USER MANUAL
LOTUS
ULTRASONIC SURGICAL SYSTEM & ACCESSORIES

BOWA
LOTUS

10522en-ISSUE18

Table of Contents

1. Using this operating manual 5

1.1. Revision Index 5

1.2. Validity 6

1.3. Icons and labeling 7

1.3.1. Structure of warning instructions 7

1.3.2. Risk levels in warning instructions 7

1.3.3. Tips 7

1.3.4. Other symbols and marks 7

2. Intended Purpose 8

2.1. Indications 8

2.2. Contra indications 8

2.3. Expected users 8

2.4. Intended patient group 8

2.5. Clinical Benefit 8

3. Safety 9

3.1. General safety instructions 9

3.2. Personal safety instructions 9

3.2.1. Patients with pacemakers 10

3.2.2. Hazard-free patient positioning 10

3.2.3. Ambient conditions 10

3.2.4. Correct use of the device and accessories 11

3.3. Product-related safety instructions 11

3.4. Safe handling (general instructions) 12

3.5. Hazards in laparoscopy 13

3.5.1. Procedure-related hazards 13

3.5.2. Device-related hazards 13

4. Description of the Generator 14

4.1. User interface components 15

4.1.1. Front panel user interface components 15

4.1.2. Rear panel user interface components 15

4.1.3. Rear panel messages 16

4.1.4. Audio-Visual information 17

4.1.5. Audio-Tones 17

4.2. Symbols 18

4.2.1. Ratings on the rear panel 19
4.3. Packaging information 19
4.4. Components Required for Operation 19
4.5. Operating conditions 19
5. Preparation 20
5.1. Setting up the LOTUS system 20
5.1.1. Attach the footswitches (optional) for the LG4 20
5.1.2. Assemble the instrument 21
5.1.3. Attach the instrument to the generator 23
5.2. Switch on the LG4 24
5.2.1. Initialise the handpiece 25
5.2.2. Activate the LOTUS shears 26
5.2.3. Change power level 26
5.2.4. Turn off the LOTUS LG4 generator 26
6. Troubleshooting 27
7. Preparation 29
7.1. Warnings and Guidelines 29
7.2. Preparation of the accessories 29
7.3. Disinfecting and cleaning 30
7.3.1. Cleaning the generator 30
7.3.2. Processing instructions (Transducer) 30
7.3.3. General Information 31
7.3.4. Device-specific Information 31
8. Equipment care 34
8.1. Waveguide inspection 34
8.2. Transducer / Waveguide usage 34
8.3. Storage of equipment between cases 35
9. Maintenance and repair 35
9.1. Maintenance 35
9.1.1. Technical Safety inspection (TSI) 35
9.2. Repairs 36
10. Storage 37
11. Electromagnetic Compatibility (EMC) 37
11.1. Guidelines and Manufacturer's Declaration in Accordance with IEC 60601-1-2:2014 38
12. Disposal 41

13. Technical Specification 42
14. Technical Service 43

1. Using this operating manual

This operating manual is part of the device.

The manufacturer assumes no liability nor provides any warranty whatsoever for damage and consequential damages that arise due to non-compliance with the operating manual.

Read the operating manual carefully and thoroughly before using this device.

Store the operating manual in a safe place throughout the service life of the device.

Keep the operating manual accessible to operating room personnel.

Give the operating manual to each successive owner and/or user of this device.

Always update the operating manual whenever you receive additional information from the manufacturer.

1.1. Revision Index

Unit version	Last revised
Valid for LG4 firmware version 6 or higher	2017/05

1.2. Validity

This operating manual applies only to the devices in the following items list:

ITEM	Product Code
LOTUS Dissecting Shears Straight Transducer Open 200	SV3-200
LOTUS Dissecting Shears Curved Transducer Laparoscopic 400	CV3-400
LOTUS Dissecting Shears Straight Transducer Bariatric 500	SV3-500
LOTUS Enhanced Shears Curved Transducer Open 200	ES4-200CT*
LOTUS Enhanced Shears Curved Transducer Laparoscopic 400	ES4-400CT*
LOTUS Enhanced Shears Curved Transducer Bariatric 500	ES4-500CT*
LOTUS Liver Resector Straight Transducer Open 200	LR3-200
LOTUS Liver Resector Straight Transducer Laparoscopic 400	LR3-400
LOTUS Dissecting Shears Straight Handpiece Open 200	DS4-200SD
LOTUS Dissecting Shears Curved Handpiece Open 200	DS4-200CD
LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400	DS4-400CD
LOTUS Dissecting Shears Straight Handpiece Bariatric 500	DS4-500SD
LOTUS Dissecting Shears Curved Handpiece Bariatric 500	DS4-500CD
LOTUS Dissecting Shears Curved Handpiece Bariatric 500	LR4-200SD
LOTUS Liver Resector Straight Handpiece Laparoscopic 400	LR4-400SD
LOTUS Dissecting Shears Curved Handpiece Open 200 / 360°	DS5-200CD
LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400 / 360°	DS5-400CD
LOTUS Dissecting Shears Curved Handpiece Bariatric 500 / 360°	DS5-500CD
LOTUS Liver Resector Straight Handpiece Open 200 / 360°	LR5-200SD
LOTUS Liver Resector Straight Handpiece Laparoscopic 400 / 360°	LR5-400SD
LOTUS Enhanced Shears Curved Transducer Open 200 / 360°	ES5-200CT*
LOTUS Enhanced Shears Curved Transducer Laparoscopic 400 / 360°	ES5-400CT*
LOTUS Enhanced Shears Curved Transducer Bariatric 500 / 360°	ES5-500CT*
LOTUS Enhanced Shears Curved Transducer Bariatric 500 / 360°	LR5-200ST*
LOTUS Liver Resector Straight Transducer Laparoscopic 400 / 360°	LR5-400ST*
LOTUS Series 4 Generator	LG4
LOTUS Generator Cart	LGC
LOTUS CART, equipment trolley, assembled	902-070
LOTUS LG4 Carry Case	LC4
LOTUS LG4 Footswitch	LF4
LOTUS reprocessing basket with lid 550x150x77 mm	773-984
LOTUS reprocessing basket with lid 640x150x77 mm	773-985
LOTUS reprocessing basket with lid for Series 5;650x150x68 mm	773-986
LOTUS reprocessing basket with lid for Series 5;730x150x68 mm	773-987
LOTUS Cart Footswitch Holder	LCFH1
LOTUS Autoclave Tray	LAT1
LOTUS Series 4 User manual	BOWA-IFU_10522_LOTUS-LG4_ISSUE18_en

* Only for LG4 generators with software version issue 6 or later

1.3. Icons and labeling

1.3.1. Structure of warning instructions

⚠ SIGNAL WORD

"Risk type, source and consequences there of" (Personal injury)!

► Measure for risk prevention.

NOTE

"Risk type, source and consequences there of" (Property damage)!

► Measure.

1.3.2. Risk levels in warning instructions

Symbol	Risk level	Probability of occurrence	Consequences of non-compliance
	**DANGER**	Immediate risk	Death, serious injuries
	**WARNING**	Possible risk	Death, serious injuries
	**CAUTION**	Possible risk	Minor injuries
	**NOTE**	Possible risk	Property damage

1.3.3. Tips

Tips and additional information to facilitate tasks

1.3.4. Other symbols and marks

Symbol or mark	Meaning
☑	Prerequisite for an activity
►	Activity with one step
1. 2. 3.	Activity with several steps in a binding sequence
⇩	Result of preceding activity
•	List (first level)
•	List (second level)
Emphasis	Emphasis
....., see Section xxx	Cross reference

2. Intended Purpose

Ultrasonic surgical equipment for cutting and coagulation of tissue.

2.1. Indications

LOTUS ultrasonic surgical generator & accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. The System may be used as an adjunct to or substitute for electrosurgery, lasers, and traditional scalpels in general, plastic, gynaecologic, urologic, thoracic, exposure to orthopaedic structures (such as joint space), and other open and laparoscopic procedures in adult patients.

