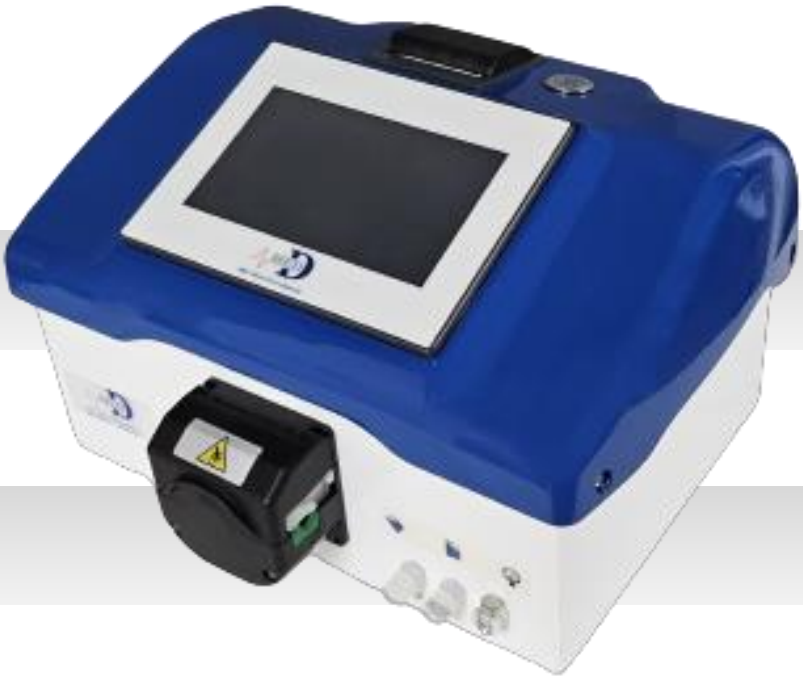
DMED - Medical Device Engineering

DATA SHEET

SMART ENDO BOX

SEB 1000



Summary

1. Introduction

1.1 Preliminary informations

MODEL	SEB 1000

Producer	DMED - Medical Device Engineering
Manufacturer	DMED - Medical Device Engineering
CND	Z12029010 – STERILIZERS FOR ENDOSCOPES
RDM	1459670
Intended use	Device to support the washing and cleaning of flexible endoscopes.
Risk Class	Class I

1.2. Certifications and reference standards

MDR CONFORMITY - REFERENCE STANDARDS

CEI EN 61010-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential requirements
EN 61326-1: 2022	Electrical equipment for measurement, control and laboratory use - Electromagnetic compatibility requirements - Part 1: General requirements.
UNI CEI EN ISO 14971:2022	Medical devices – Application of risk management to medical devices.
COMPANY STANDARDS	
UNI CEI EN ISO 13485:2021	Medical devices - Quality management systems - Requirements for regulatory purposes.

1.3 Field of application

The SEB 1000 prewash station is designed to ensure optimal prewash of **flexible endoscopes**, one per wash cycle.

2. Device features

2.1 Materials and general parameters

The materials designed and used for the professional design and construction of the SEB1000 pre-wash stations are shown in the following table.

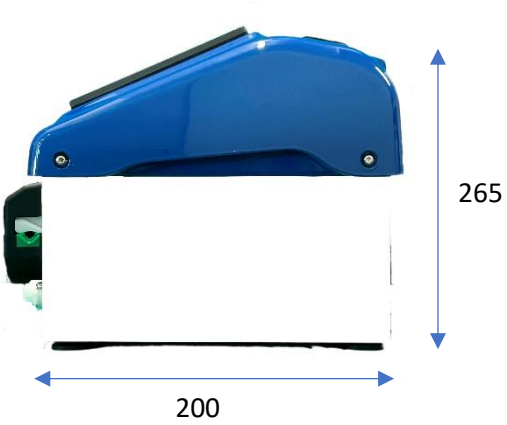
COMPONENT	**MATERIAL**
Upper shell	Plexiglass
Lower part	Expanded polystyrene

This other table lists the **general parameters** of the equipment.

