Installation and User Instructions

RotaScope Core Series

Endoscope and Probe Drying Cabinet

CE

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All pertinent state, regional, and local safety regulations must be observed when installing and using this product. For reasons of safety and to help ensure compliance with documented system data, Authorised Distributor technicians shall perform repairs to components.

When devices are used for applications with technical safety requirements, the relevant instructions must be followed.

Failure to observe this information can result in injury or equipment damage.

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General Notice: Some product names used in this manual are used for identification purposes only and may be trademarks of their respective companies.

Table of Contents

1 PREFACE

1.1 Description of the Operator

The RotaScope Endoscope Drying Cabinets are designed for Drying of Endoscopes after reprocessing in healthcare environments.

The Operator is a Trained and Authorized person, who consistently operates the RotaScope and its approved accessories, and/or performs the unloading/loading of the Endoscopes in the RotaScope.

The User must not tamper or modify the RotaScope.

Any modifications, servicing, or repairs must be done by a Smartline Medical Trained Professional or a Trained Professional that is under instruction from Smartline Medical.

This document is intended for the User and Smartline Medical Trained Professionals of the RotaScope, accessories and software.

Authorised Distributors are approved by Smartline Medical Pty Ltd for sales, and technical support

1.2 Explanation of Safety Warnings

The following Safety Precautions must be observed when operating or servicing the RotaScope. For emphasis, certain Safety Precautions are repeated throughout the manual. It is important to review ALL Safety Precautions before operating or servicing the unit.

Warning Cabinet	
WARNING	• Cabinet to be installed and levelled by an Approved Distributor • Only Approved Distributors may install, service or repair Smartline Medical equipment • Avoid contact of electrical components with water and moisture. • Do not connect to any external electronic devices. • Do not lean on cabinet. • HEAVY! Do not lift cabinet without lifting equipment
Warning Integrated Air System	
WARNING	• Machine Noise: 47 Decibels maximum measured at 1 Meter distance • Only Approved Distributors may install, service or repair Smartline Medical equipment • Avoid contact of electrical components with water and moisture. • High voltage 240V • Do not remove covers or guards

1.3 Retaining Instructions

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in serious injury or death.

Follow all the instructions. This will avoid fire, explosions, electric shocks, or other hazards that may result in damage to property and/or severe or fatal injuries.

The product shall only be used by persons who have fully read and understand the contents of this user manual.

Ensure that each person who uses the product has read these warnings and instructions and follows them.

Keep all safety information and instructions for future reference and pass them on to subsequent users of the product.

The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with the safety instructions. In such cases, the warranty will be voided.

1.4 Obtaining Documentation and Information

1.4.1 Internet

The latest version of the documentation is available at the following address:
http://www.smartlinemedical.com

1.4.2 Ordering Documentation

Where multiple devices are supplied usually a single copy of the Instructions For Use is provided - further copies can be provided free of charge upon request.

Documentation, user instructions and technical information can be ordered by calling Smartline Medical on +61 (07) 5478 9977

1.4.3 Support and service

For information about:

- Publications and materials
- Information, technical assistance or ordering user instructions
- Service-related questions

Smartline Medical | 55 Cordwell Road, Yandina, Qld, 4561
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1.4.4 Name and address of the manufacturer

The following natural or legal person makes the device, to which this user manual applies, suitable for use within the European Union and is considered to be the manufacturer of the device:

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2 Description of the product

2.1 Intended Use and Reasonably Foreseeable Misuse

This RotaScope has been designed to dry and store up to nine Flexible Thermolabile Endoscopes and other types of probes, including TOE Probes.

The RotaScope is intended to be used for Operators in a healthcare environment to store and dry Thermolabile Endoscopes or probes after being reprocessed.

The RotaScope shall not be used for any other function except for the storing and drying of Thermolabile Endoscopes and probes.

The RotaScope shall be used with the following original accessories and components only:

- Endoscope Hang Hooks
- Optional - Approved Endoscope Hose Connection Kits (Purchased Separately)

It is essential that the user of this manual is aware of the potential hazards associated with the unit and its accessories. All operators should be familiar with the safety precautions and warnings given in this section prior to attempting to operate the unit. If the unit is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

2.2 Technical Data (Performance characteristics of the RotaScope Cabinet)

Parameter	Unit
Device name	RotaScope Core
Designation	Class 1
Type	Endoscope Storage Cabinet
UNSPC Commodity Code	42295002
Customs HS Code	9018908400
Technical life span	7 Years
Expiry Date	N/A
Capacity	Up to nine (9) endoscopes or probes
Energy consumption	250W
Size (Mass)	2363mm H x 600mm W x 600mm D – Base Cabinet
Weight	140 kgs (308 lbs)
Chemical composition	Various
Services Supply	220V-240V 10A or 110-120V 15A

Emission of noise	47 dB measured at 1m
HEPA Quality	H13: 0.2 micron 99.99% efficiency
Altitude	Up to 2000m
Overvoltage Category	Category II

2.3 Product Compliance

This product complies to all known relevant European Directives. The Declaration of CE Conformity can be found in the Appendix at the end of this manual. The Products comply with the following relevant product safety standards:

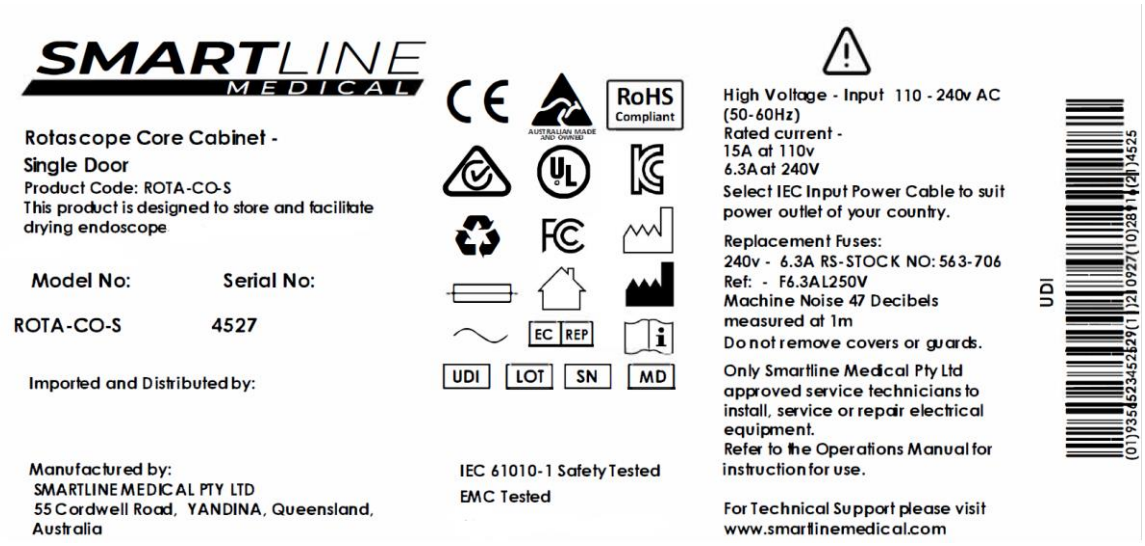
- ISO-9001
- CE
- EMC Tested IEC 60601-1
- IEC 61010-1 Safety Tested

2.3.1 Compliance Labels

RotaScope Cabinet – Compliance Label affixed at top front of cabinet behind the façade.

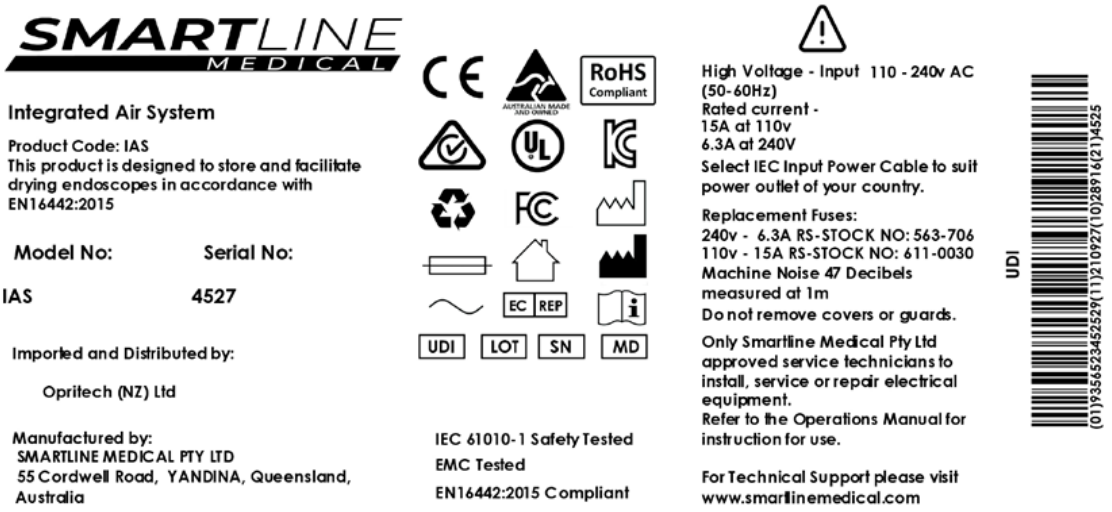
IAS Label is fitted to the side of the IAS.

2.3.1.1 RotaScope Cabinet Product Compliance Label



Located at the top front of the Cabinet behind the façade

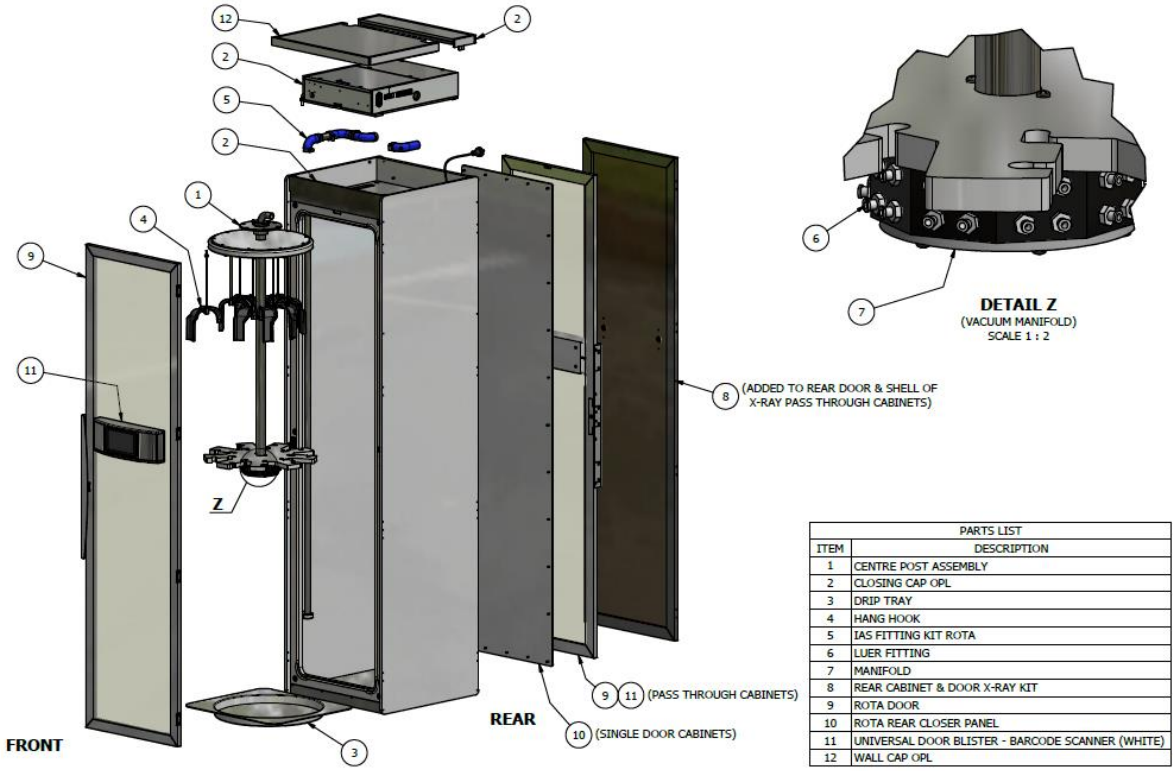
2.3.1.2 Integrated Air System Compliance label



