SPECIFICTIE TEHNICĂ COMPLETATĂ

Modelul: LOTUS Series 4 Generator; Ref. LG4; Producător: BOWA-electronic GmbH; Țara: Germania.

Specificarea tehnică deplină solicitată de către Specificarea tehnică deplină ofertantă de către autoritatea ofertantă autoritatea contractantă Dispozitiv electro-chirurgical cu instrumente/piese de **DA** Dispozitiv electro-chirurgical cu instrumente/piese de mina destinate pentru disecția si coagularea țesutului. mina destinate pentru disecția si coagularea țesutului. • Principiul de funcționare: pe baza tehnologiilor tip • DA Principiul de funcționare: pe baza tehnologiilor "Power seal" sau "Enseal" sau "Harmonic". "Harmonic" - tip ultrasunet TORSINAL. pag. 3 din Quick user guide • Functie de disectie si coagulare ultrasonica. • DA Funcție de disecție si coagulare ultrasonica pag. 4, 15 din Quick user guide • Functie de coagulare bipolara. • NU Functie de coagulare bipolara. Este un dispozitiv de generare cu ultrasunet nu are nimic in comun cu diatermocugulatorul. • DA Posibilitatea de a efectua disecția si coagularea Posibilitatea de a efectua disecția si coagularea vaselor vaselor cu diametrul/grosimea de pina la 7 mm. pag. 1 cu diametrul/grosimea de minim 7mm. din fisierul nume BOWA-PUB-LOTUS-SURGERY-7MM-SEALING. pdf • DA 1 port pentru conectarea accesoriilor de lucru. pag. Minim 1 port pentru conectarea accesoriilor de lucru. 10 din Quick user guide • Abilitatea de a ajusta amplitudinea oscilatiilor • Da Abilitatea de a ajusta amplitudinea oscilatiilor duzei/accesoriilor pentru disecția / coagularea cu duzei/accesoriilor pentru disecția / coagularea cu ultrasunete. Pag. 7 - 11 din Quick user guide ultrasunete. Prezenta tehnologiei adaptive de țesut care va permite • DA Prezenta tehnologiei adaptive de tesut care va o precizie și o performanță chirurgicală mai mare prin permite o precizie și o performanță chirurgicală mai mare optimizarea dinamică a livrării energiei ca răspuns la prin optimizarea dinamică a livrării energiei ca răspuns la schimbarea caracteristicilor fizice ale țesutului. schimbarea caracteristicilor fizice ale țesutului. pag. 12-13 din Quick user guide • Recunoașterea automata al instrumentelor conectate • DA Recunoașterea automata al instrumentelor pentru a minimiza timpul de configurare al lor. conectate pentru a minimiza timpul de configurare al lor. pag. 11 din Quick user guide • Sistemul de auto-testare a generatorului, capacitatea • DA Sistemul de auto-testare a generatorului, de a diagnostica corectitudinea conexiunii instrumentelor capacitatea de a diagnostica corectitudinea conexiunii cu sistem de notificare si alarme cu indicator vizual si instrumentelor cu sistem de notificare si alarme cu sonor. indicator vizual si sonor. pag. 21 din LOTUS LG4 Instructions for use • Display touchscreen. • **NU** Display touchscreen. • Posibilitatea utilizării dispozitivului dat la pacienții cu • DA Posibilitatea utilizării dispozitivului dat la pacienții cardiostimulator implantat. cu cardiostimulator implantat. pag. 7 din LOTUS LG4 Instructions for use • Posibilitatea activarii instrumentelor manuala si cu • DA Posibilitatea activarii instrumentelor manuala si cu commutator de picior. commutator de picior. pag. 7, 15 din LOTUS LG4 Instructions for use Alimentare 210-240V, 50 Hz. DA Alimentare 210-240V, 50 Hz. pag. 38 din LOTUS LG4 Instructions for use ACCESORII: ACCESORII: • Piesa de mina cu functiile de disectie, coagulare, • DA Piesa de mina cu functiile de disectie, coagulare, cavitare bazata pe tehnologia cu ultrasunete- 6 buc. cavitare bazata pe tehnologia cu ultrasunete - 20 buc. PN DS5-400CD pag. 15 din Quick user guide. • Posibilitatea de a efectua disectia si coagularea vaselor • DA Posibilitatea de a efectua disectia si coagularea cu diametrul/grosimea de minim 7 mm. vaselor cu diametrul/grosimea pina la 7 mm.

Recomandat totsi pian la 5 mm.

- Piesa de mina tip "pistol".
- Prezenta tehnologiei adaptive de țesut care va permite o precizie și o performanță chirurgicală mai mare prin optimizarea dinamică a livrării energiei ca răspuns la schimbarea caracteristicilor fizice ale țesutului.
- Posibilitatea autotestarii la conectare la generatorul de putere.
- Indicarea erorilor de funcționalitate la ecranul de afișare al generatorului.
- Posibilitatea regularii puterii aplicate cu butoane integrate in miner.
- Pentru intervenții chirurgicale deschise si endoscopice.
- Frecventa oscilatiilor 50 Khz ± 1KHz.
- Lungimea 35cm ± 2 cm.
- Vârful de tip incovoiat.
- Lungimea lamei de lucru active: 15 mm ± 2 mm.
- Apertura de deschidere al branselor: 12mm ± 2mm.
- Posibilitatea rotirii lamelor la 360 °.
- Sterilizabila.
- Accesoriu interconector dintre generatorul si însuși si piesa de mina, care conține traductoare piezoelectrice care convertesc energia electronică în vibrații ultrasonice pentru a alimenta piesele de mina, reutilizabil, autoclavabila. -1 buc.
- Piesa de mina cu vârf ajustabil, lungimea minim 4-9 cm, forma vârfului curbata, sterila- 6 buc.

Cerințe de certificare:

Anul producerii minim 2022.

Termen de garanție nu mai mic de 24 luni din momentul instalării.

Instalare, darea in exploatare, instruirea de către participantul câștigător - obligatoriu

Training pentru utilizatori la instalare și la solicitare - obligatoriu.

Servicii de mentenanță preventivă pe perioada de garantie.

În cazul defecțiunii dispozitivului aflat in garanție, termenul reparației va fi adăugat la perioada de garanție totală.

- DA Piesa de mina tip "pistol". pag. 5 din Quick user guide
- DA Prezenta tehnologiei adaptive de țesut care va permite o precizie și o performanță chirurgicală mai mare prin optimizarea dinamică a livrării energiei ca răspuns la schimbarea caracteristicilor fizice ale țesutului. pag. 12-13 din Quick user guide
- **DA** Posibilitatea autotestarii la conectare la generatorul de putere. **pag. 11 din Quick user guide**
- DA Indicarea erorilor de funcționalitate la ecranul de afișare al generatorului. pag. 10-12 LOTUS LG4 Instructions for use
- **DA** Posibilitatea regularii puterii aplicate cu butoane integrate in miner. **pag. 7 din Quick user guide**
- DA Pentru intervenții chirurgicale deschise si endoscopice. Conform lungimei indicate mai jos este correct sa spunem ca este laparoscopic. Dar LOTUS G4 areposibilitate de conectare si instruemntelor de pentru chirugie deschisa. Vezi pag. 10 din LOTUS The powerful torsional ultrasonic scalpel.
- DA Frecventa oscilatiilor 37 KHz pag. 9 din Quick user guide
- DA Lungimea 349 mm 34.9 cm pag. 10 din LOTUS The powerful torsional ultrasonic scalpel.
- DA Vârful de tip incovoiat. pag. 10 din LOTUS The powerful torsional ultrasonic scalpel.
- **DA**Lungimea lamei de lucru active: 15 mm ± 2 mm.
- **DA** Apertura de deschidere al branselor: 12mm ± 2mm.
- DA Posibilitatea rotirii lamelor la 360 °.
- Sterilizabila tip autoclavabil a transductorului.
- Accesoriu interconector dintre generatorul si însuși si piesa de mina, care conține traductoare piezoelectrice care convertesc energia electronică în vibrații ultrasonice pentru a alimenta piesele de mina, reutilizabil, autoclavabila. 1 buc. PN:ES5-400CT (autoclavabil) pag. 15 din Quick user guide.
- DA Piesa de mina cu vârf ajustabil, lungimea 179 mm, forma vârfului curbata, rotirea la 360 ° fata de miner, sterile PN DS5-200CD 20 buc + PN ES5-200CT 1 buc autoclavabil pag. 15 din Quick user guide
 Cerințe de certificare:

DA Anul producerii 2023.

DA Termen de garanție de 24 luni din momentul instalării.

DA Instalare, darea in exploatare, instruirea de către participantul câștigător - obligatoriu

DA Training pentru utilizatori la instalare și la solicitare - obligatoriu.

DA Servicii de mentenanță preventivă pe perioada de garantie.

DA În cazul defecțiunii dispozitivului aflat in garanție, termenul reparației va fi adăugat la perioada de garanție totală.