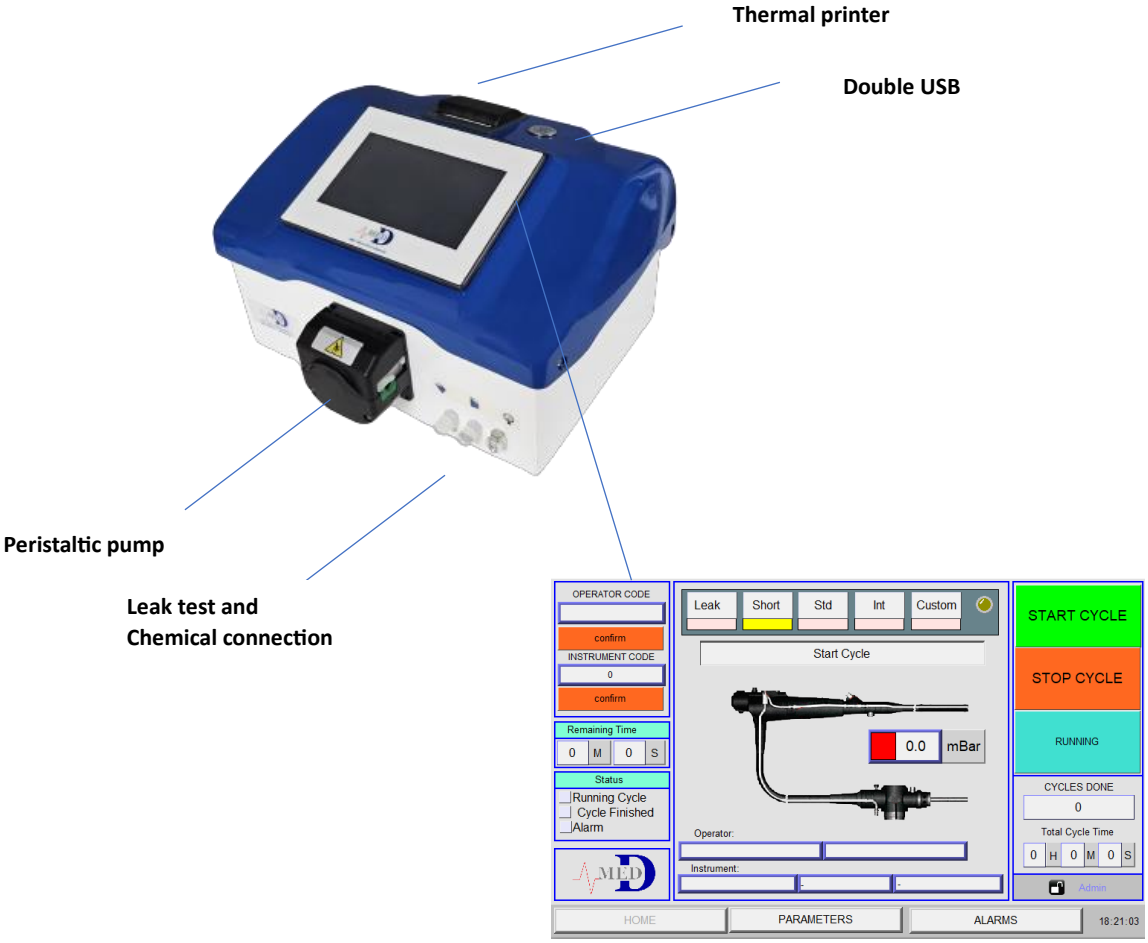
PARAMETER	**VALUE**
Weight	8 kg
Maximum Power Input	75 W

2.2 Dimensional parameters

Below are the **views and relevant dimensional dimensions in millimetres** of the medical device model SEB1000



2.3 Structural features



Simple and intuitive 7” touch-screen interface

2.3 Functional Features

The following table shows the functional characteristics guaranteed by the machine during the endoscope pre-wash operating cycles. The various programmes, with their durations and water consumption for each phase, will be described later in section 2.5.

GUARANTEED FUNCTIONALITY DURING WASHING CYCLES
Leak test performed at the beginning of the cycle and throughout the duration of the cycle.
Automatic single-shot chemical dosing.
Pulsatile flow of each channel.
Duration of each washing phase can be set according to your own internal protocol.
Possibility of setting the brushing phase both before and after the washing phase.
Step confirmation system with audible and visual signals to keep track of the steps performed by the machine.
Possibility of repeating the same phase if necessary.
Possibility to put the procedure on stand-by by pausing the washing pump.
Possibility of performing a channel purge at the end of each cycle phase.
Operator and instrument recognition system automatically via barcode gun.

2.4 Traceability

The following table shows the **traceability** characteristics of the pre-wash station mod. SEB 1000.

TRACEABILITY FEATURES
Complete traceability and recording of machine cycle data
Guaranteed paper traceability thanks to on-board thermal printer
Traceability of the chemical agent used
Operators (100), endoscopes (200) will be identified by their own barcode, which can be registered and identified on the equipment thanks to the barcode gun
Cycle traceability data can be exported via USB and Ethernet in .csv format.

The information and data within the reports printed on thermal paper, relating to each cycle to ensure paper traceability, are shown in the following table.

INFORMATION IN PAPER REPORTS
Name of hospital and department.
Device model and serial number.
Total number of cycles performed.
Name of the operator responsible for the cycle.
Model, brand and serial number of the washed endoscope.
Times of each individual phase, total cycle time and detergent consumption.
Type of programme chosen.
Duration of the leak test.
Possible alarms.

It can be printered for up to 65 cycles per roll paper

2.5 Reprocessing programs

The water consumption depends on sink dimension. The range is from 20 to 35 liters/cycle.

The following section will specifically describe the washing characteristics within each programme, as well as detailing the timing of each phase.

2.5.1 Timing of individual phases

	Program 2: Short
Leak test	*12 s*
Pre-disinfection	
Rinse 1	
Cleaning	*300 s*
Rinse 2	*85 s*
Disinfection	
Final rinse	*85 s*
Total	*480 s*

In addition, different types of programmes can be set:

- Programme 1, with leak test only
- Programme 3, or standard
- Programme 4, or intensive
- Programme 5, or custom

The name of the programmes is purely indicative, as each of them is **fully customisable**, in the phases and times of each.