Located on the right rear side of the IAS on top of the cabinet

2.4 Product elements

2.4.1 RotaScope Cabinet Components



PARTS LIST	
ITEM	DESCRIPTION
1	CENTRE POST ASSEMBLY
2	CLOSING CAP OPL
3	DRIP TRAY
4	HANG HOOK
5	IAS FITTING KIT ROTA
6	LUER FITTING
7	MANIFOLD
8	REAR CABINET & DOOR X-RAY KIT
9	ROTA DOOR
10	ROTA REAR CLOSER PANEL
11	UNIVERSAL DOOR BLISTER - BARCODE SCANNER (WHITE)
12	WALL CAP OPL

*The Cabinet may be configured with a Rear Door if it is the Pass-Through version

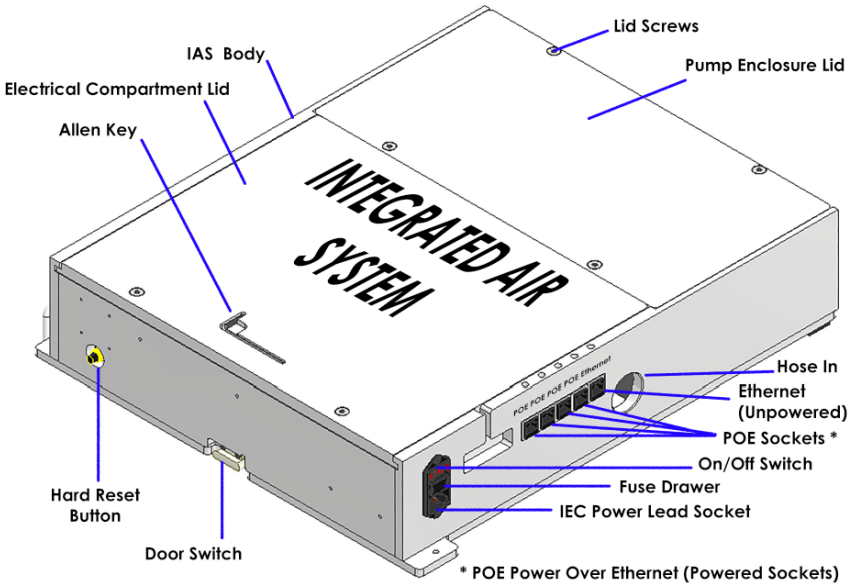
**The Cabinet may also include an X-Ray Kit on the rear door to prevent transmission of the X-Ray through the cabinet.

*** Core cabinets will not have a Universal Door Blister, instead will have an electronic keypad lock

2.4.2 IAS Components

Integrated Air System – Located on top of Cabinet – Contains Pumps and Electrical Parts

Service by an Authorised Distibutor only



Located on the top of the drying cabinet, the Integrated Air System (IAS) is an assembled unit that provides the vacuum and HEPA filtered air for the drying function of the cabinet.

The IAS contains pumps, and control equipment including the data system, and termination points for connection to mains power and to the system network and devices.

2.4.3 Internal Cabinet Components

2.4.3.1 Identifying the Hang Hook and Connection components

The RotaScope Centre Pole, Hang Hooks and Vacuum Manifold

A rotating Centre Pole is located inside each RotaScope cabinet. Up to 9 Endoscopes are vertically hung on numbered Hang Hooks. The Hang Hooks are designed to be easy to load, gentle on scopes and easy to clean. Hang Hooks may be adjusted high or low for Long or Short Scopes and easy access. The Centre Pole can be manually rotated for scope selection.

The Vacuum Manifold (above left) is the point that each scope is connected to the cabinet airflow via the Scope Hose Connection Kits (described later in this document).

The Top Plate (Top Disk) retains the Hang Hooks and has vacuum airflow Luer Fittings for connecting scopes via the Scope Connector Hose Kits – the Top Plate is Numbered for scope location.

The Centre Disk (1) retains scope lumens and is numbered for scope location identification.

2.4.3.2 Hang Hooks – options

A RotaScope Cabinet Centre Pole may be fitted with various hooks to store different scopes

Image above left shows an Probe Hang hook and **Image above right shows a standard hang hook** which is provided as adjustable stainless hang rods which are set up at install to suit your scopes.

Various ENT Hooks are available, and an Authorised Distributor will assist you with ordering special needs hang hooks will hold most types of flexible scopes

A mix of ENT and Standard Hang Hooks may be used in a cabinet at the same time

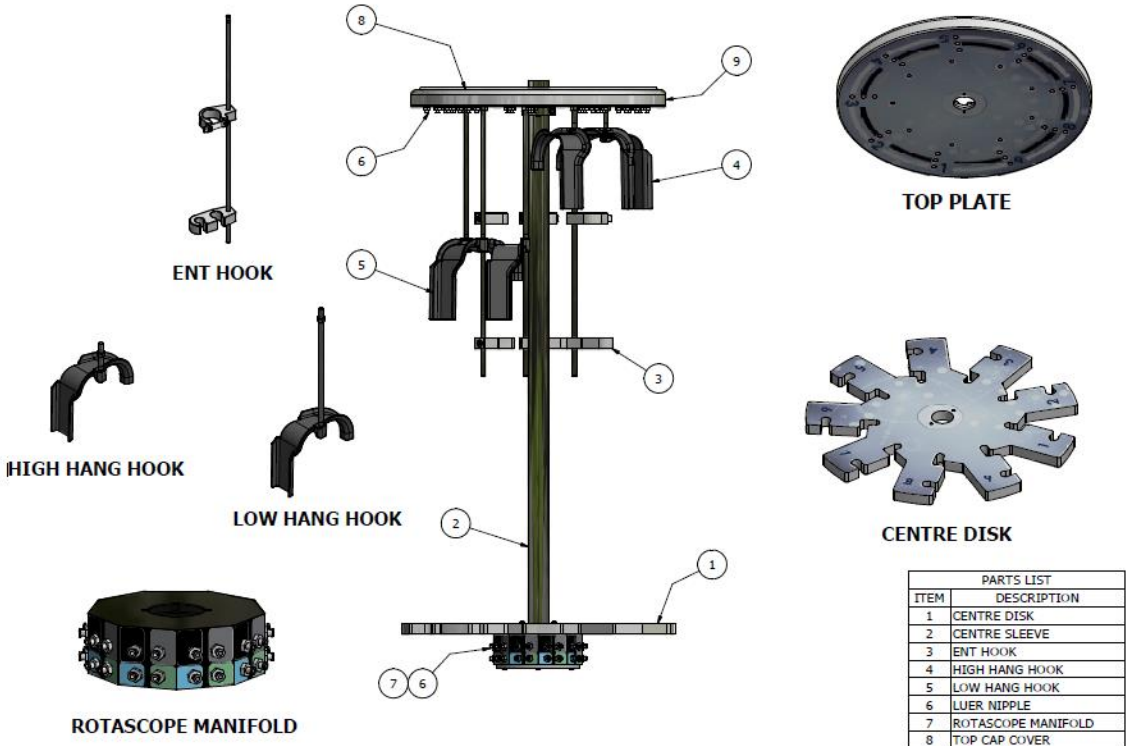
Cleaning hooks regularly is important – see **"Cabinet Cleaning"** which is described later in this document

Weekly Cabinet Cleaning is described later in this document

2.4.3.3 RotaScope Centre Pole and Manifold Details

RotaScope Centre Pole: OVERVIEW:

The Top Disk of the centre pole



PARTS LIST	
ITEM	DESCRIPTION
1	CENTRE DISK
2	CENTRE SLEEVE
3	ENT HOOK
4	HIGH HANG HOOK
5	LOW HANG HOOK
6	LUER NIPPLE
7	ROTASCOPE MANIFOLD
8	TOP CAP COVER
9	TOP PLATE

The hang hooks may be selected to suit various types and lengths of scopes

Please see your Authorised Distributor for assistance in better understanding the various Hang Hook Options to make hanging scopes easy and safe

2.5 Understanding Product and Controls and Indicators

2.5.1 What is the product?

RotaScope is a Medical Drying and Storage Cabinet for drying the outside surfaces and internal tubes in flexible medical endoscopes and probes.

RotaScope Cabinets hold up to nine scopes/probes on Hang Hooks located in the cabinet (Vertical storage of endoscopes).

2.5.2 How does the product work? – Overview

Room air, from an airconditioned room, is drawn into the cabinet via air pumps (miniature side channel blower vacuum pumps).

The pumps push room air through HEPA filters into the cabinet to dry the outside surfaces of the Endoscopes or probes.

Scopes have up to seven tiny tubes (Lumens) that run through the inside of the scope to deliver air, water, gas and instruments into the patient. These tubes need to be dried after a scope is washed, to prevent any tiny remnants of biofilm or free radical bugs from proliferating.

After reprocessing, in simple terms, "A dry scope is a good scope".

For each stored scope, there are 7 small luer hose connection nipples located on the manifold and Top Disk of the centre pole.

The manifold provides vacuum that draws air through the small hoses that run inside of the endoscope to dry each tiny channel tube (Lumen).

Scope Connector Hose Kits have special connectors fitted, that allow one end of the **Scope Connector Hose** to join to ports on the scope, whilst the other end connects to the cabinets vacuum manifolds. The hoses are colour coded to match the coloured sticker icons on the manifold and top disk, to ensure the hoses are connected to the correct fitting.

In this way the air system sends HEPA filtered air into the cabinet (dries the outside of the scopes), whilst sucking some of that filtered cabinet air out through the scope channels (drying the insides of the scope).

Scopes can be continuously stored up to a storage time of 31 Days in the cabinet if EN16442 approval is not required for the territory. As the Core does not have environmental monitoring and controls, it is not an EN16442 approved device. Please see the Classic Series if EN16442 approval is required. Probes at time of writing do not have a standard attached to limit storage conditions or time.

About the drying principles:

The cabinet runs at about 8 degrees Celsius warmer than the room it is located in.

The warmer air in the cabinet is dyer than the room air at about 20% RH below, due to the elevated cabinet temperature.

Bulk loose water in Scope Channels is generally removed by airflow in about 10 minutes.

Standards dictate that a scope must be dried in less than 3 hours to limit possible microbiological proliferation.

Remaining trapped moisture droplets typically found in capillary hose joins and ports will dry in about 1.5 hours from time of loading a scope

The scope channels usually DRY in under 1.5 hours

The slowest part of a scope to dry is the external control knobs on the scope control handpiece which can take up to three hours – less if patted dry with clean, lint free cloth before loading

For best results Smartline recommends purging bulk moisture out of scopes before loading, by use of medical air gun to blow out channels manually

Typical Humidity at normal preferred operation conditions:

Room Temperature	**Room Humidity**	**Absolute Water Content**
22 Degrees C	Approximately 60%	0.012 kg/m3
Cabinet Temperature	**Cabinet Humidity**	**Absolute Water Content**
30 Degrees C	39.5%	0.012 kg/m3

Vacuum air flow through scopes:

RotaScope uses a patented concept of drawing air through the scope via vacuum instead of blowing air through the scope channels for drying.

