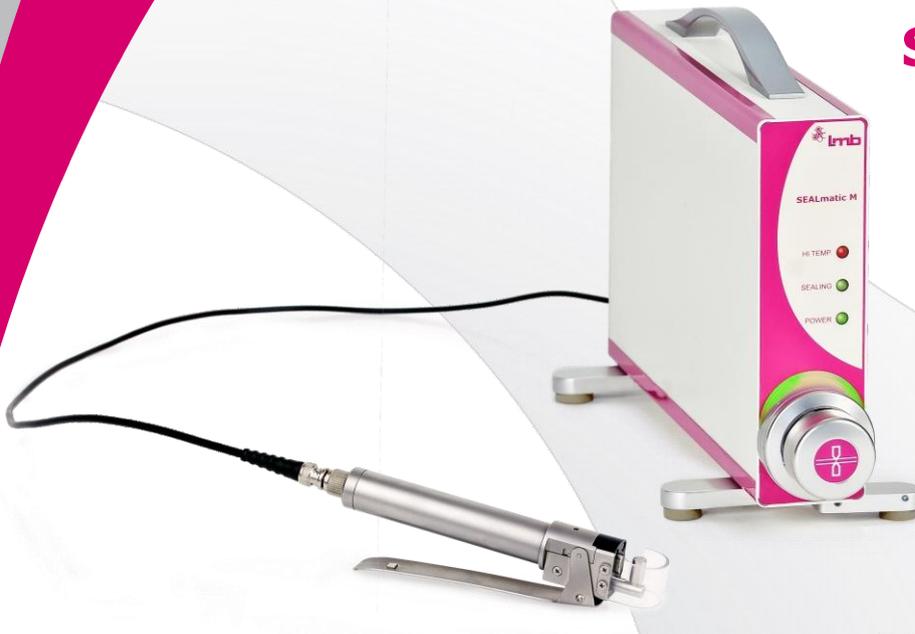


SEALmatic M



SEALmatic M is Lmb's solution for creating perfect tube segments and offering a maximum of flexibility to the user. Now SEALmatic M have INTELIGENT cooling system. Individual units can be used in standalone mode or combined freely to make a segmenting device with high variety of segment sizes. With its appealing design, carrying handle and low weight it assures a high level of mobility within the donation room. Sealing handle can be easily attached to offer even more flexibility. Outstandingly low hemolysis figures and a very quick sealing time of less than two or three seconds round out SEALmatic M as the perfect assistant in blood donation.

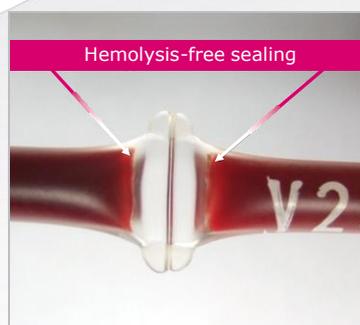


Features

- Smart silent working mode during sealing. FAN will be turned ON only when temperature rises.
- Noise friendly working environment with Sealmatic M
- Splash guard - against bursting tubes and blood leakage (optional)

- Ergonomic design
- User friendly
- Stand alone and segmentation work
- Sealing handle as an option
- Reliability
- Only 1-3 sec for one seal
- Tube diameter from 2,5mm to 6,5 mm can be sealed 3 nr.
- Low hemolysis technology
- High precision start seal optical switch
- Easy to clean
- Auto calibrating for similar tube sizes
- Service friendly
- Detachable sealing head cover enables easy cleaning of sealing electrodes
- Easy access for tube insertion

Illumination ring: for sealing monitoring



Sealing area shape



Successful sealing



Sealing error

SEALmatic M



Connection of the multiple devices

Technical data

Dimensions 60(W) x 250(H) x 396(L) mm

Weight 4,1 kg + handle (0,4 kg)

