JTS Lengthening Protocol & Operation Manual

Drive Unit to be used with JTS Extendible Implants

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JTS Lengthening Protocol

Lengthening Instructions

The JTS Non-Invasive Extendible Distal Femoral prosthesis requires extending on a regular basis to keep pace with the growth in the contralateral limb. The Juvenile Tumor System Mobile Limb Extender (JTS MLE) was developed to provide a non-invasive extending control mechanism for the JTS extendible implant. This drive unit produces a controlled expansion of the prosthesis without a need for surgical intervention.

There are two main parts in the JTS System:

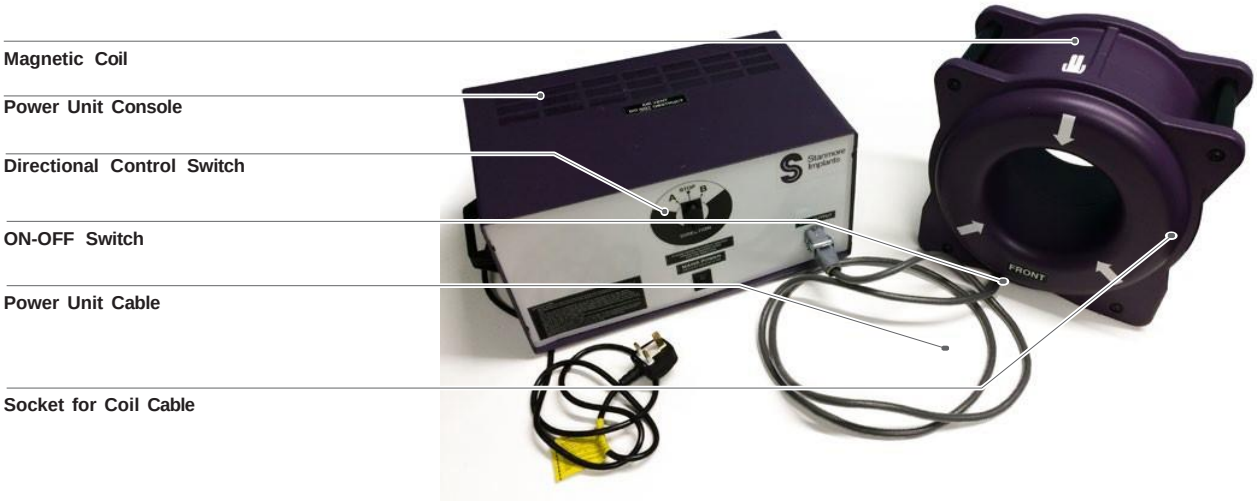
JTS Extendible Implant
The JTS Extendible Implant consists of a patient specific implant with a telescoping shaft connected through a gearbox to a disc magnet. The implant is surgically implanted into the patient according to a standard surgical procedure.

The JTS Drive Unit (MLE)
As the patient's contralateral limb grows, the JTS MLE is used to extend the im- planted prosthesis by placing the limb containing the implanted prosthesis into the magnetic coil.

The JTS MLE has two main components: a cylindrical magnetic coil and a power unit console. When the magnetic coil is energized, a rotating magnetic field is generated, which captures the implant magnet, causing it to rotate in synchronization. The rotary motion of the magnet is converted through a gearbox with a 13,000:1 reduction into a linear motion causing the implant to extend in a very controlled manner.

The magnetic field generated by the drive unit is concentrated in the inner space of the coil itself with very little field on the outer surface of the coil. The maximum value of the magnetic flux is less than 100 mille-Tesla RMS. In general, the field is very weak and therefore there are no special precautions required during operation of this equipment. However, it is recommended that keys, wallets, change or phones are not placed within the coil.

When the implant is being extended there should be no noticeable discomfort for the patient, however the patient may notice slight vibrations, or mild stretching of the tissues surrounding the joint. It is recommended that extensions of 4mm increments are targeted per session with sufficient time between extensions to allow soft tissues to recover from any mild stretching.



