LUGITSCH-STRASSER GMBH
MEDIZINTECHNIK

A-8230 Hartberg
Schildbach 119

Tel. +43 3332 610 00
Fax: +43 3332 642 18

www.lugitsch-strasser.at • info@lugitsch-strasser.at

Technical instructions

Washing water sterilizer
System L500

for

sterilization of infectious fluids

SN 0123

LABO-SK, s.r.o.

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Subject to change

Model 4/2020
Rev. 4/2020

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Reference symbols

Certain text areas are marked with special warnings, maintenance instructions and notes in this manual. These notes and warning symbols are as follows:

Warnings

This symbol indicates a warning in the text of the manual. The symbol warns that disregarding the warning may lead to serious accidents which may be associated with a life-threatening danger. The symbol is also used to mark safety components, etc.

Maintenance instructions

This symbol marks certain important maintenance instructions to prevent damage to the unit.

Notes

This symbol marks important tips and advice which simplify operation of the device.

1. Device description

The washing water sterilizer type System L500 serves for fully automatic sterilization of continuously produced infectious washing water of up to 40 liters per hour.

Infectious fluids are heated between 1 and 60 minutes to 110 – 134 °C and are thereby steadily sterilized. After cooling, the disinfected liquid is fed into the sewer system. Solids > 0,5 mm are sterilized e.g. through a high pressure sterilizer.

The sterilization device consists of stainless steel housing in which all mechanical and electrical parts and components are situated.

The overall process ensures a clean, odourless and energy-saving operation.

The device is very gentle for the sewer system and the whole environment due to the low outlet temperature of < 50 °C after end of sterilization.

Utmost attention has been paid to safety when adjusting the device concept. The control system guarantees a fully automatically monitored operation.
The storage tank is sized so that the contaminated washing water is stored with leaky system. In case of failure, the unit switches over in a safe condition.

1.1 Safety instructions

Maintenance and service must be performed only by authorized personnel.

The washing water sterilizer is only suitable for the filling of washing water.

Read the operating instructions carefully before commissioning.
It must be documented that the manual - especially with regard to safe operation - was understood by the user.
Turn off the device and unplug power supply before you open the housing or before any inspection work.

Perform inspection, maintenance and repair work only with safety gloves because of danger of infection.
Protection functions may be impaired by improper use.
It is forbidden to empty solvents (flammable liquids) in the washing basin – **Explosion hazard!!**

Fault on Display

1	PT100 Steriliz. temp.
2	PT100 Drain temp.
3	Tank is full
4	Emergency-off
5	Safety pressure
6	Steriliz. Temp. too low
7	Steriliz. Temp. too high
8	Check level
9	Feed-in time too long
10	Power failure
11	Error heating
12	Error feed pump
13	Error motor protection
14	Heating too long
15	Draining too long
16	Pressure transmitter
17	Pressure too high
18	Washing water too hot
19	Drain valve
20	Calligator empty
21	Unit leaking
22	Temperature limiter

1.3 Documentation – program listing

Each sterilization cycle is fully automatic and stored on USB stick.

The printout of the program can be printed over the network.

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AUSTRIA +43 3332 61000

STERILIZER	1	
TIME:	13:48:22	
DATE:	12.12.2016	CH1: STERILIZINGTEMP.
BATCH:	106	CH2: DRAINTEMP.
PROGRAM:	1	CH3: STERILIZINGPRESSURE

STERILIZINGTIME	00:05:00
STERILIZINGTEMP	134 °C

PROGRAM	**CH1**	**CH2**	**CH3**
HEATING			
13:48:26	012.2	015.7	0976
13:51:26	018.6	015.6	0977
13:54:26	026.4	015.4	0976
13:57:26	033.8	015.3	0977
14:00:26	041.5	015.3	0977
14:03:26	049.3	015.3	0976
14:06:26	056.1	015.2	0976
14:09:26	063.0	015.1	0980
14:12:26	070.7	015.2	0979
14:15:26	077.4	015.1	0977
14:18:26	084.4	015.0	0978
14:21:26	090.6	014.7	0977
14:24:26	095.4	014.7	0979
14:27:26	099.4	014.5	1027
14:30:26	105.2	014.4	1285
14:33:26	111.8	014.3	1584
14:36:26	117.6	014.3	1940
14:39:26	123.6	014.2	2354
14:42:26	129.6	014.3	2835
14:45:26	134.6	014.3	3207
STERILIZING			
14:45:31	134.7	014.3	3189
14:46:31	134.8	014.3	3146
14:47:31	134.6	014.4	3149
14:48:31	134.4	014.5	3120
14:49:31	134.6	014.5	3112

DISCHARGE

14:50:31	134.1	014.5	3086
14:54:31	133.6	039.9	2988
14:58:31	132.6	037.1	2842
15:02:31	127.3	032.1	2514

END

15:03:18	119.2	019.5	1064

PROCESS FINISHED AND OK SIGNATURE:

1.4 Monitoring device

Process control

The process control monitors the proper functionality of all relevant electrical components during the whole sterilization process.