2.2. Contra indications

- The system is not indicated for use in direct contact with the heart, the central cardiovascular system or the central nervous system.
- The system is not indicated for cardiac surgery.
- The system is not indicated for incising bone structures.
- The system is not indicated for contraceptive tubal occlusion.
- The system is not indicated where its surgical techniques are contraindicated.
- The system is not indicated if, in the opinion of experienced physicians or according to current professional literature, such use would cause endangerment of the patient for example due to the general condition of the patient) or if other clinical contraindications are present.
- The instruments are not indicated for coagulation and dissection of vessels exceeding 5.0 mm in diameter.

2.3. Expected users

This device is intended for a user group that comprises surgeons and qualified clinical professionals.

2.4. Intended patient group

The LOTUS Ultrasonic Surgical Generator & Accessories can be used for all adult patients. There are no restrictions regarding different patient groups.

- The ultrasonic generator must not be used if, according to the opinion of an experienced physican or according to current professional literature, any hazard exists.
- Care must be taken if the patient has an implanted cardiac rhythm management (CRM) device, such as an implantable Cardioverter Defibrillator (ICD) or pacemaker. In these cases, the manufacturer of the CRM-device and/or the responsible cardiologist must be consulted.

2.5. Clinical Benefit

The Ultrasonic Surgical Generator & Accessories can be used in various surgical interventions that require:

- Coagulation and/or vessel / tissue sealing (up to 5 mm vessels),
- Dissection of tissue,
- Blunt dissection of tissue,
- Grasping and manipulation of tissue.

3. Safety

3.1. General safety instructions

The LOTUS system:

- Should be used with an appropriate power level commensurate with the required task.
- Should be used with correct surgical technique.

▶ Ensure that no electronic devices that are subject to interference from electromagnetic fields are set up in the vicinity of the device.

▶ Observe the instructions on electromagnetic compatibility provided in the Electromagnetic Compatibility (EMC)section.

▶ Always connect the device to a mains power system with a protective earth lead in order to prevent electric shock.

▶ Always transport LOTUS using adequate packaging.

Additional devices that are connected to electrical medical devices must satisfy relevant IEC or ISO standards (e.g. IEC 60950 for data processing devices). Furthermore, all configurations must comply with the standardised requirements for medical systems (see IEC 60601-1-1 or Section 16 of the 3rd edition of IEC 60601-1 as relevant). Anyone who connects additional devices to electrical medical devices is automatically a system configurator and thus responsible for meeting standardised system requirements. Please note that local laws prevail over the aforementioned standard requirements. In case of questions, please contact your local dealer or Technical Service.

To protect personnel, the manufacturer recommends the use of a smoke evacuator to extract electrosurgical smoke, e.g. BOWA SHE SHA.

3.2. Personal safety instructions

To prevent accidental activation of the Transducer, the scrub nurse should avoid touching the three contact points on the black Transducer casing.

⚠ WARNING

Care should be taken when in contact with tissue between activations!

▶ Avoid accidental activation.

⚠ WARNING

Avoid the risk of electric shock!

▶ This equipment must only be connected to a mains supply with protective earth.

⚠ WARNING

Hot instrument tips can cause burns!

The tip of the instrument may still be hot and can cause burns after it has been switched off.

- ▶ Do not place the instrument on the patient or come into contact with the instrument dip.

NOTE

Avoid touching or holding the blade at the end of the energized waveguide!

- ▶ It is a tissue cutting and cauterising device.

⚠ WARNING

Avoid resting the blade on skin or sensitive tissue such as bowel for at least 10 sec. after cessation of energising!

- ▶ It will have become hot while cutting. All ultrasonic systems dissipate heat quickly.

3.2.1. Patients with pacemakers

Device-related patient leakage currents can possibly influence the function of the pacemaker. Malfunction or destruction of the pacemaker can endanger the life of the patient or result in irreversible injuries to the patient.

- ▶ In the case of patients with pacemakers, consult the cardiologist and/or specialist pacemaker consultant before using the ultrasound generator.
- ▶ Keep a fully operational defibrillator within reach.

3.2.2. Hazard-free patient positioning

- ▶ Ensure that the patient is resting on a suitable surface in order to prevent pressure necrosis.

3.2.3. Ambient conditions

NOTE

If the waveguide touches any metal object while activated, sparks may be produced!

- ▶ Do not operate LOTUS in a potentially explosive or flammable area.

- ▶ LOTUS is only intended for use in an operating theatre (professional healthcare facility environment).
- ▶ Do not use the generator in the immediate vicinity of the patient.

3.2.4. Correct use of the device and accessories

Inadvertent activation of the Transducer outside the user's field of vision can injure the patient.

- ▶ Activate the device only when your field of vision is clear and you can quickly deactivate the device at all times.
- ▶ If the device is activated inadvertently, switch it off immediately using the on/off switch.
- ▶ Take particular care when using a foot switch or Handpiece.

Damage may occur through incorrect preparation, user errors or faults in the equipment.

- ▶ Ensure that no conductive fluids (e.g. blood or amniotic fluid) have penetrated the handle or Transducer.
- ▶ Use only insulated accessories.
- ▶ Check all instruments for sharp edges and projecting parts before use.
- ▶ Use only accessories that are free of defects and in good working order.
- ▶ Do not remove hot instrument tips from the patient's body directly after cutting or coagulation.

The user may cool a hot blade / jaw in saline.

NOTE

Avoid damage to the patient and the trocar!

- ▶ Ensure that the jaw is in the closed position whenever the device is inserted or withdrawn from the cannula.

3.3. Product-related safety instructions

LOTUS devices are developed in accordance with the current state of technology and generally accepted safety rules. Despite this, using these products can lead to risks to the life and health of the user or third parties and/or damage to the device or other objects.

- ▶ Use only approved accessories, see section accessories and replacement parts.
- ▶ Use the device only when it is free of technical defects and in good working order and only for the intended purpose, always remaining aware of safety requirements and risks and complying with this operating manual.
- ▶ Malfunctions that can adversely affect safety (e.g. deviations from the permissible operating conditions) must be repaired without delay.
- ▶ Only wipe down the generator with cleaning agents and disinfectants that are approved in the country of use for surface cleaning.
- ▶ Never immerse the generator in water or cleaning agents.
- ▶ Never boil the generator and never disinfect it mechanically.
- ▶ If any fluids penetrate the device, drain them immediately.

Damage to the device can lead to an undesirable increase in output power due to improper operation of the device.

NOTE

Avoid clamping the jaw too hard on incompressible “soft” tissue, bone or inorganic objects such as rubber gastric bands!
The Handpiece can generate high forces in this state which could result in damage to the instrument or in extreme cases detachment of the jaw during use:

- ► Clamp lightly and let the ultrasound do the work.

NOTE

If the Handpiece becomes damaged or deformed in any way either prior to or during use:

- ► Replace it.
- ► Do not attempt to repair any damaged or deformed devices.
- ► Contact our technical service.

The jaw liner may be damaged if the jaw is closed against an activated waveguide without tissue between them.

The LOTUS LG4 has an equipotential terminal on the back panel. This is provided for compatibility with other medical systems requiring such connections. This conductor is not intended for protective earthing. Refer to EN 60601-1 for details of use with Medical Electrical Systems.

3.4. Safe handling (general instructions)

- ► Before each use, check to ensure that the equipment is functioning properly, is in good working order and connected properly.
- ► Observe the instructions on intended use in conformance with standards.
- ► During use, always observe and comply with the audible signals and/or error messages of the device.
- ► The device and accessories may be operated and used only by people who have the necessary training, knowledge and experience.
  - This device should only be used by surgeons who are:
    (1) trained in the types of surgical procedures that are to be carried out and
    (2) trained in the specific use of ultrasonic surgical instruments.
- ► Regularly inspect the accessories for damage to the insulation, proper operation and expiration date (Handpiece).
  - Before use it is recommended that cables are inspected for damaged insulation.
  - Before use it is recommended that the waveguide is inspected for damage.
- ► Instruments must not be laid upon the patient or other devices.
- ► Wear suitable gloves during operations.
- ► Report any incidents or near misses to your country’s medical devices regulatory agency. When doing so, follow your own facility’s internal reporting system. Notify your local BOWA specialist retailer in such cases.

