EC-3885F2 ¹⁶⁹	Pentax	85	Colonoscope
EC-3885M2 ¹⁶⁹	Pentax	85	Colonoscope
EC-3885S2 ¹⁶⁹	Pentax	85	Colonoscope
EC-3885FK	Pentax	85K	Colonoscope
EC-3885FK2	Pentax	85K	Colonoscope
EC-3885MK ¹⁶⁹	Pentax	85K	Colonoscope
EC-3885MK2 ¹⁶⁹	Pentax	85K	Colonoscope
EC-3885SK2 ¹⁶⁹	Pentax	85K	Colonoscope
EC-3885TFK	Pentax	85K	Colonoscope
EC-3885TMK ¹⁶⁹	Pentax	85K	Colonoscope
EC-201WM	Pentax	201	Colonoscope

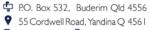
FUJINON SCOPES

Name	Brand	Series	Туре
EC-450ZW5/M	Fujinon	450	Colonoscope
EC-490ZW5/M ^{262, 264}	Fujinon	490	Colonoscope

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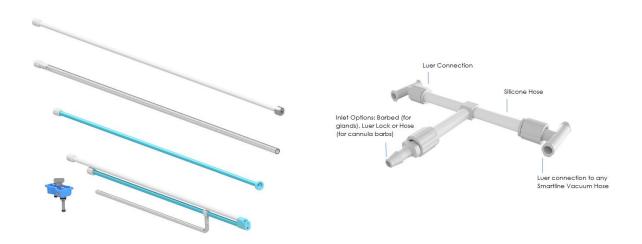
EC-250WM5	Fujinon	250	Colonoscope
EC-450WM5	Fujinon	450	Colonoscope
EC-530FM	Fujinon	530	Colonoscope
EC-530MT ²⁹³	Fujinon	530	Colonoscope
EC-530WM	Fujinon	530	Colonoscope
EC-530WTM ²⁶³	Fujinon	530	Colonoscope
EC-590WM	Fujinon	590	Colonoscope
EC-590ZW/M	Fujinon	590	Colonoscope
EC-250DM5	Fujinon	250	Colonoscope
EC-450DM5	Fujinon	450	Colonoscope
EC-530DM	Fujinon	530	Colonoscope
EC-450WM	Fujinon	450	Colonoscope
EC-530WM3	Fujinon		Colonoscope
EC-530MWM3	Fujinon		Colonoscope
EC-590WM4	Fujinon	590	Colonoscope
EC-590ZW3M	Fujinon	590	Colonoscope

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RotaScope[™]

ANNEX B – INSTRUCTIONS FOR USE – ENDOSCOPE HOSE KIT CLEANING



Olympus Endoscope Vacuum Hose Kit (09.HK-OL) Washer rack Hose Connection Kit (09.SC-WRHKC)

Note: applicable to other scope brand variants also – Endoscope Vacuum Hose Kits join Endoscopes to the RotaScope or SlidaScope Drying Cabinet airflow system

High-level disinfection of each hose connector should be undertaken weekly (during the cabinet cleaning cycle).

Cleaning may be Manual or Automated and can also be autoclaved to gain shelf life.

Below is the minimum requirement to ensure hoses are in a satisfactory condition to provide a clean connection between the endoscope and the cabinet.

During Weekly Cleaning, please reference the following instructions and modify where required, to suit the equipment available to the department.

Smartline have created a modular accessory called a "Washer Rack Vacuum Hose Connection Kit", that can be utilised during the cleaning process.

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MANUAL CLEANING

RECOMMENDED STEPS:

- 1. Prepare appropriate amount of cleaning solution (biofilm remover or enzymatic detergent solution) in a sink, as per the manufacturer's instructions.
- 2. Remove hose/s to be cleaned from cabinet and place in sink.
- 3. Make sure the hoses remain fully immersed throughout the cleaning process.
- 4. Use a small soft brush to clean the connectors at each end of the hose.
- 5. Wipe exterior surfaces of hoses with a nonabrasive and lint free cloth.
- 6. Check that all visible debris have been removed.
- 7. Attach hoses to a Washer Rack Hose Connection Kit.
- 8. Use a syringe to push fresh solution through hoses and then flush out. Repeat a minimum of two more times, do not flush out on last action.
- 9. Achieve contact time with hoses submerged for the appropriate timeframe outlined in the chosen cleaning solution IFU.
- 10. Purge cleaning solution from channels while fully immersed.
- 11. Repeat steps 7-10 until all hoses have been flushed and purged.
- 12. Discard cleaning solution.
- 13. Use a syringe to push fresh water through hoses to remove all cleaning solution.
- 14. Thoroughly wash exterior of all hoses with fresh water to remove all traces of cleaning solution.
- 15. Remove hoses from sink and hold in a vertical position to allow water to drain out. Use a syringe or medical air supplied air gun to purge any remaining water from the inside of the hose.
 - a. Dry in a drying cabinet where possible.
 - b. Dry with medical grade air where possible.
- 16. Remove hoses from the Washer Rack Hose Connection Kit.
- 17. Hang hoses back inside endoscope cabinet connected to forced air for additional drying.



BATCH WASHERS

or

RECOMMENDED STEPS:

- 1. Attach hoses to a Washer Rack Hose Connection Kit and attach to a washer rack.
 - a. Insert barb by inserting it into a rubber grommet
 - b. or remove barb and utilise luer fitting onto suitable washer rack luer connection
 - c. or remove luer fitting slip hose over a suitable injector barb on washer rack
- 2. Connect the male luer ends of the **Endoscope Vacuum Hose Kit** to a washer rack for cannulated items.
- 3. Run the washer on an appropriate setting for model and chemicals used.
- 4. Remove hoses from washer rack and hold in a vertical position to allow water to drain out. Use a syringe or medical air supplied air gun to purge any remaining water from the inside of the hoses.
 - a. Dry in a drying cabinet where possible.
 - b. Dry with medical grade air where possible.
- 5. Remove hoses from the Washer Rack Hose Connection Kit.
- 6. Hang hoses back inside endoscope cabinet connected to forced air for additional drying.

STERILISING FOR STERILE STORAGE

RECOMMENDED STEPS:

After Manual or Automated disinfection of the hose kits, it is at times efficient to sterilise the hose kit for external storage, this especially applies to sites that use a secondary hose kit (Swap out hose kit for cleaning). By doing this you can achieve 7 days or more storage prior to use in the cabinet.

RECOMMENDED STEPS:

- 1. Take disinfected and dried hoses from cleaning area or drying cabinet.
- 2. Add hoses individually or in appropriate groups into a steripeel bag or on a tray and wrapped in sterilization wrap (AKA Kimguard).
- 3. Put into steriliser on a suitable cycle that does not exceed 121°C.
- 4. At completion of cycle, remove from the steriliser and store in an appropriate storage environment (sterile storeroom).
- 5. When required, hoses can be removed from sterile packaging and hung directly into the cabinet.
- 6. Note: Regular sterilisation of **Endoscope Vacuum Hose Kits** may have a detrimental effect on the materials and replacement may be required.