Anexa 17

Pe perioada garanției timpul de intervenție în caz de defecțiune minim 24h.

Documente confirmative:

La livrarea dispozitivului medical obligatoriu: Manual de utilizator în limba română și engleză Manual de service si manual de utilizare in conformitate cu LEGEA Nr. 102 cu privire la dispozitivele medicale din 09.06.2017, capitolul 4 Articolul 14. P. 3.

Ghid rapid în limba română laminat atașat de dispozitiv.

DA Pe perioada garanției timpul de intervenție în caz de defecțiune minim 24h.

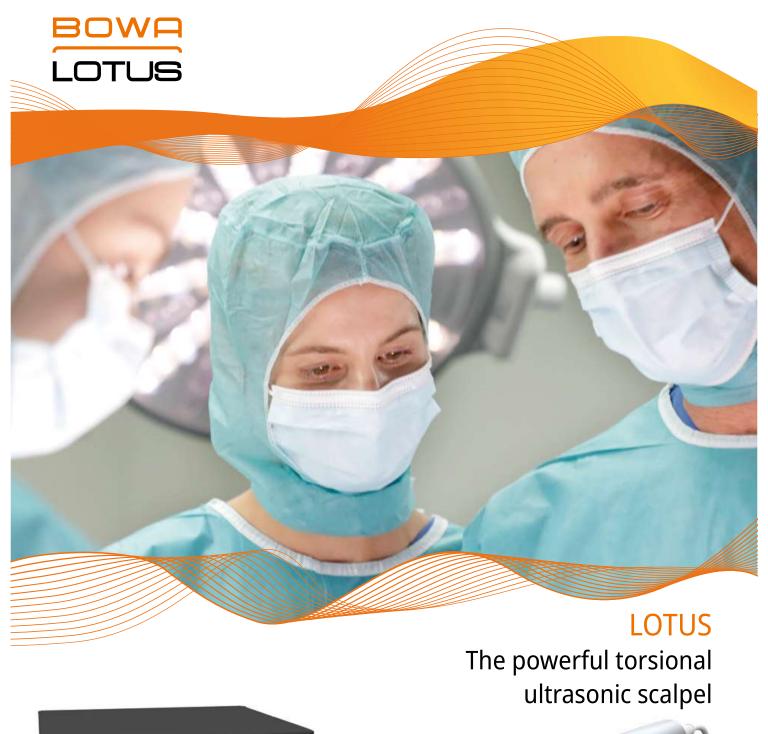
Documente confirmative:

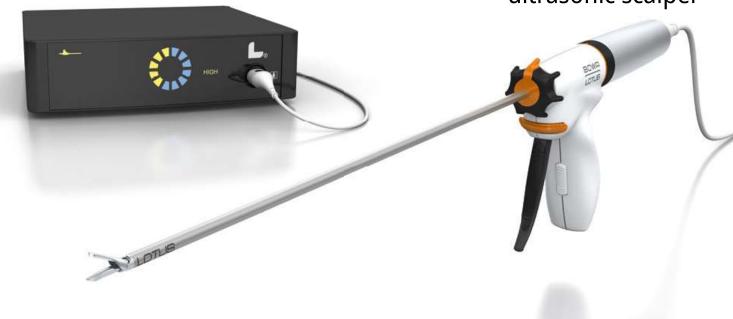
DA La livrarea dispozitivului medical obligatoriu:

DA Manual de utilizator în limba română și engleză

DA Manual de service si manual de utilizare in conformitate cu LEGEA Nr. 102 cu privire la dispozitivele medicale din 09.06.2017, capitolul 4 Articolul 14. P. 3.

DA Ghid rapid în limba română laminat atașat de dispozitiv.





LOTUS dissecting shears

Surgical PRECISION

The unique, torsional ultrasonic energy enables the surgeon to control the tissue effect depending on the power level and the jaw closing force applied.

Through the trigger pressure, the user can directly influence the degree of haemostasis and cutting speed.





AREAS OF APPLICATION



General surgery



Thoracic surgery



Gynaecology



ENT



Urology



Bariatric surgery

"Within my gynaecology practice, I typically use LOTUS for my complex endometriosis resections.

I find the speed and accuracy of the dissection a real advantage.

It is a versatile instrument that with practice can perform a variety of functions, such that it can be the primary instrument for most major laparoscopic procedures."

Dominic Byrne, MD

FRCOG FBSGE, Consultant Gynaecologist, Royal Cornwall Hospitals Trust

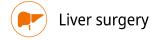
LOTUS Liver Resectors

Ultrasonic dissectors specifically designed for liver parenchyma

Optimised for efficient coagulation and dissection of the liver parenchyma. Torsion ultrasound can be used to dissect the parenchyma to expose, skeletalise and isolate structures in the liver bed.



AREA OF APPLICATION





2 Instruments for open and laparoscopic liver surgery



LOTUS system



Three power levels with clear display

- The LOTUS generator has a clear and easy-to-read visual display and provides acoustic feedback during use.
- The additional "ULTRA LOW" power level enables particularly slow and carefully controlled power output for efficient haemostasis.





- OPERATIONAL ADDED VALUE OF ULTRASONIC DISSECTION

- Rapid tissue dissection
- Controlled coagulation zone
- Safe closure of vessels
- Reduction of intraoperative instrument changes due to dissection and coagulation in one instrument



LOTUS training on the BOWA Academy



A qualified support team



Cooperation with surgical societies

Torsional ultrasonic energy

User-controlled application for efficient haemostasis and rapid dissection

Unique energy output directly into the target tissue

With torsional ultrasonic energy, the waveguide tip oscillates in a small arc around its axis. In doing so, the energy can be focused to ensure a targeted compression of the grasped tissue.



The blade oscillates around its longitudinal axis at 36,000 Hz.

Efficient dissection and coagulation

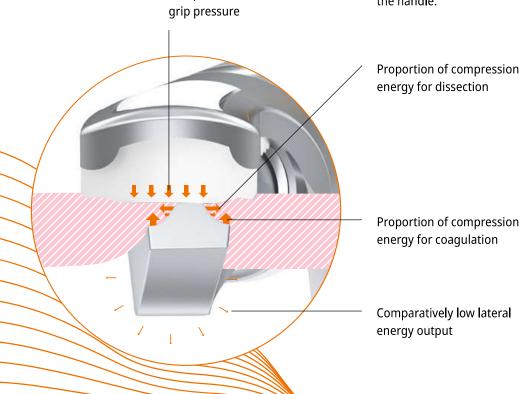
8

The compression force is responsible for direct energy transfer into the tissue and produces haemostatic dissection and coagulation in the form of heat.

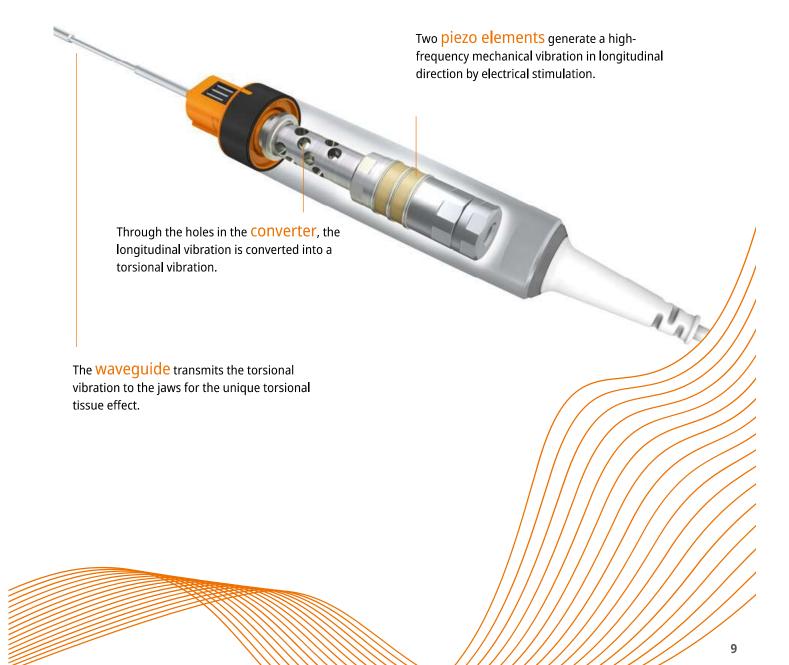
Compression via

Advantages of torsional ultrasonic energy

The targeted energy output reduces energy dissipation compared to conventional longitudinal ultrasonic instruments. Unintentional distal energy output can thus be minimised. The efficiency of coagulation and dissection can be controlled by the surgeon when applying force on the handle.