Mains isolation is achieved by use of the double pole mains switch located on the rear panel.

3.5. Hazards in laparoscopy

3.5.1. Procedure-related hazards

A laparoscopic procedure may lead to the following risks:

- Haemorrhage caused by tissue injury or ineffective Haemostsis.
- Mechanical or thermal damage of tissue with the risk of acute or delayed bleeding, organ perforation or fistula formation.
- Injury caused by sticking of the instrument tip to the tissue treated.
- Leakage from tissues or organs treated.
- Infection at the site of application.
- Side effects associated to plume and vapor Formation.
- Device breakage and loss of components in the body cavity.

3.5.2. Device-related hazards

- Ultrasonic surgery can cause lateral thermal damage to the tissue depending on the power setting and application time. It can occur when using for a prolonged period of continuous activation without a pause.
- Tissue lateral thermal spread can lead to inadvertent damage of adjacent organs or structures.
- Coagulation necrosis is greater when used continuously without a rest period.
- To prevent the risk of a burn, the user should remove any visible tissue build up from the device.
- Resting the blade on skin or sensitive tissue after cessation of energising shall be avoided for at least 10 s as it will have become hot while cutting. The user may cool a hot blade / jaw in saline.

4. Description of the Generator

The LG4 provides an ultrasonic scalpel channel to the surgeon with a single socket for the Transducer. The LG4 has the option to be operated by a footswitch via air switch nozzles located on its rear panel.

The LG4 incorporates an LCD screen on the rear panel that displays frequency during activation, error codes when needed and Transducer lifetime values on boot up.

The generator running the Transducer is microprocessor controlled and is designed to produce ultrasonic energy at the resonant frequency of the attached Transducer within a range of 35 to 37 kHz.

Careful control of the generator output ensures that the energy delivered to the Transducer increases automatically in response to increasing load; in effect, as the Transducer's waveguide is loaded, more energy is supplied to the shears.

Figure 1: LG4 LOTUS generator - switched off

4.1. User interface components

4.1.1. Front panel user interface components

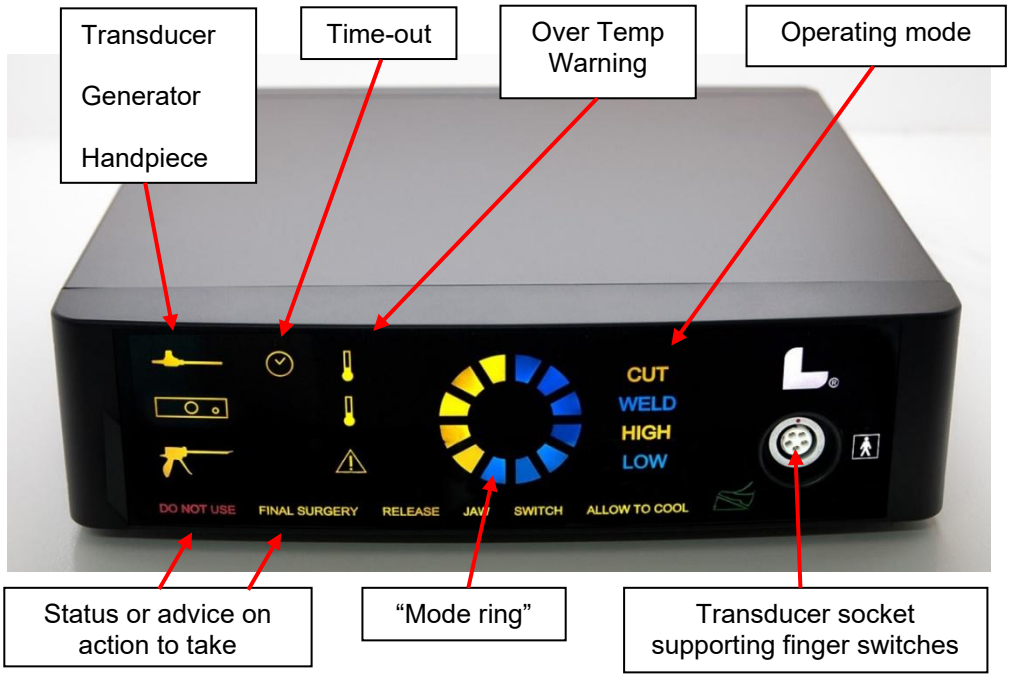


Figure 2: Essential features of generator front panel

4.1.2. Rear panel user interface components

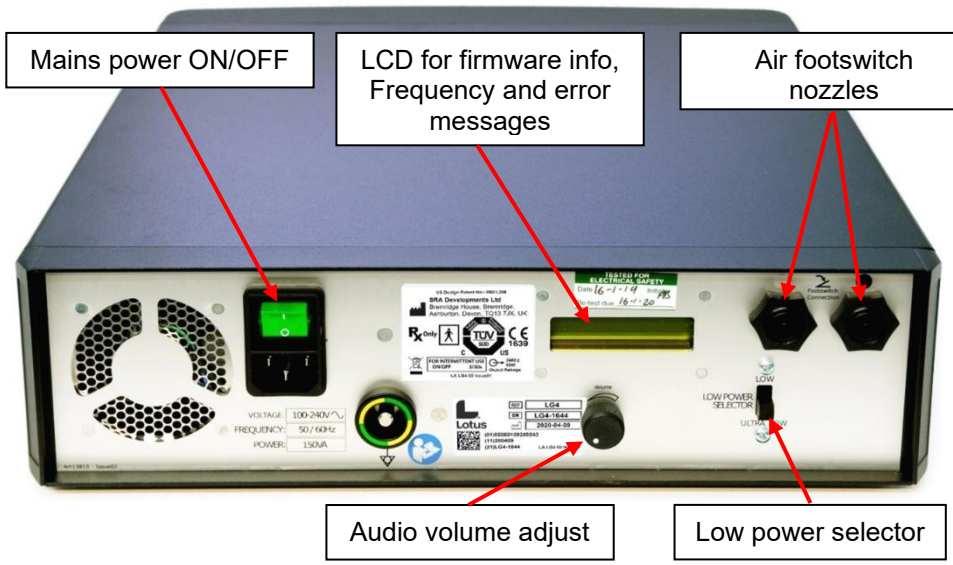


Figure 3: LG4 generator rear panel (exemplary illustration)

4.1.3. Rear panel messages

Message	Status	Action required
SRA Developments LG4 Issue x	Start-up message. Shows the issue number of the software "x" "LG4" may be replaced by HEXxxxx	Now awaiting Transducer to be plugged in
SRA Developments TDCR = xx% Used	Start-up message with Transducer. Shows the % usage of the Transducer	Now awaiting toggle switch
SRA Developments LO ▓▓▓▓	The Toggle Switch has been operated and the Transducer is ready to be activated	Now awaiting use
00000 Hz HI ▓▓▓▓▓▓▓	High power is selected (via footswitch or handpiece)	No action required
36000 Hz LO ▓▓▓▓	Topline shows the frequency. After releasing the switch, it will display the final running frequency	No action required
Released Switches LO ▓▓▓▓	The Activate Button has been held on for too long. No output	Release Activate Button on Handpiece or on footswitch
SRA Developments Release Switches	Either Activate or Toggle Button (or footswitch) has been pressed during switch on	Release Activate or Toggle Button when switching on generator
Check Transducer Ease Grip and Retry	Transducer has been loaded too heavily	Release switch, then reactivate using less pressure on the jaw
	Transducer is over-temperature	Allow Transducer to cool
Check Transducer Restart	Transducer may have bad connection	Check Transducer connection Replace is required
Transducer Limit LO ▓▓▓▓	Transducer is approaching 100 % lifetime and must be replaced	Replace Transducer after completion or procedure
Change Tdcr Transducer Limit		
Transducer Limit Final Surgery		
Transducer Expired Change Transducer	Transducer has reached 100 % lifetime and must be replaced	Use another Transducer - no usage is allowed
Change Transducer Restart	Transducer frequency too low and feedback signal is low	Switch supply off & on Replace Transducer if seen 3 times
Tdcr Leakage Change Tdcr	Generator has detected voltage on the Transducer	Switch supply off & on Replace Transducer if seen 3 times
Frequency Error Service Due	The generator has detected serious internal problem	Switch supply off & on If message seen again, generator required service
Poor ADC Signal Service Due		
LED ERROR Service Due		
WG Fatigue Change TDCR	The generator has detected that the waveguide has fatigued or is about to fatigue	Replace Transducer

4.1.4. Audio-Visual information

The screen is highly visible, especially in a darkened operating room, indicates operating mode selected and gives concise instructions on action required in the event of disruption to normal operation.
All of the visual indicators available are shown in Figure 4.