Glossary of Terms

JTS MLE
Juvenile Tumor System Mobile Limb Extender

Drive Unit
A MLE, consisting of two main parts: a power unit console and a magnetic coil

Power Unit Cable
Connects the power unit console to the electricity in the wall

On/Off Switch
Located on the front of the power box console, turns the system on and off

Directional Control Switch
Located on the front of the power box console. Settings are A, B and stop

Magnetic Coil
External electromagnetic Coil

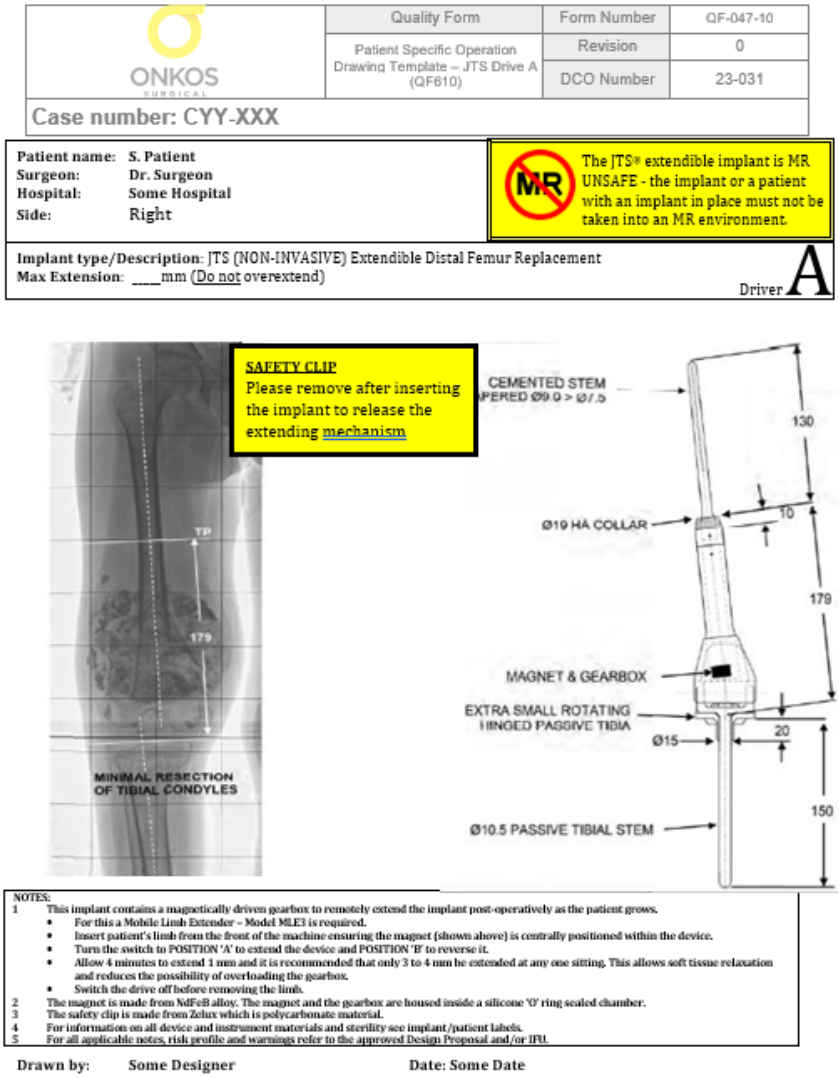
Coil Cable
Attached to the magnetic coil, to be connected to the power unit console

Patient Specific Operative Drawing
States the direction of the setting (A or B) for each specific patient implant

Lengthening Requirements

Lengthening of the JTS implant does not require surgical intervention and is usu- ally performed in an outpatient setting. The following are required to perform a JTS lengthening:

- Trained Health Care Practitioner - a suitably qualified and trained Healthcare Practitioner who has read and understood this document.
- JTS MLE - consisting of the power unit console, magnetic coil, and power unit cable.
- Patient Specific Operative Drawing (shown below) - This document contains important information pertaining to the specific patient which details the ap- propriate settings to lengthen the JTS implant, and also the maximum length achievable for the implant. If this documentation is unavailable, an additional copy can be obtained from your local representative or by contacting Onkos Surgical directly.
- Stethoscope to enable the operator to audibly confirm the JTS implant's mecha- nism rotating and extending the implant.
- Timer to enable timing of the lengthening procedure.



ONKOS SURGICAL	Quality Form	Form Number	QF-047-10
	Patient Specific Operation Drawing Template – JTS Drive A (QF610)	Revision	0
		DCO Number	23-031

Case number: CYY-XXX

Patient name: S. Patient
Surgeon: Dr. Surgeon
Hospital: Some Hospital
Side: Right

MR The JTS® extendible implant is MR UNSAFE - the implant or a patient with an implant in place must not be taken into an MR environment.