Generation of the torsional vibration



LOTUS dissecting shears, 360° rotation			
Open surgery 200 / 360°, curved jaw	176 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	DS5-200CD ES5-200CT
Laparoscopy 400 / 360°, curved jaw	349 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	DS5-400CD ES5-400CT
Bariatric surgery 500 / 360°, Curved jaw	434 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	DS5-500CD ES5-500CT

LOTUS dissecting shears			
Open surgery 200, curved jaw	176 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	DS4-200CD ES4-200CT
Laparoscopy 400, curved jaw	349 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	DS4-400CD ES4-400CT
Bariatric surgery 500, curved jaw	434 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	DS4-500CD ES4-500CT

LOTUS liver resector, 360° rotation		<u>. </u>	
Open surgery 200 / 360°, straight jaw	176 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	LR5-200SD LR5-200ST
Laparoscopy 400 / 360°, straight jaw	349 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	LR5-400SD LR5-400ST

LOTUS liver resector		<u> </u>	
Open surgery 200, straight jaw	176 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	LR4-200SD LR3-200
Laparoscopy 400, straight jaw	349 mm	Handpiece (disposable, 10 pcs./VPE) Transducer (reusable)	LR4-400SD LR3-400

Only for LG4 generators with software version 6 or higher



Optional accessories LOTUS foot switch LG4 LF4 LOTUS CART, equipment trolley, assembled 902-070 LOTUS reprocessing basket with lid For transducers: ES5-200CT, ES5-400CT, LR5-200ST, LR5-400ST 650x150x68 mm 773-986 For transducers: ES4-200CT, ES4-400CT, LR3-200, LR3-400 550x150x77 mm 773-984

For transducers: ES4-500CT

640 x 150 x 77 mm

773-985



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INSTRUCTIONS FOR USE LOTUS SERIES 4 ULTRASONIC SURGICAL SYSTEM & ACCESSORIES





THE SYMBOLS GLOSSARY IS PROVIDED ON PAGE 13 OF THIS DOCUMENT



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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 designated in chapter 3.2.1 Nameplate (see page 14) and to the following items in the system overview:

LOTUS Parts 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 Laparoscopic 400	ES4-400CT
LOTUS Enhanced Shears Enterotomy Transducer Laparoscopic 400	ES4-400CTE
LOTUS Double Blade Transducer Open 100	DB3-100
LOTUS Double Blade Transducer Laparoscopic 400	DB3-400
LOTUS Liver Resector Straight Transducer Open 200	LR3-200
LOTUS Liver Resector StraightTransducer Laparoscopic 400	LR3-400
LOTUS Vessel Welder Straight Transducer Open 200	W3-200
LOTUS Vessel Welder Straight Transducer Laparoscopic 400	W3-400
LOTUS Dissecting Shears Straight Handpiece Open 200	DS4-200SD
LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400	DS4-400CD
LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400 (Richardson)	DS4-400CD2
LOTUS Dissecting Shears Straight Handpiece Bariatric 500	DS4-500SD
LOTUS Open Double Blade Sleeve	DB3-100D
LOTUS Laparoscopic Double Blade Sleeve	DB3-400D
LOTUS Liver Resector Straight Handpiece Open 200	LR4-200SD
LOTUS Liver Resector Straight Handpiece Laparoscopic 400	LR4-400SD
LOTUS Vessel Welder Straight Handpiece Open 200	VW4-200SD
LOTUS Vessel Welder Straight Handpiece Laparoscopic 400	VW4-400SD
LOTUS Series 4 Generator	LG4
LOTUS Generator Cart	LGC
LOTUS LG4 Carry Case	LC4
LOTUS LG4 Footswitch	LF4
LOTUS Cart Footswitch Holder	LCFH1
LOTUS Autoclave Tray	LAT1
LOTUS Series 4 User Manual	SRA-No.: IFU10522 BOWA-No.: BOWA-IFU-11895-LOTUS-LG4-EN

^{*} Single items may not be available in your country



Icons and labelling 1.3

Structure of warning instructions



△ SIGNAL WORD

"Risk type, source and consequences thereof" (Personal injury)! Measure for risk prevention.





"Risk type, source and consequences thereof" (Property damage)! Measure.

1.3.2 Risk levels in warning instructions

Symbol	Risk level	Likelihood	Consequences of non-compliance
<u>^i</u>	DANGER	Probable	Death, serious injuries
	WARNING	Possible	Death, serious injuries
<u>^</u>	CAUTION	Possible	Minor injuries
0	NOTE	Possible	Property damage

1.3.3 Tips



Tips and additional information to facilitate tasks

1.3.4 Other symbols and marks

Symbol or mark	Meaning
•	Activity with one step
1.	Activity with several steps in a binding
2.	sequence
3.	
•	List (first level)
•	List (second level)
Emphasis	Emphasis
, see Section xxx, page xxx	Cross reference



2 Safety

2.1 Intended use

LOTUS Series 4 Ultrasonic Surgical System & Accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. LOTUS Series 4 Ultrasonic Surgical System and Accessories may be used as an adjunct to or substitute for electrosurgery, laser surgery, and traditional scalpels in general, gynecological, thoracic surgery, and exposure to orthopedic structures (such as hip joint).

The essential constituents of the system are a portable generator and a plug-in Transducer. Handsets come in various formats depending on the instrument characteristics required.

The ergonomic handset comprises a reusable acoustic unit (Transducer) with integral cable connected into a single use Handpiece (or Sleeve).

Do not use the device if, in the opinion of an experienced physician or according to current professional literature, such use would endanger the patient, due for example to the general condition of the patient, or if other contraindications are present.

We require that the device is operated under the supervision of qualified and authorized personnel. The surgeon and medical staff must be trained in the fundamental principles, rules for use and risks of surgery and must be familiar with these in order to safely and reliably prevent putting patients, staff and equipment at risk.

Contact your LOTUS distributor for training and training material.



Any other use is neither intended nor proper and must be effectively prevented.

When setting up the generator, ensure easy access to the power cable so it can be disconnected from the device. (IEC 60601-1:2012, Section 4.1)

2.2 Contra indications



The Double Blade is not indicated for the cutting of vessels exceeding 1.5 mm in diameter or for bone tissue.

Care should be taken when operating in the vicinity of nerves.



2.3 General safety instructions

- The LOTUS system:
 - Should be used only for those procedures for which it is indicated.
 - 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 EMC section, page
- 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, see page 39.



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

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.

Prevent accidental activation!

Avoid the risk of electric shock.

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

2.4.1 Ambient conditions





💔 NOTE

If the waveguide touches anything metal while activated, sparks may be produced.

- Do not operate LOTUS in a potentially explosive or flammable area.
- LOTUS Series 4 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.



2.4.2 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.

The use of LOTUS in cases where a patient or an operator of the unit has been fitted with a cardiac pacemaker is left to the discretion of the consultant in charge of the procedure (although no electrical flow is made through, or into, the patient and many clinical papers on the use of ultrasound in the proximity of cardiac pacemakers have been published).

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.

2.5 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 accessories and replacement parts, page 3.
- 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.
- Wipe down the device only 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.

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.

2.6 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 (see Section 2.1, page
- During use, always observe and comply with the audible signals and/or error messages of the device (see Sections 3.1.1/3.1.2, pages 10/12).
- 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 devices.
- Wear suitable gloves during operations.

8

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

If the Double Blade comes into contact with bone, a temperature rise of up to 5°C may be seen.



3 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 shears is microprocessor controlled and is designed to produce ultrasonic energy at the resonant frequency of the attached shears 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



3.1 User interface components

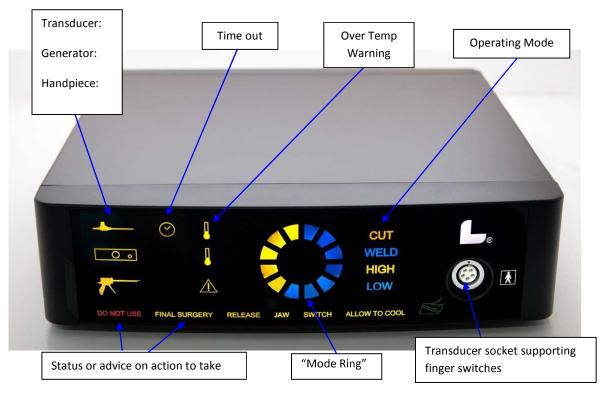
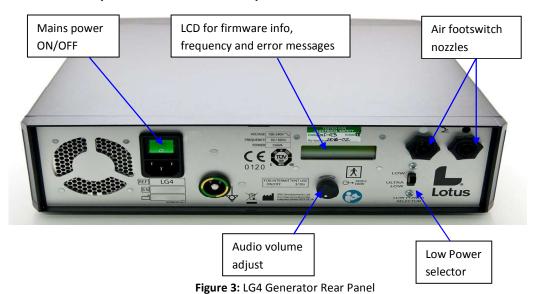


Figure 2: Essential features of Generator Front Panel

3.1.1 Rear panel user interface components



10 Instructions for use LOTUS LG4



Rear Panel Messages

The LCD on the rear panel will display messages that indicate the status of the equipment. The following table shows the possible displays:

Message	Status	Action required
SRA Developments	Start up message. Shows the issue	Now awaiting Transducer to be
LG4 Issue x	number of the software "X"	plugged in
LG4 ISSUE X	"LG4" may be replaced by HEXxxxxx	
SRA Developments	Start up message with Transducer.	Now awaiting toggle switch
TDCR= xx% Used	Shows the % usage of the Transducer.	
SRA Developments	The Toggle Switch has been operated and	Now awaiting use
LO	the Transducer is ready to be activated.	
00000Hz	High power is selected	No action required
н	(via footswitch or Handpiece)	
00000Hz	Weld Mode is selected	No action required
PWMH	(requires a Welder Transducer)	
	Top line shows the frequency. After	No action required
36000Hz	releasing the switch it will display the final	'
LO E	running frequency.	
Release Switches	The Activate Button has been held on for	Release Activate Button on
LO	too long. No output.	Handpiece or on footswitch
	Either Activate or Toggle Button (or	Release Activate or Toggle Button
SRA Developments	footswitch) has been pressed during	when switching on generator
Release Switches	switch on.	
Check Transducer	Transducer has been loaded too heavily	Release switch, then reactivate using
Ease Grip and Retry	,	less pressure on the jaw
,	Transducer is over-temperature	Allow Transducer to cool.
Check Transducer	Transducer may have bad connection	Check Transducer connection
Restart	,	Replace if required
Transducer Limit		·
LO		
Change Tdcr		
Transducer Limit	Transducer is approaching 100% lifetime	Replace Transducer after completion
Transducer Limit	and must be replaced	of procedure
Final Surgery		
Transducer Expired	Transducer has reached 100% lifetime and	Use another Transducer – no usage is
Change Transducer	must be replaced	allowed
Change Transducer	Transducer frequency too low and	Switch supply off & on. Replace
Restart	feedback signal is low.	Transducer if seen 3 times
Tdcr Leakage	Generator has detected voltage on the	Switch supply off & on. Replace
Change Tdcr	Transducer.	Transducer if seen 3 times
Frequency Error		
Service due		Switch sweets off 9
Poor ADC Signal	The generator has detected a serious	Switch supply off & on.
Service Due	internal problem.	If message seen again generator
LED ERROR	1	requires service.
Service Due		
	The generator has detected that the	Replace Transducer.
WG Fatigue	waveguide has fatigued, or is about to	
Change TDCR	fatigue.	



3.1.2 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.

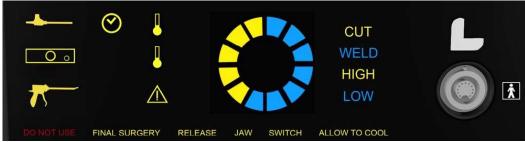


Figure 4: Status, fault and advice indicators

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.

Audio Tones

Rising flourish	LG4 is booting to standby mode
No Tone	LG4 is in standby mode
Triple tone – low-medium-low pitch	Device Type 1 Handpiece Power Select Button has been pressed to initialize Handpiece
Continuous low pitched tone	Device Type 1 continuous acoustic output at the LOW power level
Continuous high pitched tone	Device Type 1 continuous acoustic output at the HIGH power level
Triple tone – low-medium-high pitch	Device Type 1 mode is changing from LOW to HIGH power
Triple tone – high-medium-low pitch	Device Type 1 mode is changing from HIGH to LOW power
Triple tone – low-medium-medium pitch	Device Type 2 Handpiece Power Select Button has been pressed to initialize Handpiece
Pulsing high pitched tone	Device Type 2 pulsed acoustic output
Single sustained tone – medium pitch	Device Type 2 mode is changing from WELD to CUT
Triple tone – high-high-high pitch	Device Type 2 mode is changing from CUT to WELD
Double beep −high>low pitch	 The generator has reset itself after a minor problem such as a mistuning event, time-out or over-temperature warning or The generator has encountered a minor problem that requires power switch to be cycled OFF/ON or 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



3.2 Symbols Glossary

REF	Model number
SN	Serial number
	Manufacturer
	Date of manufacture
100-240V	Mains AC voltage
\sim	Alternating current
50/60Hz	Mains AC frequency
150VA	Input power
	Warning sign
*	Type BF equipment
36kHz	Frequency of output
50W	Output power
$ \bigcirc $	Volume
2	Footswitch connection
\$	Equipotential connection
	Follow instructions for use
<u>X</u>	Electrical and electronic equipment. Return waste to a collection system or treatment and recycling facilities. Follow decontamination instructions before returning waste.
\triangle	General caution sign
Ronly	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



3.2.1 Nameplate

See explanation of symbols in ch. 3.2.



Figure 5

3.3 Packaging information

You'll find detailed packaging information in the current data sheets.

3.4 Components required for operation

- Power cable
- Foot switch (optional)
- Transducer
- Handpiece
- Generator

3.5 Operating conditions

Temperature: +10 °C to +30 °C
Relative humidity: 30% to 75%
Atmospheric pressure: 810hPa to 1060hPa



4 Preparation

4.1 Setting up the LOTUS system





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

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.

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

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If the device was previously stored or transported at temperatures below +10 $^{\circ}\text{C}$ 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, page 14).
- 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 the EMC Section, page 34.
- 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.

4.1.1 Attach the footswitches (optional) to the LG4

If you are using a Double Blade, or 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.

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4.1.2 Attach the Transducer



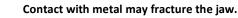
▲ DANGER

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 ch. 1.2.



NOTE



▶ Do not allow an energized waveguide to come into contact with any metal surface. In particular avoid energizing 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 Transducer.

Select the appropriate pre-sterilized Transducer:

- LOTUS Dissecting Shears Straight Transducer Open 200
- LOTUS Dissecting Shears Curved Transducer Laparoscopic 400
- LOTUS Dissecting Shears Straight Transducer Bariatric 500
- LOTUS Enhanced Shears Curved Transducer Laparoscopic 400
- LOTUS Double Blade Transducer Open 100
- LOTUS Double Blade Transducer Laparoscopic 400
- LOTUS Liver Resector Straight Transducer Open 200
- LOTUS Liver Resector Straight Transducer Laparoscopic 400
- LOTUS Vessel Welder Straight Transducer Open 200
- LOTUS Vessel Welder Straight Transducer Laparoscopic 400
 - 1. Remove the plug cap by pulling the knurled rings on the plug and the autoclave cap. (See Figure 11)
 - 2. Align the red dot on the cable plug with the red dot on the generator socket. (See Figure 12)
 - 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).

4.1.3 Attach the single use Handpiece/Sleeve



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 ch. 1.2.



For detailed information see the operating manual for the Handpiece.



4.1.3.1 Shears, Enhanced Shears, Liver Resector & Welder

- 1. Slide the tip of the Transducer's waveguide through the small aperture inside the rear of the Handpiece socket to engage the two parts.
- 2. Simply align the coloured orientation mark on the "upright" fin of the rotation wheel, with the red dot or white stripe on the top front of the Transducer case (see Figure 7+8).
- 3. Gently push the Transducer fully into the Handpiece, see figure 9.

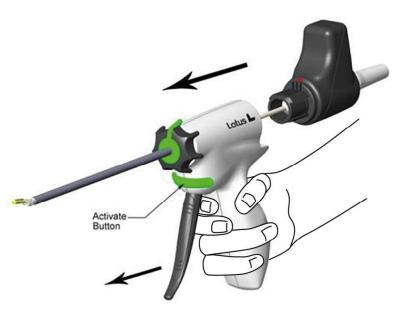


Figure 6



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.

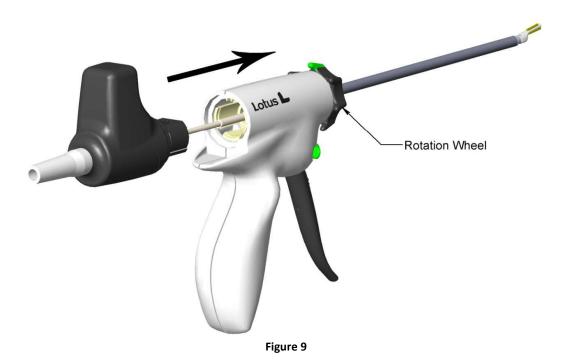


Figure 7





Figure 8



Align the red dots on the Transducer and Handpiece. Slide the Transducer's waveguide through the small aperture in the rear of the Handpiece and gently push the Transducer home.



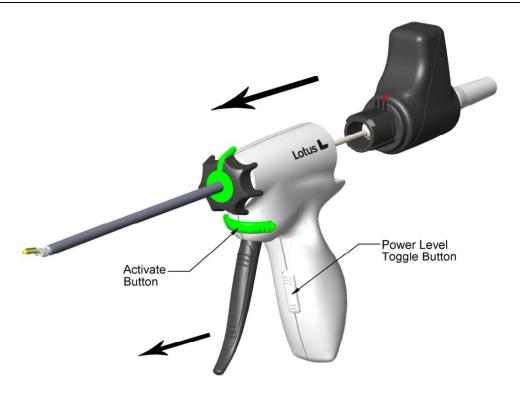


Figure 10



Figure 11

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.