Figure 4: Status, fault and advice indicators

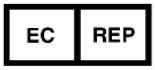
This screen momentarily illuminates all of its symbols when the LG4 is first switched on. There is a speaker volume control on the rear of the generator.

Handle the Transducer with care.
Do not attempt to modify the Transducer.
No modification of this equipment is allowed.

4.1.5. Audio-Tones

Rising flourish	LG4 is booting to standby mode
No Tone	LG4 is in standby mode
Triple tone – low-medium-low pitch	Handpiece Power Select Button has been pressed to initialise Handpiece
Continuous low pitched tone	Continuous acoustic output at the LOW-power level
Continuous high pitched tone	Continuous acoustic output at the HIGH-power level
Triple tone – low-medium-high pitch	Mode is changing from LOW to HIGH power
Triple tone – high-medium-low pitch	Mode is changing from HIGH to LOW power
Double beep –high>low pitch	1. The generator has reset itself after a minor problem such as a mistuning event, time-out or over-temperature warning or 2. The generator has encountered a minor problem that requires power switch to be cycled OFF/ON or 3. The Low Power Selector slide switch on the rear panel has been adjusted in either direction.
Triple beep – high>high>high pitch	A more serious problem has been detected such as Transducer connection

4.2. Symbols

Symbol	Designation
	Labeling of electrical and electronic devices in accordance with Directive 2002/96/EC (WEEE); see Disposal
	Caution!
	Manufacturer
	Date of manufacture
	Observe use instructions
	Medical device
	Model number
	Serial number
	Authorised representative in the European community/ European union
100-240 V	Mains AC voltage
50/60 Hz	Mains AC frequency
150 VAC	Input power
36 kHz	Frequency of input
50 W	Output power
	Alternating Current
	Type BF equipment
	Volume
	Footswitch connection
	Equipotential connection
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

4.2.1. Ratings on the rear panel

The device has been approved with the ratings shown below. These ratings are stated on the rear panel of the device.

Power supply input	100…240 V~, 50/60 Hz
Power consumption	150 VA
Output - Frequency of operation	36 kHz

4.3. Packaging information

You will find detailed packaging information in the current data sheets.

4.4. Components Required for Operation

- Power cable,
- Footswitch (optional),
- Transducer,
- Handpiece,
- Generator.

4.5. Operating conditions

Temperature	+10 °C…+40 °C
Relative humidity	30 %...75 %
Atmospheric pressure	780 hPa…1060 hPa

5. Preparation

5.1. Setting up the LOTUS system

NOTE

Electromagnetic fields are generated during normal use of the device. This can adversely affect other devices!

The Handpiece can generate high forces in this state which could result in damage to the instrument or in extreme cases detachment of the jaw during use:

► Ensure that no electronic devices are placed in the vicinity of the device.

WARNING

Electric shock hazard!

► Always connect the device to a grounded power distribution system in order to prevent electric shock.

The device may be used only in rooms used for medical purposes that meet the requirements of IEC 60364-7-710.

If the device was previously stored or transported at temperatures below +10 °C or a, non-condensing, relative humidity above 75% it will take approximately three hours to adjust to room temperature.

1. Observe the specified operating conditions, see section Operating conditions.
2. Place the generator on one of the following platforms:
   - a table,
   - an equipment trolley,
   - a console suspended from a ceiling support or wall-mounted brackets.
3. Place the generator a sufficient distance away from other electronic equipment, see section Electromagnetic Compatibility (EMC).
4. Position the generator with the front facing the patient and surgeon.
5. Do not place any other devices on the generator.
6. Do not place any other objects on or above the generator.
7. Connect the power cord.

5.1.1. Attach the footswitches (optional) for the LG4

If you do not want to use the Handpiece finger switches, push the footswitch tubes firmly onto the nozzles on the rear of the generator. Ensure the black collared tube connects to the black marked nozzle and the grey collared tube connects to the grey marked nozzle.

5.1.2. Assemble the instrument

⚠ DANGER

The use of Transducers or Handpieces not supplied as part of the LOTUS system may damage the generator and create a safety hazard for the operator and patient!

► Use only approved accessories see section Validity.

NOTE

Contact with metal may fracture the jaw!

► Do not allow an energised waveguide to come into contact with any metal surface. In particular avoid energising the waveguide tip directly against the hinged jaw if the (white) PTFE jaw liner is damaged or displaced.

For detailed information see the operating manual for the Handpiece and for the Transducer.

The following table shows the Transducers and their corresponding Handpieces:

Transducer		Compatible with handpiece	Colour code
Code	**Description**		
SV3-200	LOTUS Dissecting Shears Straight Transducer Open 200	DS4-200SD	
CV3-400	LOTUS Dissecting Shears Curved Transducer Laparoscopic 400	DS4-400CD	
SV3-500	LOTUS Dissecting Shears Straight Transducer Bariatric 500	DS4-500SD	
ES4-200CT	LOTUS Enhanced Shears Curved Transducer Open 200	DS4-200CD	
ES4-400CT	LOTUS Enhanced Shears Curved Transducer Laparoscopic 400	DS4-400CD	
ES4-500CT	LOTUS Enhanced Shears Curved Transducer Bariatric 500	DS4-500CD	
LR3-200	LOTUS Liver Resector Straight Transducer Open 200	LR4-200SD	
LR3-400	LOTUS Liver Resector Straight Transducer Laparoscopic 400	LR4-400SD	
ES5-200CT	LOTUS Dissecting Shears Straight Transducer Open 200 / 360°	DS5-200CD	
ES5-400CT	LOTUS Dissecting Shears Curved Transducer Laparoscopic 400 / 360°	DS5-400CD	
ES5-500CT	LOTUS Dissecting Shears Straight Transducer Bariatric 500 / 360°	DS5-500CD	
LR5-200ST	LOTUS Liver Resector Straight Transducer Open 200 / 360°	LR5-200SD	
LR5-400ST	LOTUS Liver Resector Straight Transducer Laparoscopic 400 / 360°	LR5-400SD	

1. Simply align the coloured orientation mark on the “upright” fin of the rotation wheel, with the red dot or coloured stripe on the top front of the Transducer case see figure 5 & 6.

Figure 5

Figure 6

2. Slide the tip of the Transducer’s waveguide through the small aperture inside the rear of the Handpiece socket to engage the two parts and gently push the Transducer fully into the Handpiece, see figure 7.