Implant type/Description: JTS (NON-INVASIVE) Extendible Distal Femur Replacement
Max Extension: ____mm (Do not overextend)

Driver A

NOTES:
1. This implant contains a magnetically driven gearbox to remotely extend the implant post-operatively as the patient grows.
   - For this a Mobile Limb Extender – Model MLE3 is required.
   - Insert patient's limb from the front of the machine ensuring the magnet (shown above) is centrally positioned within the device.
   - Turn the switch to POSITION 'A' to extend the device and POSITION 'B' to reverse it.
   - Allow 4 minutes to extend 1 mm and it is recommended that only 3 to 4 mm be extended at any one sitting. This allows soft tissue relaxation and reduces the possibility of overloading the gearbox.
   - Switch the drive off before removing the limb.
2. The magnet is made from NdFeB alloy. The magnet and the gearbox are housed inside a silicone 'O' ring sealed chamber.
3. The safety clip is made from Zelux which is polycarbonate material.
4. For information on all device and instrument materials and sterility see implant/patient labels.
5. For all applicable notes, risk profile and warnings refer to the approved Design Proposal and/or IFU.

Drawn by: Some Designer **Date:** Some Date

Equipment Set Up

When setting up the MLE for patient use, please ensure that the following is per- formed prior to the patient's arrival:

- Ensure that safe manual handling practices are observed.
  WARNING: The Power Unit Console weight is approximately 16 kilograms and the Magnetic Coil weight is approximately 36 kilograms. The units are considered to both be 2 person lifts.
- Check the equipment, including all cables, to ensure that there is no damage. Contact your local Onkos representative if there is any evident damage to any of the components.
- Ensure that the Drive Unit and the Magnetic Coil have a matching serial number.
- Both the Power Unit Console and the Magnetic Coil must be placed on a level surface during use. The top of the storage containers provide ample room for set up.
- Connect the Magnetic Coil to the Console via the coil cable. Latch the locking clip over the coil connection.
- The directional control switch should be set at "STOP".
- The "on/off" switch is set to the "off" position.
- Plug the Power Unit Cable in at the back of the Power Unit and into a suit- able power outlet.
- Turn the unit on.

Before lengthening the JTS implant using the MLE, the patient must be assessed by a suitably qualified and trained Healthcare Practitioner to determine the amount of extension required for the session.

The amount of extension expected from a lengthening procedure is directly propor- tional to the amount of time that the implant is inside the energized magnetic coil.

CAUTION: The implant extends 1mm for every 4 minutes. To achieve a recommended lengthening of 4mm, the JTS implant will need to be placed within the energized magnetic coil for 16 minutes.

Patient Positioning

After the device set up is completed, the patient should be brought into the treatment area and positioned as follows:

- Please instruct/assist the patient in removing his/her shoes.
- The patient should be positioned comfortably sitting in a chair with their hips the same height as the center of the magnetic coil.
- Please use proper cushioning so that the patient's limb is adequately supported during the lengthening.
- Consult the Patient Specific Drawing for the location of the gearbox within the JTS implant.
- Place the patient's limb into the Magnetic Coil so that the patient can view the word "front" and the arrows on the coil and is orientated in the same direction as the figure on the top of the coil.

CAUTION: Incorrect directional insertion of the patient's limb into the coil may

result in a reversal of implant extension.

CAUTION: The inner diameter of the opening of the Magnetic Coil is 16cm.

Note: The front of the coil is labeled with a "FRONT" and Arrows. These labels must face the patient as the limb is inserted into the Coil.

The Lengthening Procedure

01 Turn the power unit switch to the on position. There should be an audible sound of the internal fan running. The fan will run for approximately 60 seconds; it will then stop and will not come on again unless the unit is turned off and on again. If there is no audible fan, please consult the Trouble Shooting section on page 08.

02 Referring to the Patient Specific Operation Drawing, select the “A” or “B” setting on the Directional Control Switch to lengthen the JTS implant. Check the location of the gearbox within the implant and ensure that the patient’s leg is situated so that the gearbox is centralized within the magnetic coil.

