1.21.1

MEDIVATORS® ISA®

Endoscope Reprocessor

1.21.1

PRODUCT DATA SHEET

MEDIVATORS
A Cantel Medical Company

Technological categories

Supplying company	Medivators Inc.
Device model	MEDIVATORS® ISA® Endoscope Reprocessor
Manufacturer	Cantel Medical (Italy) S.r.l.
Year in which the model started production	2015
Year in which the model was first marketed	2015
Intended use	Room temperature chemical washer-disinfector for endoscopes and endoscope accessories

Certifications and regulations

The device complies with all European and international standards currently applicable indicated below:

Complies with the Medical Device Directive	93/42 EEC and updates
Medical device category in compliance with Directive 93/42/EEC and updates	II b
Complies with the following CEI standards	CEI EN 61010 CEI EN 61010-2-040 CEI EN 61326-1 CEI EN 62366
Complies with the following UNI standards	UNI EN ISO 15883-1 UNI EN ISO 15883-4 UNI CEN ISO/TS 15883-5
Notified Body and EC Certificate (Medivators ISA - DM EC 0051)	IMQ, Certificate Nb. 1812/MDD
Notified Body and EC Certificate (Chemicals - DM EC 0546)	CERTIQUALITY, Certificate Nb. 995/CE001/2
Certification of the Manufacturer's Quality System	Certiquality Certificate Nb. 1050 - UNI EN ISO 9001 Certificate Nb. 995 - UNI CEI EN ISO 13485

General characteristics of the system

Medivators ISA turi didelę talpą, kurioje galima plauti/dezinfekuoti lanksčius ir kietus endoskopus

1.1	**Reprocessing chambers**	MEDIVATORS® ISA® Endoscope Reprocessor has a large basin for the reprocessing of flexible or rigid endoscopes and endoscope accessories.
	Plaunamų endoskopų skaičius	
1.2	**Number of reprocessible endoscopes**	One flexible or a one rigid endoscope. Vienas Lankstūs, arba kietas endoskopas
1.21.5	**Endoscope brands compatibility**	All brands of endoscopes on the market (Olympus, Pentax, Fujifilm, Karl Storz, etc.)
1.15	**Endoscope loading type**	Top loading Suderinama su visų gamintojų endoskopais (Olympus, Pentax, Fujifil, Karl Storz) Endoskopo pakrovimas iš viršaus
	Operating conditions	Reprocessing is carried out at room temperature (25 ± 5° C). Temperature control is ensured by 2 PT-1000 probes located inside the basin.
1.6	**Endoscope leak test**	The system automatically carries out the leak test at the start of the cycle and checks that the correct pressure is maintained throughout the entire reprocessing cycle. If anomalies are found, the cycle is immediately interrupted, keeping the endoscope safe.
	Nuotėkio testas viso ciklo metu Esant nuokrypiui plovimo ciklas nutraukiams	
	Inspection of channel connection and patency Kanalo jungties tikrinimas	Continuous and individual monitoring of flow in each single channel. Pastovus individualus kanalų monitoravimas
1.7	**Type of endoscope connections**	The device has an interlocked connection system that allows the endoscope to be connected to up to 6 channels + 1 auxiliary channel + leak test.
	Monitoruojamų kanalų kiekis 6.	
1.3	**Contact with chemical products**	Double washing/disinfection system: immersion and spraying (spray arm)
	Self disinfection cycle	Manual self-disinfection cycle programmed with automatic start.
	Isopropyl alcohol cycle	It is possible to select a full cycle or disinfection only cycle with alcohol.
1.4	**User interface**	15” touch-screen color monitor for the management of the user interface and cycle parameters input. 15" Prisilietimui jautrus ekranas
	vartotojo sąsaja	
	Printer	Built-in
	Operator and endoscope recognition through RFID system	Yes, supplied as standard.
1.14	**Basin opening and closing system**	By foot switch control. Dubens atidarymas- Kojinis jungiklis
	Alarm management system	Notification of alarms with a failure type description of and possible solutions to allow the operator to identify immediately the type of problem and if possible its resolution; all alarms are also entered at the end-of-cycle report to avoid usage of incorrect reprocessed instruments.
	Moving the machine	The device is equipped with anti-static swivel casters for easy moving, facilitating cleaning, maintenance and transportation.

Sistema automatiškai atlieka nuotėkio testą ciklo metu ir patikrina ar viso plovimo metu išlaikomas tinkamas slėgis

Dvigubo plovimo/ dezinfekavimo sistema: panardinimas ir apipurškimas

Used Chemical solutions

1.11	**Description of validated chemical solutions** Cheminės priemonės aprašymas	Tests carried out to validate the washing and disinfection processes in the MEDIVATORS® ISA® Endoscope Reprocessor confirm the efficacy of processes using only the following chemical solutions: **Detergent/Decontaminant:** - ISACLEAN™ Detergent; **High level disinfectant/ sterilant:** - ISASPOR® Single Shot Disinfectant; Neperdirbamos dezinfekcijos priemonės Detergent and High Level Disinfectant/Sterilant solutions are single-shot and are automatically dispensed.
1.13	**Detergent solution** Plovimo priemonė	ISACLEAN Detergent, Multi-enzymatic concentrated solution, active on microbial biofilm
	Detergent tank capacity	1 tank of 10 l Enziminis ploviklis
	High level disinfectant sterilant Aukšto lygio dezinfekcijos priemonės	ISASPOR Single Shot Disinfectant, concentrated 5% peracetic acid solution (Sol. A) and ISAZONE® ingredient (Sol. B) Peracto rūgštis
	High Level disinfectant/sterilant tank capacity	2 tanks of 10 l (Sol. A+ Sol. B) Or alternatively, 2 tanks of 5 l (Sol. A + Sol. B)
1.17.3	**Quantity of chemical solutions used per cycle** Chemikalų kiekis vienam ciklui	190 ml of high level disinfectant/sterilant Dezinfekanto sunaudojimas 190ml ISASPOR Single Shot Disinfectant **Solution A** 190 ml of high level disinfectant/sterilant ISASPOR Single Shot Disinfectant **Solution B** 16 ml of ISACLEAN detergent Ploviklio sunaudojimas
1.17.2		
	Recommended Process temperature	25 ± 5°C
	Disposal of chemical solutions	At the end of every disinfection cycle, used and waste solutions are discharged directly in the sewage system without need for further treatment, in accordance with the existing standards.

1.21.4

Description of cycles

Type of selectable cycles 1.12	**Standard cycles:** Plovimo – dezinfekcijos ciklo trukmė 20 min. 1. Complete cleaning-disinfection cycle (20* min.); 2. Disinfection-only cycle (12 min.); 3. Self-Disinfection cycle (20 min.). Additional cycles can be added to provide changes only to non-critical parameters and/or if a final alcohol purging phase (optional) is required. *In optimal operating conditions
Complete cleaning-disinfection cycle	**Complete cleaning-disinfection cycle (20 min. long)** 1. Initial leak test 2. Water and detergent load 3. Cleaning 4. Draining 5. Water load 6. Rinsing 7. Draining 8. Water and disinfectant solution load 9. Disinfection 10. Draining 11. Water load 12. Rinsing 13. Draining 14. Purge of endoscope channels
“Disinfection cycle”	**Disinfection cycle (12 min.)** 1. Initial Leak test 2. Water and disinfectant solution load 3. Disinfection 4. Draining 5. Water load 6. Rinsing 7. Draining
Auto-disinfection cycle	**Self-disinfection cycle (20 min.)** 1. Initial Leak test 2. Water and disinfectant solution load 3. Sterilization 4. Draining 5. Water load 6. Rinsing 7. Draining 8. Purging
1.19 **Volumes of water used per cycle**	Complete cycle 31 liters Vandens sunaudojimas per ciklą 31 L Disinfection cycle 17 liters Self-disinfection cycle 17 liters

Water/air filtering system

Water filters provided	1st stage 0.45 µm filter 2nd stage 0.1 µm filter
Water filter life cycle	4 months
Air filters	0.2 micron N. 1 purging air filter 0.2 micron N. 1 leak test air filter
Air filter life cycle	4 months
Monitoring filter life	Visualization of last change and time to the next change for each filter. The system will inform the operator for any expired filter through a “maintenance” alert.