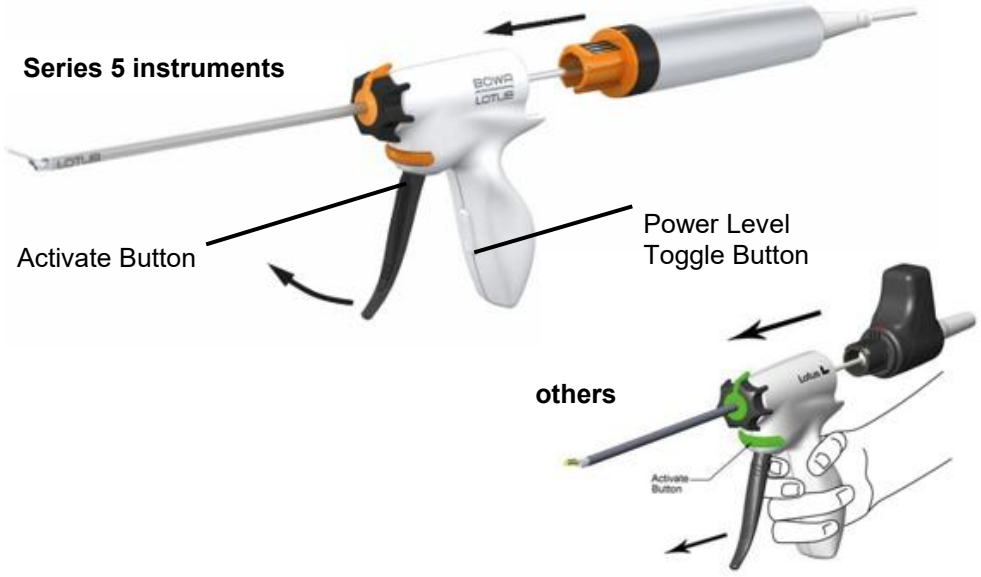


Figure 7

NOTE

Avoid damage to the jaw liner!

► When connecting the shears Handpiece to the Transducer it is essential that the finger trigger is fully pushed forward.

5.1.3. Attach the instrument to the generator

LOTUS instruments are manufactured with two different plug types.

Figure 8

When using an instrument equipped with a plug shown in figure 8 proceed as follows:

1. To remove the protective cap, hold the grip area on the plug with one hand, and hold the grip area on the cap with the other hand. Pull back the cap to release.
   Only remove the protective cap when you are outside the sterile area.
2. Align the coloured dot on the cable plug with the red dot on the generator socket, see Figure 10.
3. Push the plug into the socket until it clicks.
4. To remove, pull back on the knurled part of the plug (not the cable).

Figure 9

If the transducer is equipped with a plug shown in figure 9:

The connector is sealed and therefore does not require a protective cap.

1. Align the coloured dot on the cable plug with the red dot on the generator socket, see figure 10.

When the Transducer button is activated the associated Transducer light on the generator will light up.

Figure 10

2. Push the plug into the socket properly.
3. To remove, never pull the plug out by the cable.

5.2. Switch on the LG4

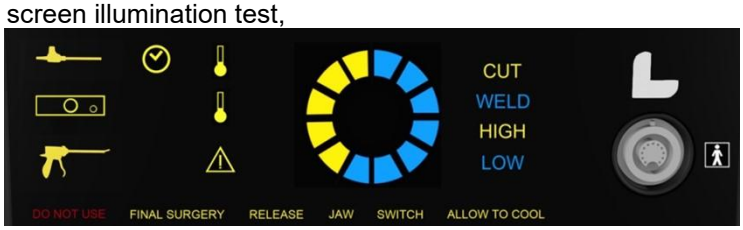
1. Connect the mains lead to the rear of the generator.
2. Select the required LOW power setting. Set the Low Power Selector slide switch on the rear panel up for standard Low power, or down for Ultra Low power.

High power remains unchanged in either setting.

You can change Low power selection any time during the procedure, and as often as you require, simply by adjusting the Low Selection Slider up or down between activations.
The fast double beep “Warning” tone is given whenever the Low Power Selector slide switch is adjusted in either direction.

- Full details of the audio tones can be found in section Audio-Visual information.
- Full details of LCD messages can be found in section Rear panel user interface components.

3. If present, do not remove the cap from the Transducer plug in the sterile field.
4. Plug the Transducer into the front socket.
5. Press the green ON/OFF power switch at the rear of the unit. The generator will now power up with an audio indicator (a flourish of tones), conduct a brief full screen illumination test,



and then read the device type register in the EEPROM (built into the Transducer plug).

As the LG4 does this, the yellow Transducer symbol illuminates for one second,

before extinguishing to leave the LG4 in standby mode.

If the Transducer is not plugged in when the rear power switch is switched on, then the LG4 will boot up without the EEPROM read stage. In this case the Transducer must now be plugged in. The LG4 will then automatically read the EEPROM, illuminating the Transducer symbol for one second.

5.2.1. Initialise the handpiece

When the surgeon is ready to use the Transducer, they must initialise it to enable power.
This is done simply by pressing the white Power Select (Toggle) button, on either the Handpiece or the footswitch, once.

The LG4 screen changes to LOW.
A three-tone sound (low-medium-low pitch) sound signifies initialisation.

Low Power Selector slider UP ***LOW***

Low Power Selector slider DOWN ***ULTRA LOW***

The device is now ready for use.

5.2.2. Activate the LOTUS shears

1. Press the Activate button on the Handpiece.
   This will energise the Transducer for surgery. An audible indicator signifies power delivery to the Transducer via a continuous low-pitched tone.

   ↳ The Transducer symbol will illuminate whilst the Transducer is active.

2. To terminate power, release the coloured button. If the button is held down continuously for 20 seconds, the audio indicator sound will change from continuous to pulsed.

   ↳ After a further 5 seconds the generator will terminate power for safety. At “time-out” power is cut, the audible indicator stops, and the screen clears to:

3. The hazard, clock and release switch symbols remain illuminated as long as the Activate button is pressed. When it is released, normal operation resumes.

5.2.3. Change power level

1. Press the white Power Select (Toggle) button.
   ↳ The LG4 screen changes to HIGH:
   ↳ A triple tone (low-medium-high pitch) sound signifies the mode change.

2. Press the Activate button on the Handpiece.
   ↳ This will energise the Transducer for surgery. An audible indicator signifies power delivery to the Transducer via a continuous low-pitched tone.
3. To terminate power, release the coloured button. If the button is held down continuously for 20 seconds, the audio indicator sound will change from continuous to pulsed.
4. Press the white Power Select (Toggle) button, on either the Handpiece or the footswitch, again to revert to LOW.
   ↳ A triple tone (high-medium-low pitch) sound signifies the mode change

5.2.4. Turn off the LOTUS LG4 generator

1. Press the green ON/OFF power switch at the rear of the unit.
   ↳ The screen will become entirely black.

6. Troubleshooting

 The illuminated yellow triangle indicates that a fault has occurred.

It will always be accompanied by:

- An illuminated symbol indicating the part of the equipment where the fault has occurred: Transducer, Handpiece or generator.
- Illuminated text instructing the user e. g. “Release Jaw”.

If the warning relates to expired time on the Transducer, a clock symbol will also illuminate.
If the warning is temperature related, a thermometer symbol will also illuminate.

1. DO NOT USE – Transducer lifetime is near, or over, 100%. A high-low tone will sound. This prevents further use of the Transducer. Switch the generator OFF then ON to clear the message. Re-energise the Transducer away from the patient.
   ↳ If the message recurs, then change the Transducer and return it for service.

2. FINAL SURGERY – Transducer lifetime is low. This will only occur during use.

3. RELEASE JAW – triple scan has misfired giving a “Release Jaw” warning.
   ↳ A high-low tone will sound.

4. RELEASE SWITCH – (Handpiece button or footswitch is held in).
   ↳ A high-low tone will sound.

5. ALLOW TRANSDUCER TO COOL – Transducer frequency is too low.
   ↳ A high-low tone will sound. Try again after 5-10 seconds.

6. TRANSDUCER / WAVEGUIDE PROBLEM - The generator has detected a problem – either with the connections to the Transducer or the waveguide has fatigued. The warning light will flash, and a triple high-high-high tone will sound and repeat. Switch the generator OFF then ON to clear the fault. Re-energise the Transducer away from the patient – if the fault recurs, then change the Transducer and return it for service.

7. Preparation

7.1. Warnings and Guidelines

⚠ WARNING
Electric shock hazard!
- ▶ Always connect the device to a grounded power distribution system in order to prevent electric shock.

When carrying out any work on contaminated medical devices, the guidelines of the Employer's Liability Insurance Association and relevant national Health & Safety legislation must be observed.