When plugging into the generator, make sure the coloured markings line up.



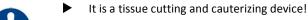


When the Transducer button is activated the associated Transducer light on the generator will light up.

4.1.3.2 Double Blade



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



Avoid resting the blade on skin or sensitive tissue such as bowel for at least 10s after cessation of energizing

► It will have become hot (70-100°C) while cutting. All ultrasonic systems dissipate heat quickly.



4.2 Switch on the LG4

- 1. Connect the mains lead to the rear of the generator.
- 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.

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Device Type 2 Handset (Welder) is unaffected since Low power is not used 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 3.1.2 Audio-Visual Information.
- Full details of LCD messages can be found in 3.1.1 Rear panel user interface components, p. 11.
- 3. 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:



5

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.



4.2.1 Initialize the Handpiece

When the surgeon is ready to use the Transducer they must initialize 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 either:

Device Type 1

Shears, Liver Resector, Double Blade mode – LOW - for Device Type 1. A three tone sound (low-medium-low pitch) sound signifies Type 1 Initialization.



or:

Device Type 2

Welder mode – WELD – for Device type 2, depending on which type of Transducer has been connected. A three tone sound (low-medium-medium pitch) sound signifies Type 2 Initialization.



The device is now ready for use.



4.2.2 Activate the LOTUS Shears

1. Press the Activate button on the Handpiece.

This will energize the Transducer for surgery. An audible indicator signifies power delivery to the Transducer via either:

Continuous low pitched tone for Transducer Device type 1 or

Slow pulsed high pitched tone for Transducer Device type 2.

The Transducer symbol will illuminate whilst the Transducer is active.

2. To terminate power, release the green button. If the button is held down continuously for 20 seconds the audio indicator sound will change from continuous to pulsed for a Device type 1.

There is no change in the already pulsed audio indicator for a Device type 2.

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.

4.2.3 Change Power Level

Press the white Power Select (Toggle) button.
 The LG4 screen changes to either:

HIGH – for a Device Type 1: A triple tone (low-medium-high pitch) sound signifies the mode change.



or

CUT – for a Device Type 2: A single sustained tone (medium pitch) sound signifies the mode change.





2. Press the Activate button on the Handpiece. This will energize the Transducer for surgery. An audible indicator signifies power delivery to the Transducer:

Continuous high pitched tone for Device type 1 or type 2

3. To terminate power release the green button. If the button is held down continuously for 20 seconds the audio indicator sound will change from continuous to pulsed for a Device type 1.

There is no change in the already pulsed audio indicator for a Device type 2.

4. Press the white Power Select (Toggle) button, on either the Handpiece or the footswitch, again to revert to either LOW or WELD once more.

For a Device Type 1: a triple tone (high-medium-low pitch) sound signifies the mode change. For a Device Type 2: a triple tone (high-high-high pitch) sound signifies the mode change.

4.3 Turn Off the LOTUS LG4 generator

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



5 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.

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.



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



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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 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.





Preparation

Warnings & 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.

î	Follow instructions and warnings issued for cleaning and equipment use. 285°F (140°C) is NOT to be exceeded during the reprocessing steps. Do NOT use ULTRASONIC WASHING or CYDEX. Do NOT sterilize LOTUS Generator. Scratches or dents to the Waveguide can result in breakage or malfunction. Care should be taken to remove debris or tissue that may collect on the LOTUS Generator.
Limitations on Reprocessing	End life is generally determined by wear or damage during surgical cases. Inspect Transducers thoroughly for damage between uses. Damaged instruments should be replaced to prevent potential patient injury and loss of metal fragments into the surgical site.

6.1 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 sterilized before use. Effective cleaning and disinfection are essential for effective subsequent sterilization of instruments.

- Ensure that only adequately validated device- and product-specific methods are used for cleaning, disinfection and sterilization and that the validated parameters are complied with in each cycle.
- 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.

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

6.2 Disinfection and cleaning





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

Never sterilize the LOTUS generator. Instead, clean or disinfect it.

6.2.1 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:

- Ensure the generator is turned off and the mains lead is unplugged. 1.
- 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.

- Using above solution, lightly moisten a soft, clean cloth. Wipe surfaces of the generator. 3.
- 4. Using tap water, lightly moisten a soft, clean cloth. Wipe surfaces of the generator.
- 5. Dry generator surfaces with a soft clean cloth.
- 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.



6.2.2 Reprocessing the Transducer

Ensure that following use the Single Use Handpiece/Double Blade Sleeve has been removed from the Transducer and disposed of in an appropriate sharps bin.

Reprocessing instructions have been validated by the manufacturer to ensure capability of LOTUS system reuse. Instruments should be sterilized prior to use using the following guidelines. It is the responsibility of the user to ensure that reprocessing is performed in a controlled manner using validated and calibrated equipment. Any deviation by the reprocessor 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 LOTUS dealer if further information is needed.

Reprocessing Guidelines:

Fit the attached end cap over the free end of the Transducer cable. Push the control it clicks into place. Manual Cleaning Prepare enzymatic cleaning solution (e.g. Gigazyme Plus) to manufacturer's instructions. Soak soiled instruments in enzymatic solution for 5 minutes. When cleaning, fully submerge the instruments in the cleaning solution. Brush soft non-metallic bristle brush or cloth to remove all traces of blood and debric concentrating on any crevices, seams, or other surface discontinuities. Clean hand recesses using an appropriate brush ensuring that the full depth of the fer reached. Ensure instruments are visibly clean before progressing to the next sollind holes and recesses are repeatedly filled and emptied with running water Dry instruments immediately after final rinse. Do not exceed 285°F (140°C) Automated Cleaning Instruments may require manual cleaning prior to automated cleaning to impute the removal of adherent soil. Brush with a non-metallic bristle brush in enzym cleaning solution. Load instruments such that crevices, seams, surface discontinuities, holes and recesses can drain. Clean using the "Instruments" cycle in a validated washer disinfector and a pheneutral cleaning agent intended for use in automatic cleaning (e.g. Getinge En Detergent). The cleaning cycle should incorporate pre-rinse (minimum 3 minu wash (minimum 14 minutes), rinse (minimum 7 minutes), thermal rinse (minimum 2 minute at 200°F/93°C), and drying steps - Do not exceed 285°F (140°C). An alkaline cleaning solution such as, for example, Serchem pH Plus Detergent pH up to 13.2 may be used instead of, or in addition to, an enzymatic solution Inspect all instruments prior to sterilization or storage to ensure the complete removal of soiled surfaces. Visually inspect instruments, if soil is still present clean instruments again.	dy fluids
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When cleaning, fully submerge the instruments in the cleaning solution. Brush soft non-metallic bristle brush or cloth to remove all traces of blood and debri concentrating on any crevices, seams, or other surface discontinuities. Clean hand recesses using an appropriate brush ensuring that the full depth of the fer reached. Ensure instruments are visibly clean before progressing to the next some limit holes and recesses are repeatedly filled and emptied with running water Dry instruments immediately after final rinse. Do not exceed 285°F (140°C) Automated Cleaning Instruments may require manual cleaning prior to automated cleaning to impute removal of adherent soil. Brush with a non-metallic bristle brush in enzymocleaning solution. Load instruments such that crevices, seams, surface discontinuities, holes and recesses can drain. Clean using the "Instruments" cycle in a validated washer disinfector and a pheneutral cleaning agent intended for use in automatic cleaning (e.g. Getinge En Detergent). The cleaning cycle should incorporate pre-rinse (minimum 3 minu wash (minimum 14 minutes), rinse (minimum 7 minutes), thermal rinse (minimum at 200°F/93°C), and drying steps - Do not exceed 285°F (140°C). An alkaline cleaning solution such as, for example, Serchem pH Plus Detergent pH up to 13.2 may be used instead of, or in addition to, an enzymatic solution Inspect all instruments prior to sterilization or storage to ensure the complete removal of soiled surfaces. Visually inspect instruments, if soil is still present clean instruments again.	
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	e
Inspect cables for wear and damage, ensuring that no cracks, tears, or other d	
is found.	damage
Check to see that waveguides are free of scratches.	
Report any damage found to the LOTUS representative.	



Wrapping	Double wrap in accordance with local procedures, using standard procedures wrapping techniques such as those described in ANSI/AAMI ST46-1993.
	Label contents of wrapped tray using indelible marker or other sterilization compatible label system.
Sterilization	Transducers can be autoclaved a maximum of 50 times.
	Sterilization 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 stabilize.
	Transducers are NOT to be submerged in water to expedite cooling.
	Do NOT sterilize the generator.
	These components have been validated for sterilization by the following method in a vacuum autoclave. The parameters for this being 270°- 277°F (134-137°C) for a minimum of 3 and a maximum of 4 minutes with a 5 minute drying cycle (If national standards dictate autoclaving up to 18 minutes, this is possible but not preferable.)
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 sterilization 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.