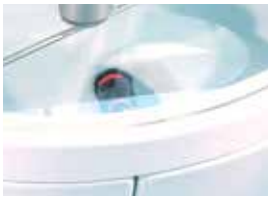
Traceability

RFID system	The device guarantees the traceability of endoscopes, operators products through the RFID system.
1.9 1.10 **Software for archiving and ensuring the traceability of washing/disinfection processes (electronic traceability)**	Visual display monitoring of devices undergoing washing/ disinfection with attached count down to the end of cycle. For every cycle data are printed and stored in the PC internal memory. Data can be exported on an external drive.
Registering and printing washing/disinfection cycle data Programinė įranga skirta archyvavimui ir plovimo/ dezinfekavimo procesų sekimui	**Parameters included in the print-out:** • Serial number of device • Date • Cycle starting and ending time • Progressive cycle number • Cycle type • Endoscope data (Model, serial number, ID etc.) • Physician (optional) • Patient (optional) • Operator starting the cycle • Cycle phases with relative contact times • Operator inserting the instrument • Cycle outcome • Operator taking out the endoscope Kiekvieno ciklo metu duomenys surenkami ir išsaugomi PC vidinėje atmintyje, Duomenys gali būti eksportuoti į išorinį diską

Operator safety

The device guarantees high standards of operator safety:	**1. Hands-free operation and RFID system:** Using an endoscope-operator RFID system reduces significantly or eliminates the chance of infection by contact, accelerates endoscope loading / unloading operations and reduces the possibility of errors.
	2. Substituting chemical solutions: The chemical solution substitution procedure does not require any handling by the operator of the chemical products used. As stated in the user manual, when changing product tanks, wear PPE clothing, gloves and protective goggles.
	3. Closed system: The device operates in a closed system and does not require air suction systems because it operates at room temperature and with low concentrations of peracetic acid. It is possible to connect the device to an air suction system by means of the appropriate duct placed on the back of the device.





Accessories

Accessories provided	1 Self disinfection connection kit
Accessories on demand	• Endoscope connectors • Thermostatic Mixing valve • Air compressor • Kit medical device compliant to EN 1717 • Isopropylic alcohol at 70%

DESCRIPTION OF THE TECHNICAL SPECIFICATIONS OF THE MEDIVATORS® ISA® ENDOSCOPE REPROCESSOR

- **Dimensions (LxHxP)**
  70 cm x 102,5 cm (140 cm with display) x 65 cm
  Dydis su monitorium 70 x 65 x 140 cm
- **Weight**
  ~ 75 kg

- **Electric power supply**
  The required electric power supply must be single-phase between 100V and 240V with a 50/60Hz frequency range.

- **Nominal power**
  Maximum power is 300W
  Maksimali suvartojama elektros energija 300 W
- **Compressed air**
  MEDIVATORS® ISA® Endoscope Reprocessor must be connected to an oil-free compressed air system with pressure between 4 and 6 bar and a minimum flow rate of 20 l/min.
  A stainless steel connection with a hose fitting for a 5mm diameter tube has been provided on the device as a standard accessory.
  Should there be no oil-free compressed air system, an oil-free medical compressor can be installed (optional).

- **Water supply**
  The water supply for the medical device must be “potable” with hardness values between 8°fH and 50°fH (4,5°–28°dH, 80–500 ppm) at a temperature between 20°C and 30°C (provided by means of a thermostatic water mixing valve) at a pressure of maximum 4 bar and with a flow rate of 10 l/min. A connection with 3/4” joint is provided. The filling tube is included with the WD. A back-siphonage prevention mechanism that complies with the requirements of IEC 61770 is included.

- **Draining the machine**
  The device is equipped with a hose fitting connection for the drainage tube to connect to the drainage system by means of a flexible tube provided as a standard feature.
  The maximum height above ground for the drainage duct must be 510 mm.

- **Operating ambient humidity**
  The accepted limit for proper use of the device should be less than 80% humidity (non-condensing).

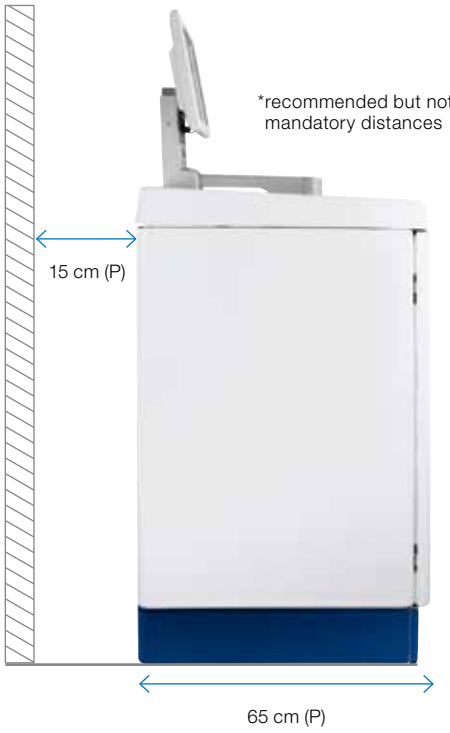
- **Operating temperature**
  The Room operating temperature of for MEDIVATORS ISA Endoscope Reprocessor cannot be less than 5°C or more than 40°C .
  For the system to function properly, it should must not be located close to heat sources.

- **Environmental emissions**
  MEDIVATORS ISA Endoscope Reprocessor, which operates in as a closed circuit, does not release emissions into the environment. In any case, the emissions that may occur when replacing tanks or opening the basin do not have toxic or harmful effects on humans. It is recommended to install the device in rooms with adequate ventilation (10 air changes per hour)

- **Transportation and storage**
  MEDIVATORS ISA Endoscope Reprocessor must be maintained and stored in compliance with the following conditions: 5–40°C temperature, 20–80% humidity and 500–1060 hPa pressure

- **Drainage duct height**
  max. 51 cm

DIMENSIONS



Dubens dydis 60 x 70 cm

MEDIVATORS
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REMOVING THE ENDOSCOPES FROM THE BASIN

To correctly remove the endoscope from the basin, proceed as reported below:

1. Wear personal PPE.
2. Proceed with operator recognition by bringing the operator tag close to the RFID A reader as reported below.
3. Disconnect the connecting tubes from the relevant endoscope channels.

1.14

4. Disconnect the mobile interconnection block from that fixed to the basin by turning the red lever on the mobile interconnection block clockwise until open.
5. Remove the endoscope from the basin.
6. Close the basin cover using the pedal (black band present on the lower part of the equipment). This will be followed by a short acoustic signal confirming the command has been implemented.

ENDOSCOPE TREATMENT CYCLES

The MEDIVATORS® ISA® Endoscope Reprocessor has numerous cycles that are validated for the treatment of endoscopes, as reported in the following table (Table 1).

The self-disinfection cycle refers to sterilization of the circuit and the water filters.

Cycle	Duration	Description
Complete Disinfection	20 min	Washing and disinfection cycle
Complete Double Clean Disinfection	25 min	Double Washing and disinfection cycle
Disinfection	12 min	Disinfection cycle only, with no cleaning
Self-Disinfection	20 min	Internal circuit sterilization cycle

Table 1. The MEDIVATORS ISA Endoscope Reprocessor pre-set cycles

It is also possible to perform a final drying cycle using isopropyl alcohol (optional).

INTERNAL COMPONENTS

Figure 4
Chemical solutions and alcohol (optional) of the MEDIVATORS® ISA® Endoscope Reprocessor.

❶ **Alcohol Bottle (optional):** The alcohol bottle is located to the upper right inside the front housing.

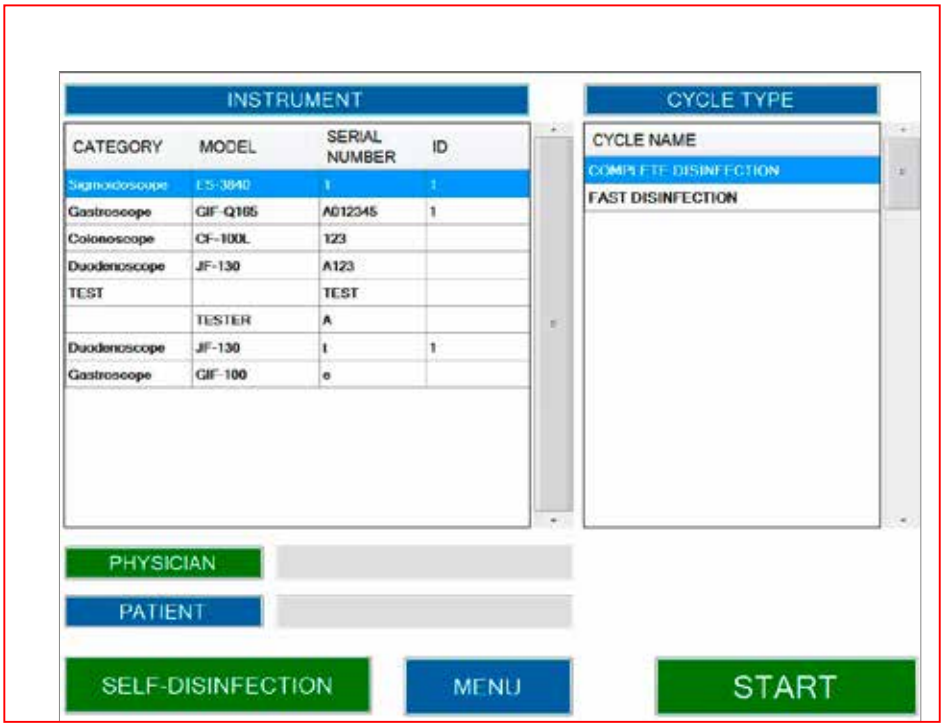
❷ **Tank – Part A:** Contains Solution of 5% peracetic acid.