The correct temperature-pressure profile is programmatically checked within the whole sterilization cycle. Each sterilization cycle is fully automatic.

1.5 Optional equipment

Standard version

As for the standard version, all components such as control, operating unit as well as washing basin with fittings are integrated in functional and elegant stainless steel housing. See figure 1.

Figure 1
Washing water sterilizer

1.6 Additional tank - OPTION

There is the possibility to deliver an additional tank for the storing of infectious liquids including pumping system. The additional tank can also be situated in other premises.

2. Process and program description

2.1 Process description

The water tap is activated contact by means of infrared, the washing water is pumped from the washing basin via the storage tank into the sterilization vessel by means of a pump.
As soon as the defined filling level in the sterilization vessel has been reached, the sterilization process starts automatically.
The washing water is heated to a maximum of 2,1 bar 134 °C in the sterilization vessel. A flow line leads back to the storage tank to reach the sterilization temperature in the sterilization vessel. Therefore, the air caused by the heating and the condensate can escape from the sterilization vessel via a sterile filter. Furthermore, the entire piping system to the drain valve is sterilized in the sterilization phase by a circulation pump. This ensures a consistent temperature distribution in the washing water.
The program version works with a holding time of 1 up to 60 minutes and a temperature of 110 °C up to 134 °C (maximum throughput 1000 l/24 h). After completed thermal sterilization the now sterile liquid is cooled in a heat exchanger to 50 °C and emptied into the drain. The temperature in the sterilization chamber is monitored by a PT 100 temperature sensor. In case that the measured value is under the adjusted sterilization temperature the process is cancelled and an error message is displayed, recorded and carried out via a potential-free contact. In the event of a failure all valves are closed, so that under no circumstances infectious washing water gets into the drain.

2.2 Program description

- Sterilization temperature 110 °C to 134 °C
- Heating time: approx.15 to 30 minutes
- Sterilization time: 1 to 60 minutes
- Cooling time: approx. 10 minutes
- Total cycle time: on average 50 to 110 minutes

3. Installation

Installation requirements
To guarantee operational safety and a failure-free operation the installation site has to meet the following requirements:

- room temperature at least 10° C - up to a maximum of 35 °C
- security clearance at least 10 cm (at least three sides of the unit)
- Relative humidity < 80 %
- Altitude: 0000 - 2000 meters

The below mentioned installations have to be existent to be able to operate the washing water sterilizer type L500:

- Euro socket 5-pole 3 x 400/230 V, 50 Hz
- Fuse 16 A slow
- Minimum diameter of sewer junction 40 mm and up to 70 °C temperature-resistant. The junction must be laid vertically or with a maximum of 15 cm from the floor.
- Cold water connection of at least ½“ flow pressure 1,5 - 6 bar < 7 dH
- Cold and hot water connection at least ½ " flow pressure 1,5 - 6 bar for mixing battery at the sink
- Optionally a mixed water connection of at least ½“ flow pressure 1,5 - 6 bar for drain cock at washing basin.
- Optionally a cooling water circuit at least ½ "
- The distance of all connections to the installation site shall be not more than 1 meter.
- All electrical and pipe connections have to be checked before commissioning, as they can become loose during transport.
- Insert the suction lance 6S1 for the Calligator in the canister
- Remove the sterile filter from the control cabinet and place it on the tank connection
- Check the direction of rotation of the 3M1 pump after commissioning

6. Declaration of conformity

CE – Konformitätserklärung
CE declaration of conformity

Hiermit erklären wir, dass der nachstehend bezeichnete Sterilisator in seiner Konzipierung und Bauart sowie in der von uns in Verkehr gebrachten Ausführung den grundlegenden Sicherheits- und Gesundheitsanforderungen der EG – Richtlinie entspricht.
Bei einer mit uns nicht abgestimmten Änderung des Waschwassersterilisators verliert diese Erklärung ihre Gültigkeit.