7 Equipment care

7.1 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 "recognizable" 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.

5

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.



7.2 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 energizes 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 preset markers for warning or termination, the LG4 will alert the user.

7.3 Storage of Equipment between Cases

It is recommended that the Transducers (with attached cables) are stored, between surgeries, in a large autoclave tray. 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.

Maintenance and repair

8.1 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.



8.1.1 Safety inspection

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 listed on page 39.

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 13 Technical Service, page 39.



8.2 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 authorized 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.

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.

Storage conditions:

Temperature: -10 °C to +50 °C Relative humidity 10 to 90 %

Atmospheric pressure: 500hPa to 1060hPa

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10 EMC (Electromagnetic Interference)

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.
- 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.



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.

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 3m 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 radiofrequency 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.



10.1 Guidelines and manufacturer's declaration in accordance with IEC 60601-1-2:2014

Table 1

Guida	nce and manufacturer's	declaration – electromagnetic emissions
LOTUS is intended for use in the	•	•
The customer or the user of LOTL	IS 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
Harmonic emissions IEC 61000-3-2	No testing – no connection to public mains network	those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations /flicker emissions IEC 61000-3-3	No testing – no connection to public mains network	

Table 2

LOTUS is intended for use in the			
The customer or the user of LOT	TUS should assure that it is use	ed in such an environment.	
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment -
			guidance
Electrostatic discharge (ESD)			Floors should be conductive.
IEC 61000-4-2	±8 kV contact	±6 kV contact	No synthetic material should be used in the
	±15 kV air	±8 kV air	environment.
		(1)	The relative humidity should be in the range
			40% to 60%.
Electrical fast transient/burst	±2 kV for power supply	±2 kV for power supply	Mains power quality should be that of a typical
IEC61000-4-4	lines	lines	commercial or hospital environment.
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical
IEC 61000-4-5	± 2 kV common mode	± 2 kV common mode	commercial or hospital environment.
Voltage dips, short	0 % U _⊤ (2)	0 % U _T	Mains power quality should be that of a typical
interruptions and voltage	(100 % dip in U _T)	(100 % dip in U _T)	commercial or hospital environment. If the user
variations on power supply	For 0.5 cycle	For 0.5 cycle	of LOTUS requires continued operation during
input lines	at: 0°, 45°,90°, 135°,	at: 0°, 45°,90°, 135°,	power mains interruptions, it is recommended
IEC 61000-4-11	180°, 225°,270°, 315°	180°, 225°,270°, 315°	that LOTUS be powered from an uninterruptible
			power supply.
	0 % U _⊤	0 % U _T	
	(100 % dip in U _T)	(100 % dip in U _T)	
	For 1 cycle	For 1 cycle	
	 <70 % U _⊤	 <70 % U _⊤	
	(30 % dip in U _T)	(30 % dip in U _T)	
	For 25/30 cycles	For 25/30 cycles	
	0 % U _T	0 % UT	
	(100 % interrupt in U _T)	$(100\% \text{ interrupt in } \text{U}_{\text{T}})$	
	For 250/300 cycles	For 250/300 cycles	
Power frequency (50/60 Hz)	3 A/m	No testing	No magnetically sensitive components.
magnetic field	3 7/111	No testing	No magnetically sensitive components.
IEC61000-4-8			

- (2) U_T is the a.c. mains voltage prior to application of the test level.

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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 Electromagnetic environment guidance level 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 $d = 1.2\sqrt{P}$ Conducted RF 3V rms 3V rms IEC 61000-4-6 150kHz to 80 MHz d = $1.2\sqrt{P}$, 80MHz to 800MHz Outside ISM bands d = $2.3\sqrt{P}$, 800MHz to 2.3GHz 6V rms 6V rms In ISM bands 0.15 MHZ to 80 MHZ where P is the maximum power output rating of 80 % AM at 1 kHz the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres Radiated RF 3 V/m 3 V/m (m). IEC 61000-4-3 80MHz to 2.5GHz Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a Immunity to proximity 9 V/m should be less than the compliance level in each fields from RF wireless 710 MHz, 745 MHz, frequency range.^b communications 780 MHz, 5240 MHz, Interference may occur in the vicinity of equipment 5500 MHz, 5785 MHz equipment marked with the following symbol. 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.

b $\,$ Over the frequency range 150 kHz to 80 MHz , field strengths should be less than 3 V/m $\,$

a Field strengths from fixed transmitters, 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.



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	Separation di	stance according to frequenc	y of transmitter
output power of		m	
transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800MHz to 2.5 GHz
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
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 metres (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.

11 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 centre, see section 13.

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12 Technical Specification

Dimensions:	Generator:	340mm (width) x 95mm (height) x
		340mm (depth)
		13.4" (width) x 3.7" (height) x 13.4"
		(depth)
Weight:	Generator:	4.3 kg
	Transport case:	10.5 kg (loaded with generator)
	Transducer:	0.37 kg
Fuse Type:		None (internal fuses only)
Power supply input		100V - 240V, 50/60Hz
Power consumption		150VA
Output - Frequency of		36 kHz
operation		
Output - Accuracy of frequency		1%
display		
Output – Power		70 W ± 30 W *
Mode of Operation		Intermittent ON/OFF, 3/30s
Insulation Classification	Generator:	Class 1
	Transducer:	Type BF
Environment for Transportation	Temperature:	-10°C to +50°C
& Storage:	Relative humidity:	10% to 90%
	Atmospheric pressure:	500hPa to 1060hPa
Environment for Use:	Temperature:	+10°C to +30°C
	Relative humidity:	30% to 75%
	Atmospheric pressure:	810hPa to 1060hPa

^{*}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: 2012 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.



13 Technical Service

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

BOWA

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

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

Contact for UK:



Bremridge House, Bremridge, Ashburton, Devon, TQ13 7JX, UK

Phone: (44) (1364) 652426 Fax: (44) (1364) 653589 www.sradevelopments.co.uk www.lotusultrasonicscalpel.com

a BOWA-electronic GmbH & Co. KG company

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CE marked according to Medical Device Directive 93/42/EEC



SRA Developments Ltd Bremridge House, Bremridge, Ashburton, Devon, TQ13 7JX, UK

"Tissue Welding" by Ultrasound: Is Torsional Mode Superior to **Longitudinal Mode for Sealing Blood Vessels?**

SS Ching, MJ McMahon

Academic Unit of Surgery, The General Infirmary at Leeds



The Leeds Teaching Hospitals NHS



Background & Aims

Ultrasonic coagulating shears are popular alternatives to electrosurgical instruments during laparoscopic surgery.

One of the abilities of ultrasonic shears is "tissue welding", a process of sealing blood vessels that involves the simultaneous application of energy to denature tissue proteins and pressure to facilitate bonding of these proteins.

Recently a torsional mode ultrasonic coagulating shears has been developed for endoscopic surgery.

This study compared the effectiveness of this torsional mode device with a longitudinal mode device for the haemostasis of medium- and large-sized arteries.

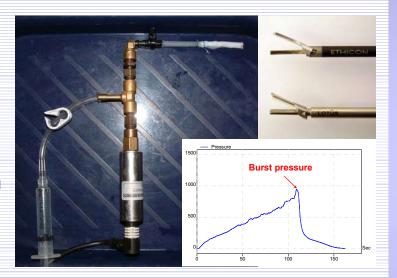


Methods

Porcine carotid arteries were prepared by removing the surrounding connective tissues in vitro. Each vessel was coagulated and cut at different sites by both longitudinal mode (Harmonic Scalpel®, Ethicon Endo-Surgery) and torsional mode (LOTUS™, SRA Developments Ltd.) devices using the lower power settings. Each seal was then tested for the acute burst pressure.

A catheter was placed into the open end of the vessel and secured with a ligature. The catheter was connected to a pressure monitor and saline was gradually infused to increase the artery's intraluminal pressure until there was leakage from the sealed end. The acute burst pressure was defined as the peak pressure recorded.

Statistical differences were evaluated by Mann-Whitney U Test and linear regression analysis.



Results

A total of 104 seals were made. There was no overall difference in acute burst pressures.

Torsional mode:

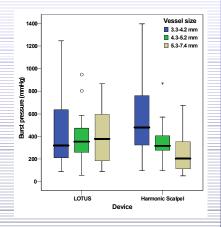
n=52, median 353, range 56-1247 mmHg. Longitudinal mode:

n=52, median 324, range 52-1395 mmHg.

Burst pressures in the 3.3-4.2 mm and 4.3-5.2 mm groups were not statistically different between the two devices (p = 0.193 and 0.579 respectively).

Burst pressure for torsional mode was significantly higher than longitudinal mode in the 5.3-7.4 mm group (p = 0.027).

There was a significant correlation between burst pressure and diameter of vessels for longitudinal mode device (r = -0.552, p = 0.000).