Elevated temperature and Vacuum (in theory) can assist in drying faster.

By using vacuum, infection control is better, as the connecting hoses are on the exit side of the air flow through the scopes.

Air is drawn into the distal tip (camera end of the scope which goes into the patient) from the distal tip air is drawn through the scope channels (lumens), then through the Scope Connection Hose Kits to the cabinet vacuum manifold.

The benefit of this airflow pathway is that the air passes through the scope channels individually to each set of sensors for each channel port of the manifold sensor board.

Some scope channels are Y junctions – despite the joins each channel is seen independently as the air is drawn from each port so that there are no amalgamated air flows, thus the cabinet can dry each channel or section of scope channel independently.

Cabinet/environmental conditions:

Recommended that the cabinet is located in room with constant air conditioning at 22 degrees C (maximum 38 degrees C)

Recommended Room Humidity <90%

Cabinet Internal Operating Temperature 22-45 Degrees C – (Usually 30-37)

Cabinet internal pressure approximately +15 Pa, Vacuum in Air System – approximately -17,000 Pa.

Cabinet Humidity is usually around 10 - 45% depending on room humidity and temperature.

2.6 Visual Signals at Cabinet

Cabinet coloured lighting indicates overall cabinet status as below:

White = Door Open

3 Safety Instructions

- Cabinets MUST BE positioned on a stable, level floor.
- Cabinet power cable must be securely plugged into a standard GPO & switched On.
- Inspect door components of the equipment prior to use as well as daily – inspection to also be performed on rear door where fitted.
    - Inspect the door components i.e.: handle, hinges, and locking mechanism (where fitted) for functionality, wear and tear or damage.
    - Is the door easy to open and shut?
    - Are there any obstructions in front of, or near the door to prevent it from opening?
    - Do the cabinet interior lamps illuminate when the door is opened & extinguish when the door is closed?
- Inspect the silicone connection hoses & luer fittings for wear & tear or damage.
- Are the silicone connection hoses connected to the cabinet 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?
- If any inspection fails, please advise your supervisor as soon as possible.

⚠WARNING

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in serious injury or death.

3.1 How to Use the Product Safely

- Some staff may have difficulty reaching scopes when loading or unloading the cabinet, due to the height of the loaded scopes. It is advisable that an appropriate step stool be used. Consult with your local Occupational Health Officer to determine a safe work method for your site.

3.1.1 Control screens, and electrical enclosures

- Do not open and access the control units without specific training from the Authorised Distributor.

3.1.2 Technical life span

- Annual service and preventative maintenance are required
    - To ensure you get the best performance out of your 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 Integrated Air

System IAS, and basic ongoing cabinet maintenance of cabinet fittings and fixtures.

- The viable lifecycle of the cabinet is 7 years from date of purchase

3.1.3 Condition of the Endoscope

Verification is required that all channels allow the passage of air before the device is loaded into the storage cabinet 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 the washer's channel monitoring; however, extensive air flushing (Purging) of all channels is recommended before placing the endoscope in the cabinet to purge any bulk water left inside endoscope channels from the washers.

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.

Scopes should have channels blown dry with medical air from handpiece ports including biopsy channel and thumb ports for suction and air/water.

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

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.

3.1.4 In case of power failure

Restore power as quickly as possible to the endoscope storage cabinet or transfer endoscopes to a fully operational cabinet.

3.1.5 Personal Protective Equipment

Standard hospital PPE (scrubs or gown, masks and gloves) should be used when interacting with the internals of this cabinet to reduce any chance of contamination.Personal hygiene (hand washing or use of gloves) must be considered when interacting with the inside of the cabinet.

3.1.6 Product limitations and restrictions

Endoscope cabinets are for storage and or drying of endoscopes, including internal channels, in a controlled environment. The controlled environment ensures that there is no deterioration of microbiological quality of the endoscope.

The drying function supplements drying after manual or automated disinfection. The storage cabinet allows for safe delivery of Endoscopes for an extended period after reprocessing.

Note 1 – Drying Cabinets are intended to dry and store thermolabile flexible endoscopes – however the endoscopes should be free from bulk liquid saturation which may affect the anticipated drying rate of the endoscope when loaded into the cabinet. Drying cycles of AER (Automatic Endoscope Repressors), should be set to allow for the removal of bulk liquids where possible, and or, Endoscopes should be purged by manual purging to remove bulk liquid before loading into the drying cabinet.
Endoscopes that have undergone manual cleaning processes only should be purged of bulk liquids before loading into the drying cabinets.

Note 2 – Strong recommendation is given to verify the microbiological quality of the endoscopes intended to be stored in the cabinet before installation of the cabinet by ensuring scopes have followed the recommended manufacturers decontamination guidelines

Note 3 – Storage cabinets are not designed to clean or disinfect endoscopes and any contaminated endoscopes may still be contaminated after the storage.

Note 4 – Storage Cabinets housing thermolabile endoscopes are NOT considered medical devices

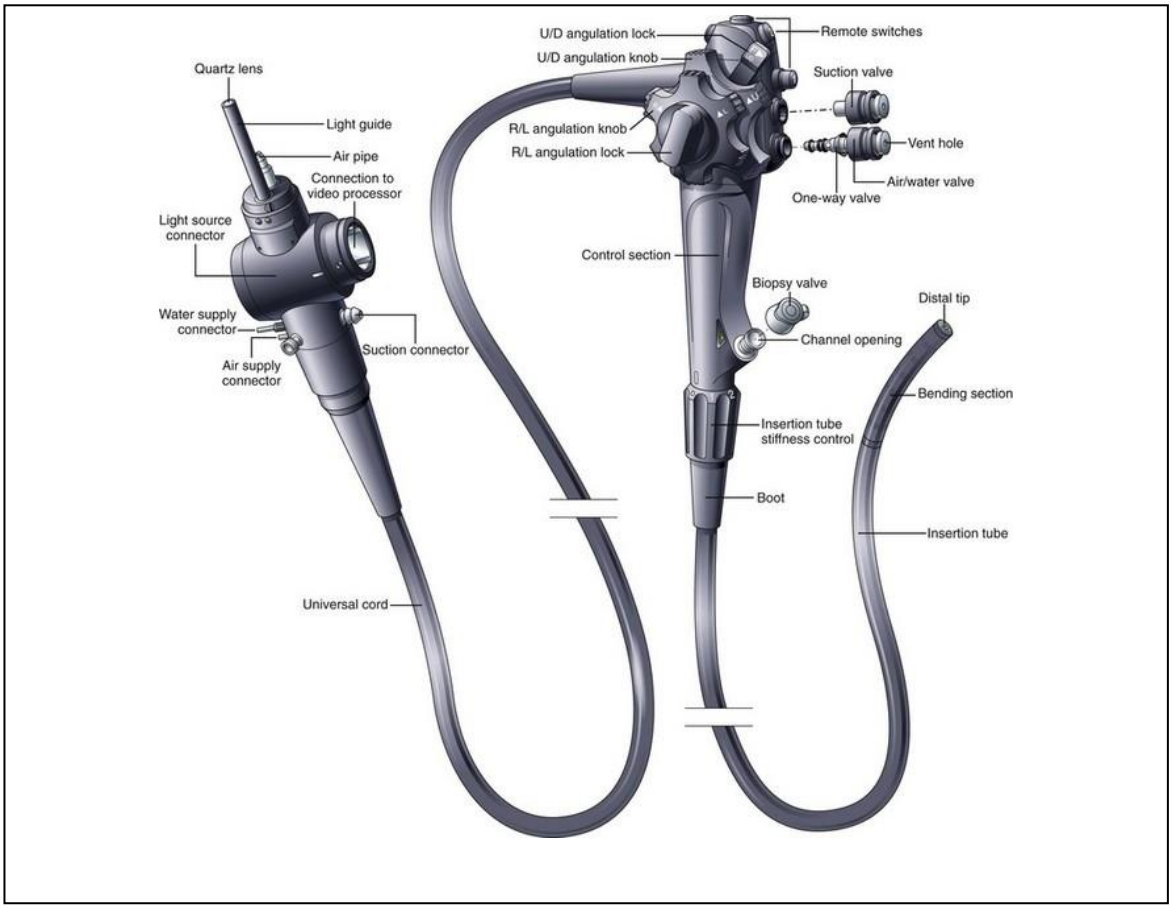
The aim of drying endoscopes after suitable reprocessing, is to remove moisture from the scope and channels in under three hours, to prevent microbiological growth.

Installation/Service safety – Installation and Service should be conducted by Authorised Distributors only. Cabinets that have been installed, serviced or altered by non-authorised technicians will not be deemed to be fit for purpose, and will not be covered by warranty.

3.1.7 Maintenance safety information

To ensure you get the best performance out of your cabinet, it is an operational requirement to have a Maintenance Contract in place. Maintenance Contracts are to be set up through the Maintenance Department. A Maintenance Contract is an annual service agreement covering servicing, and or, replacement of equipment e.g., filters and parts. Maintenance is to be conducted by Authorised Distributors only.

3.2 General Anatomy of an Endoscope



The image above outlines the various parts of a typical thermolabile flexible endoscope

Whilst the design and functions of endoscopes may vary – the Drying Principles remain the same across various scope families and brands.

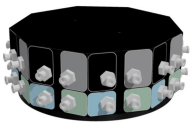
The cabinet is designed to Store and Dry various approved endoscopes, externally and internally via connection to the drying cabinet air system using **Scope Connector Hose Kits**.

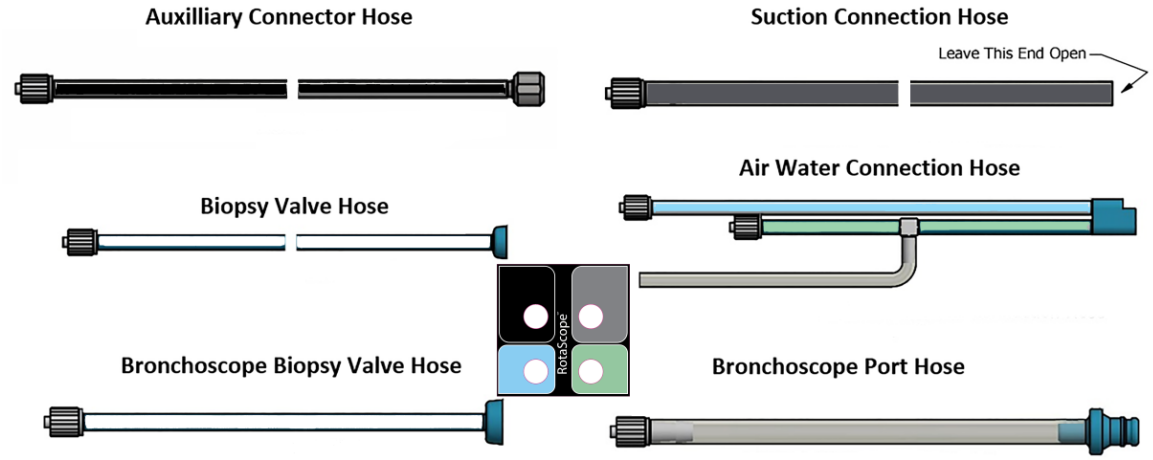
3.3 Scope Connector Hose Kits

Scope Connector Hose Kits are separately purchased for each scope that is to be loaded into the cabinets.

