

*DMED - Medical Device Engineering*

# DATA SHEET

AUTOMATED ENDOSCOPE PRECLEANING SYSTEM

**SEB 2000**





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# 1. Introduction

## 1.1 Preliminary informations

<i>MODEL</i>	SEB 2000
<i>Producer</i>	DMED - Medical Device Engineering
<i>Manufacturer</i>	DMED - Medical Device Engineering
<i>CND</i>	Z12029010 – STERILIZERS FOR ENDOSCOPES
<i>RDM</i>	1687940
<i>Intended use</i>	Device to support the washing and cleaning of flexible endoscopes.
<i>Risk Class</i>	Class I

## 1.2. Certifications and reference standards

### **MDR CONFORMITY - REFERENCE STANDARDS**

<b><i>CEI EN 61010-1</i></b>	Medical electrical equipment – Part 1: General requirements for basic safety and essential requirements
<b><i>EN 61326-1: 2022</i></b>	Electrical equipment for measurement, control and laboratory use - Electromagnetic compatibility requirements - Part 1: General requirements.
<b><i>UNI CEI EN ISO 14971:2022</i></b>	Medical devices – Application of risk management to medical devices.

### **COMPANY STANDARDS**

<b><i>UNI EN ISO 9001:2015</i></b>	Quality Management Systems - Requirements
<b><i>UNI CEI EN ISO 13485:2021</i></b>	Medical devices - Quality management systems - Requirements for regulatory purposes.

## 1.3 Field of application

The SEB 2000 prewash station is designed to ensure optimal prewash of **flexible endoscopes**, one per wash cycle.

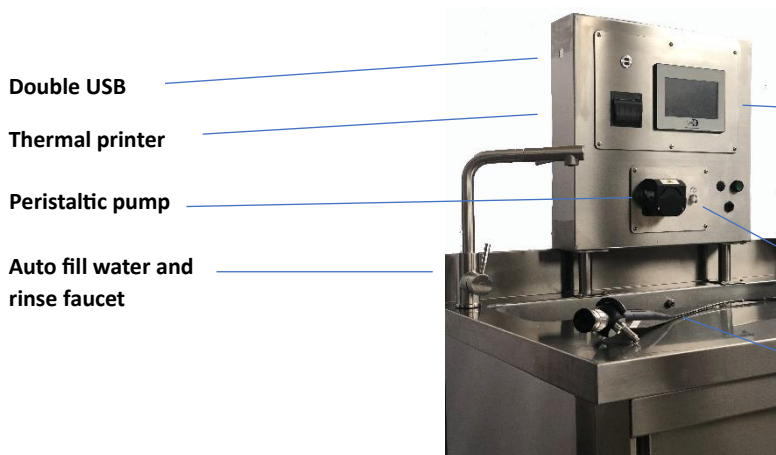
## 2. Device features

### 2.1 Materials and general parameters

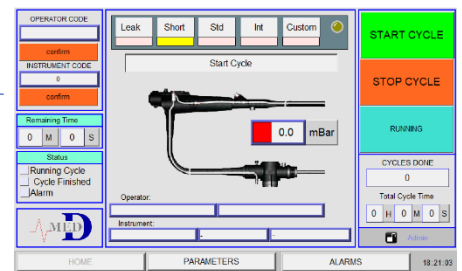
Since SEB 2000 is an automatic pre-wash system integrated in a sink, the dimensions of the complete device depend directly from the dimensions of the sink chosen for the installation of the device.

The system can be installed in a pre/existing counter.

### 2.2 Structural features



Simple and intuitive 7" touch-screen interface



Leak test

Automatic detergent loading

### 2.3 Functional Features

The following table shows the functional characteristics guaranteed by the system 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

<i>Leak test performed at the beginning of the cycle and throughout the duration of the cycle.</i>
<i>Possibility to choose if the leak test will be performed together the water and chemical filling or separated</i>
<i>Automatic single-shot chemical dosing.</i>
<i>Possibility to add another dosing pump for a separate step.</i>
<i>Pulsatile flow of each channel.</i>
<i>Duration of each washing phase can be set according to the internal protocol.</i>
<i>Possibility of setting the brushing phase before or after the washing phase.</i>
<i>Step confirmation system with audible and visual signals to keep track of the steps performed by the machine.</i>
<i>Possibility to set the automatic step confirmation for automatic cycle ( contact less mode)</i>
<i>Possibility of repeating the same phase if necessary.</i>
<i>Possibility to put the procedure on stand-by by pausing the washing pump.</i>
<i>Possibility of performing a channel purge at the end of each cycle phase.</i>
<i>Operator and instrument recognition system automatically via barcode gun.</i>

## 2.4 Traceability

The following table shows the **traceability** characteristics of the pre-wash station mod. SEB2000.

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

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
<i>Name of hospital and department.</i>
<i>Device model and serial number.</i>
<i>Total number of cycles performed.</i>
<i>Name of the operator responsible for the cycle.</i>
<i>Model, brand and serial number of the washed endoscope.</i>
<i>Times of each individual phase, total cycle time and detergent consumption.</i>
<i>Type of programme chosen.</i>
<i>Duration of the leak test.</i>
<i>Brushing tips</i>
<i>Possible alarms.</i>



## 2.5 Reprocessing programs

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	
<i>Leak test</i>	<i>12 s</i>
<i>Pre-disinfection</i>	
<i>Rinse 1</i>	
<i>Cleaning</i>	<i>300 s</i>
<i>Rinse 2</i>	<i>85 s</i>
<i>Disinfection</i>	
<i>Final rinse</i>	<i>85 s</i>
<i>Total</i>	<i>480 s</i>

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 SEB2000 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: <ul style="list-style-type: none"><li>• Air is blown continuously even in the event of an alarm, without interruption until the error is reset.</li><li>• 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.</li></ul>

### 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 SEB2000 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.

REQUIREMENTS FOR WATER CONNECTION	
G 3/8"	Water (Cold and hot)
G 1-1/2" or Ø 40mm	Drain
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
<b>Flow divider</b>	Autoclavable flow divider
<b>Silicon hoses kit DT</b>	Autoclavable silicone hoses for detergent dosing
<b>Silicon hoses kit TS</b>	Autoclavable silicone hoses for leak testing
<b>Thermal printer</b>	Thermal paper with guaranteed stability of 10 years

### 4.2 Accessories

ACCESSORIES	FEATURES
<b>Endoscope connectors</b>	Manual washing kits included in every endoscope instrument can be used with SEB2000 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.