Power Supply

Voltage 100-240 VAC

Frequency 50-60 Hz

Power consumption (sealing) 200 VA max

Power consumption (on standby) 30 VA max

Power fuse 3,15 A/slow

RF generator

Nominal output power 50 W for load res. 50 Ohm

Sealing frequency 40,68 Mhz ± 5 kHz

Clamp & Sealing handle

Sealing jaws gap (opened) 5 ±0,2 mm

Sealing jaws gap (closed) 0,07 mm

Length of RF cable: 168 cm

Weight of handle with cable: 0,46 kg

Dimensions: 213 / 68 mm

Housing material: stainless steel, brass and plastic

LED indicator in sealing head

RoHS compliant

Environmental

Temperature Working conditions +10°C - +40°C

Temperature Storage conditions -20°C - +50°C

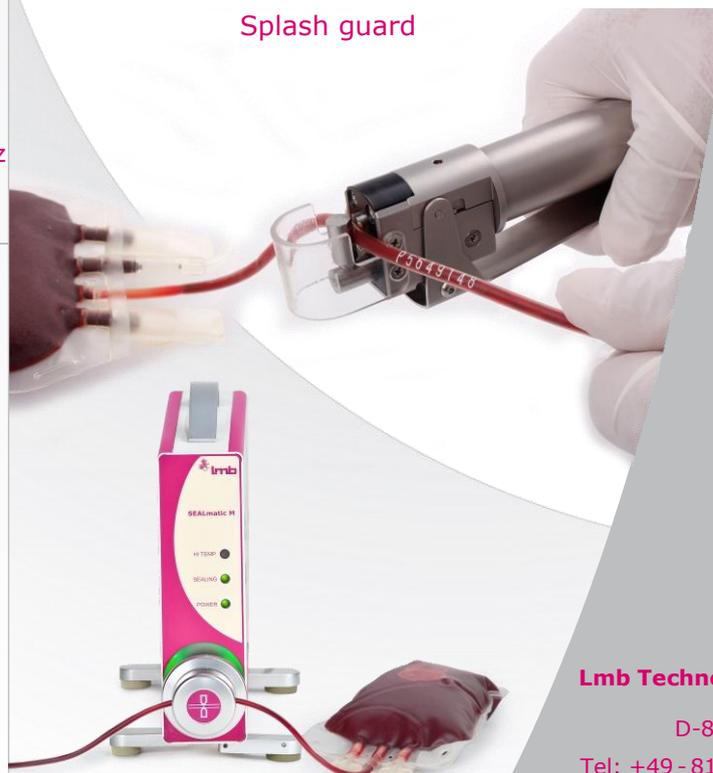
Compliance data

Classification Medical device class I

Directive and Standards applied EN 60601-1, EN 60601-1-2, RoHS



Splash guard



info@lmb.de

User Manual

For

Lmb Tube Sealers SEALmatic M/H

Version 2.3
March 2016



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Important

This manual is subject to periodic review, update, and revision. Customers are cautioned to verify that the manual's information applies to the software and hardware present in the equipment.

This product performs as described in this manual, and in accompanying labels and/or inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided.

This product must be cleaned and checked periodically. Do not use a defective product. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Do not repair this product or any of its parts other than in accordance with written instructions provided by Lmb Technologie.

The user of this product shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Lmb Technologie.

The safety, reliability, and performance of this device can only be assured under the following conditions:

- If the device has been used according to the accompanying operating instructions.
- If fittings, extensions, readjustments, changes, or repairs have been carried out by Lmb Technologie authorized representatives.
- If it is used in buildings having ground equalization wiring that complies with relevant local standards and regulations.

Disclaimer

Information provided by Lmb Technologie is believed to be accurate and reliable. However, Lmb Technologie assumes no responsibility for the use of such information nor for any infringement of patents or other rights of third parties, that may result from its use.

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1 Introduction

This user manual gives basic information about normal operation and behavior of device. It contains the full technical specification of the device and all the necessary information and support for the operator. In order to achieve the optimal result we recommend that the user reads this document carefully before any operation with the product.

The information in this document is subject to change without prior notice in order to improve reliability, design and function.

1.1 Intended use of product

1,2 nr. SEALmatic M is a device for simultaneous sealing of single or multiple tube segments. It is built for sealing PVC-tubes, especially blood bag tubes or plasmaphereses sets.

1.2 Product features

- Very quick sealing 1-3 sec single sealing
- Modular design that easily adds device in system and vice versa – device from cascade connection can function as standalone
- Single or SEGMENTER mode of working
- Adjustable lengths of segments (65/70/75/80/85/90/95 mm) 1 nr.
- Light and audible indication of correct/ incorrect sealing
 - Cap (sealing head protector for safe operation) can be easily detached for cleaning of the sealing jaws
- Low hemolysis sealing
- Automatic self-test
- Auto adjusting for similar types of tubing
- Lightweight design

Optional: Sealing handle – adding more flexibility for single sealing tasks.