Colour Coded Scope Connector Hose Kit Examples:

Pole Manifold





Hose colour is matched to similar connection port identification stickers

A Luer Lock fitting at one end of the connecting hose, terminates to the relevant Luer Nipple on the cabinet Vacuum Manifold Block – these fittings require just a quarter turn to securely fit the hose onto the cabinet air system.

On the other end of each hose is a fitting that will suit termination onto the relevant scope channel port.

The **Scope Connector Hose Kits** are used to connect different Brand Endoscopes and different types of Endoscopes to the drying system.

Each different Endoscope has specific Endoscope Channels (Lumens) which perform varied functions during endoscope use. To dry each of these channels, hoses with specialized fittings are tested to ensure correct fit and drying performance, for each approved scope.

Each hose is colour coded and matched with the correct port fittings so that the scope channels can be connected to the scope and system correctly.

A colour coded sticker on the scope cabinet Vacuum Manifold Blocks is used to visually match the coloured hose with the coloured sticker.

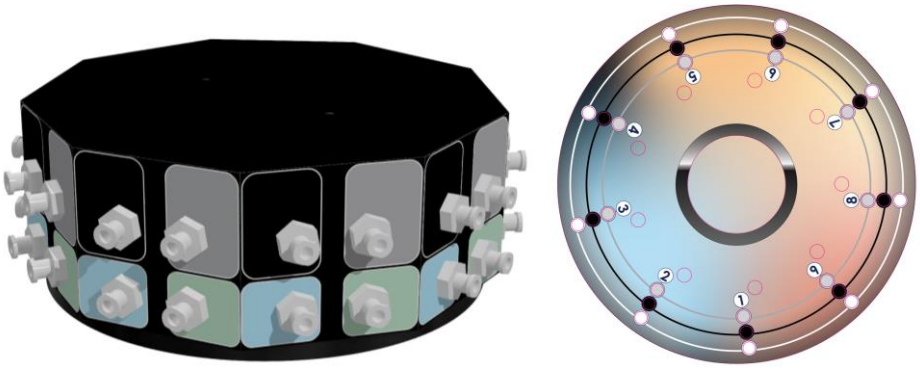
3.3.1 Scope Connector Hose Kits - Colour Coding:

Scope Connector Hose Kit - Colour Coding:

The manifold is fitted with a colour coded sticker to match with coloured hoses

Name/Location	Port No On sticker	Hose ID mm	Hose OD mm	Colour	Sample
Handpiece					
Auxiliary	1	4.0	6.5	BLACK	
Biopsy	2	4.0	6.5	WHITE	
Spare	3	4.0	6.5	LT GREY	
Umbilical					
Suction	4	5.8	9.0	DK GREY	
Air	5	4.0	6.5	LT GREEN	
Water	6	4.0	6.5	LT BLUE	
Auxiliary / Jet	7	4.0	6.5	BLACK	
Lower Air Pipe	-	3.2	6.4	CLEAR	

NOTE: See your Authorised Distributor for detailed selection of **Scope Connector Hose Kits** to suit your specific Endoscope connection to the cabinet air system



Match Hose Colour with Sticker colour on Centre Pole Manifold or Top Disk Stickers

3.3.2 Scope Connector Hose Kits – Cleaning IFU

RECOMMENDED STEPS for Manual Cleaning Scope Connector Hose Kits:

(IFU) Instructions For Use

1. Prepare appropriate amount of cleaning solution (biofilm remover or enzymatic detergent solution) in a sink, as per the chemical 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. Optionally, 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.**

Hang hoses back inside endoscope cabinet connected to forced air for additional drying.

This page may be printed and displayed at your wash area

Scope Connector Hose Kits and ESC connectors (Endoscope 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 hose kit to the scopes or the cabinet we recommend manually disinfecting the hoses and lines. Alternatively, the hose kits may be autoclaved as per your local guidelines.

3.3.3 Selecting Scope Connector Hose Kits, for your fleet of Scopes

There are many Brands and Models of Endoscopes available. Each scope has specific connection points that need to be matched with approved connection fittings. Approved fittings ensure that air will successfully pass through the scope to dry the scope in the recommended time in the cabinet.

When sharing the Endoscope Model Number, it is very important to exactly capture the precise details including Capital and lower-case letters, hyphens, numbers and spacings – e.g. EC-760ZP-V/L Examples of approved scope kits can be seen below – As there are so many, they are not listed individually in this manual – please refer to the ***ApprovedScopeList.pdf*** and refer to your local Distributor to obtain full details of each required Scope Connection Hose Kit.

Examples below of Scope Connection and Approved Scope detail sheets

SMARTLINE MEDICAL

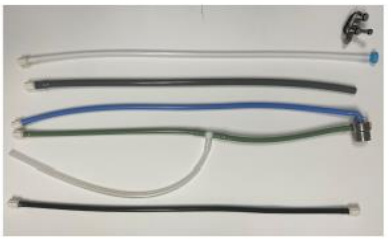
+61 5478 9977 www.smartlinemedical.com
55 Cordwell Road, Yandina, Queensland 4561 AUSTRALIA
ABN 34 119 209 611

Instructions for Use:
90.KIT-FU-001 - Fuji 700 Series Kit

Kit Includes:

Item Code	Item Description	Unit	Qty
90.AW-FU-001	Fuji Air Water Connector Hose (Blue/Green)	Each	1
90.BIO-001	Universal Biopsy Valve Hose (White)	Each	1
90.CS-FU-002	Fuji 700 Series Channel Separator	Each	1
90.SUC-001	Universal Suction Connection Hose (Grey)	Each	1
90.UNI-002	Univeral Luer Connection Hose (Black)	Each	1

Included items:



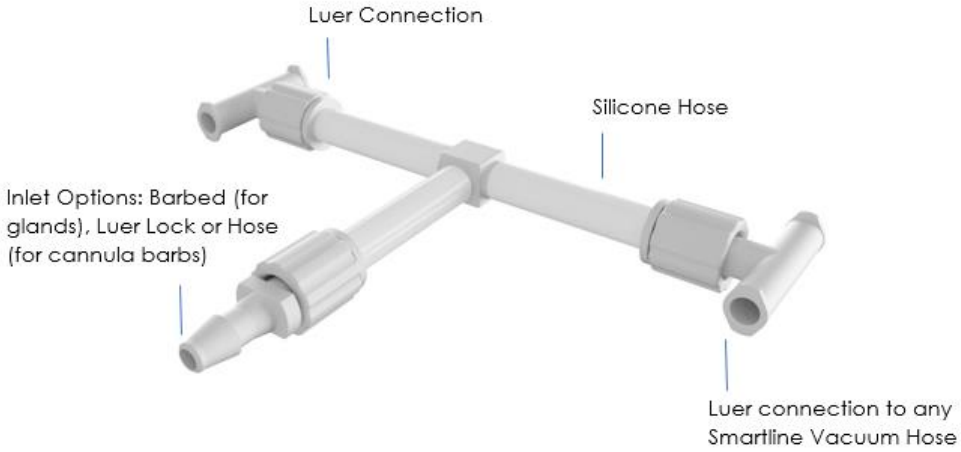
Suits Scopes: EC-760R-V/L; EC-760ZP-V/L; EC-760ZP-V/L; EC-740T/L; EG-760Z; EG-760CT; EG-760R; EG-760Z; EG-760CT; EC-720R/L; EC-720R/I; EC-720R/M; EC-730RV/L; EC-760R-V/M; EC-760R-V/I; EC-760P-V/L; EC-760P-V/M; EC-760ZP-V/M; EC-760Z-V/M; EC-760Z-V/L; EC-760S-V/L; EC-740T/M;

For a copy of the **ApprovedScopeList.pdf** – please email – sales@smartlinemedical.com for the latest version or contact your local Authorised Distributor

3.3.4 Washer Rack Hose Connection Kit (Optional)

A modular accessory is available, that can be utilised during an Automated Cleaning Process.

Washer Rack Hose Connection Kit (09.SC-WRHKC)



The **Washer Rack Hose Connection Kit** is an accessory used by the Central Sterilising Department in combination with some type of Automated Instrument Washer

The purpose of the Washer Rack Hose Connection Kit is to connect several hoses (Scope Connector Hose Kits) simultaneously to reduce reprocessing costs

The Inlet is connected to an Automatic Washer – the 4 Luer connections are connected to cabinet Scope Connector Hose Kits.

Note: Scope Connector Hose Kits, join Endoscopes to the RotaScope Drying Cabinet airflow system

High-level disinfection of each Scope Connector Hose Kit, should be undertaken weekly (during the Cabinet Cleaning Cycle).

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

During Weekly Cleaning, please reference the Scope Connector Hose Kits Cleaning IFU above – some instructions may need to be modified where required, to suit the equipment available to the department.

3.3.4.1 Approved Scope List

EN16442:2015 Standards requires that the cabinet manufacturer publishes an Approved Scope List. The most current ***ApprovedScopeList.pdf*** is available upon request via email sales@smartlinemedical.com

3.4 Cleaning of Cabinets IFU (Instructions For Use)

Cabinets must be cleaned in no more than a seven-day repeated cycle.

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 and should be avoided.

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

Note: Liquids issued out of an endoscope at time of loading into the drying cabinet, usually indicates that the scope has not been suitably purged or that the drying cycle of the washer has not been set to a suitable run time.

Note: Frequently loading very wet scopes into drying cabinets may result in increased bioburden forming on scope cabinet surfaces and is to be avoided.

Scope handling, preparation and loading techniques should be explored by HSO (Health Service Organisations) to determine a best practice formula that suits the equipment and practices in the decontamination department. Please consult with an Authorised Distributor for guidance.

This page may be printed and displayed near the cabinets as a weekly cleaning guide

3.4.1 Internal Surfaces Cabinet Cleaning IFU (Instructions For Use)

Cleaning of the RotaScope cabinet should be carried out in accordance with local guidelines in less than 7-day intervals.

- Remove all scopes from the cabinets and store appropriately
- 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.
- Cleaning the human touch-points, where operators frequently touch, is particularly important. Methodical manual cleaning of these points should occur.
- Hang Hooks should be frequently cleaned
- Any fluids inadvertently spilled or dripped onto the cabinet are to be wiped up immediately using a soft lint free cloth

NOTE -Please do not use cleaners containing ammonia or alcohol or abrasive materials, as it may damage cabinet surfaces.

This page may be printed and displayed near the cabinets as a weekly cleaning guide

3.4.2 Cleaning External Surfaces

Cleaning external surfaces:

Wipe down all surfaces with a mild detergent and soft lint free cloth

- Pay particular attention to high human touch-points such as door handles
- If the cabinet is located within an operating room – follow typical procedures for cleaning an operating room
- If the cabinet is located in a scope processing room – follow typical procedures for cleaning a scope processing room

NOTE -Please do not use cleaners containing ammonia or alcohol or abrasive materials, as it may damage cabinet surfaces.

NOTE – Detergent Wipes and or Disinfectant wipes may be used to clean the external surfaces of RotaScope cabinets

This page may be printed and displayed near the cabinets as a weekly cleaning guide

3.4.3 Safe Disposal

Test procedure to facilitate safe disposal of the device and related waste substances

- The Cabinets are manufactured using mostly acrylic plastics, stainless steel and ROHS approved electronic components. Most parts can be substantially recycled for care of the environment. However, the cabinets should be thoroughly cleaned before disposal, and consultation with local recycling parties should be undertaken in accordance with your environmental, infection control and recycling policy.