When preparing and using the solutions, follow the chemical manufacturer's specifications, ensuring correct dilution, exposure time and service life. Incorrect concentration may result in damage. Consider the microbiological range of action of the chemicals used.

National laws and regulations must be observed.

7.2. Preparation of the accessories

- ▶ Prepare the accessories as described in the corresponding operating manuals.
- ▶ Check the accessories before and after use for damage and to ensure that they are working properly.

Instruments must always be cleaned, disinfected and sterilised before use. Effective cleaning and disinfection are essential for effective subsequent sterilisation of instruments.

1. Ensure that only adequately validated device- and product-specific methods are used for cleaning, disinfection and sterilisation and that the validated parameters are complied with in each cycle.
2. Observe applicable national regulations and the hygiene regulations of the hospital or clinic.

The disinfectant used for preparation is solely intended for personal protection and does not replace subsequent disinfection steps.

The lifetime of the instruments is determined by their function and how carefully they are used and handled.

7.3. Disinfecting and cleaning

NOTE

Incorrect handling of the device can cause damage to the unit!

- ► Never sterilise the LOTUS generator. Instead, clean or disinfect it.

7.3.1. Cleaning the generator

⚠ WARNING

Risk of electric shock and fire!

- ► Unplug the power connection before cleaning the device.
- ► For cleaning surfaces, use the approved cleaning agents/disinfectants only as specified by the manufacturer.
- ► Ensure that no liquid penetrates the device.

The LG4 LOTUS generator may be cleaned as follows:

1. Ensure the generator is turned off and the mains lead is unplugged.
2. Dilute a neutral pH detergent according to the IFU of the detergent being used.
   It is recommended to use cleaning and disinfection agents which are suitable for surface cleaning of medical devices made of plastic, metal and glass.
   The manufacturer accepts no responsibility if other types of cleaning and disinfecting agents are used.
   Follow the instructions provided by the manufacturer of the cleaning agent.
3. Using above solution, lightly moisten a soft, clean cloth. Wipe surfaces of the generator.
4. Using tap water, lightly moisten a soft, clean cloth. Wipe surfaces of the generator.
5. Dry generator surfaces with a soft, clean cloth.
6. We recommend wipe-down disinfection using *Dr. Schumacher – Cleanisept Wipes.*

⚠ DANGER

Infection hazard!

- ► Incorrectly reprocessed medical devices expose patients, users and third parties to a risk of infection as well as the risk that the medical device may malfunction.

7.3.2. Processing instructions (Transducer)

Please ensure that following use the Single Use Handpiece has been removed from the Transducer and disposed of as clinical waste. These processing instructions according to EN ISO 17664-1 have been validated by the manufacturer to ensure the capability of the LOTUS system for reuse (please see following table and corresponding foot notes). Instruments should be cleaned, disinfected and sterilised prior to use using the following guidelines. It is the responsibility of the user to ensure that processing is performed in a controlled manner using validated and calibrated equipment. Any deviation by the processor from these instructions should be evaluated for effectiveness and potential adverse consequences. All Transducers are provided clean but not sterile. All Transducers have been inspected prior to

shipment. Please contact your local dealer or Technical Service if further information is needed.

7.3.3. General Information

- ▶ Follow instructions and warnings issued by the manufacturer for processing and equipment use.
- ▶ Do NOT use ULTRASONIC WASHING or Cidex® OPA.
- ▶ Manual reprocessing methods are not recommended due to their significantly lower effectiveness.
- ▶ Transducers must always be cleaned, disinfected and sterilised before use.
- ▶ Effective cleaning and disinfection are essential for effective, subsequent sterilisation of the Transducers.

1. Ensure, that only adequately validated device- and product-specific methods are used for cleaning, disinfection and sterilisation and that the validated parameters are complied with in each processing cycle.
2. Observe the applicable national legal regulations and the hygiene regulations of the hospital or clinic.

- ▶ BOWA assumes no warranty for malfunction of Transducers in connection with disinfectants or the methods used, including the effectiveness of the disinfectants, if the specified process is not followed.
- ▶ Only the sterilisation methods listed below are to be used:
  - Fractionated vacuum procedure (with adequate device drying)*,
  - Steam Steriliser in accordance with EN 13060 or EN 285,
  - Validated in accordance with EN ISO 17665,
  - Maximum sterilisation temperature 134°C, including tolerance according to EN ISO 17665 (137°C incl. tolerances of the steam steriliser according to EN 13060 or EN 285),
- ▶ * Using the less effective gravitation method requires an additional validation (longer sterilisation times may be necessary).
- ▶ The use of other methods (such as hot air sterilisation, ethylene oxide, formaldehyde, radiation, or low temperature sterilisation) are NOT permitted and BOWA accepts no responsibility for the use of other sterilisation methods.
- ▶ Observe the following, if such methods are used:
  - EN ISO 14937,
  - Standards relevant to the method.
- ▶ Demonstrate the suitability and effectiveness of the method, taking into account the specific product geometry in the context of the validation (including investigation of sterilisation medium residues, if appropriate).
- ▶ Sterilisation in the transportation packaging is not allowed.
- ▶ Use a suitable sterilisation packaging and/ or suitable sterilisation container:
  - In accordance with EN ISO 11607/ EN 868,
  - Suitable for steam sterilisation (temperature resistance up to 137°C, sufficient steam permeability),
  - Serviced regularly (sterilisation container).

7.3.4. Device-specific Information

- ▶ 140 ºC (285 ºF) is NOT to be exceeded during the reprocessing steps.
- ▶ Do NOT use ULTRASONIC WASHING.
- ▶ Scratches or dents to the Waveguide can result in a breakage or malfunction.
- ▶ For those transducers with an end cap, place the end cap on the plug when the Transducer is not connected to the generator, in particular during transport, storage and reprocessing.

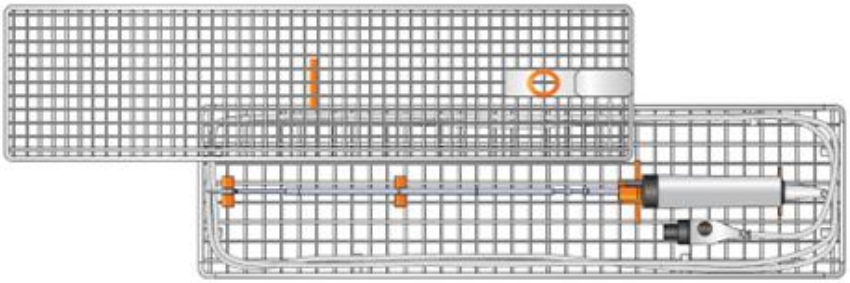
- For those transducers with an end cap, remove the end cap immediately prior to connecting to the generator in the non-sterile area.
- To protect the Waveguide, it is recommended to use the processing trays listed below for automated cleaning and sterilisation. Should you decide to use an alternate method of retaining the device during this process, ensure that the device is protected from damage at all times. Failure to adequately protect the device could lead to premature failure.

Limitations on processing

- Transducers can be processed a maximum of 50 times.
- End of life is generally determined by wear or damage during a surgical procedure.
- Carefully inspect instruments between uses to verify proper functionality.
- Damaged instruments should be replaced to prevent potential patient injury and loss of metal fragments into the surgical site.

Immediately after use

- Immediately after use, wipe down all components and remove any surplus body fluids and debris.
- For those transducers with an end cap, fit the attached end cap over the free end of the Transducer cable. Push the cap until it clicks into place.