1.3 Product standard and options

SEALmatic STANDARD


STANDARD CONFIGURATION:

- Power supply EURO-plug x1pc
- Dummy cable for standalone usage x1

12 nr.

Optional: Sealing Handle

AS A SEGMENTER

STANDARD CONFIGURATION:

- **Power supply EURO-plug x1pc**
- **Termination cable for standalone usage for every device in the system** (if you want to use some sealer from segment as single sealer)
- **Short Interconnection cable-inner** (*connection between devices*)
- **Long Interconnection cable-outer**

For 4 sealers in segment you need :

- 3 pcs of Short Interconnection cable-inner
- 1 pc of Long Interconnection cable-outer
- N pcs of Dummy cable (depends on number of sealers which you want to use additionally as single sealer)

SEALmatic H



STANDARD DEVICE CONFIGURATION AND EQUIPMENT:

- Power supply EURO-plug x1pc
- Sealing handle x1pc



Only as a single unit

Options and accessories

PICTURE	DESCRIPTION
	<p>Different international plugs</p>
	<p>Customized Logo-hardware CL-10000</p>
	<p>Color option CL-10002</p>

2 Safety

2.1 Types of Warnings, Cautions and Notes



Warning: A warning indicates precautions to avoid the possibility of personal injury or death.



Caution: A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.



Note: A note provides other important information.

2.2 General Safety Instructions



Warnings

•DO NOT USE BEFORE READING AND UNDERSTANDING THIS MANUAL.

- Changes or modifications not expressly approved by Lmb Technologie could affect the safety and effectiveness of the system and will void the system's warranty.
 - The system contains no user-serviceable components.
 - Changes or modifications not expressly approved by Lmb Technologie could affect the safety and effectiveness of the system and will void the system's warranty.
 - Failure of operation - If SEALmatic M fails during any part of the self-test procedures or current leakage tests, remove it from operation until qualified service personnel have corrected the situation.
 - Electrical shock and flammability hazard - Before cleaning or servicing the device, always turn it OFF and disconnect the power cord from the AC power supply.
 - Electrical shock hazard - Do not remove the side covers. An operator may only perform maintenance procedures specifically described in this User Guide. Refer servicing to qualified service personnel trained in the repair of this equipment.
 - This equipment must be properly grounded.
-
- Do not under any circumstances remove the grounding conductor from the power plug.

- Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
- If there is any doubt about the integrity of the protective earth conductor arrangement, do not operate the device until the AC power supply protective conductor is fully operational.
- Damaged Equipment – Any product that has been dropped or damaged should be checked by a qualified service technician to insure proper operation before use.
- The product is to be used only by, or on, the order of medically trained personnel.



Cautions

- Disposal of this device should be performed in accordance with local regulations.
- Keep out of the reach of children.
- Never remove the clamp cover during the sealing process.
- Do not disassemble any part of the device. This system is not user-serviceable.
- If the electrical cable becomes unplugged during operation, reinsert the cable and restart the device.



Notes

- The SEALmatic M is intended only for connection to the Lmb Technologie supplied accessory: Sealing handle.
- These instructions do not purport to cover all possible contingencies that may arise during operation or maintenance. If you require further information regarding this instrument, please contact Lmb Technologie.
- This instrument should only be opened by a duly authorized representative. The unit should only be opened in an anti-static environment. Failure to do so may damage the device.

3 Packaging

3.1 Unpacking the product before use

Remove the device from the shipping carton and inspect for possible damaged parts. Report any damage immediately to Lmb Technologie service centre. The original packing case should be used for storage and for transporting the system to a new location. Do not discard any shipping materials.

Device is delivered in disassembled state. Please follow the procedure for assembling as described in this manual. Assembling must be done by qualified persons. If any problem appears during assembling procedure please stop further activities and call technical support.



When unpacking, make sure that all components are present, and check for any damaged parts.

SEALmatic M is shipped with one of each of the following items:

- SEALmatic M main unit
- Power supply cable
- "Termination cable" for stand-alone usage ("dummy" cable)
- User manual

Optional: Sealing handle

SEALmatic H is shipped with one of each of the following items:

- SEALmatic M main unit
- Power supply cable
- "Termination cable" for stand-alone usage ("dummy" cable)
- Sealing handle
- User manual



SEALmatic M in multi device configuration requires following accessories:

- **Interconnection Cable for SEALmatic M- inner (for each two devices in segment connection)**
- **Interconnection Cable for SEALmatic M -outer (one per segment)**

3.2 Preparing the product for first use

During the transport, legs of the device are in parallel position with the bottom of the device. For the working condition of the device (ready to use), every foot has to be rotated 90° and fixed with the two screws.