2.5.2 Cleaning features

It can be used any type of cleaning agent on the market in liquid form.

2.6 Safety

The SEB1000 medical device is equipped with all the necessary safety measures to guarantee the safety of operator, endoscope and patient, as well as to limit cross-contamination as much as possible. The following tables show the design solutions adopted to guarantee the safety of all those involved in the prewash cycle of the flexible endoscopes.

2.6.1 Safety Measures

Operator measures

OPERATOR SAFETY SYSTEMS
Reduction in operator errors due to the automation of all the steps involved in the normally manual pre-washing that each endoscope must undergo before being reconditioned in the endoscope washer.
Reduction of possible osteoarticular diseases of the operator, in particular carpal tunnel inflammation, due to the automation of each phase made available by the equipment.

Endoscope safety and limiting cross-contamination

ENDOSCOPE SAFETY SYSTEMS
Acoustic and visual alarm system with error messages to signal malfunctions.
In the event of an alarm, the cycle is immediately interrupted.
In the event of an error indicating failure of the leak test, the machine protects the endoscope by means of two solutions, both of which are necessary to prevent leakage into the instrument: • Air is blown continuously even in the event of an alarm, without interruption until the error is reset. • A clear message is generated on the display indicating to the operator the need to remove the endoscope from the water. The error is not resettable until removal of the instrument is indicated.

3. Installation requirements

3.1. Electrical requirements

ELECTRICAL REQUIREMENTS	
Supply voltage	230V 1P + N ± 5%
Power supply frequency	50 Hz
Input power	75 W
Maximum amperage	1 A

3.2 Internet connection requirements

INTERNET CONNECTION REQUIREMENTS	
LAN socket	LAN socket RJ45
LAN socket datas	IP address
	Subnet Mask
	DNS address
	Gateway

3.3. Water requirements

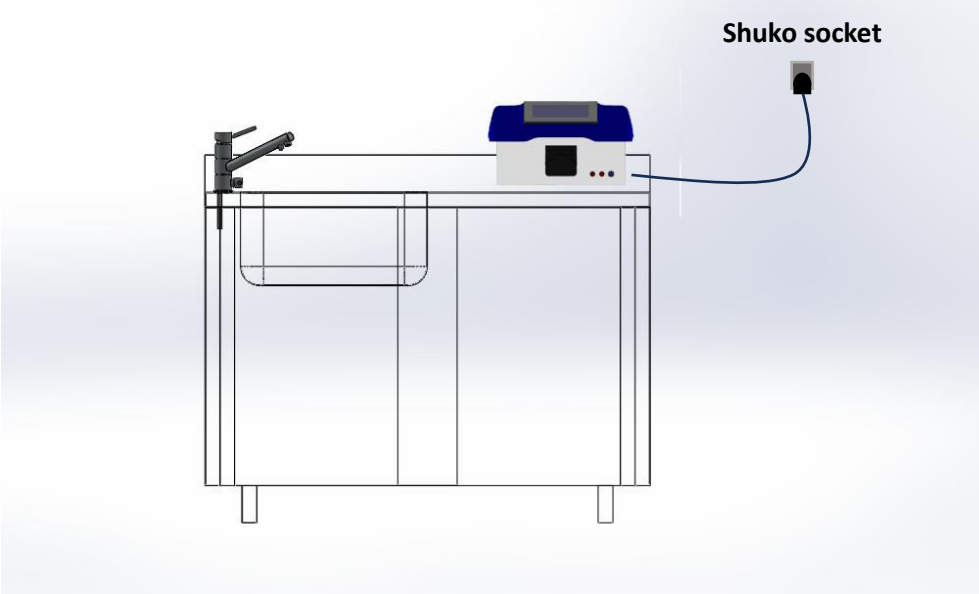
The SEB1000 pre-wash station must be able to be positioned and used in conjunction with a sink, with the possibility of supplying hot water with a temperature of between 20°C and 40°C into the wash tank.

WATER FEATURES	
Temperature	Between 20°C and 40°C
pH	6.5-9

3.4 Environmental requirements

ENVIROMENTAL REQUIREMENTS	
Room temperature	15°C to 30°C
Relative humidity	From 30% to 80%
Recommended ventilation frequency	> 10 Changes room/h

3.5 Installation scheme



4. Consumables and accessories

4.1 Consumables

CONSUMABLE	FEATURES
Flow divider	Autoclavable flow divider
Silicon washing hoses	Autoclavable silicone hoses for instrument washing
Thermal paper	Thermal paper with guaranteed stability of 7 or 10 years

4.2 Accessories

ACCESSORIES	FEATURES
Endoscope connectors	Manual washing kits included in every endoscope instrument can be used with SEB1000 without extra cost. Anyway connectors are available for each channel of endoscopes of any model and brand, such as Pentax, Olympus, Fujinon, Storz, Wolf and others.