❸ **Tank for– Part B:** it contains Buffer

❹ **Detergent Tank:** This contains the detergent used in the washing process.

Insert the personal ID code. This then opens the cycle select page:

1.5.1



Norėdami pasirinkti atliekamo ciklo tipą, vieną kartą paspauskite virš vykdomo ciklo pavadinimo

1.5.1 To select the type of cycle to be performed, press once above the name of the cycle to be run so as to display the corresponding line. Press the instrument to be reprocessed once so as to display the corresponding line.

Once completed, press the START button to start the cycle.

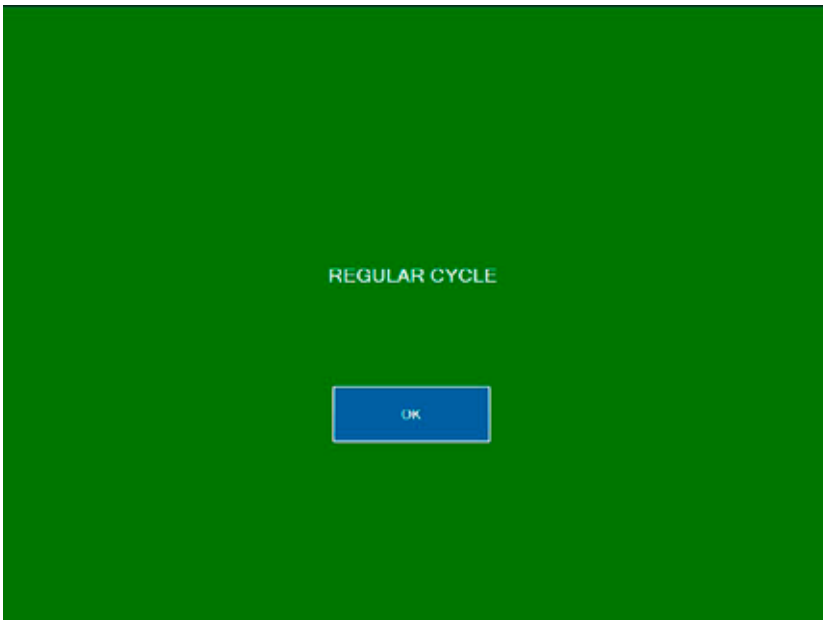
On this page, there are two OPTIONAL panels indicating the physician and the patient, in the case of use, the text inserted here will be printed in the cycle report.

With regard to the PHYSICIAN, pressing the LIST button to the right of the white line makes it possible to select one of the options previously included in the list.

CYCLE END PROCEDURE

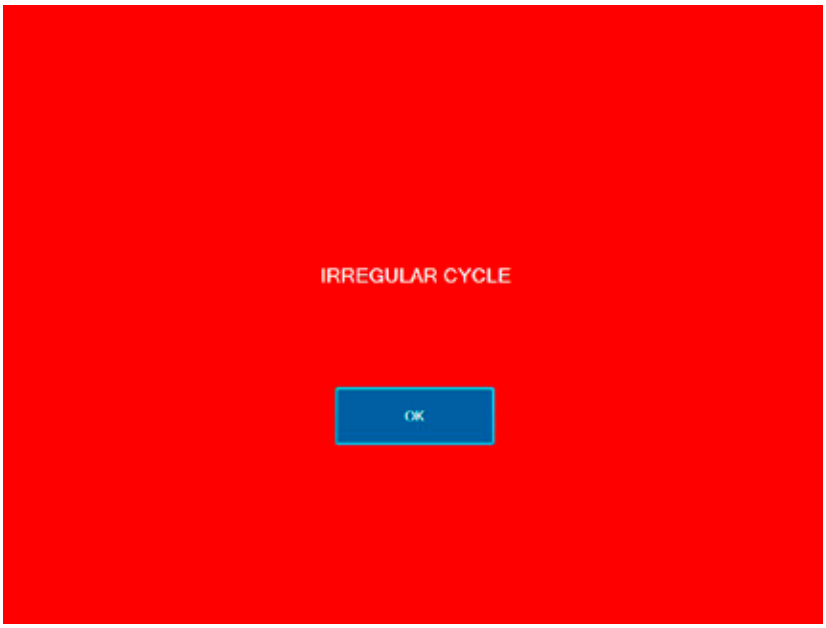
1.14 Pasibaigus ciklui, negalima atidaryti dangčio, kol nepaspaudžiamas mygtukas OK.

1.5.3 On completion of a cycle, it is not possible to open the cover until the OK button is pressed. In the case of a regularly completed cycle, the green "REGULAR CYCLE" screen appears, accompanied by an acoustic signal, indicating the correct conclusion:



In the case of an irregularly completed cycle, a red "IRREGULAR CYCLE" screen appears, accompanied by an acoustic signal, indicating the incorrect conclusion (this sound is different from that for a regular cycle):

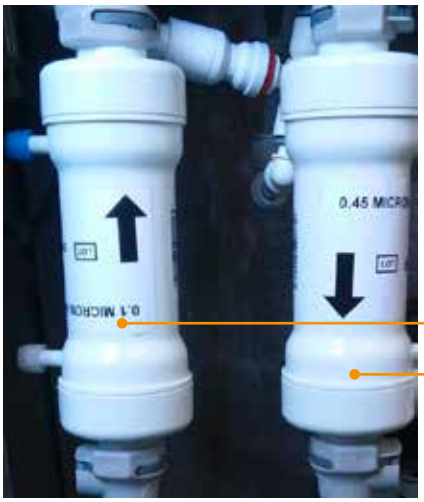
Again in this case, it is not possible to remove the endoscope until the OK button is pressed.



FILTRATION SYSTEMS

MEDIVATORS ISA yra sukomplektuotas su vandens ir oro filtravimo sistema, galinčia garantuoti įrenginio efektyvumą.

1.16 The MEDIVATORS® ISA® Endoscope Reprocessor is equipped with a water and air filtration system capable of Warrantying the efficacy of the reprocessing cycles performed.



1. 0.1 MICRON
2. 0.45 MICRON

Water filter

- The device is equipped with a dual water filtration system:
- 0.45 micron water filter capsule;
- 0.1 micron water filter capsule;
- A pair of water filters are supplied with the equipment on installation.
- Replacement of both water filters is scheduled with a frequency of 6 months.
  However, the lifespan of the water filters might be less than expected due to poor water quality at the installation site.

Code	Description
93250-222	Water Filter Kit Colder (0.1 µm + 0.45 µm)

Replacement of the water filters must be performed by qualified technical staff authorized by the manufacturer. Otherwise the efficacy of the washing and sterilization processes is NOT Warrantyd.

Any damage resulting from failure to replace the water filters and/or the use of NON ORIGINAL filters and/or operations performed by NON authorized personnel will invalidate any type of Warranty. The use of filters other than those indicated by the manufacturer does NOT Warranty the efficacy of the washing and disinfection processes.

INTENDED USE OF THE MEDIVATORS® ISA® ENDOSCOPE REPROCESSOR

The MEDIVATORS ISA Endoscope Reprocessor is a medical device designed for the cold chemical washing and disinfection of rigid and flexible endoscopes and endoscopic accessories.

The MD must NOT be used for any purposes not envisaged by the manufacturer and/or NOT reported in the present manual.