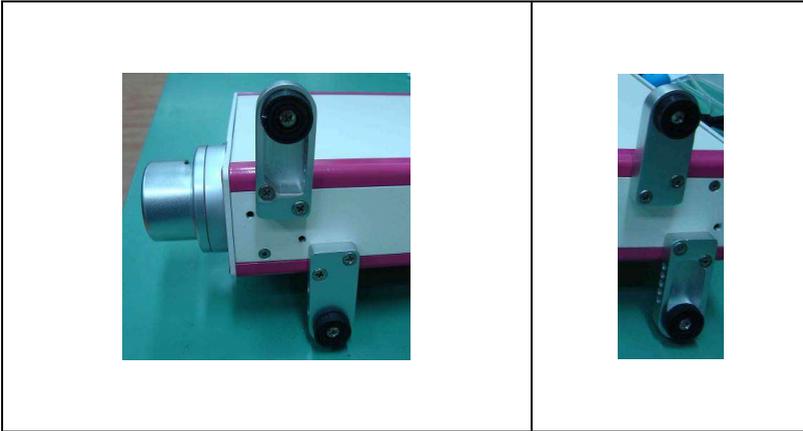


Figure 1: "Foot"

Second function of legs is to provide equidistance connection between the neighboring devices. Final position of mounted devices can be seen below.

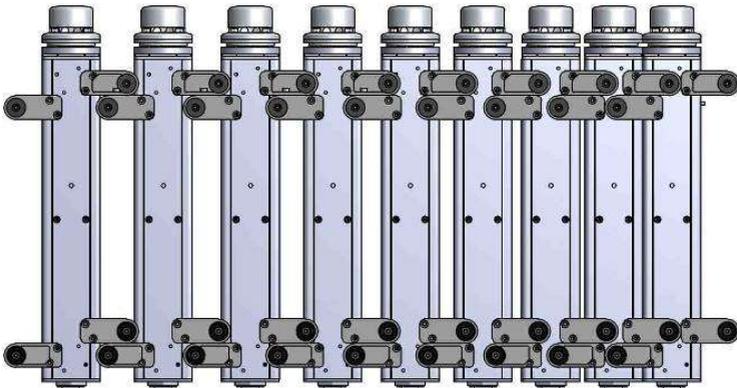


Figure 2: Interconnection of the multiple devices- view 1

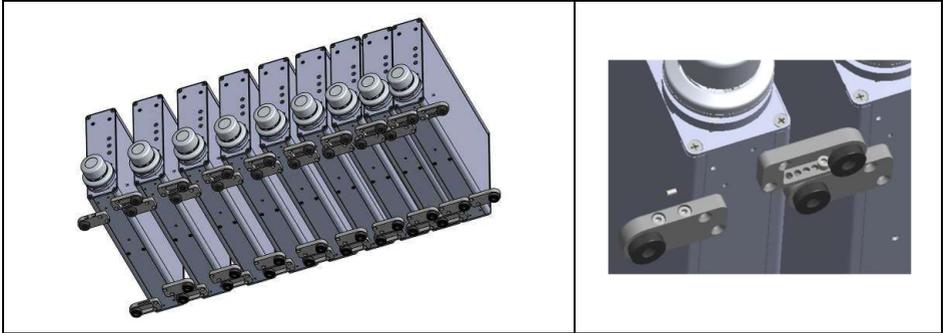


Figure 3: Interconnection of the multiple devices- view 2 & detail

3.3 Packing the product after use

If the device has to be shipped to the producer for service and repair the original packing container has to be used. If this container is not available any more please use similar or ask Lmb for recommendations.

Follow disassembling procedure as described in this manual. Please open the container box ('s) taking care about the top side!

Before first operating of device wait a few minutes that device temperature is stabilized at the room temperature and to avoid any condensation might result in difference on stock and room temperature.

4 Explanation of symbols

The following symbols may appear on the product itself, label or shipping materials.