4 Terms and definitions used in this manual

Term	Meaning
AER	Automated Endoscope Preprocessor (Automatic Scope Washer)
AER	Automatic Endoscope Reprocessor (Scope washer)
Air Intake Filter	The air intake filter) is located in the IAS (Integrated Air System) Housing on top of the cabinet. The Air Intake Filter must be replaced annually by an Authorised Distributor at Annual Service
Annual Service	RotaScope Cabinets should be serviced by way of an annual service contract each year. The service should be performed by an Authorised Distributor. The service will include inspection, calibration if required, and includes the replacement of filters, pumps and is described in detail in the Annual Service Agreement.
Approved Scopes	See list of Approved endoscopes appendix – listing scopes approved as suitable to be dried and stored in RotaScope Cabinets See - ***ApprovedScopeList.pdf***
Cabinet Pressure	The positive pressure inside the cabinet – this should be greater than the adjacent rooms ensuring positive pressured HEPA Filtered Air is always purging out of the cabinet preventing room air from occupying the cabinet The Cabinet pressure can be viewed on the Main Screen of the Cabinet Control Screen located on the cabinet door/s The cabinet air is exchanged approximately 12 times per hour to remove moisture from the cabinet environment and maintain a positive pressure of around > 25Pa pressure
Channels	Also called Endoscope Lumens, Scope Ports, E.g Biopsy, Auxiliary, Air channel, Water channel, Balloon channel, Suction channel – spare/other – to connect to a scope channel colour coded hoses with specialized fitting are used and connect to the scope ports – see Scope Ports
Door Lock	Electronic Door locks are located in the middle of each door behind the door handle – the locks are controlled by an electronic keypad to unlock.
DRY	Allowable Storage Time may also be dependent on local guidelines and should be considered by your HSO policy.

	The recognised description of a DRY endoscope has previously been cited in EN16442:2015 section 6.4.3.1 which states that "to test that a scope has been dried, Compressed air shall be passed through the scope channels and the use of Litmus paper should indicate the evidence of residual water". If scopes are suitably washed, checked, purged and loaded into the RotaScope then residual moisture should never appear on litmus paper when tested in accordance with EN16442 methods. If scopes fail to dry in under three hours in a RotaScope Cabinet, then this should be explored with an Authorised Distributor.
EN16442	European / British Standard - EN16442:2015 - Controlled environment storage cabinet for processed thermolabile endoscopes
GPO	General Power Outlet (Mains Power Point 110/240V)
HEPA Filter	A HEPA Filter (High Efficiency Particulate Absorbing) is located in the IAS (Integrated Air System) housing on top of the cabinet. The HEPA Filter is Class 14 i.e. 99.99% , 0.3um (0.3 Micron) The HEPA Filter must be replaced annually by an Authorised Distributor at Annual Service
Hose Connection Kits	Each stored endoscope needs to be connected to the cabinet airflow system, so that the scope channels (Lumens) are dried internally RotaScope Cabinets require a Hose Connection Kit to be purchased for each type of scope stored The colour coded hoses have a Luer fitting on one end to terminate onto the luer fittings located on the Manifold Block which is on the Centre Pole
Humidity - Cabinet	The humidity inside the Scope Cabinet – this can be viewed on the Main Screen of the Cabinet Control Screen located on the cabinet door/s
IFU	Instruction For Use
Manifold	The Manifold also called the "Vacuum Connection Block" is located on the Centre Pole – The Manifold features Luer connection nipples that connect scope channels via Colour Coded Connection Hoses to the Vacuum air flow for drying the scope channels (Lumens) Match hose colour to the coloured stickers to ensure correct connection
Pass Through	RotaScope Cabinets may be configured with an optional rear door, enabling the cabinet to be installed in-wall, allowing scopes to be loaded on one side (Front door), stored, and unloaded on the

	opposite side (Rear Door) – for improved work flow and infection control
PPE	Personal Protective Equipment
RotaScope Cabinet	An Endoscope Drying and Storage Cabinet. Features include: 9 scope Hang Hooks, independent HEPA filtered Air supply
Scope Connector Hose Kits	Also called "Vacuum Hoses" or "Hose Kits" Colour coded hoses with connection fittings – used to connect the cabinet airflow to various channel connection fittings of an endoscope, to dry endoscope lumens. Bought separately.
Scope Port	Also called Channel Connector, Channel Port, Scope Fitting, Button Ports or other names These connection fittings are small specific fittings on the scope umbilical plug or hand piece – they are used to connect air hoses or blockers to the scope enabling termination to the cabinet airflow or other fittings for flushing the endoscope channels internally.
X-Ray Door Kit	An X-ray proof optional door kit, may be fitted to Pass-Through Cabinets, to assist in the prevention of X-Rays being transmitted through the cabinet

4.1 Graphical Symbols

4.1.1 Explanation of graphical symbols in relation to the product

Symbol	Meaning
	Warning/Caution
	IEC Mains Power Supply
	CE Certification
	Date Of Manufacture
	FCC Compliance
	Instructions For Use Icon
	Indoor Use
	Medical Device
	RCM Compliance

LOT	Batch Number Recorded
RoHS Compliant	ROHS Compliance
SN	Serial Number Recorded
UDI	Unique Device Identifier
⎓	IEC DC Powered

4.2 Personal Protective Equipment

PPE	Instruction
Gloves	To avoid potential contamination of endoscopes and internal surfaces it is recommended gloves are worn while interacting with the inside of a cabinet.
Scrubs	To avoid potential contamination of endoscopes and internal surfaces it is recommended scrubs are worn while interacting with the inside of a cabinet.
Gown	In the instance that scrubs are not in use, to avoid potential contamination of endoscopes and internal surfaces it is recommended gowns are worn while interacting with the inside of a cabinet.
Mask	To avoid potential contamination of endoscopes and internal surfaces it is recommended masks are worn while interacting with the inside of a cabinet.

5 PREPARATION

5.1 How to Transport and Store the Product

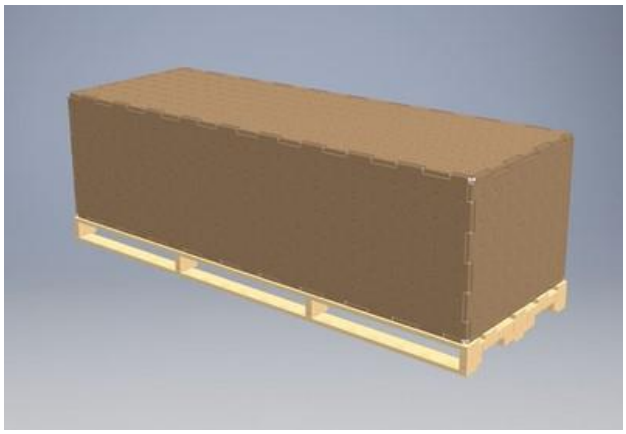
Cabinets and additional parts thereof are delivered in a dismantlable crate. Only suitably trained technicians should attempt the unloading and transporting the items.

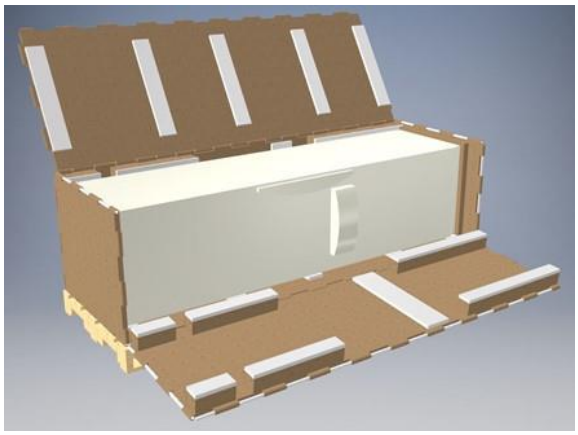
While the cabinet remains in a crate, heavy lifting equipment must be used.

Non-commissioned cabinets should be stored in the corresponding crates or plastic film in a clean and dry area.

⚠WARNING

Do not attempt to lift cabinets without prior education and advice from a suitably trained technician.





The cabinet is delivered in a crate 2453mmL x 852mmW x 775mmH which weighs approximately 190kg

The crate should only be moved with mechanical lifting aids or a forklift

The crate cardboard outer carton can be recycled – other materials should be disposed of in general waste bins

5.1.1 Dimensions, mass and center of gravity

Cabinet Body 600mm Wide x 600mm Deep x 2363mm High including Lid (Top Cap)

Pass Through Cabinet including Control Screen Front and Rear Door 600mm Wide x 760mm Deep x 2363mm High. Approximate Weight RotaScope 160Kg (107kg per m3)

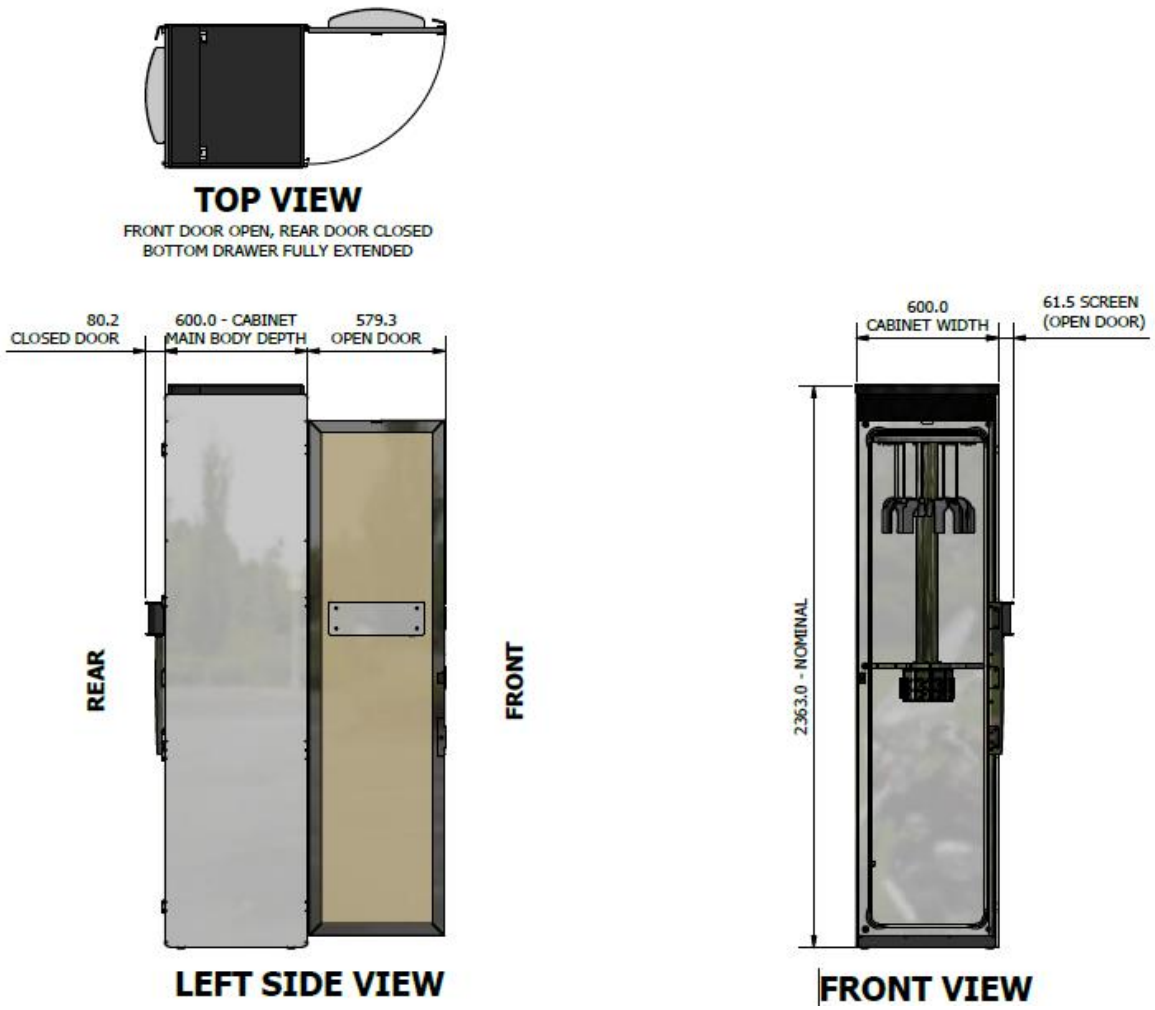


Fig. 3 – Cabinet Body Dimensions – note add depth of Screen or Screens (Front to Rear) for Single or Pass-Through doors

5.1.2 Lifting, handing and transporting the product

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.