THE MAIN CHARACTERISTICS OF THE MEDIVATORS ISA ENDOSCOPE REPROCESSOR INCLUDE:

- Configuration conforming with the current European regulations and international standards UNI EN ISO 15883-1/4 and UNI CEN ISO/TS 15883-5.
- A personal and touch-screen computer (PC) dedicated to the user interface and recording of the cycle parameters.
- A spacious basin for the reprocessing of endoscopes and/or endoscopic accessories.
- The possibility to have a drying cycle with alcohol (optional).
- The use of safe and validated single shot detergent and sterilizing/disinfectant chemical solutions, compatible with the various brands of endoscope available on the market.
- A validated process (equipment and chemicals) for use at room temperature.
- Continuous monitoring of the channel pressure, the flow rates in the channels and the general parameters throughout the entire cycle.
- A rapid and unique interconnecting system for the endoscope channel connectors Warrantying the proper control of flow rates in the endoscope channels.
- Operator and endoscope recognition system using RFID (Radio-Frequency Identification).
- The possibility to perform the self-disinfection cycle using programmable automatic start-up.
- Air filtration system capable of Warrantying the complete sterility of the process, and dual filter system for the water feed (0.45 µm - 0.1 µm).
- Traceability of the processes in hardcopy format (using the integrated printer) and electronic format (using complete traceability management software).
- Opening of the lid by pedal (hands-free).
- Capable of adapting to all hospital situations, even in small spaces, thanks to compact size.

1.5.4 • Acoustic and visual alarm signals with a description of the type of fault to allow the operator to immediately identify the type of problem. Garsiniai ir vaizdiniai aliarmai su gedimo aprašymais, leidžiančiais operatoriui nustatyti problemą

- Tanks for the detergent/decontaminant and high level sterilizing/disinfectant solutions A and B, that are safe with no harmful emissions.

The equipment must only be used by qualified personnel and only after having attended a training course organized by the manufacturer or by personnel authorized by the manufacturer.

DESCRIPTION OF THE VALIDATED CHEMICAL SOLUTIONS

The MEDIVATORS® ISA® Endoscope Reprocessor uses specific and validated chemical solutions in order to obtain an effective cleaning and disinfection process.

In particular:

FOR THE CLEANSING PHASE:

ISACLEAN™ multienzyme detergent/decontaminant:

- For the cleaning cycle, MEDIVATOR ISA Endoscope Reprocessor uses ISACLEAN multienzyme detergent/decontaminant, a certified medical device (CE 0546) specific for the removal of microbial biofilms.
- ISACLEAN multienzyme detergent/ decontaminant is available in 10 L or 5 L tanks.
- A 10 L tank of ISACLEAN multienzyme detergent/ decontaminant allows the execution of approx. 625 cycles.
- A 5 L tank of ISACLEAN multienzyme detergent/ decontaminant allows the execution of approx. 312 cycles.

INTERCEPT® PLUS detergent/decontaminant:

- For the cleaning cycle, MEDIVATOR ISA Endoscope Reprocessor uses INTERCEPT PLUS Detergent, specific for the removal of microbial biofilms.
- INTERCEPT PLUS detergent/decontaminant is available in 5 L tanks.
- A 5 L tank of INTERCEPT PLUS detergent/ decontaminant allows the execution of approx. 147 cycles.

FOR THE DISINFECTION PHASE:

ISASPOR® SINGLE SHOT or RAPICIDE® PA High Level Disinfectant/Sterilizing solution:

- For the disinfection cycle, the MEDIVATOR ISA Endoscope Reprocessor uses ISASPOR® Single Shot High Level Disinfectant/Sterilant, a certified medical device (CE0546) or RAPICIDE PA Disinfectant/Sterilant.
- When using ISASPOR HLD/Sterilant the device consists of a tank containing solution A (5% peracetic acid) and a tank containing solution B (containing ISAZONE®*) ingredient.
- When using RAPICIDE PA Disinfectant/Sterilant the device consists of a tank containing solution A (5% peracetic acid) and a tank containing solution B (containing Buffer) ingredient.
- ISASPOR Single Shot HLD/Sterilant is available in 10 L tanks (10 L Solution A + 10 L Solution B) or in 5 L tanks (5 L Solution A + 5 L Solution B). RAPICIDE PA Disinfectant/Sterliant is available in 5 L tanks (5 L Solution A + 5 L Solution B).
- ISASPOR Single Shot HLD/Sterilant or RAPICIDE PA Disinfectant/Sterliant is available in 5 L tanks (5 L Solution A + 5 L Solution B).
- A 5 L tank of ISASPOR Single Shot HLD/Sterilant or RAPICIDE PA Disinfectant/Sterilant allows the execution of approx. 26 cycles.
- A 10 L tank of ISASPOR Single Shot HLD/ Sterilant allows the execution of approx. 52 cycles.
- 1.17.1 The detergent and high level disinfectant/sterilizing solution used for each cycle are single use (single shot). Ploviklis ir aukšto lygio dezinfekavimo / sterilizavimo priemonė kiekvienam ciklui naudojamas tirpalas yra vienkartinis (single shot)
- The medical device distribution system ensures that, for each cycle, the correct amount of concentrated product is withdrawn from the tanks and ensures that said products are injected into the basin containing the endoscope.
  Paskirstymo sistema užtikrina, kad kiekvienam ciklui būtų panaudojamas tinkamas kiekis koncentruoto produkto

*molecule patented by Cantel Medical.

1.5.2

Insert the personal ID code. This then opens the cycle select page:

Norėdami pasirinkti atliekamo ciklo tipą, vieną kartą paspauskite virš ciklo pavadinimo, kad būtų rodoma atitinkama eilutė. Vieną kartą paspauskite pakartotinai apdorotą instrumentą, kad būtų rodomas atitinkama eilutė

To select the type of cycle to be performed, press once above the name of the cycle to be run so as to display the corresponding line. Press the instrument to be reprocessed once so as to display the corresponding line.

Once completed, press the START button to start the cycle.

On this page, there are two OPTIONAL panels indicating the physician and the patient, in the case of use, the text inserted here will be printed in the cycle report.

With regard to the PHYSICIAN, pressing the LIST button to the right of the white line makes it possible to select one of the options previously included in the list.

g. SWITCH OFF THE PC: it is obligatory that this button be used to shut-down the PC. **Any other PC shut-down procedure could cause damage to the PC itself, which DOES NOT fall within the scope of the manufacturer's Warranty.**

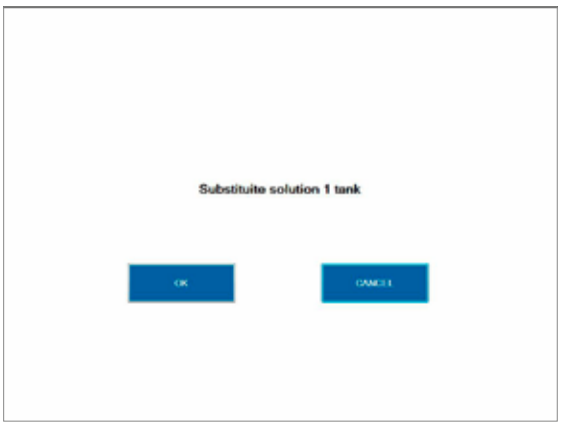
TANK REPLACEMENT PROCEDURE

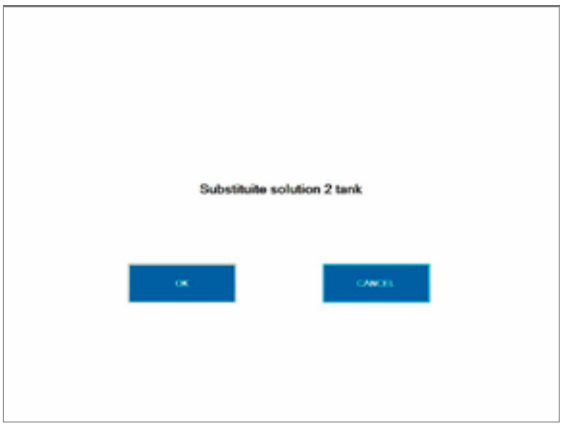
1.5.5 Ciklo metu įranga aptikusi trūkumą ar perteklių vieno iš produktų, informuoja vartotoją vaizdiniais ir garsiniais signalais, kad reikia pakeisti atitinkamą talpą

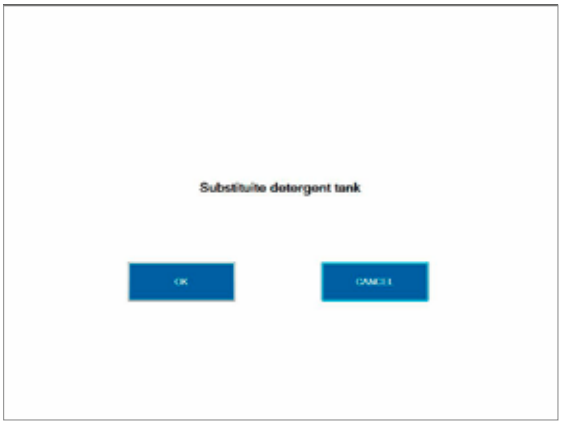
During the cycle, if the equipment detects a lack or partial load for one of the products, it informs the user of the need to replace the relevant tank by means of visual and acoustic messages.