	<p>The WEEE symbol, indicating separate collection for WEEE- Waste of electrical and electronic equipment</p>
	<p>Attention! You must take precautions when using the device. Refer to the documents that accompany the device before use</p>
	<p>RoHS2 compliant</p>
	<p>The system has CE mark.</p>

5 Technical Datasheet

SEALMATIC		M	H
General technical data			
Dimensions (with feet and clamp cover mounted)		M - 60(W)x225(H)x396(L) mm H - 60(W)x225(H)x363(L) mm	
Weight		4,1 kg + handle(0.4kg)	3,5kg + handle(0.4kg)
Segment length (mm) 4 nr		65/70/75/80/85/90/95	
Power Supply			
Voltage 11 nr.		100-240 VAC, sing.ph. AC	
Frequency		50-60Hz	
Power consumption (sealing)		200VA max	
Power consumption (on stanbay)		30VA max	
Power fuse		3.15A/slow	
Sealing head & RF generator			
Nominal output power		50W+/-10% for load res. 50ohm	
Sealing frequency		40.68 MHz ± 5kHz	
Standard sealing time 9 nr.		1-3 seconds (depending on type of tubing)	
Overheat protection		60°C	
Sealing timeout alarm		7,5 sec ± 1 sec	
Sealing jaws gap (opened)		5 ±0,2mm	
Sealing jaws gap (closed)		0,07mm	
Sealing handle			
Dimensions		220 / 70 mm	
Weight		0,4 kg	
Length of cable		168 cm	
Environmental			
Temperature (Working conditions) 10 nr.		10 ÷ +40°C	
Humidity (Storage, Transport and Working conditions)		20 ÷ 90 % non-condensed	
Temperature (Storage &Transport conditions)		-20 ÷ +50°C	
Compliance data			
Classification		Medical device class I	
Directive and Standards applied 13,14 nr.		MDD 93/42/EEC EN 60601-1; EN 60601-1-2 ; RoHS2	
Classification (Protection against electric shock)		Class I, Type B	

6 Device Description

6.1 Description of front and rear panel

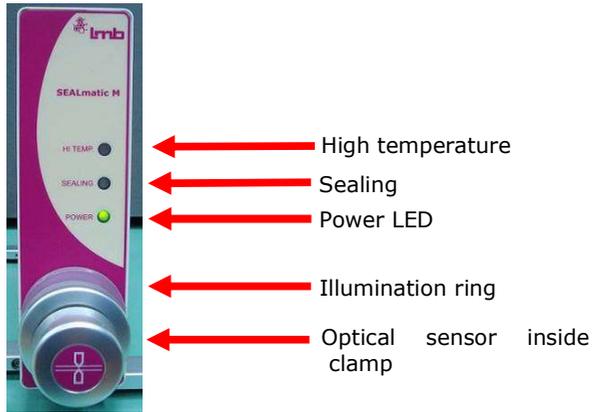


Figure 4: LED diodes at the device's front plate

LED diodes placed at the front of the device are used for monitoring self-test or sealing process.

Termination cable-standalone usage/Signal from the previous device-cascade connection

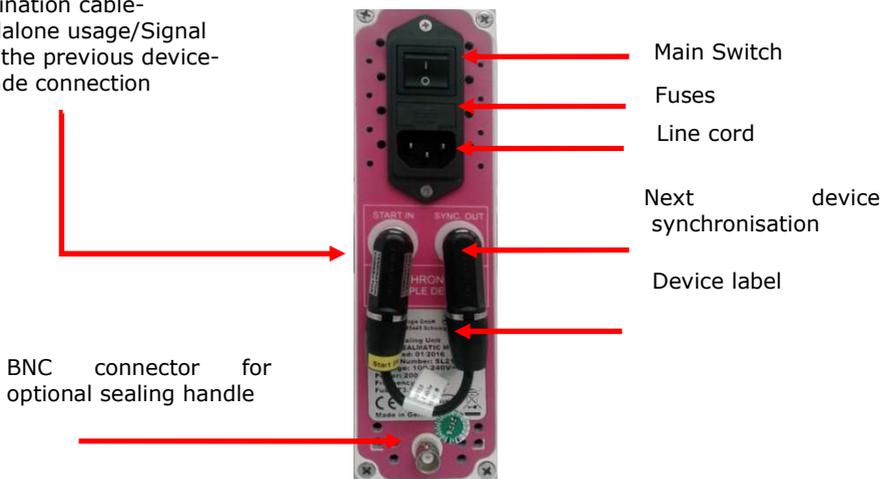


Figure 5: Back side of SEALmatic M device

Power supply and inter-connection between the devices is obtained through the back side of the device (Fig. 5).