LOTUS reprocessing basket with lid

Possible combinations:

REF basket	REF Transducer		
773-984	SV3-200	ES4-200CT	LR3-200
	CV3-400	ES4-400CT	LR3-400
773-985	SV3-500	ES4-500CT	
773-986	ES5-200CT	LR5-200ST	
	ES5-400CT	LR5-400ST	
773-987	ES5-500CT		

Processing step	Description
Manual pre-cleaning	
1. Soaking[1]	Soak the product at room temperature (<25 °C) for at least 15 minutes. This should be carried out immediately, but in any case, no more than 2 hours after use. Only use enzymatic cleaning agents which are suitable for the manual cleaning of medical devices (e. g., DGHM or FDA approval or CE marking). Remove all visible soiling with a soft plastic brush. BOWA recommends the use of neodisher® MediClean forte (Chemische Fabrik Dr. Weigert).
2. Rinsing	Rinse the product thoroughly for at least 1 minute at room temperature (<25 °C) under running tap water (at least drinking water quality). Allow residual water to drip off sufficiently.
Automatic cleaning, thermal disinfection and drying	
3. Automatic cleaning[2]	Use a washer-disinfector (WD) with tested effectiveness (according to ISO 15883) and a neutral to alkaline (max. pH 11.5), enzymatic cleaning agent. Depending on the concentration, agents including alcohol- and/or aldehyde-containing ingredients may be used. Ensure that the cables are not kinked or pinched. BOWA recommends the use of neodisher® MediClean forte (Chemische Fabrik Dr. Weigert) at 55 °C for 10 minutes. The intermediate rinsing must include at least two rinsing steps with fully demineralised water (deionised water)* (at least 1 minute each at >10 °C).
4. Thermal disinfection[3]	An A0- value >3000 must be maintained. BOWA recommends a temperature of 90 °C for at least 5 minutes and the use of deionised water.
5. Drying	Drying is carried out according to the WD programme and depends on the total load. The maximum temperature is 100 °C for 25 minutes. If necessary, dry with filtered compressed air at max. 3 bar.
6. Inspection	After automatic cleaning and disinfection, carry out a visual inspection for residues. If necessary, repeat all processing steps. Inspect all instruments prior to sterilisation or storage to ensure the complete removal of soiled surfaces. Visually inspect instruments. If soil is still present, clean instruments again. Inspect cables for wear and damage, ensuring that no cracks, tears or other damage is found. Check to see that waveguides are free of scratches. Report any damage found to the LOTUS representative.
Steam sterilisation	
7. Steam sterilisation[4]	BOWA recommends steam sterilisation using the fractionated vacuum method with a sterilisation time of 3–20 minutes and a temperature of 134–137 °C in a suitable sterilisation packaging. Sterilisation is best achieved on the day preceding the surgery but must be at least one hour prior to use to allow the equipment to cool and stabilise. Transducers are NOT to be submerged in water to expedite cooling. Do NOT sterilise the generator.

BOWA validation:

[1] Soaking with neodisher® MediClean forte (Chemische Fabrik Dr. Weigert), 1%
[2] Automatic cleaning with neodisher® MediClean forte (Chemische Fabrik Dr. Weigert), 0,5% in processing tray
[3] Thermal disinfection at 90°C for 5 minutes in processing tray
[4] Fractionated vacuum method in half cycle with 3 vacuum phases at 132 °C and 1,5 minutes, packaging: processing tray double wrapped in sterilisation pouches
* At least water quality similar to purified water (PW; Aqua purificata) or water with lower microbial contamination.

Storage

- Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extremes in temperature and humidity.

Return

- Before returning the LOTUS system or any individual components to the manufacturer, please ensure that washing and sterilisation have been carried out. All equipment must undergo a valid cycle. A certification of decontamination must accompany the system or any individual components on their return.

The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing is performed using equipment, materials and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

8. Equipment care

8.1. Waveguide inspection

LOTUS Transducer waveguides are susceptible to damage if forced into contact with metal (e.g. hand instruments and clamps etc.) when active.

The consequence of scratching the waveguide is to raise the mechanical stress in the region of the scratch (creating a “stress raiser”) when the waveguide is vibrating. If the stress is raised sufficiently there is a risk of the waveguide suffering metal fatigue and cracking. Fatigue failure is more likely if the stress raiser is close to one of the fixed points of maximum mechanical stress in the vibrating waveguide.

If a waveguide does suffer metal fatigue as a result of a stress raiser causing a crack, the waveguide will no longer possess a resonant frequency “recognisable” by the generator. The generator will be unable to vibrate the waveguide and will then give audio-visual warnings to “release jaw”.

This is because the generator can find no resonant frequency in the “operational frequency window”. If this is repeated with the Handpiece removed from the Transducer then the waveguide has fatigued.

Report to your local LOTUS representative any Transducer with a waveguide that has a scratch deep enough to be detected by sliding a fingernail over it.

8.2. Transducer / Waveguide usage

Unlike most major competitors, the LOTUS system has a Transducer with a titanium waveguide that can be decontaminated and reused. This is an important factor in reducing the cost per case.

However, they cannot be reused indefinitely, and a lifetime is set within which optimum performance can be expected. In order to monitor the so-called “lifetime” of

the Transducer and waveguide an electronic erasable programmable read only memory chip (EEPROM) is housed inside the cable plug of every Transducer.

Every time the generator energises the Transducer, the duration of the operation is monitored by the LG4 then written to the EEPROM, overwriting the previous total. When the total run-time reaches pre-set markers for warning or termination, the LG4 will alert the user.

8.3. Storage of equipment between cases

It is recommended that the Transducers (with attached cables) are stored, between surgeries, in a large autoclave basket. Care should be taken to ensure that the cables are not kinked close to the connector.

To prevent damage to the instruments and contamination of the environment, instruments must be stored and transported to the preparation location in closed containers.

9. Maintenance and repair

9.1. Maintenance

⚠ DANGER

Infection hazard!

- ▶ Carry out a surface disinfection and wrap the device in addition to the shipping packaging material before allowing the device to leave the hospital or office to avoid spreading germs and infections.

- ▶ Check the generator, the device trolley and the accessories (e.g. foot switch, cable) after each use for damage or defects. In particular, make sure that the insulation is intact on all cables.
- ▶ Do not use any damaged equipment.
- ▶ Replace defective accessories immediately.
- ▶ Have the safety inspection for the generator performed once a year. Please consult and comply with the respective service instructions for additional technical information.

9.1.1. Technical Safety inspection (TSI)

The hospital is responsible for ensuring that the unit has an electrical safety check, performed by qualified service personnel, at least once a year.

Any shorter safety inspection cycles specified in national regulations must be observed.

- ▶ Do not remove the covers from LOTUS LG4.
- ▶ The LOTUS LG4 generator does not require periodic calibration.

- ▶ If the generator detects an internal problem, it will display a “Service Due” message on the rear LCD. If this is seen, contact your local LOTUS representative to arrange repair.

There are no user-serviceable parts in the LOTUS system.

Any damage to the Transducer, Handpiece or cables should be reported to the local LOTUS representative at the earliest opportunity.

- ▶ The generator and accessories may be inspected only by persons who have the required training, knowledge or experience and who can perform the inspection independently.
- ▶ With regard to the safety inspection, you must comply with the country-specific rules and regulations.

The tester documents the inspection results and measured values according to the printed test record in the service manual. If you do not have a copy of the service manual, please contact your dealer or one of the service addresses, see section Technical Service.
In the case of severe deviations from the values of the service test record, or if the specified maximum values were exceeded:

- ▶ Send the device to the service centre, see section Technical Service.

9.2. Repairs

NOTE

You can damage the device by doing your own repairs and modifications of medical equipment!

- ▶ If a repair is necessary, have it done only by the service centre.
- ▶ Never carry out any repairs yourself.

The manufacturer is liable for safety, reliability and performance of the device under the following conditions:

- Full compliance with all instructions regarding the installation and proper use for the intended purpose contained in this operating manual was maintained.
- Changes, repairs, new settings and similar procedures were carried out only by persons authorised to do this work.
- The electrical installations in the relevant room meet the local requirements and statutory provisions.

Fast and satisfactory repairs can only be guaranteed when all required data have been supplied in full.

The following information is required for returning the device:

- Complete address,
- Model number,
- Serial number,
- Software Version.

► Describe the problem, the appropriate application and the accessories used

10. Storage

- ▶ Clean the device thoroughly before you put it into storage.
- ▶ Store the device in a clean, dry place in accordance with the storage conditions.