Herewith we declare that the appliance designated below, on the basis of its design and construction in form brought onto the market by us, is an accordance with the relevant safety and health requirements of the EC Directive.
If alterations are made to the washing water sterilizer without prior consultation with us, this declaration becomes invalid.

Gerät: **Appliance:**	**Waschwassersterilisator** **Washing water sterilizer**
Typ: **Type:**	**L500** **L500**
Serien-Nr.: **Serial No.:**	**0123** **0123**
EG – Bestimmungen: **EC Council Directives:**	**2006/95/EG Niederspannungsrichtlinie** **97/23/EWG Druckbehälter-Richtlinie** **EMV 2004/108 EG** **2006/95/EC Directive** **97/23/EC PD Directive** **EMC 2004/108 EG**
Angewandte Normen u. techn. Spezifikationen: **Applied standards & technical specifications:**	**EN 61010-1:2010** **EN 61010-1:2001+Ber. 1:2002+Ber.2:2004** **EN 61010-2-040:2005** **EN 61326-1:2013** **DIN EN 12128** **ÖNORM EN ISO 12740**
Ort und Datum der Ausstellung: **Place and date of issue:**	**Schildbach, 27.05.2020**
Name: **Name:**	**Gerhard Lugitsch-Strasser**
Funktion: **Position of signatory:**	**Geschäftsführer** **business manager**

7. Standards, guidelines

The washing water sterilizer is based on the following standards and guidelines:

- **ÖVE/ÖNORM EN 61010-1:2010**
- **EN 61010-1:2001+Ber. 1:2002+Ber. 2:2004**
- **EN 61010-2-040:2005**
- **ÖVE/ÖNORM EN 61326-1:2013**
- **DIN EN 12128**
- **ÖNORM EN ISO 12740**
- **2006/95/EG low voltage directive**
- **97/23/EC PD Directive**
- **2004/108 EMC Directive**

8. Warranty

- 1 year warranty on material and manufacturing errors (Option: extension to 2 years)
- 5 years warranty on stainless steel and pressure vessel

9. Process validation for washing water sterilizer L500 system (Option on request)

Thermoelectric tests:
Complete filling with maximum wastewater volume of 30 liters at a holding time of 1 - 60 min. and a sterilization temperature 110 - 134 °C

Three sterilization processes are carried out for each program. There is a connection 6/4 “ for the validation at the front of the sterilization vessel.

Including provision of measuring equipment as well as test report.
Tests concerning the minimum temperatures in the sterilization vessel.

and/alternatively

microbiological test with bioindicators,
via validation connector 6/4“ introduceable – on request

sampling under sterile conditions – on request

Enclosed you will find a confirmation of 1st February 2017 about the necessary level of pathogen reduction issued by the Medical University of Graz Univ. Prof. Mag. Dr. Franz F. Reinthaler

10. Technical data

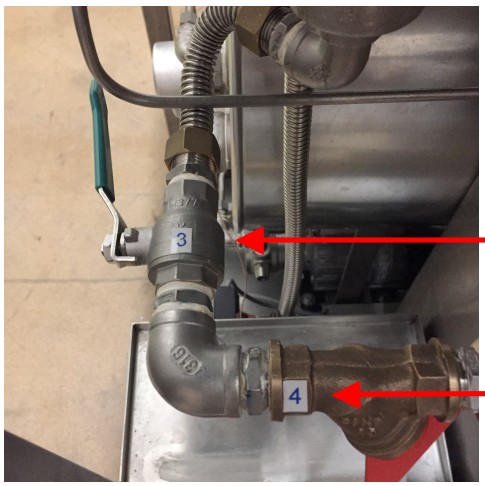
Sterilization temperature	**110 – 134 °C**
Maximum drain temperature	**50 °C**
Throughput	**To 1000 l/24 h**
Supply voltage	**3 x 400 V+N, 50 Hz**
Nominal capacity	**7 KW**
Fuse Protection	**3 x 16 A**
Energy consumption	**4 KW/batch, 55L cold water/batch**
Depth	**750 mm**
Width/with additional tank	**600 mm/1200 mm**
Hight	**900/1500 mm**
Closed floor base with moisture sensor	
cold water	**2 – 6 bar, > ½ " < 7 dH**
hot water	**2 – 6 bar, > ½ "**
Option Batch printer	
Option potential-free contact for fault	
Option Storage with USB Flash Drive	
Option Eyewash bidirectional according to DIN 15154-2	
Option 3.6 kw heater for wall mounting	
Option Disinfectant dispensers stainless steel with initial filling	
Option Soap dispenser stainless steel with initial filling	
Option Ethernet interface for maintenance / diagnostic sequence analysis, including hardware and software	
Option additional software with hardware 5.7 "color touch screen for maintenance / diagnostics via RS 422 or via LAN	
Option Additional tank > 200 liters	
Option cooling water circuit	**> ½ " < 10 °C**