6.2 Technology

SEALmatic device uses dielectric heating technology for heating of the tubes. Strong RF signal is provided by RF generator mounted inside the device.

6.3 Alert Specification

Signal sequence during normal Self-test:

- 1) SEALING LED (and light ring) – Flashing 1x GREEN,
- 2) SEALING LED (and light ring) – Flashing 1x RED
- 3) SEALING LED (and light ring) – Flashing 1x Orange
- 4) HIGH TEMP LED – 1x RED
- 5) Audio signal – BEEP – 1x



Last device in segment will show HIGH TEMP LED 2xRED during step 4 – that device is recognized in segment like MASTER device.

Error during self-test signals:

- 1) SEALING LED (and light ring) – Flashing RED
- 2) LONG BEEP audio signal



Error during self-test process usually means there is something blocking the clamp jaws from touching (left over piece of tubing or dirt).

6.4 Device functions

SEALmatic device can be used for 3 types of sealing:

- Single sealing – using sealing head
- Single sealing – using sealing handle (H-standard, M-optional)
- Segmenting – multi use with more than one device

In segmenting mode segment size can be adjusted by customer needs to sizes stated in technical data table.

7 User instructions

7.1 Setup and operations

7.1.1 Single unit

Default configuration is single unit. It is suitable for laboratories, medical centers or blood transfusion centers where using single tube sealing is enough for most of the daily needs.

Connect the Termination cable as on Figure 7. Connector with marking termination connector should be placed into "START-IN" plug and other side into "SYNC. OUT" at back side of the device. This will set up the device to work in standalone mode.



Figure 6: "Dummy"- termination cable for standalone usage

7.1.2 Sealing handle

- Connect the Termination cable as for single unit device.
- Connect RF cable to the sealing handle and BNC connector (at the back side of SEALmatic) by gently inserting it and turning it slightly clockwise.



Figure 7: Connecting RF cable to handle



Figure 8: Connecting RF cable to SEALmatic

7.1.3 Segmenter – multiple devices



Figure 9: Cascade connection of multiple devices

For the tube segments preparation, multiple devices have to be connected between each other in line (Fig. 9). It assumes that number of the devices is two or more. The number of segments prepared is one less than devices participating in chain (e.g. with five devices connected- four segments are made). The connection's direction is from the right to the left.

The length of the segments is adjusted by the distance between the neighboring devices. This distance can vary between the segments and it can be set by the change of distance with device feet. The segment length can be between 60 and 95mm in steps of 5 mm.



Figure 10: Chassis connectors at the back-side



Figure 11: Long Inter-connection cable

12 nr.

At the back side of the device, there are two chassis plugs for implementation of the cascade connection- "START-IN" and "SYNC.-OUT" (Fig. 10).

Connection between first and last device in segment connection is achieved by using of long inter-connection cable (Fig. 11).



Interconnection cable (connector with label termination connector) must be connected at START IN on backside of first device in segment (Picture 11)

First and last device in line must be connected with longer inter-connection cable from Start-IN to Sync OUT as seen on the picture below.

Sealers in between must be connected with shorter inter-connection cables from Start-IN to Sync OUT as seen on the picture below.



Figure 12: Connection between the neighboring devices for two and more

7.2 Sealing process

7.2.1 Single sealing – using sealing head

Basic mode of device's operation is single unit configuration (Fig.13) without sealing handle.



Figure 13: Standalone device

To perform a sealing using a single device follow these steps:

- 1) Put tube inside the clamp – LIGHT RING needs to show GREEN LIGHT (tube detected signal)
- 2) Sealing process starts – SEALING LIGHT is ORRANGE
- 3) End of sealing
 - a) Good sealing – SEALING LIGHT GREEN + 2x short BEEP
 - b) Bad sealing – SEALING LIGHT RED + 1x LONG BEEP

Sealing is activated by sensor switch (inside the clamp). Smart sealing algorithm is automatically applied to detect and adjust the sealing time to tube thickness, material and liquid inside. The whole system adjusted itself to achieve the shortest possible sealing time.



If segments are prepared with one device, user must take care that length of the segments should not be less than 50mm. Shorter distance may cause tube leakage.

If the clamp electrodes are shortened (without the tube in between), it is indicated like irregular situation. RF generator is not started – to avoid the damage. At the front panel of the device it is signaled by the red light on the sealing LED and on the illumination ring, together with audible alarm (beeps).