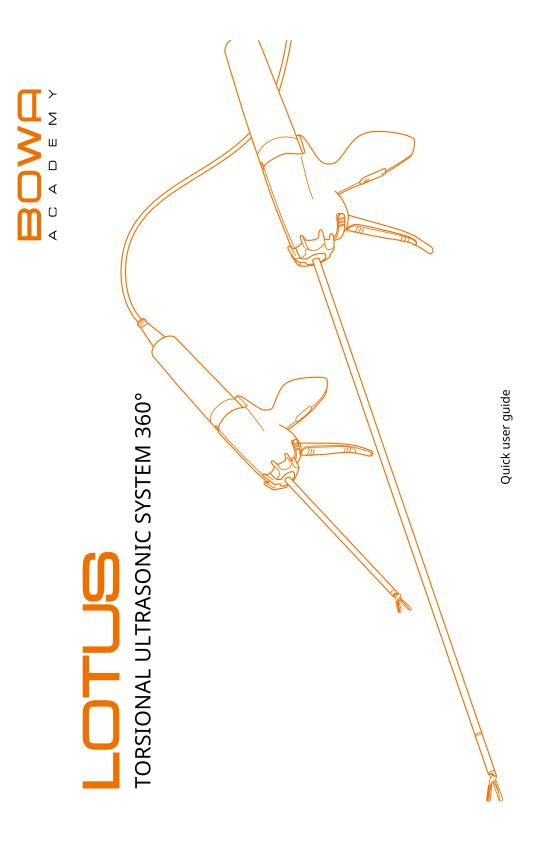


Conclusions

Both torsional and longitudinal mode ultrasonic coagulating shears can achieve secure haemostasis on vessels up to 5 mm in diameter.

The torsional mode device has the extended ability to coagulate larger-sized vessels up to 73mm in diameter with the same degree of confidence.

Increasing vessel size is correlated with lower burst pressures for the longitudinal mode device.



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- 2.1 System overview
- 2.2 Set-up of handpiece and transducer
- 2.3 Generator 2.4 Definition of symbols

3. Cleaning in the sterile field

4. Compatibilities

IMPORTANT INFORMATION

This quick guide is a brief summary of the most important working steps and information. It does not replace the instructions for use. For detailed instructions, please carefully read the instructions for use of the LOTUS series 4.

1.1 | TECHNOLOGY

LOTUS torsional technology



Diagram showing the functional principle



Diagram showing the functional principle

Conventional ultrasonic instruments

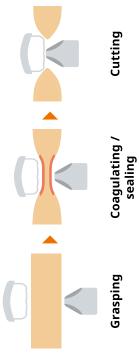
Energy is directed lengthwise through the tip of the instrument. This leads to high losses from energy dissipation at the instrument tip. Inadvertent distal drilling into the tissue is a possible consequence.

LOTUS torsional ultrasonic system

The energy of the LOTUS system is directed perpendicular (90 degrees) to the axis of the blade. Coupled with the blade geometry, the energy is focused in the region of the jaw. Due to the reduction of the risk of inadvertent damage from distal energy dissipation, LOTUS also affords a higher level of safety.

1.2 | TISSUE EFFECTS

1.3 | APPLICATIONS



types of soft tissues – large pedicles, vascular structures LOTUS can be used for haemostatic dissection of all and even tough tissue such as cervix or scar tissue.

Surgical specialities:

General surgery

Gynaecology

Thoracic surgery

The clear tactile feedback affords the surgeon very precise

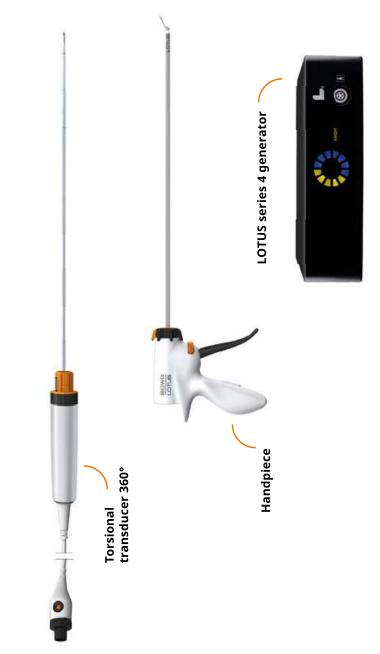
control over the cut.

The contact pressure exerted on the handle has a direct influence on the cutting speed of the LOTUS ultrasonic

Urology

1. BASICS | 2. SET-UP | 3. CLEANING IN STERILE AREA | 4. COMPATIBILITIES

2.1 | SYSTEM OVERVIEW



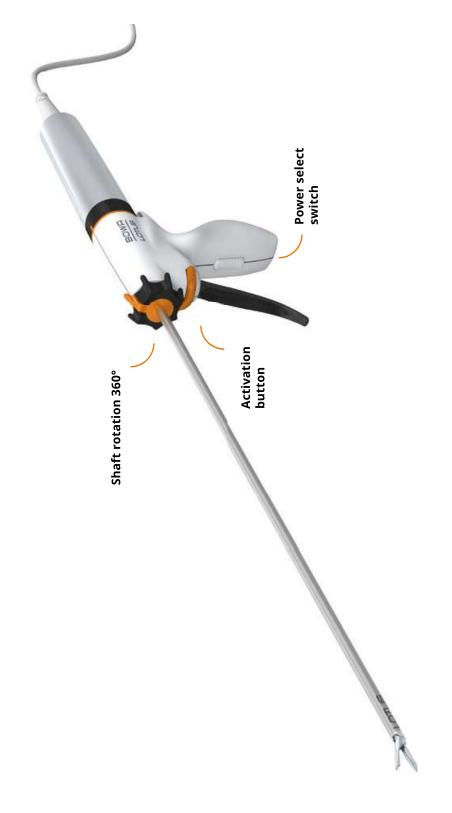
1. BASICS | 2. SET-UP | 3. CLEANING IN STERILE AREA | 4. COMPATIBILITIES

2.2 | SET-UP OF HANDPIECE AND TRANSDUCER





- Open the jaw by operating the handpiece.
- Turn the coloured marking on the rotation wheel to the 12 o'clock position.
- Make sure that the coloured markings on the transducer and rotation wheel are aligned with each other.
- Make sure that the jaw is open and then slide the transducer and handpiece together.
- This does not require any tools.



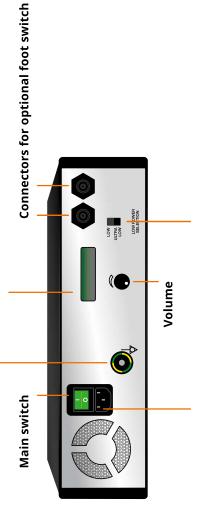
1. BASICS | 2. SET-UP | 3. CLEANING IN STERILE AREA | 4. COMPATIBILITIES

2.3 | GENERATOR



The service life of the transducer is limited to 250 minutes. It is stored in the instrument and can be read out on the rear of the device when the transducer is plugged in.

Equipotential bonding



Socket for mains cable

The power switch allowing the generator to be switched on is situated on the rear of the device. Once the generator is switched on, all generator symbols light up briefly to ensure that the LED display works properly.

The switch on the rear of the device can be used to adapt the LOW power setting. You can switch between ULTRA LOW and LOW power levels. The HIGH level can then still be activated with the power select switch.

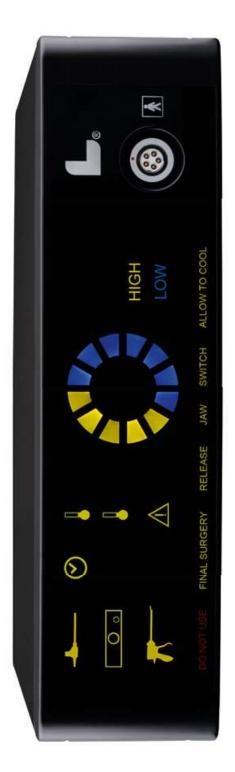


If you press the activation button, the transducer symbol on the generator lights up as an indicator.

Power select switch

the HIGH power level, press the power select switch again. To use the device, press the power select switch first. The system is initialised at the LOW power level. To switch to

2.4 | DEFINITION OF SYMBOLS



SYMBOLS	DESCRIPTION OF SYMBOLS	MEANING	ACTION REQUIRED
	Transducer symbol does not light up.	Transducer has reached the permissible service life.	Transducer needs to be replaced.
	Transducer symbol lights up briefly.	Transducer has been recognised.	
+	Transducer symbol lights up continuously.	Transducer needs to be serviced after the surgery.	Return the decontaminated transducer for servicing.
	Transducer symbol lights up when Activation symbol indicating that the activation button is pressed. the instrument is in use.	Activation symbol indicating that the instrument is in use.	
7	Only the "L" lights up.	The generator stays in standby mode before initialisation.	Briefly press the power select switch to start up.
NOT POM	"LOW" lights up.	The system is switched on at the "LOW" power level.	Use the power select switch to change between "HIGH" and "LOW" energy settings.
HIGH	"HIGH" lights up.	The system is switched on at the "HIGH" power level.	Use the power select switch to change between "HIGH" and "LOW" energy settings.