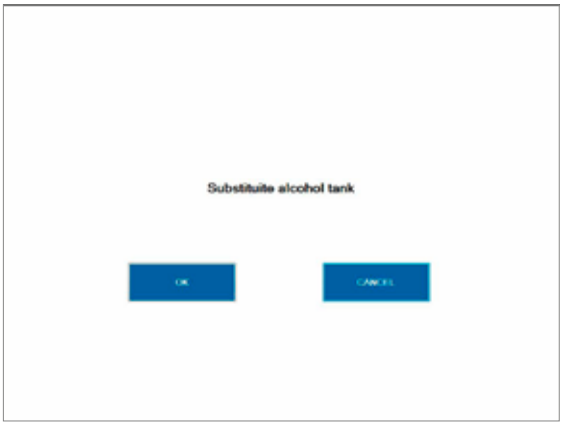
This warning is managed so as to allow the operator to be able to replace the corresponding product tank without the need to interrupt and restart the cycle from the start.

When an absence of product load is detected, the screen displays one of the following messages:





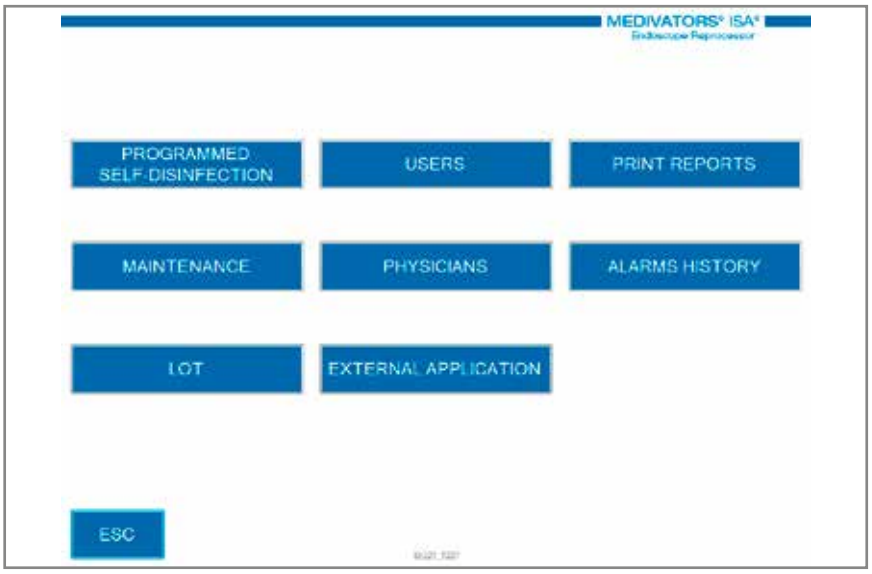


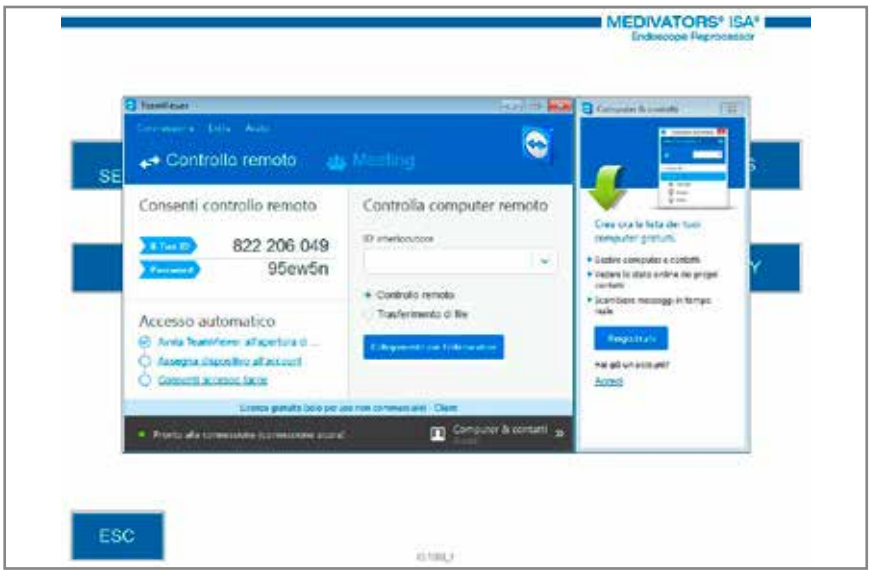


1.8 EXTERNAL FUNCTION OPTION.

If activated, this option activates a button in the MENU, that connect MEDIVATORS® ISA® software with an external application

Medivators ISA programinė įranga gali būti prijungta prie išorinės programos





In this case, external application is a software for connection: remote control.

Šiuo atveju išorinė programa yra prisijungimo programinė įranga: nuotoliniam valdymui.

ENDODRY®

Storage & Drying System | **Dry & Store**

MEDIVATORS
A Cantel Medical Company

THE COMPLETE CIRCLE OF PROTECTION

As the global vanguard in infection prevention, only Cantel Medical delivers the Complete Circle of Protection, a full-value, proactive partnership dedicated to helping you remove risk, streamline operational efficiencies and optimize your success.

A Higher Standard for Endoscope Drying and Storage

Lanksčių endoskopų saugojimas ir džiovinimas

2.1 **Ensure Your Flexible Endoscopes Remain Safe and Dry During Storage**

2.6 2.6.1 MEDIVATORS Storage and Drying Cabinet continuously forces HEPA filtered air through all endoscope channels, ensuring the endoscope is dry and fluid-free.

MEDIVATORS laikymo ir džiovinimo spinta nuolat filtruotą orą (HEPA filtrais) per visus endoskopo kanalus, užtikrindama, kad endoskopas būtų sausas ir neatsirastų skysčių.

- Continuous ventilation eliminates residual moisture that can lead to bacteria growth
- Circulation of dry HEPA filtered air through each endoscope channel and around the outer sheath ensures the endoscope is dry prior to use.
- Short drying cycle improves scope turn-around time

Protect Fexible Endoscopes from Damage

Cassette system eliminates free swinging of the distal tip and protects the endoscope during transport and storage.

- Transporting flexible endoscopes in cassettes reduces endoscope damage and related repairs by 25-30%
- Quick, efficient transfer from automated endoscope reprocessor to storage cabinet via cassette system

Customizable to Fit Your Facility's Needs

Space-conscious design available in various configurations to meet the requirements of any facility.

2.4
- Available in single-sided or pass-thru models (front and back door) for separation of wet and dry areas

Galimi vienpusiai arba pass-thru modeliai (priekinės ir galinės durys), skirtos drėgnoms ir sausoms zonoms atskirti

- Compatible with ADVANTAGE PLUS® Reprocessor or DSD hook-ups to increase department efficiencies

Maximize Patient Safety

MEDIVATORS Storage and Drying Cabinet uses a cassette to minimize touching and potential recontamination.

- Reduced worker handling minimizes endoscope recontamination and optimizes infection control
- No disconnection and reconnection of endoscope channels to hook-up ensures proper connectivity and time savings
- SMART Light (green, blue, red) for quick cabinet status identification

Data Management Ensures Endoscope Drying Cycle Compliance

Continuous data monitoring provides detailed information on the drying status of all endoscopes.

- Constant air circulation controls temperature and humidity within the cabinet
- Barcode scanner for ease of endoscope ID and endoscope tray location; touchscreen for quick visualization
- SMART Connect data interface with ADVANTAGE PLUS Reprocessor and ENDORA® Endoscope Tracking System

DRY & STORE

Bacteria pose significant risk to endoscopes during endoscope storage. Cantel's transport, drying and storage solutions are designed to protect valuable inventory, reduce cross contamination touchpoints, eliminate moisture in the endoscope channels and control humidity. Higher humidity or moisture in endoscope channels is known to aid bacterial growth.