10.1 Maintenance

<u>Daily visual inspection</u>
Check the washing sterilizer for leaks during commissioning or even daily.
Maintenance after 2500 batch/annually

Cleaning of dirt trap if necessary
In case that the washing water does not flow off the washing basin, the dirt trap is blocked or the tank is full.

1. Use protective gloves
2. Close ball valve (Pos. 3)
3. Place container under dirt trap
4. Open dirt trap (Pos. 4)
5. Clean dirt trap sieve and reinstall it
6. Reopen the ball valve (Pos. 3)
7. Empty the water from container into washing basin
8. Solids from the dirt trap with grain size > 1 mm are sterilized over a high pressure sterilizer



The exchange of safety-related components such as PT100 temperature sensor, safety valve, pressure transmitter, safety temperature limiter must be documented!
The spare parts must be calibrated after installation, this calibration must be documented!

10.2 Faults

	Display Anzeige	**Description** Beschreibung	**Cause** Ursache
1	**PT100 sterilization temp.** PT100 Steriltemp.	-**check sensor of sterilizing chamber temperature 10R1** -Fühler Sterilisierkammertemperatur 10R1 prüfen	-**sensor of sterilizing chamber temperature 10R1 defective** - Fühler Sterilisierkammertemperatur 10R1 defekt
2	**PT100 drain temp.** PT100 Abflusstemp.	**-check sensor 10R2 of discharge temp.** - Fühler 10R2 Abflusstemperatur prüfen	**-sensor 10R2 defective** -Fühler 10R2 defekt
3	**Tank overfill** Tank überfüllt	**-Check Tank full level switch 5S3** -Niveauschalter Tank voll 5S3 prüfen	-**actuated level switch 5S3** -Niveauschalter 5S3 ausgelöst **-washbasin valve leaking 8Y3** -Magnetventil 8Y3 Wasserablauf Waschbecken undicht
4	**Emergency stop** Not-Aus	-**check emergency-OFF switch 5S6** -Not-Aus Schalter prüfen 5S6	**-pushed emergency-OFF** -Not-Aus gedrückt
5	**Sterilization temp. too low** Steriltemperatur zu niedrig	**-check feed L1,L2,L3** -Anspeisung L1,L2,L3 prüfen **- heater element or heating contactor defect** **-**Heizung oder Heizschütz defect **-Level switch steam generator 6S2 defect** -Niveauschalter Dampferzeuger 6S2 defekt	- **sterilization temp. is too low** -Sterilisiertemperatur unterschritten
6	**Sterilization temp. too high** Steriltemp. zu hoch	-**heating contactor defect** -Heizschütz defekt	- **exceeded sterilization temp.** -Sterilisiertemperatur überschritten
7	**Check tank level** Tank Niveau prüfen	-**check level switch 5S5 or 5S4** -Niveauschalter 5S5 oder 5S4 prüfen	-**level switch 5S5 has not switched even though 5S4 has opened** -Niveauschalter 5S5 hat nicht geschalten obwohl 5S4 geöffnet hat