As the RotaScope 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.

To lift, handle or transport the product safely:

Only attempt to lift it after receiving appropriate education from an Authorised Distributor
Always use lifting and mobility assistance devices
Never attempt to lift or move a cabinet without assistance (two persons minimum)

Storing the product

RotaScope cabinets should be installed and stored in continuous operating environment ie. Standard office working conditions need to be always provided. Room temperature range 10 C° to 30 C°, relative humidity between 40% and 70%.

To store the product safely:

Keep cabinet in crate until being transferred into desired installed position
If the cabinet needs to be removed from crate prior to install, maintain the protective packaging until install and store in a clean and dry location
Once installed, follow the standard cleaning regime

5.1.3 Storing the product during intervals in normal use

Once installed the cabinet should remain running when not in use and weekly cleaning regime should be maintained. If decommissioned or relocated, the cabinet must be handled and stored appropriately as per this manual and must be reinstalled an undergo a full or partial IQ, OQ and PQ. (Installation Qualification as described in EN16442:2015 Standards)

To store the product during intervals in normal use:

Cover the cabinet in a suitable temporary protective material.
Uncover at time of re-commissioning.
Complete IQ, OQ and PQ

5.1.4 Securing the product against shocks

Only use suitable shock protected power outlets, maintain a test and tag regime on power leads.

5.1.5 Securing the product against electrical shock

- Keep the cabinet free from liquids
- Maintain a suitable install environment
- Indoor use only

5.1.6 Securing the product against impact

- Keep the cabinet protected against hard bumps by people, trolleys and moving objects
- Maintain a suitable install environment
- Do not lean heavy objects against the cabinet

5.2 How to Install the Product

⚠WARNING

Installation of the Cabinet must be only done by a minimum of two suitably trained, approved installation technicians and under the supervision of an Approved Distributor

5.2.1 Removal of the transport and packaging restraints – unpacking the cabinet from the crate

The cabinets arrive on site in a crate which can be fully dismantled.

Follow the steps below to avoid injury:

Instructions to unpack:

⚠WARNING

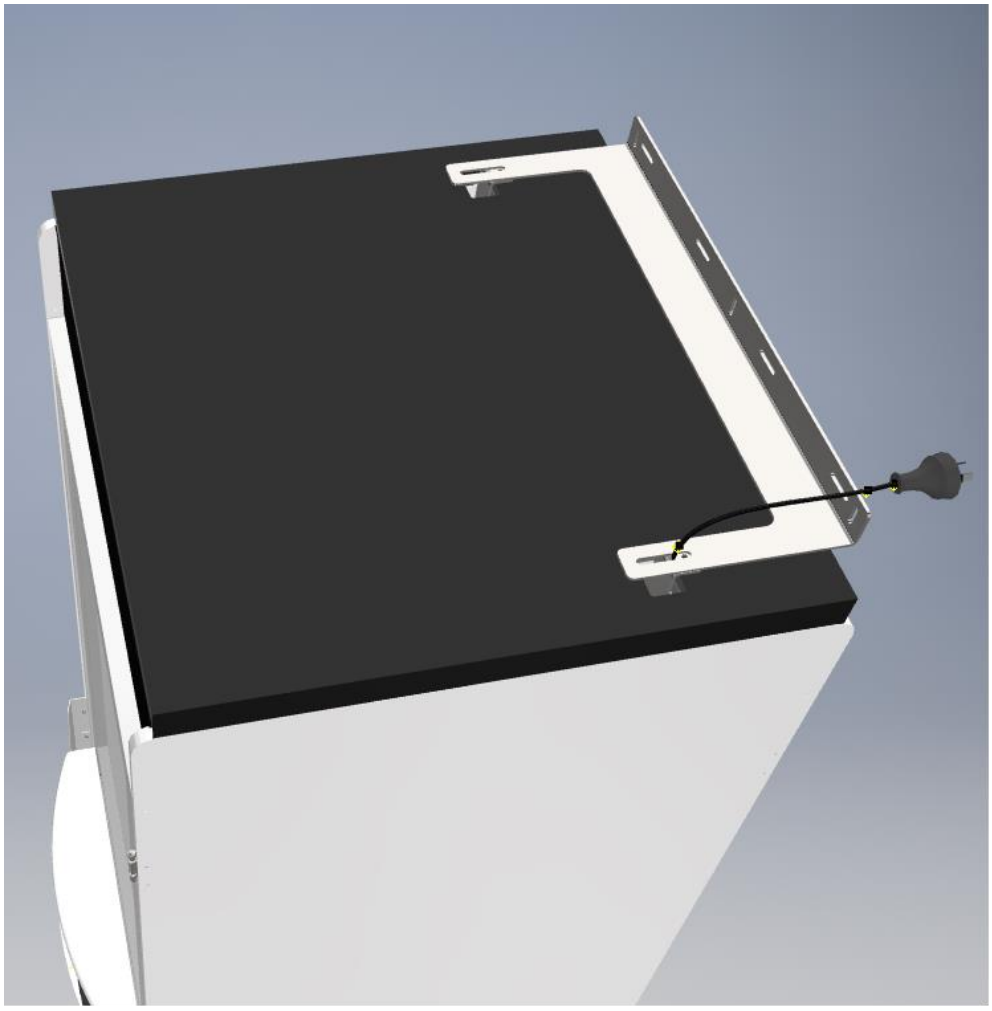
Warning the RotaScope Cabinet is heavy weighing 140 kg

1. Remove the packing straps by cutting the plastic straps with scissors
2. Wear eye protection when cutting straps to avoid eye damage if tight straps stray whilst being cut
3. Remove the outer cartons and dispose of, via a cardboard recycling bin
4. Remove the packing straps from around the cabinet and pallet base - dispose of in a General Waste Bin
5. Remove the cartons located at one end of the cabinet – The Cartons contain Baskets and ancillary devices in cartons – retain for use later
6. Remove the foam packaging edges from the cabinet and dispose of in a General Waste Bin
7. With two people, carefully slide the cabinet base past the end of the pallet so that you can stand the cabinet up
8. With two people stand the cabinet up on its feet and unpack the packaging material (Stretch wrap and foam insulation sheet)
9. Exercise extreme caution and practice safe lifting methods whilst standing the cabinet – dispose of the wrapping in general waste bin
10. Using a suitable lifting trolley or mechanical aids as needed – move the cabinet approximately into position.

NOTE: Not all cabinets have stickers on the cabinet sides as they may be assembled into groups of cabinets – select the appropriate cabinets so that stickers are positioned to be visible when finally installed. Usually, cabinets are numbered with serial numbers or identification – refer to the cabinet floor plan layout provided before install.

5.2.2 Free Standing Cabinet Wall Mount

Single Door cabinets require the top of the cabinet to be mounted to the wall to ensure stability. The supplied bracket should be mounted to the top of the cabinet and secured to the wall, preferably into solid structure or stud. See below.

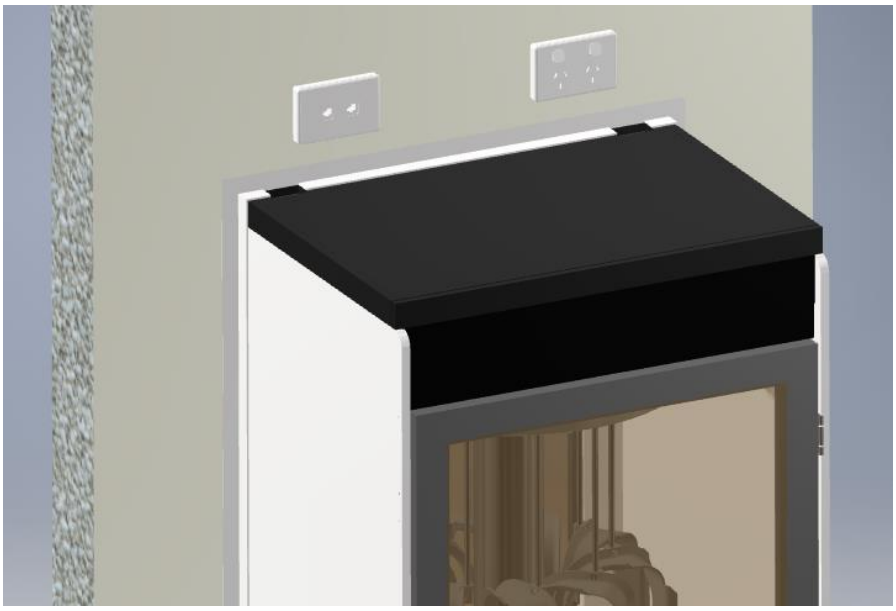


5.2.3 Pass Through Units

If specifically ordered, Pass-Through cabinets may be supplied with a rear door, which includes a display screen, and scanner. The function of the rear door screen is exactly the same as the front door screen. The rear door allows scopes to be loaded in the Reprocessing Room but unloaded in the Procedure Room (Operating Theatre). Power and data points should have been installed during building construction of the wall, so that cables neatly pass from the top of the cabinet to the power and datapoints. Consult appropriate wall cut out drawings in the Smartline Distributor Portal for wall cut out size and GPO positioning.
The cabinets are trimmed and neatly fitted into the wall with small flashings (Cover strips) that seal the cabinet into the wall preventing room air exchanging between the rooms. Ensure these are sealed to the cabinet and wall using silicone or a similar sealant.

Cabinet Front *located in the* ***Reprocessing Room***

Cabinet Rear *seen in the* ***Procedure Room***



X-Ray proof door kit:

If a Pass-Through Scope Cabinet requires an X-Ray proofing, an X-Ray proof Door can be fitted to the cabinet. The shielding complies with a 20kg/m2 Lead equivalence protection level, suitable for most theatres that perform X-Ray functions.

X-Ray Proof Door shown

5.2.4 Power Connection:

1. Depending on the site layout and location of cabinets, plug in any cabinets and refer to the site layout drawing provided prior to install
2. Plug Cabinet power cord into a GPO
3. Check the Cabinet ON/OFF switch (located on the side of the IAS) at the top of the cabinet
4. Cabinet will power up automatically upon receiving power

5.2.5 Packaging contents

The cabinet will come with the following packaging materials:

- Treated timber pallet skid
- Cardboard Outer Carton
- Polystyrene corner foam

- Stretch plastic wrap
- Protective foam sheets
- Protective paper coating

5.2.6 Verification of the product

At completion of install, a cabinet must be verified via the Authorised Distributor using the Smartline Medical approved Auditing Tools for an Installation and Operational Qualification (IQ & OQ) or local standard. Following this, a Performance Qualification (PQ) should be carried out by a suitably trained technician and is the responsibility of the HSO, if required by local regulations.