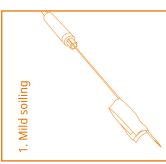
SYMBOLS	DESCRIPTION OF SYMBOLS	MEANING	ACTION REQUIRED
RELEASE SWITCH	Warning symbol, "RELEASE" and "SWITCH" light up.	 The power select button or the activation button is being pressed during initialisation. The power select button is pressed and held after the power level was switched. 	Release the power select button. The generator automatically undergoes a re-start.
RELEASE SWITCH	Warning symbol, "RELEASE" and "SWITCH" and symbols "Handpiece" and "Clock" light up.	Long-term activation for more than 25 seconds. The device takes a short pause for safety reasons.	Release the activation button. The generator automatically undergoes a re-start.
ALLOW TO COOL	The warning symbol and the symbols "ALLOW TO COOL", "Thermometer" and the transducer symbol light up.	The transducer or the acoustic waveguide gets warm.	 Take the transducer out of the handpiece and wipe it down with a moist swab to cool it down immediately. The transducer may be defective or damaged and needs to be replaced.
RELEASE JAW	The warning symbol, "RELEASE JAW" and the transducer symbol light up.	Pressing too hard on the hand- piece.	Release the handle lever and the activation button. The generator resets automatically after 1–2 seconds.

SYMBOLS	DESCRIPTION OF SYMBOLS	MEANING	ACTION REQUIRED
FINAL SURGERY	The warning symbol, the symbols The transducer has reacher "Clock", "FINAL SURGERY" and the than 98% of its service life. transducer symbol light up.	The warning symbol, the symbols The transducer has reached more The surgery can be completed. "Clock", "FINAL SURGERY" and the than 98% of its service life. After disconnecting the transducer from the generator, transducer from the generator, the transducer is deactivated and cannot be used again.	The surgery can be completed. After disconnecting the transducer from the generator, the transducer is deactivated and cannot be used again.
DO NOT USE	The warning symbol, "Clock", "DO NOT USE" and the transducer symbol light up.	The transducer was inadvertently reprocessed and connected again after the message "FINAL SURGERY" had been shown. The transducer cannot be used any longer.	Please replace the transducer.

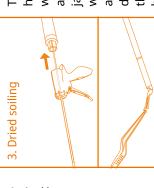
CONTRAINDICATIONS AND WARNINGS:

For a complete list of the warnings, indications and contraindications, please refer to the complete instructions for use enclosed with the device.

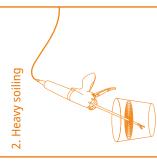
3. | CLEANING IN STERILE AREA



Clean the acoustic waveguide of the transducer and the jaw of the handpiece with a moist cloth. Take the transducer out of the handpiece for this purpose, if required.



Take the transducer out of the handpiece. Clean the acoustic waveguide of the transducer with a moist swab. Soiling around the jaw mechanism can be removed with forceps or a wet swab as appropriate. Make sure not to damage the jaw on the handpiece through excessive force or bending.



Immerse the instrument in a vessel containing sterile water or saline solution and press the activation button. In order to remove any residual soiling, wipe down the acoustic waveguide of the transducer and the jaw of the handpiece with a moist cloth.



IMPORTANT: Do not use any metal objects to remove soiling from the acoustic waveguide as this may lead to scratches or other damage. WE RECOMMEND THAT YOU PREVENT ANY AND ALL CONTACT OF METAL OBJECTS WITH THE ACOUSTIC WAVEGUIDE (E.G. BLADES, CLIPS, TOUCHING GRASPING FORCEPS, ETC.).

4. | COMPATIBILITIES





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L (mm) REF	shears, rotatable 360°
	LOTUS dissecting she

°, °,	Handpiece (disposable, 10 pcs. / Pu) DS5-200CD Transducer (reusable) ES5-200CT Handpiece (disposable, 10 pcs. / Pu) DS5-400CD Transducer (reusable) ES5-400CT Handpiece (disposable, 10 pcs. / Pu) DS5-500CD
5007 360°, curved Jaw	Transducer (reusable) ES5-500CT

LOTUS dissecting shears, rotatable 360°	otatable 360°	
y 200 / 360°,	Handpiece (disposable, 10 pcs. / PU)) LR5-200SD
straight jaw) LR5-200ST
Laparoscopy 400 / 360°, 3	Handpiece (disposable, 10 pcs. / PU)) LR5-400SD
straight jaw) LR5-400ST

LOTUS dissecting shears	v		
Open surgery 200,	176	Handpiece (disposable, 10 pcs. / PU) DS4-200CD	DS4-200CD
curved jaw	2	Transducer (reusable) ES4-200CT	ES4-200CT
Laparoscopy 400,	3/10	Handpiece (disposable, 10 pcs. / PU) DS4-400CD	DS4-400CD
curved jaw	f	Transducer (reusable)	ES4-400CT
Bariatric surgery 500,	737	Handpiece (disposable, 10 pcs. / PU) DS4-500CD	DS4-500CD
curved jaw	<u>}</u>	Transducer (reusable) ES4-500CT	ES4-500CT
LOTUS liver resector			
Open surgery 200,	176	Handpiece (disposable, 10 pcs. / PU)	LR4-200SD
straight jaw	2	Transducer (reusable)	LR3-200
Laparoscopy 400,	3/10	Handpiece (disposable, 10 pcs. / PU) LR4-400SD	LR4-400SD
straight jaw	7	H.	- 200

Transducer (reusable) LR3-400

Laparoscopy 400, straight jaw



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a BOWA - electronic GmbH & Co. KG company

EC DECLARATION OF CONFORMITY

SRA Developments Ltd Bremridge House, Bremridge, Ashburton, Devon, TQ13 7JX, United Kingdom

with its European Representative

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

We hereby declare with sole responsibility that the LOTUS Series 4 Ultrasonic Surgical System and Accessories conforms to the essential requirements of the following:

Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993)

with applied standards:

BS EN ISO13485 / BS EN ISO 17665-1 / BS EN 556-1 / BS EN ISO14971 / BS EN ISO10993-1 / BS EN 1041 / BS EN ISO 15223-1 / BS EN 11135 / BS EN ISO 11607-1 / EN 60601-1 / EN 60601-1-2

CE Marking

Class IIb according to annex II (excluding Section 4)

CE 1639

Notified Body

SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium Nr. 1639

Bremridge,

01.06.2021

Managing Director

Martin Heinrich



a BOWA – electronic GmbH & Co. KG company

Schedule of items for the LOTUS Series 4 Ultrasonic Surgical System and Accessories

Code	Device Name
LG4	LOTUS Series 4 Generator
DS4-200SD	LOTUS Dissecting Shears Straight Handpiece Open 200
DS4-200CD	LOTUS Dissecting Shears Curved Handpiece Open 200
DS5-200CD	LOTUS Dissecting Shears Curved Handpiece Open 200 / 360°
DS4-400CD	LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400
DS4-400CD2	LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400 (RICHARDSON)
DS5-400CD	LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400 / 360°
DS4-500SD	LOTUS Dissecting Shears Straight Handpiece Bariatric 500
DS4-500CD	LOTUS Dissecting Shears Curved Handpiece Bariatric 500
DS5-500CD	LOTUS Dissecting Shears Curved Handpiece Bariatric 500 / 360°
LR4-200SD	LOTUS Liver Resector Straight Handpiece Open 200
LR5-200SD	LOTUS Liver Resector Straight Handpiece Open 200 / 360°
LR4-400SD	LOTUS Liver Resector Straight Handpiece Laparoscopic 400
LR5-400SD	LOTUS Liver Resector Straight Handpiece Laparoscopic 400 / 360°
ES4-400CT	LOTUS Enhanced Shears Curved Transducer Laparoscopic 400
ES5-400CT	LOTUS Enhanced Shears Curved Transducer Laparoscopic 400 / 360°
ES4-200CT	LOTUS Enhanced Shears Curved Transducer Open 200
ES5-200CT	LOTUS Enhanced Shears Curved Transducer Open 200 / 360°
ES4-500CT	LOTUS Enhanced Shears Curved Transducer Bariatric 500
ES5-500CT	LOTUS Enhanced Shears Curved Transducer Bariatric 500 / 360°
SV3-200	LOTUS Dissecting Shears Straight Transducer Open 200
CV3-400	LOTUS Dissecting Shears Curved Transducer Laparoscopic 400
SV3-500	LOTUS Dissecting Shears Straight Transducer Bariatric 500
LR3-200	LOTUS Liver Resector Straight Transducer Open 200
LR5-200ST	LOTUS Liver Resector Straight Transducer Open 200 / 360°
LR3-400	LOTUS Liver Resector Straight Transducer Laparoscopic 400
LR5-400ST	LOTUS Liver Resector Straight Transducer Laparoscopic 400 / 360°
LF4	LOTUS LG4 Footswitch