The temperature of the RF generator is measured, and if the temperature exceeds 60 °C (during very frequent sealing for example) further seals are stopped until generator is cooled. It is signaled by LED diode on the front panel followed by beeps on every three seconds. This will ensure long and reliable work of the RF generator.



To protect device from blocking the jaws in case of malfunction maximum sealing time is set at 7,5±1sec. If this time is exceeded device will signal sealing error.



- **This instrument is a sealing equipment using radio frequency for welding and the electrical emission. The operating frequency 40.68 MHz, is high. Make sure that other instruments and equipment near the sealing unit can withstand this emission.**
- **Never touch the electrodes with your fingers during the sealing period! This may cause burn damages!**
- **Contains electronic components which are classified as dangerous for the environment and the equipment must be left to a recycling station when disposed.**
- **Please ensure that tubes for sealing are with dry surface.**

7.2.2 Single sealing – using sealing handle

Sealing can be performed using sealing handle (H-standard, M-optional) connected to BNC connector at the back side of the device.

To perform a sealing using a sealing handle follow these steps:

1. Put tube inside the handle and close it by squeezing the handle
 2. Sealing process starts – SEALING LIGHT is ORRANGE (handle and device)
 3. Wait for sound signal
 4. End of sealing
- c) Good sealing – SEALING LIGHT GREEN + 2x short BEEP
 d) Bad sealing – SEALING LIGHT RED + 1x LONG BEEP



Light on the sealing handle is used only to inform that sealing started. Do not use this light as indicator that sealing is finished (use beep sound from SEALmatic device)!!!

7.2.3 Segmenting

Multiple device work principles

Optical switches that are placed inside the clamps are used to detect that tube is within the cap (jaws of the clamp), and that tube is properly placed.

- **Turning on ALL DEVICES** – Devices need to be turned on ONE BY ONE. The last device in segmenting line will be used as master device and it will inform that starting procedure was OK by blinking HI TEMP light twice.
- 7 nr. • **Correct placement of the tubes inside the clamp-** If tube is placed correctly there will be green light on the illumination indicator, and when all sealers inline detect that tube is inside, sealing will start on all clamps nearly in the same time.
- 6 nr. • **SEALING STATUS-** During sealing light indicator will change the color to "orange". When sealing is finished indicator will switch OFF with sound notification.

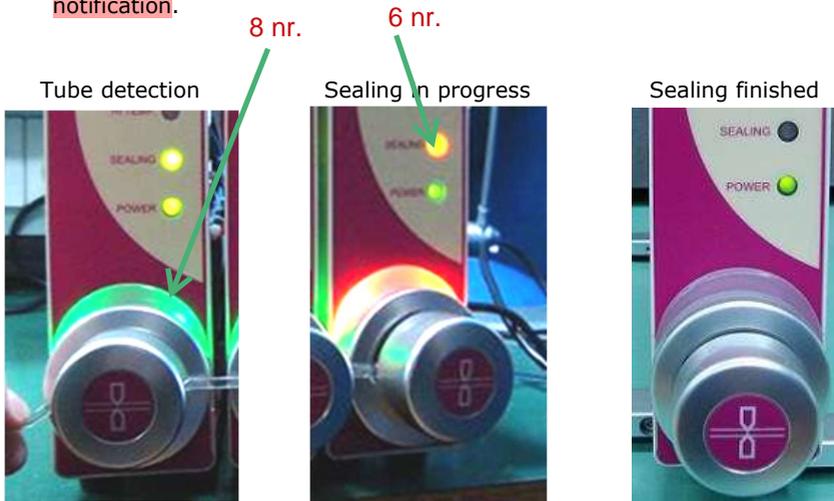


Figure 14: SEALmatic process alerts



It is possible to do a partial segmenting by placing the tube inside at least 2 devices. Sealing will be performed on selected devices while other devices stay in idle mode if not used.

8 Troubleshooting

The following table shows possible errors and symptoms and possible correction measures (troubleshooting).

Explanation:

The table contains correction measures of two different classes. **Class A**-measures can be executed by the operator of the device, **class B**-measures shall be executed by trained service technician.