5.2.7 Minimum space needed.

The cabinet has a total size of 600mm Wide x 600mm Deep x **2363mm** High and requires a minimum of 1200mm Deep and 2400mm Ceiling height and must not be installed less than 100mm from any wall. See diagram below.

Passthrough models require 1800mm deep.

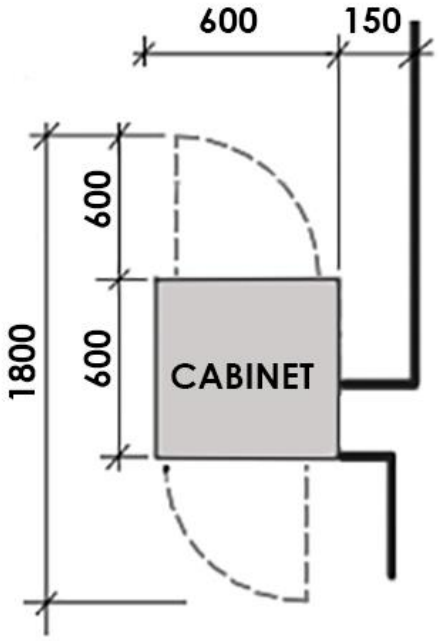


Fig. 4 – Spatial Requirements

5.2.8 Layout plan

Each Install Location requires a layout plan and schematic to be drawn prior to install.

A site layout and install document will be provided prior to installation for each site.

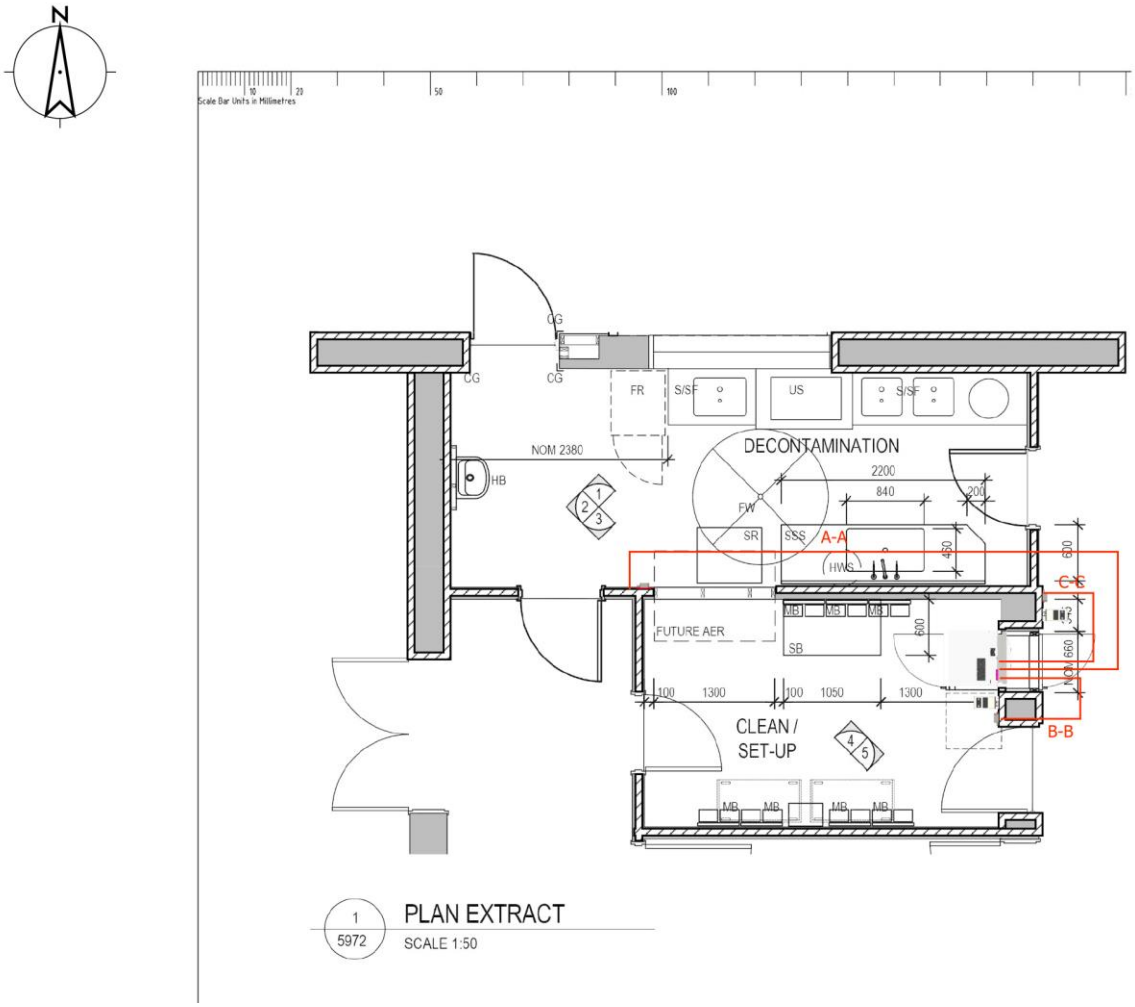


Fig. 5 – Example Layout Plan

5.2.9 Required Tools

⚠WARNING

Never attempt to lift or move a cabinet without the appropriate training and support, always use two technicians to move and lift a cabinet.

Required tools:

- Battery Drill/Driver (Philips Head No2 Driver)
- Level
- Shifter (adjustable wrench)
- Socket set
- Box Cutter (Stanley Knife or similar)
- Platform Ladder
- Dolly Trolley
- Screwdriver set
- Wall plugs (Dry wall anchors - Wall Mates)
- Stud Finder
- Hospital Grade Disinfectant

5.3 How to Commission the Product

Prior to use, the cabinet must undergo thorough disinfection firstly by the Approved Distributor and finally at a clinical level clean should be performed by the Hospital/Departmental Staff.

In-service training will be carried out by an appropriate training provider and is supplemented by video training.

5.3.1 Calibration of the device

⚠WARNING

Calibration of the cabinet will be done firstly inhouse at the commencement of manufacture and is checked again during the Install and Operational Qualification (IQ,OQ) by the Authorised Distributor.

6 OPERATION/USE Verification

⚠WARNING

How to Verify Correct Installation and Operation of the Device:

6.1.1 Verification of correct installation

Follow the IQ and OQ procedure - this should be performed by the Authorised Distributor

6.1.2 Verification of correct maintenance

Manage the annual servicing requirements via an Annual Service Agreement

6.1.3 Verification of correct cleaning/disinfection.

Arrange the correct PQ (Performance Qualification) to be done in accordance with local standard.

6.1.4 Operational environment

The cabinet should only be used indoors and in a controlled environment of 0 – 35 Degrees Celsius

6.1.5 Instruction for devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body

– Not applicable

6.1.6 Starting/Stopping the product operation

To Start and Stop the products operation, simply remove power to the cabinet via the GPO.

Alternatively – a fused power switch is located on the side of the IAS (Integrated Air System) which incorporates the electronic control devices of the Cabinet Control System. The IAS is located on the top of the cabinet behind the removable façade.

6.2 What to Do in Emergency and Exceptional Situations

If the cabinet goes into an alarm state and cannot be rectified, contact your local Authorised Distributor

In case of an emergency:

- Turn off the device
- Contact your local Authorised Distributor

7 MAINTENANCE

⚠WARNING

The RotaScope shall only be maintained by a qualified and trained Authorised Distributor

How to Maintain the Product

7.1.1 Planned maintenance of RotaScope.

Maintenance tasks shall be done according to the following plan:

Task	Frequency
Replacing the Intake Filter	Every 12 months
Replacing HEPA Filter	Every 12 months
Replacing the Air Pumps	Every 24 months

7.2 How to Inspect the Product

7.2.1 Weekly inspection tasks

Task	Action
Weekly Cabinet Clean	Use Hospital Grade Disinfectant to wipe over every internal surface of the cabinet as per the IFU in this manual
Weekly Scope Hose Connection Set Clean (Clean Hoses or swap-out with a previously cleaned hose kit)	Remove and replace hoses from cabinet and have them disinfected using the manual or automated disinfection process as per the IFU in this manual

8 TROUBLESHOOTING AND REPAIR

⚠WARNING

All repairs should be done by an Authorised Distributor.

8.1 How to Identify and Solve Problems

8.1.1 Troubleshooting and repair by non-skilled persons

If an issue cannot not be resolved by the following troubleshooting guide, please contact your Authorised Distributor and a service technician will be in contact to troubleshoot or attend your site if required.

Error	Cause	Solution
Product does not start	Power Failure / Blown Fuse / Electronic Failure	Restore Power and reset via "Alarm Acknowledge Button" on Cabinet Control Screen Or replace a part via a service technician
Cabinet WHITE Lights Stays On	Door Open	Close Door
Door will not unlock	1. Passcode 2. Battery	1. Refer to lock manual https://awm.net.au/wp-content/uploads/2018/03/MINIK10-User-Manual-2020.pdf 2. Refer to lock manual https://www.minik10.com.au/_files/ugd/4303d3_15010d006da84c6da74c28cb4765897a.pdf

8.2 Repair

8.2.1 Repair by skilled persons

⚠WARNING

All repairs must be done by an Authorised Distributor.

9 DISPOSAL

Prior to disposal, the cabinet must undergo a thorough disinfection.

9.1 How to Disassemble the Product

To disassemble the product:

Disassemble the Cabinet into obvious assemblies using basic hand tools

a) Remove Acrylic Lid Top Caps – separate with other Acrylic materials e.g. Cabinet Body
b) Remove Aluminium Doors and Discard Door Seals – remove acrylic clear panel and group with acrylic parts – separate door control screen housing assembly – group aluminium door with metal items – group steel handle with metal parts - remove hinges and group with metal parts - group acrylic panel with other acrylic items e.g. cabinet housing – remove door lock and cables and group with electrical items
c) Remove rear Closing Panel and Discard Door Seals
d) Remove IAS – separate Acrylic lid and housing from electrical parts – group Acrylic with other Acrylic parts – group electrical parts – dispose of insulation, stickers, filter, and silicone hoses
e) Remove Stainless parts and group with metal parts
f) Remove Acrylic Centre Disks - Group disks with other Acrylic parts – remove manifolds and separate electronic boards with electronic parts – remove manifold body parts and group with Acetal plastic parts – discard plastic luer nipples and silicone seals
g) Remove stainless steel air tube from cabinet body – group metal parts
h) Remove remaining electrical cables and cable glands and ducting from cabinet and group electrical components with other electrical components – dispose of ducts and cable glands
i) Remove cabinet leveling feet and group with metal parts, dispose of plastic feet caps
j) Acrylic Cabinet Shell - Remove external stickers and any remaining decals, screws or miscellaneous items – dispose of stickers and decals – group any reaming items e.g. electrical or metal
k) All metal screws can be grouped with metal objects

Group the remaining materials in matched groups – Acrylic plastic parts, metals, electrical cables, electronic boards, batteries, Acetal manifolds,
Make safe the storage of grouped items for assessment by various disposal or recycle agents

9.2 How to Recycle Parts

See in conjunction with 8.3 Safe disposal of product

To recycle part A: Acrylic Plastics

1. Contact a plastic recycling company
2. Gather and Assess Acrylic Plastic with representative
3. Dispatch goods to recycle company as agreed upon inspection

To recycle part B: Metals

1. Contact Metal recycling Company
2. Gather and separate all metals into types – eg Stainless steel – Mild Steel – Aluminum – Assess metals with representative
3. Dispatch goods to recycle company as agreed upon inspection

To recycle part B: Electrical/Electronic

1. Contact an electrical parts recycle Company
2. Separate and gather electronic control boards motors, cables and fittings – assess with a representative
3. Dispatch goods to a recycle company as agreed upon inspection

9.3 How to Dispose the Product

⚠WARNING

9.3.1 Test procedure to facilitate safe disposal of the device and related waste substances

Devices are designed and manufactured to facilitate safe disposal and the safe disposal of related waste substances by the user, patient, or other people. Manufacturers have identified test procedures and measures relating to disposal, so devices can be safely disposed after use. Such procedures are described below.