ENDODRY®

Storage & Drying System | **Dry & Store**

2.7

Color touch screen display for quick identification of endoscope storage time

Spalvotas lietimui jautrus ekranas

SMART Connect to ADVANTAGE PLUS® Reprocessor and ENDORA® Tracking Systems

2.3

Horizontalus endoskopų laikymas

Locking doors protect endoscope inventory

Available in left or right door swing configurations

Barcode scanner for ease of endoscope and operator identification

Compatible with ADVANTAGE PLUS Reprocessor or DSD hook-ups to increase efficiencies in your department

Convenient transport cassette for endoscope protection and recontamination prevention

Pass thru and single sided models available

2.4

ENDODRY® Cabinet Specifications

Electrical Requirements

100-240 VAC, 50/60HZ, Power Input: 75W,
Fuse: T2A (internal device) 15A (circuit)

Electrical Safety Certifications

IEC 61010-1:2010

Operating Temperature

50 - 104˚F (10 - 40˚C)

Interface

RJ45 (10/100 Mbit)

Dimensions

75 H x 24 W x 22 D (inches)
190 H x 60 W x 54 D cm
Door Swings 20.5 (inches) 52 (cm)

Weight

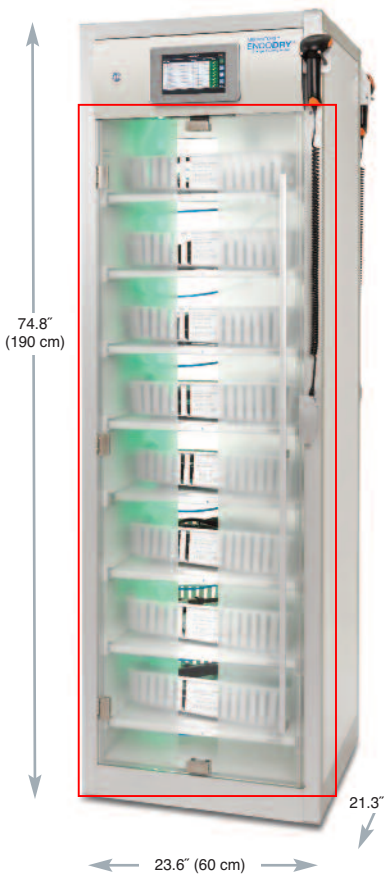
375 lbs (170 kg)

Endoscope Traceability

ENDORA® Tracking System Integration

Air Requirements

(Refer to technical documents)
Instrument grade air



2.2

Spintoje laikoma iki 8 endoskopų

ENDODRY® Cabinet Ordering Information

Model Number	Description
DRY-2001, DRY 2002, DRY-2003, DRY-2004**	ADVANTAGE PLUS® AER – Pass-thru model
DRY-1001, DRY-1002*	ADVANTAGE PLUS AER – Single-side entry
DRY-2005, DRY 2006, DRY-2007, DRY-2008*	DSD AER Platform – Pass-thru model
DRY-1003, DRY-1004*	DSD AER Platform – Single-side entry
CAS-1000	Endoscope Transport Cassette

** Available in right or left door swing configurations

*Hook-ups sold separately.

CANTEL
Global Headquarters
150 Clove Road - 9th Floor
Little Falls, NJ 07424-2139
Phone: +1.973.890-7220

MEDIVATORS
Global Headquarters
14605 28th Avenue North
Minneapolis, MN 55447-4822
Phone: +1.763.553.3300 Fax: +1.763.553.3387

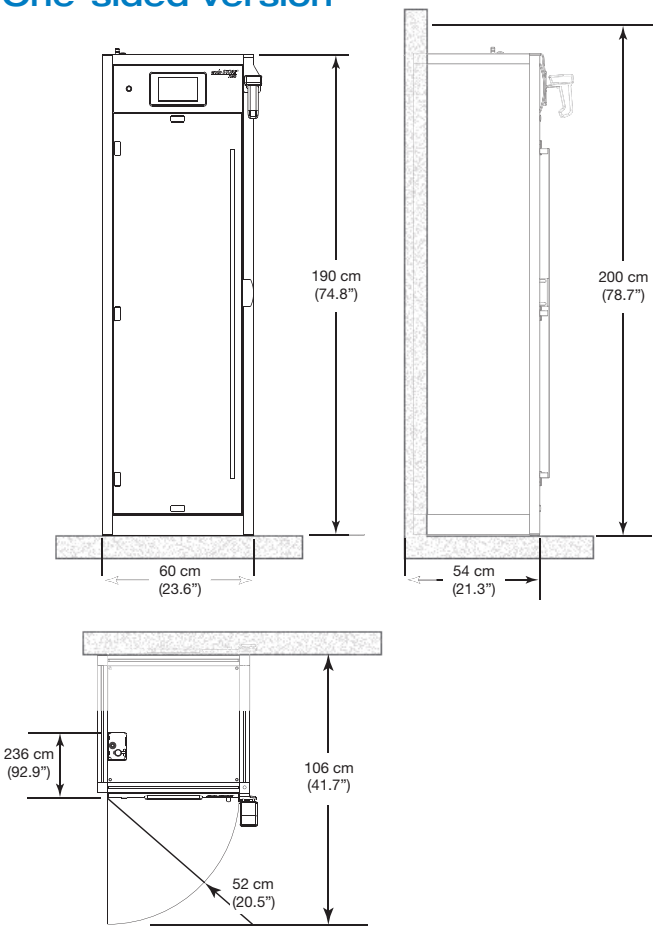
TO PLACE AN ORDER
Call: 1.800.328.3340 (Customer Service)
Fax: 1.800.686.8493
Email: custserv@medivators.com

www.medivators.com

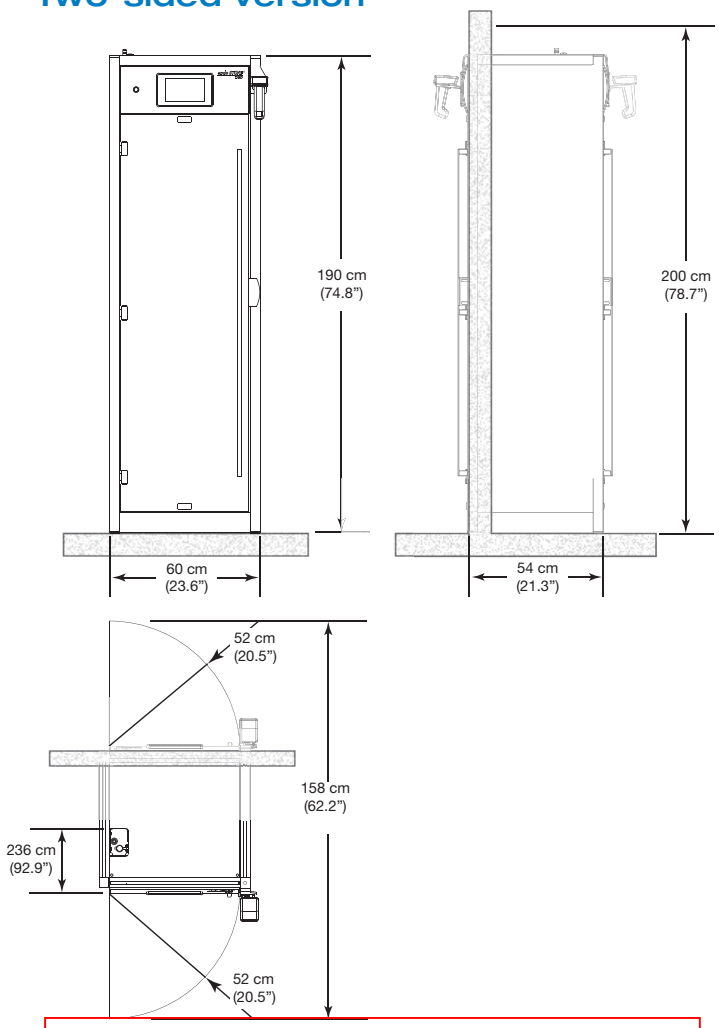
Technical Specification Sheet

MEDIVATORS™
ENDODRY™
Storage & Drying System

One-sided version



Two-sided version



Note: The ENDODRY Drying Cabinet can be ordered with left or right opening doors.

GENERAL

Dimensions:	H75" X W24" X D22" (H190cm x W60cm x D54cm)
Weight:	375 lbs (net) (170 kg net)
Operating Temperature:	50 -104°F (10-40°C)
Power Input:	75 W

ELECTRICAL CONNECTION

Power Supply:	100-240 VAC, 50/60 Hz
Fuse:	T2A/T4A (Internal device) 16 A (building)

2.9.1

AIR CONNECTION

Quality:	ISO 8573-2:2010 class 1.4.1
Oro slėgis 2 - 8 bar Pressure:	29 - 116 psi (2-8 bar)

2.9.2

Demand:	max. 3.4 cfm (95 l/min) (ANR)
Poreikis maksimalus 95 l/min	max. 10.6 cfm (16 l/min)@ 72 psi (5 bar)
Nominal Diameter:	1/4" (6mm)

INTERFACE

Serial:	RJ45
Ethernet:	10/100 Mbit

MEDIVATORS
A Cantel Medical Company

Medivators Inc.
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The Netherlands
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Cantel Medical Asia/Pacific Pte. Ltd.
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#05-01 Singapore 609933
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Medivators Inc. Beijing Representative Office
Room 1801, Floor 18th, Tower A,
Beijing Marriott Hotel, Office Building
No. 7, Jianguomen South Avenue,
Dongcheng District, Beijing 100005 China
Tel: +86 10 65204039

www.medivators.com

ENDODRY™
Storage & Drying System

USER MANUAL

ENDODRY™
STORAGE & DRYING SYSTEM

CANTEL

- **Network Print**
  All relevant process data can be printed on a controlled network printer after unloading an endoscope. An application runs on a desktop PC and controls the print process. The desktop PC and the network printer have to be provided by the operator.