8	**Feed pump taking too long** Speisezeit zu lange	**-check line** -Leitung prüfen -**check feed pump 3M1** -Speisepumpe 3M1 prüfen **-check solenoid valve 8Y5 discharge** -Magnetventil 8Y5 Ablassen prüfen **-check solenoid valve 8Y6 streaming** -Magnetventil 8Y6 Strömung prüfen	**-remove air from feed pump 3M1** -Speisepumpe 3M1 entlüften **-solenoid valve 8Y5 not water tight** -Magnetventil 8Y5 undicht **-solenoid valve 8Y6 not water tight** -Magnetventil 8Y6 undicht
9	**Power failure** Stromausfall	-**check voltage** -Spannung prüfen	**-no power** -Spannung ausgefallen
10	**Error heating** Fehler Heizung	**-check x3/7 T0,8A fluse** -Sicherung x3/7 T0,8A prüfen **-check x1/1T6,3A fluse** -Sicherung x1/1T6,3A prüfen -**check heating contactor** -Heizungsschütz prüfen -**check safety pressure switch 7S1** -Sicherheitsdruckschalter 7S1 prüfen -**check safety thermostat 7S2** -Sicherheitsthermostat 7S2 prüfen **-check emergency-OFF 5S6** -Not-Aus prüfen 5S6 **-Level switch steam generator 6S2 defect** -Niveauschalter Dampferzeuger 6S2 defekt	**-fluse x3/7 T0,8A faulty** -Sicherung x3/7 T0,8A defekt **-fluse x1/1T6,3A faulty** -Sicherung x1/1T6,3A defekt -**contactor 8K2 has not activated** -Schütz 8K2 hat nicht angezogen
11	**Error feed pump** Fehler Speisepumpe	**-check pump contactor 8K1** -Pumpenschütz 8K1 prüfen -**check motor protection 3Q1** -Motorschutz 3Q1 prüfen	-**contactor 8K1 has not activated** -Schütz 8K1 hat nicht angezogen
12	**Heating taking too long** Aufheizen zu lange	-**check heating** -Heizung prüfen **-check feed L1,L2,L3** -Anspeisung L1,L2,L3 prüfen **-check PT100 sterilization temp.** -PT100 Steriltemp. prüfen **-Level switch steam generator 6S2 defect** -Niveauschalter Dampferzeuger 6S2 defekt	**-8K2 has not switched** -8K2 hat nicht geschalten

13	**Draintime taking too long** Ablasszeit zu lange	-**drain is blocked** -Abfluss verstopft -**check discharge valve 8Y5** -Ablassventil 8Y5 prüfen -**check heat exchanger** -Wärmetauscher prüfen	**-Check filter** -Schmutzfänger prüfen **-Switch off the washing water sterilizer, switch on again after 10 seconds and restart the process** -Waschwasser Sterilisator ausschalten, nach 10 sec. wieder einschalten und Prozess neu starten
14	**Pressure transmitter** Drucktransmitter	-**pressure transmitter 4U4 defect** -Drucktransmitter 4U4 defekt	**-exceeded pressure transmitter range** -Drucktransmitterbereich über- oder unterschritten
15	**Pressure too high** Druck zu hoch	**-check pressure transmitter 4U4** -Drucktransmitter 4U4 prüfen	**- Pressure transmitter has exceeded 3500 mbar** -Drucktransmitter hat 3500 mbar überschritten
16	**Sterilization chamber leaking** Sterilisierkammer undicht	**-Check level switch 5S7** -Niveauschalter 5S7 prüfen **-Check None return valve item 10,11** -Rückschlagventil Pos. 10,11 prüfen **-check valve 8Y2, 8Y5, 8Y6** -Ventil 8Y2, 8Y5, 8Y6 prüfen **-check pressure switch 7S3** -Druckschalter 7S3 prüfen	**-Valve 8Y2, 8Y5, 8Y6 or none return valve Pos. 10,11 not water tigth** -Ventil 8Y4, 8Y5, 8Y6 oder Rückschlagventil Pos. 10,11 undicht
17	**Calligator empty** Calligator leer	**-Check level switch 6S1** -Niveauschalter 6S1 prüfen	**-canister lime binder (Calligator empty)** -Kanister Kalkbindemittel (Calligator leer) **-level switch defective** -Niveauschalter defekt
18	**Unit leaking** Gerät undicht	**-Check leak sensor 7K3** -Leckwarner 7K3 prüfen	**-by leakage water accumulating at the bottom of the unit** -durch Undichtheit sammelt sich Wasser am Geräteboden **-leak sensor defective** -Leckwarner defekt

10.3 Statement of Compliance

Statement of Compliance

Herewith the manufacturer confirms

Company Lugitsch-Strasser GmbH
Medizintechnik

that it operates decalcifier

Calligator 4722

can easily be used in the following devices

washing water sterilizer type L500
wastewater sterilizer type L500S

The undersigned is fully responsible for all faults, damages and costs which can be attributed to the decalcifier.

Schildbach, 27.05.2020 .....

stamp/signature

10.4 Transport

Possible procedure for transporting the washing water sterilizer:

- The washing water sterilizer is covered with a plastic film and bonded close to the bottom.
- It is injected into the plastic-film-cover (enclosed washing water sterilizer) with a special degassing apparatus 5 g/m³ Formaldehyde.
- The time of fumigation (fumigate - exposure - neutralize) is 6 hours.
- You may arrange for the fumigation of a virologist of the competent health authority. The time of fumigation is set individually by virologist depending on the pathogen.