To test the product before disposal:

1. Ensure that the product and accessories were cleaned and disinfected prior to disposal.
2. Confirm that cleaning was done.
3. Confirm that the person responsible for disassembly and disposal, have been advised that the product is clean and safe to dispose of.

9.3.2 Disposal of the device

To dispose the device: Confirm that your facility has resources and trained personnel to disinfect than disassemble the product for selective recycling in conjunction with selected recycling representatives.

9.3.3 Disposal of waste substances:

⚠WARNING

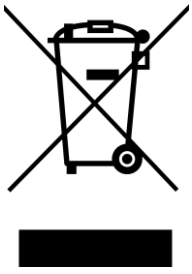
- Confirm all items have been cleaned and disinfected prior to disposal
- Check recycling labels for instruction
- Only dispose of items that are for general waste and not to be recycled
- Discard general waste via HSO waste policy

9.3.4 Disposal of electronic components

The symbol on the product, the accessories or packaging indicates that this device must not be treated as unsorted municipal waste but must be collected separately! Dispose of the device via a collection point for the recycling of waste electrical and electronic equipment if you live within the EU and in other European countries that operate separate collection systems for waste electrical and electronic equipment. By disposing of the device in the proper manner, you help to avoid possible hazards for the environment and public health that could otherwise be caused by improper treatment of waste equipment. The recycling of materials contributes to the conservation of natural resources. Therefore, do not dispose of your old electrical and electronic equipment with the unsorted municipal waste.

To dispose electronic components:

1. Separate electronic components
2. Identify the type of product or seek advice on disposal from an expert
3. Dispose of according to HSO waste disposal regulation



9.3.5 Disposal of packaging waste

The packaging is made of environmentally friendly materials, which may be disposed through your local recycling facilities. By disposing of the packaging and packaging waste in the proper manner, you help to avoid possible hazards for the environment and public health. The symbol on the packaging indicates what the packaging material is made of.

To dispose packaging waste:

1. Separate materials into wood, cardboard, metal, general waste
2. Check HSO waste management guidelines
3. Recycle and dispose of product by category

10 APPENDIX I – SUPPLIED ACCESSORIES, CONSUMABLES AND SPARE PARTS

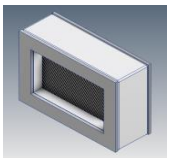
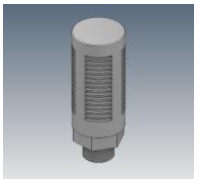
10.1 Supplied accessories

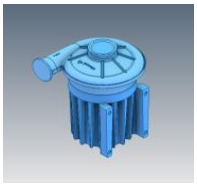
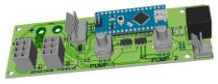
Image	Name	ID
	Hose Connection Kits	Various
	Labels	N/A

10.2 Consumables

Image	Name	Part Number
	Tip Protector	TIP PROTECTORS
	Channel Separators	See Authorised Distributor

10.3 Spare/replacement parts

Image	Name	Part Number
	FUSE 6.3A – Fuse holder at IEC Power Cable Socket	Contact Smartline
	HEPA Filter in IAS	HEPA FILTER H13
	Intake Air Filter in IAS	47.AN302

	Air Pump x2 in IAS	MINIATURE RADIAL BLOWER
	Pump Motor Control Board in IAS	MOTOR CNTRL BOARD 24VDC
	24v Transformer in IAS	TRANSFORMER MCC 24V

11 DECLARATION OF CONFORMITY FOR CLASS I DEVICE

Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III

Unique identification number of this Document: See Document no. F-218

Manufacturer Detail

Business name:	**Smartline Medical**
Registered trade name or trademark:	**Smartline Medical Pty Ltd**
Address:	**55 Cordwell Rd, Yandina Qld, 4561**
Country:	**Australia**

Declare under our sole responsibility that the device:

Basic UDI-DI:	**9356523xxxx**
Device name/Trade name:	**RotaScope Cabinet**
Product code:	**ROTA-CO**
Catalogue number:	**N/A**
Intended purpose:	**A dedicated range of cabinets designed to dry and store flexible endoscopes in a clean storage environment that prevents bacterial growth after processing. Scopes are dried internally and externally by independently supplied clean HEPA filtered forced air. The cabinet is environmentally controlled to ensure scopes can be used directly without need for re-disinfection. The product is also equipped with clear doors (single door, pass through, or pass through X-Ray) and the option of either hooks or shelves to place several endoscopes. The product is approved for 31 days of continuous storage if an EN16442 model is selected.**

Object (colour image):

Complies with CE European Directives 2021 – see F218

CE Declaration of Conformity 2021: P1

+61 7 5478 9977
www.SmartlineMedical.com
PO. Box 532, Buderim Qld 4556
55 Cordwell Road, Yandina Q 4561

CE MARK

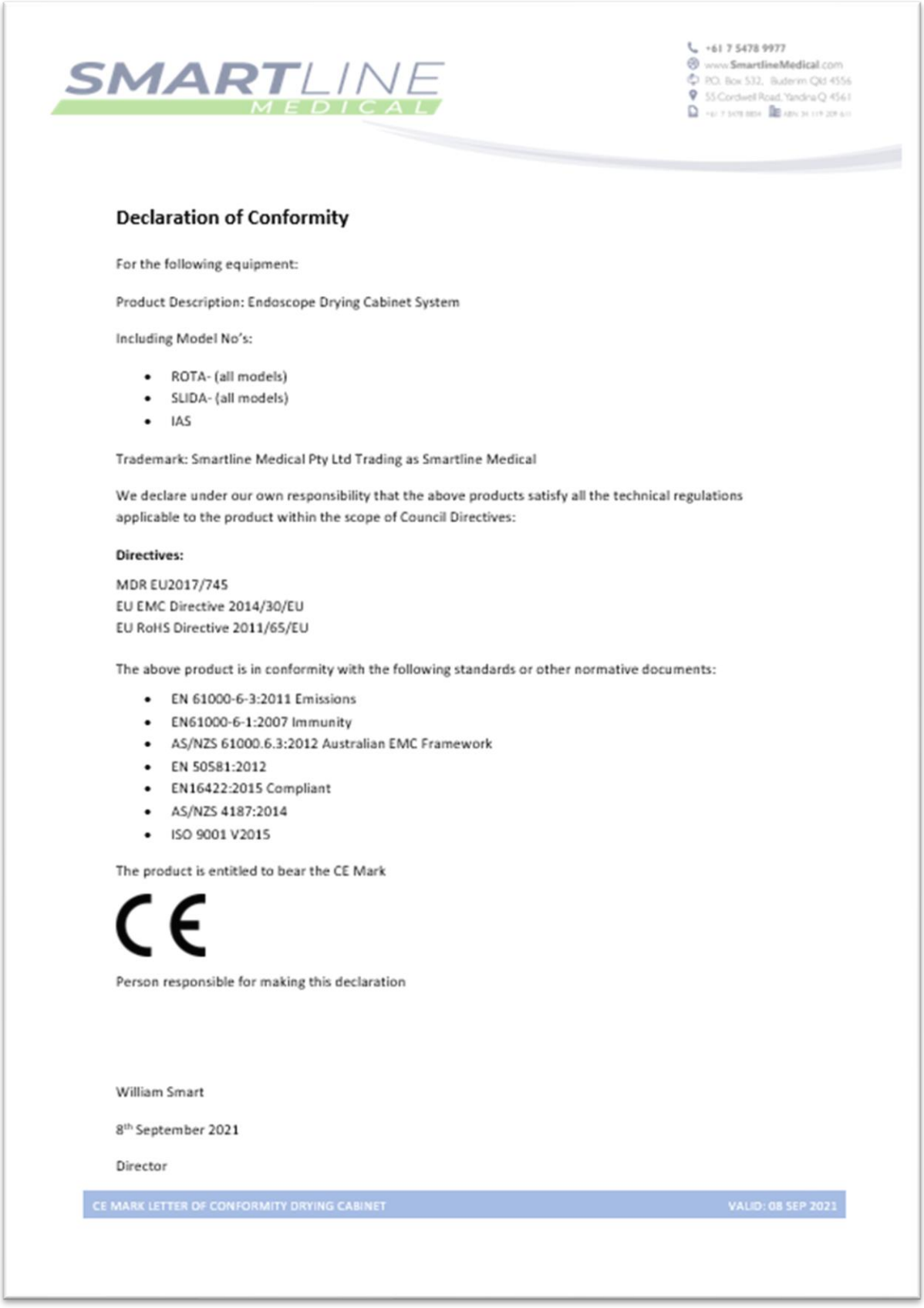
LETTER of CONFORMITY

PRODUCT

ENDOSCOPE DRYING CABINET SYSTEM

CE MARK LETTER OF CONFORMITY DRYING CABINET VALID: 08 SEP 2021

CE Declaration of Conformity 2021: P2



SMARTLINE MEDICAL

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PO Box 532, Buderim Qld 4556
55 Cordwell Road, Yandina Q 4561

Declaration of Conformity

For the following equipment:

Product Description: Endoscope Drying Cabinet System

Including Model No's:

- ROTA- (all models)
- SLIDA- (all models)
- IAS

Trademark: Smartline Medical Pty Ltd Trading as Smartline Medical

We declare under our own responsibility that the above products satisfy all the technical regulations applicable to the product within the scope of Council Directives:

Directives:

MDR EU2017/745
EU EMC Directive 2014/30/EU
EU RoHS Directive 2011/65/EU

The above product is in conformity with the following standards or other normative documents:

- EN 61000-6-3:2011 Emissions
- EN61000-6-1:2007 Immunity
- AS/NZS 61000.6.3:2012 Australian EMC Framework
- EN 50581:2012
- EN16422:2015 Compliant
- AS/NZS 4187:2014
- ISO 9001 V2015

The product is entitled to bear the CE Mark

CE

Person responsible for making this declaration

William Smart

8th September 2021

Director

CE MARK LETTER OF CONFORMITY DRYING CABINET VALID: 08 SEP 2021

RELATED DOCUMENTATION

#	Document Title	Version #	Location	Author
1	ApprovedScopeList.pdf	Aug 2021	sales@smartlinemedical.com	DW
2	CE Declaration Of Conformity F-218 V1	V1	sales@smartlinemedical.com Attached	WS
3	Workflow Overview	2021	sales@smartlinemedical.com Attached	DM

NOTE: This Manual will be frequently updated with additional information FAQ questions and more – please refer to your Authorised Distributor for updated versions