  A network connection between ENDODRY™ Storage and Drying System, desktop PC and network printer is required.

- **Label Printer**
  All relevant process data can be printed on a label printer after unloading an endoscope.

  A network connection between ENDODRY Storage and Drying System and label printer is required.

- **Sensors ***
  Svarbūs parametrai, tokie kaip temperatūra, drėgmė ir oro srautas, yra kontroliuojami ir registruojami
2.5 Critical parameters such as temperature, humidity and air flow are controlled and recorded. In case of deviation of the adjustable limits a new or extended drying phase is initiated to return to the desired climatic state in the ENDODRY Storage and Drying System.

- **Multibox ***
  For endoscopes with few channels it is possible to store more than one endoscope in the same cassette (e.g. bronchoscopes). This add-on enables the storage and recording of up to four endoscopes in one cassette.

- **Transfer ***
  After storing an endoscope in centralised ENDODRY Storage and Drying System in the endoscopy area the storage process can be continued in a decentralized ENDODRY Storage and Drying System. The process steps in the different storage locations can be recorded completely.

Operation of the ENDODRY™ Storage and Drying System

The storage cabinet has the following main functions:

- Drying and Storage functions for endoscopes after reprocessing
  - horizontal storage of up to eight endoscopes
  - using additional transport cassette (sold separately)
  - circulation of filtered air through all channels of flexible endoscopes (e.g. biopsy, water, jet channel) of every manufacturer after reprocessing
  - circulation of filtered air around the interior space of the ENDODRY Storage and Drying System
  - control with up to three different air pressures
  - reduction of the air pressure after a minimum time of circulation
  - error message management
  - optional: interface between reprocessing and operating room (two-sided version)
- Documentation and visualisation of important information for the reprocessing room
  - user I.D. via barcode reader
  - endoscope I.D. and drawer placement via barcode reader
  - documentation of drying and storage time by endoscope position
  - recording and storage of all process data
  - warning in case of failure or exceeded storage time
- Simple and safe operation
  - touch display
  - door lock with user authorisation via barcode reader

2.6.2 2.6.3 2.6.4 filtruoto oro cirkuliacija per visus lankščių endoskopų kanalus (pvz., biopsijos, vandens, įrigacinis kanalas)

Optional Operations

To enhance the functionality of the ENDODRY Storage and Drying System the following add-ons are available to purchase:

- **SMART Light**
  The storage cabinet is equipped with LED lights. The colour changes according to the storage status of the endoscopes.
  green - storage phase
  blue - drying phase
  red - failure

NOTE: Options are not available in all regions.

- **SMART Connect ***
  In connection with an ADVANTAGE PLUS™ Endoscope Reprocessor : A security query, which verifies the correct reprocessing, runs if an endoscope is loaded.

  The maximum time between reprocessing and loading an endoscope can be set (*see Chapter 6*). By loading an endoscope a warning appears if the reprocessing was faulty or the maximum transport time is exceeded. Furthermore, the user and endoscope information of an ADVANTAGE PLUS Reprocessor can be imported to the ENDODRY Storage and Drying System on demand (*see Chapter 6*) or automatically at up to three times per day (*see Chapter 6*).

- **HIS Interface ***
  The HIS add-on releases process and master data from the ENDODRY Storage and Drying System to the hospital information system. Process data (loading and unloading information of each endoscope) is released permanently. The release of master data (saved user and endoscope data) can be set in the control panel (*see Chapter 6*).

CHAPTER 5

OPERATION OF THE UNIT

Switching On/Off

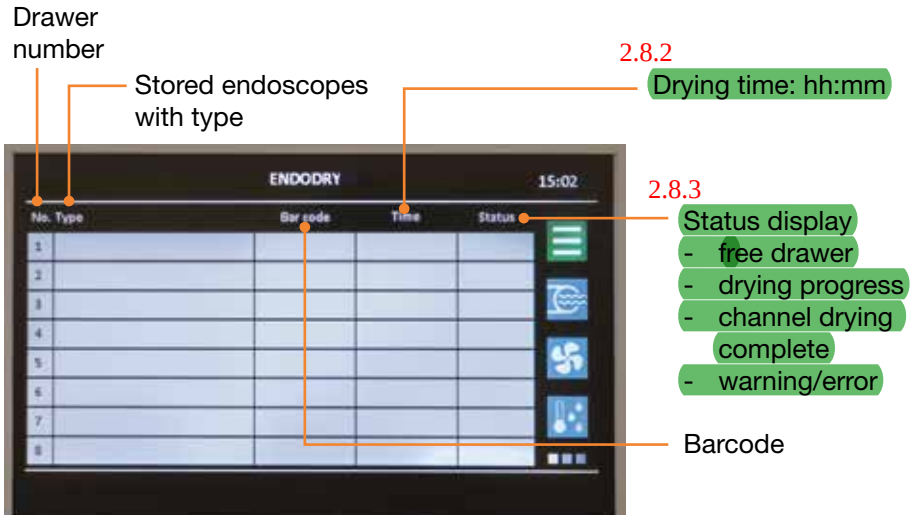
After connecting power supply, air supply and LAN connection the device can be put into operation. Turn on the storage cabinet using the on/off switch on the front of the ENDODRY™ Storage and Drying System. The blue light within the switch lights up and the touch display shows various information (*see Chapter 3 and 5*).
In the version with two-sided design the displays are distinguished as follows:

- front side= with on-off switch
- back side = without on-off switch

Information Screen

(in two-sided version: the same at front and back side)

The control panel with integrated touch display regulates all processes and visualises the operation. On the main screen the following information is displayed:



Status display:

- free = free drawer
- in progress = endoscope has been loaded, drying of internal channels has been initiated
- channel drying complete = the set drying time has been reached for internal channels
- warning/error = maximum storage time is exceeded or pressure malfunction during storage has occurred

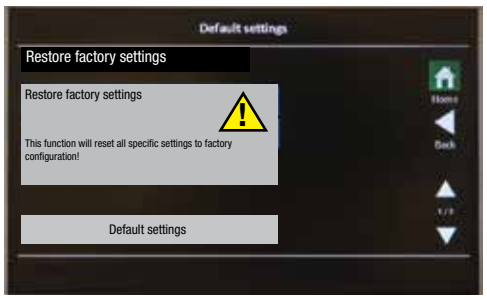
Default settings

Login as Admin required.

On the first page of the default settings a backup of the current settings can be generated and reproduced.

On the second page of the default settings the ENDODRY™ Storage and Drying System can be reset on standard settings.

WARNING: THIS FUNCTION WILL RESET ALL SPECIFIC SETTINGS TO THE FACTORY CONFIGURATION.



The following will be reset by activating the default settings:

- serial number, data of operator (department, street, ...)
- 2.11 drying phase 1 (0.5 Bar, 20 min, for ADVANTAGE PLUS™ Endoscope Reprocessor compatible systems 30 min, for DSD compatible systems.) Džiovinimo fazė 1 (20 min)
- 2.11 drying phase 2 (0.3 Bar, 40 min, for ADVANTAGE PLUS Reprocessor compatible systems 60 min, for DSD compatible systems) Džiovinimo fazė 2 (40 min.)
- storage phase (0.1 Bar)
- maximum storage time: only default value (72 h) is retained
- door lock (Operator and User) is active
- entry of patient's information and bypassing loading lock is not active
- warning close the door (2 min)
- error air pressure malfunction relative (50 %)
- all add-ons are not active
  - ✓ SMART Connect: time between reprocessing and ENDODRY Storage and Drying System (10 min)
  - ✓ SMART Connect: information entries of the data base
  - ✓ SMART Connect and HIS Interface: times 2 AM, 6 AM and 12 PM
  - ✓ Sensorik: Max./Min. values (2 °C, 1°C, 2 %, 1%)
  - ✓ Transfer: Max. transport time (10 min)

Cantel Medical (Italy) S.r.l.
a sole-quotaholder company
Via Laurentina, 169
00071 Pomezia (RM) - Italia
Tel.: +39 06 9145399
Fax: +39 06 9146099
www.cantelmedical.it

OBJECT: MANUFACTURER DECLARATION

Endoskopai, laikomi ENDODRY laikymo ir džiovinimo sistemoje 31 dieną

We, Cantel Medical (Italy) S.r.l, legal manufacturer of the ENDODRY™ Storage and Drying System, confirm that:

2.10

The endoscopes stored 31 days in the ENDODRY™ Storage and Drying System have passed the EN 16442:2015 E.1* and E.2* in an internal performance qualification under observance of the normal operation conditions and manufacturer requirements, with unchanged factory settings of the process parameters and proper handling. Endoscopes must be high level disinfected immediately prior to placing into the cabinet and they also must meet the microbiological requirements before starting the storage.