Errors / Symptoms	Class	Troubleshooting / Possible corrective actions
Main switch ON but device does not work. No light on POWER LED	A	Check if power cable is firmly inserted
	A/B	Check the fuse and replace if necessary
	A	Device malfunctioning- (contact the technical support)
Hi temp" LED is ON – sealing doesn't start	A	RF generator is overheated. Wait until generator cool down and alarm state will stop
Spark appears often during sealing	A	Wet or dirt sealing electrodes – perform cleaning/drying of the sealing heads
	A	Electrodes may not be parallel (contact the technical support)
	A	After very heavy working electrodes may become overheated. Wait until they cool down
	A	Because of the leakage of the tubes, spark created dirt on the electrodes. Clean it before next sealing
Sealing shape is not good	A	Clean the area around the electrodes and sealing cap- melted particles of the tube remains on the electrodes
	A	Electrodes are damaged (contact the technical support)
Signal is not propagated to the next device in line	A	Check the interconnection cables. Change the cables between the devices
	A	Check if the sensor in clamp is properly triggering the device (check the led indicator)
	A	Exchange the position of the devices within the chain connection

9 Cleaning and Maintenance

9.1 General cleaning instructions

Device should be cleaned as defined in maintenance checklist.
Please observe the following table of warnings and cautions:



Caution: Ensure that the device is completely dry before use.



Caution: Don't allow water or any other liquid to spill onto the device interior. Unplug the line power supply from the device before cleaning or disinfecting.



Caution: Should the system become wet, wipe off all moisture and allow sufficient time for drying before operating.



Caution: Do not soak or immerse device in any liquid.



Caution: Use cleaning solution sparingly. Excessive solution can enter the unit and cause damage to internal components.



Caution: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the unit. These substances attack the device's materials and damage the device.



Caution: Contact with solvents can cause severe deterioration of plastic parts and malfunctioning of the instrument and accessories.

Standard cleaning procedure:

- Remove loose dust on the outside of the device with a lint-free cloth. Be careful to avoid scratching of the surface.
- Use a soft cloth dampened with aqueous solution of 75% isopropyl alcohol for efficient cleaning.
- Before operating device make sure that is dried properly after cleaning.
- The device is designed exclusively for indoor use only. Additional measures have to be taken if it is to be used outdoors.
- It is not necessary to maintain the device once a year. To ensure good results, a regular cleaning should be done. On customer request, an annual service can be offered.

9.2 Cleaning of the sealing heads



5nr.

Figure 15: Cleaning of sealing head

Cleaning procedure:

- Take of the clamp protective cover (cap)
- Use cotton swab dumped with 75% percent alcohol solution to clean sealing head
- Mount the protective cover back
- Make sure that sealing heads are dry before starting the device

9.3 Maintenance schedule

Components	Recommended action	Cleaning: dates			
		weekly	monthly	yearly	Remarks
Device cleaning: Due to frequent use, the electrode heads can be highly contaminated.	Use a cotton swab dampened with aqueous solution of 75% isopropyl alcohol for efficient cleaning. Cleaning as recommended in table or after contamination with blood immediately.	✓			Monthly or more often depending on level of contamination

10 Service

Equipment should be maintained in good working order. Routine maintenance may be performed by clinic staff unless otherwise specified. Any maintenance procedure not mentioned in this guide must be performed only by Lmb Technologie authorized technical personnel.



Warning: Do not remove the cover of the device. Only perform maintenance procedures specifically described in this User Manual.



Caution: Improper use or adjustment of this system may invalidate the service warranty agreement.

10.1 Service questions

Repairs of device under warranty must be made by authorized repair centers. If the device needs repair, contact Lmb Technologie Ltd. service department or your local distributor.



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www.lmb.de

11 Spare parts

	Name	Code
1	Main Board – SEALmatic	SS-10157
2	Illumination ring	SS-10164
3	RF Generator LMB	SS-10168
4	Main Power Supply TDK-Lambda LS200-12	SS-10152
5	Filter FN 282B-4-06	SM-10408
6	Welding head	SS-10166
7	PCBA Optical switch	FM-10106
8	Aluminum Cap For Clamp	SS-10165A
9	Fuse 3.15A/Slow 5 x20mm (10 pieces)	SS-10160
10	SEALmatic carrying handle	SS-10161
11	Chassis socket for device interconnection	SS-10162
12	Interconnection Cable, inner	SS-10154
13	Interconnection cable, outer	SS-10167
14	Termination cable for standalone usage	SS-10153
15	Plexiglas illumination ring	SS-10163
16	BNC Connector SEALmatic handle	SS-10401
17	Optic cables for SEALmatic	SS-10174
18	Sealing handle	SS-10156
19	Coax Cable 1.68m for SEALmatic	SS-10175