Temperature	-20 °C…+50 °C
Relative humidity	0 %...90 %
Atmospheric pressure	500 hPa…1060 hPa

11. Electromagnetic Compatibility (EMC)

This equipment has been tested and found to comply with the limits for a medical device.

However, should interference occur, the user can try the following measures:

1. Turn equipment off and on to confirm the source of the interference.
2. Increase separation between this equipment and other devices.
3. Connect this equipment to a power socket different from that to which the other devices are connected.
4. Consult the medical physics department.

⚠ WARNING

Improper operation possible!

- ▶ Avoid use of LOTUS LG4 adjacent to or stacked with other equipment. If such use is necessary, LOTUS LG4 and the other equipment should be observed to verify that they are operating normally.

⚠ WARNING

Possibility of increased electromagnetic emissions or decreased electromagnetic immunity of this equipment! Improper operation possible!

- ▶ Do not use accessories, Transducers and cables other than those specified or provided by the manufacturer.

⚠ WARNING

Degradation of the performance of this equipment!

- ▶ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of LOTUS, including cables specified by the manufacturer.

- ▶ LOTUS LG4 is suitable for use in hospital operating theatres. Simultaneous use with active HF Surgical Equipment is not recommended.
- ▶ LOTUS LG4 should cut and coagulate tissue to the satisfaction of the user. If the performance is lost or degraded due to EM disturbances, then the generator should be switched off and then on. If performance remains impaired, then technical support should be sought.

- The use of mains cables with lengths in excess of 3 m may affect emissions and immunity compliance of the equipment.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- LOTUS medical electrical equipment needs special precautions regarding EMC and must be installed and put into service according to the EMC information provided in this manual (IEC 60601-1-2; Ch. 5.2.2.1).
- There are no user-serviceable parts in LOTUS LG4.
- Do not use LOTUS LG4 simultaneously with laser equipment or high frequency surgical equipment.

11.1. Guidelines and Manufacturer's Declaration in Accordance with IEC 60601-1-2:2014

Table 1:

Guidance and manufacturer's declaration – electromagnetic emissions		
LOTUS is intended for use in the electromagnetic environment specified below. The customer or the user of LOTUS should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	LOTUS uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	LOTUS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	No testing – no connection to public mains network	
Voltage fluctuations /flicker emissions IEC 61000-3-3	No testing – no connection to public mains network	

Table 2:

Guidance and manufacturer's declaration – electromagnetic immunity			
LOTUS is intended for use in the electromagnetic environment specified below. The customer or the user of LOTUS should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±6 kV contact ±8 kV air (1)	Floors should be conductive. No synthetic material should be used in the environment. The relative humidity should be in the range 40% to 60%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ± 2 kV common mode	±1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (2) (100 % dip in U_T) For 0.5 cycle at: 0°, 45°,90°, 135°, 180°, 225°,270°, 315° 0 % U_T (100 % dip in U_T) For 1 cycle <70 % U_T (30 % dip in U_T) For 25/30 cycles 0 % U_T (100 % interrupt in U_T) For 250/300 cycles	0 % U_T (100 % dip in U_T) For 0.5 cycle at: 0°, 45°,90°, 135°, 180°, 225°,270°, 315° 0 % U_T (100 % dip in U_T) For 1 cycle <70 % U_T (30 % dip in U_T) For 25/30 cycles 0 % UT (100 % interrupt in U_T) For 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of LOTUS requires continued operation during power mains interruptions, it is recommended that LOTUS be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	No testing	No magnetically sensitive components.
NOTES: (1) Mitigation applied because of environment. (2) U_T is the a.c. mains voltage prior to application of the test level.			

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity			
LOTUS is intended for use in the electromagnetic environment specified below. The customer or the user of LOTUS should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3V rms 150kHz to 80 MHz Outside ISM bands 6V rms In ISM bands 0.15 MHZ to 80 MHZ 80 % AM at 1 kHz	3V rms 6V rms	Portable and mobile RF communications equipment should be used no closer to any part of LOTUS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = $1.2\sqrt{P}$ d = $1.2\sqrt{P}$, 80MHz to 800MHz d = $2.3\sqrt{P}$, 800MHz to 2.3GHz where P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	
Immunity to proximity fields from RF wireless communications equipment	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz, 5785 MHz 27 V/m 385 MHz 28V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz		
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. *NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			
a Field strengths from fixed transmitter , such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which LOTUS is used exceeds the applicable RF compliance level above, LOTUS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating LOTUS. *b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*			

Table 4:

Recommended separation distances between portable and mobile RF communications equipment and LOTUS			
LOTUS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of LOTUS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and LOTUS as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz **d =** $1.2\sqrt{P}$	**80 MHz to 800 MHz** **d =** $1.2\sqrt{P}$	**800MHz to 2.5 GHz** **d =** $2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.* *NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			

12. Disposal

Always comply with the national regulations of the relevant country when disposing of or recycling the device or its components.

Symbol	Designation
	A device marked with this symbol must be put into the separate waste collection for electrical and electronic devices. Disposal is carried out free of charge by the manufacturer within the European Union.

▶ If you have any questions regarding product disposal, contact the service center, see section Technical Service.

13. Technical Specification

Parameter	Description	Specification
Dimensions W x H x D	Generator	340 x 95 x 340 mm
		13.4" x 3.7" x 13.4"
Weight	Generator	4.3 kg
	Transport case	10.5 kg
	Transducer	0.37 kg
Fuse Type		None (internal fuses only)
Power supply input		100 V…240 V, 50/60 Hz
Power consumption		150 VA
Output - Frequency of operation		36 kHz
Output - Accuracy of frequency display		1 %
Output - Power		70 W ±30 W*
Mode of Operation		Intermittent ON/OFF, 3/30 s
Insulation Classification	Generator	Class 1
	Transducer	Type BF
Environment for Transportation & Storage	Temperature	-20 °C…+50 °C
	Relative humidity	0 %...90 %
	Atmospheric pressure	500 hPa…1060 hPa
Environment for Use	Temperature	+10 °C…+40 °C
	Relative humidity	30 %...75 %
	Atmospheric pressure	780 hPa…1060 hPa
Ingress protection	Generator	IPX0
	Footswitch	IPX1

* Depending on the transducer type

The manufacturer will make available on request circuit diagrams, component part lists, descriptions and calibration instructions to assist service personnel in parts repair.

LOTUS has been designed and built in accordance with ISO 13485:2016 Quality Assurance standard for medical devices. CE conformance has been certified and the equipment fulfils the requirements of IEC 60601-1:2005 + CORR 1:2006 + CORR 2:2007 + A1:2012, EN 60601-1:2006 + A11:2011 + A1:2013, ANSI/AAMI ES60601-1; 2005/(R) 2012, CAN/CSA C22.2 No 60601-1:14.

14. Technical Service

If the unit requires repair, please contact us through your local supplier or directly:

Contact Germany:

BOWA MEDICAL
BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Straße 4-10
72810 Gomaringen | GERMANY

Phone: +49 7072 6002-0
Fax: +49 7072 6002-33
www.bowa-medical.com
info@bowa-medical.com

Contact UK:

BOWA MEDICAL UK
The trading name of SRA Developments Ltd.
Oak Tree House,
Oak Tree Business Park,
Kingskerswell
Devon. TQ12 5GJ
UK

Phone: +44 1364 652426
Fax: +44 1364 653589
www.bowa-medical.co.uk

a BOWA-electronic GmbH & Co. KG company

BOWA MEDICAL
BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany

Phone: +49 7072 6002-0
Fax: +49 7072 6002-33
www.bowa-medical.com
info@bowa-medical.com

CE 1639

CE-Marked according to
Medical Device Directive 93/42/EEC

BOWA MEDICAL UK
The trading name of SRA Developments Ltd.
Oak Tree House,
Oak Tree Business Park,
Kingskerswell
Devon. TQ12 5GJ
UK

Phone: +44 1364 652426
Fax: +44 1364 653589
www.bowa-medical.co.uk

a BOWA-electronic GmbH & Co. KG company

BOWA-IFU_10522_LOTUS-LG4_ISSUE18_en_20250903