*Annex E: Internal residual contamination of endoscopes after storage.

Signature

6/4/2021

Pomezia, June 1st of 2022

STATEMENT LETTER

We, Cantel Medical (Italy) S.r.l., a Steris Corp. company with registered office and manufacturing facilities at Via Laurentina, 169, 00071 Pomezia (RM), Italy, Cantel Medical (Italy) S.r.l., are the producer of washer-disinfector & sterilizer for flexible endoscopes Medivators ISA and drying & storage cabinet for flexible endoscope EndoDRY.

1.20.1
1.20.2

Both Medivators ISA and EndoDRY are designed to use common and interchangeable compatible to both types of equipment connector block Hookup with single channel connectivity to allow ergonomic handling avoiding additional connecting/disconnecting endoscope channels when transferring/placing reprocessed endoscope from Medivators ISA to EndoDRY cabinet for drying and storage.

Tiek Medivators ISA, tiek EndoDRY sukurti naudoti bendrus ir keičiamus, suderinamus su abiejų tipų įrangos jungčių blokais. Sujungimas su vieno kanalo jungtimi, kad būtų galima ergonomiškai valdyti ir išvengti papildomų endoskopo kanalų prijungimo/atjungimo perkeliant/dedant perdirbtą endoskopą iš Medivators ISA į EndoDRY.

.

Sincerely yours,

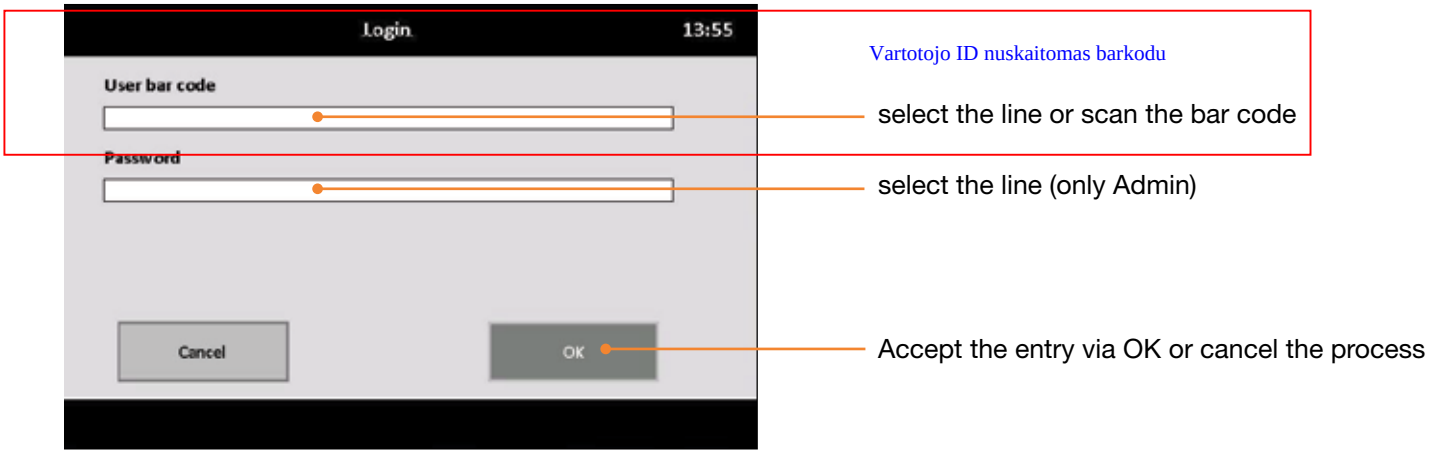
Cantel Medical (Italy),
Via Laurentina, 169,
00071 Pomezia (RM)
Italy
www.cantelmedical.eu | akenik@cantelmedical.com

Login/Logout as User or Admin

The following sections describe the menu items and their function, which can be entered by a login as User or Admin.

To release these menu items, the user has to log in with a suitable user name and if applicable password.

2.8.1 Selecting the **LOGIN** button the login screen appears.



Enter the user-number by scanning the user-barcode or selecting the user number. After selecting the edit line user- barcode, a keyboard window appears (*See Chapter 6*).

At the Login as Admin an extra password is required. By selecting the filed password, the keypad appears (*See Chapter 6*). Press the **OK** button the login process is accepted.

After the done settings or actions in the user- or Admin menu the user has to log off via the **LOGOUT** button . A return to the main screen or an inactivity in the menu within 10 minutes runs automatically to a logout.

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  - reduction of the air pressure after a minimum time of circulation
  - error message management
  - optional: interface between reprocessing and operating room (two-sided version)
- Documentation and visualisation of important information for the reprocessing room
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  - endoscope I.D. and drawer placement via barcode reader
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  - recording and storage of all process data
  - warning in case of failure or exceeded storage time
- Simple and safe operation
  - touch display
  - door lock with user authorisation via barcode reader

Džiovinimo ir laikymo laiko dokumentacija

2.5.

Optional Operations

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- **SMART Light**
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MEDIVATORS
A Cantel Medical Company

EU Medical Device Directive
93/42/EEC as Amended by 2007/47/EC
Declaration of Conformity

Product(s): Advantage/MDS Series Automatic Endoscope Reprocessing System

Manufacturer:	Medivators Inc.	EU Representative:	Medivators BV
Address:	14605 28th Avenue North Minneapolis MN 55447 USA	Address:	Sourethweg 11 6422 PC Heerlen The Netherlands

Model(s): **Advantage Plus**

Assessment of Product Based Upon:

Quality System Certification — ISO 13485 Certificate No: MD19.2990
Issued By: NSAI (0050)

CE Certification — CE Certificate No: 252.380
Conformity Assessment Route: Annex II
Issued By: NSAI (0050)

Essential Requirements Checklist — Prepared by: Regulatory Affairs — Date: Nov14

Technical File — Prepared by: Regulatory Affairs — Date: Nov14

Product Classification: Product classification based on the requirements of MDD Annex IX and EU Guidelines for Classification of Medical Devices MEDDEV 2.4.

☐	Class I	☐	Class IIa
☒	Class IIb	☐	Class III

Based on a review of the above documents, we hereby declare that the above product complies with the applicable requirements of the following standards:

ISO 15883-1
ISO 15883-4
ISO 13485
ISO 14971
EN 61010-1
EN 61010-2
EN 61326-1
EN 62366
EN 1041
EN 980

Prepared by:

Medivators Inc.
June 19, 2017

ES medicinos prietaisų direktyva

93/42/EEB su pakeitimais, padarytais 2007/47/EB

Atitikties deklaracija

Produktai): Advantage/MDS serijos automatinė endoskopo perdirbimo sistema

Gamintojas:	Medivators Inc.	ES atstovas:	Medivators BV
Adresas:	14605 28th Avenue North Mineapolis MN 55447 JAV	Adresas:	Sourethweg 11 6422 PC Heerlen Olandija

Modelis (-iai): **Privalumas plius**

Produkto įvertinimas remiantis:

Kokybės sistemos sertifikavimas	ISO 13485 sertifikato Nr.: MD19.2990 Išdavė: NSAI (0050)	
CE sertifikatas	CE sertifikatas Nr.: 252.380 Atitikties vertinimo būdas: II priedas Išdavė: NSAI (0050)	
Esminių reikalavimų kontrolinis sąrašas	Parengė: Reguliavimo reikalai	Data: Lapkričio 14 d
Techninė byla	Parengė: Reguliavimo reikalai	Data: Lapkričio 14 d

Produkto klasifikacija: Gaminių klasifikavimas pagal MDD IX priedo reikalavimus ir ES medicinos prietaisų klasifikavimo gaires MEDDEV 2.4.

☐-	I klasė	☐	IIa klasė
☒-	IIb klasė	☐	III klasė

Remdamiesi aukščiau pateiktų dokumentų peržiūra, pareiškiame, kad aukščiau nurodytas gaminys atitinka taikomus šių standartų reikalavimus:

ISO 15883-1
ISO 15883-4
ISO 13485
ISO 14971
EN 61010-1
EN 61010-2
EN 61326-1
EN 62366
EN 1041
EN 980

Parengta:

Medivators Inc.

2017 m. birželio 19 d