WARNING: Selection of the opposite setting will reverse the mechanism, resulting in shortening the implant.

03 Once the direction has been selected, begin timing.

The implant mechanism will emit a soft mechanical whirring sound to indicate that the implant’s gears are rotating. The stethoscope may be used to listen to the mechanism throughout the procedure. The closer the stethoscope is placed to the gearbox, the louder the sound will be.

WARNING: If a buzzing or humming sound is emitted from the implant, turn the power unit off, stop the timer and consult the Trouble Shooting Section, page 08.

04 The patient should feel no pain or discomfort during the lengthening, however the patient may experience some vibration and “tightening” around the joint, which may temporarily affect the patient’s range of motion. Any reduction in range of motion should be alleviated by following the patient’s regular rehabilitation regime.
If during the lengthening procedure, the patient experiences any pain, numbness or tingling, immediately turn the power unit to the off position and consult the Trouble Shooting section, page 08.

05 Once the desired amount of extension has been achieved, turn the Power Unit Directional Control Switch to the “stop” position and turn the Power Unit Console “off”.

06 Check the immediate area for any trip hazards associated with trailing cables from the Coil or Power Unit, and eliminated as applicable.

07 Remove the patient’s limb from the magnetic coil.

08 The power unit and coil can now be disconnected.

09 Place the magnetic coil and power unit console in the correct orientation within the flight cases.

Trouble Shooting

TROUBLE SHOOTING

Fan not heard on initial start up or high pitch whirring not hear from Magnetic Coil Check that all connections are secure between the power unit console, the magnetic coil, and the wall power.

Buzzing/Humming Sound from Implant within the Magnetic Coil
If you hear a buzzing/humming sound coming from the implant (not the power unit), this signals that the internal gearbox is not coupling with the magnetic field generated by the coil and the implant is not lengthening as expected.

- Check the position of the patient's limb within the coil, ensuring the the gearbox is centralized within the coil.
- Check that the patient's leg is not externally or internally rotated and the toes are pointing upward.
- Turn the Directional Control Switch to Stop for approximately 5 seconds and then Start again.
- Switch the Directional Control Switch to "A" or "B", in a reciprocating forward and reverse motion.
- Turn the Directional Control Switch to Stop and remove the limb from the coil. Have the patient stand up and stretch the limb. Attempt again.

If these measures fail to address the issue, please consult your Onkos Representative.

Warnings & Precautions

Prior to carrying out any extension to a JTS Extendible implant ensure that you have the correct Patient Specific Operation Drawing available as this will indicate the correct setting for the drive unit to extend the implant.

To prevent reduced range of motion or discomfort to patients provide adequate physiotherapy to regain full range of motion before and after extending the prosthesis.

Avoid over extension of the prosthesis to prevent discomfort to the patient or cause reduced range of motion.

Ensure that full concentration is given whilst extending an implant to prevent trauma to the patient. Lack of concentration may lead to inappropriate implant extension.

After prolonged use of the MLE device the MLE may become warm to touch. Prevent long periods of continuous use.

This equipment must only be operated by a trained operator who is familiar with the controls and has read the manual. Untrained operators may lead to trauma to the patient. Please contact your local representative or Onkos Surgical for training.

Misuse of the equipment may lead to trauma to the patient.

Caution should be exercised to prevent spillage on, or misuse of the equipment to avoid electrical shock.

Perform regular service to prevent excessive electromagnetic field exposure which might lead to nerve stimulation.

Being an electromagnetic device ferromagnetic material near the Coil might become attracted. Avoid such materials near the Coil.

Being an electromagnetic device electromagnetic interference may be experienced by sensitive equipment in a hospital environment. Avoid close proximity with sensitive equipment.

The drive unit is heavy. To avoid the risk of damage, the drive unit must only be stored and transported in the supplied flight cases.

If the equipment is accidentally damaged ensure it is fully checked prior to use. Please contact your local representative of Onkos Surgical.

This equipment must be maintained / serviced regularly to ensure proper function. Any deterioration in function of the device may lead to trauma to the patient.

Do not open the Power Unit while it is connected to a mains supply as this could lead to an electric shock.

Do not clean the drive unit or the control box with any solvent.

Ensure that the manual handling safety precautions are observed whilst lifting the equipment since the Power Unit weights approximately 16Kg (35 pounds) and the Coil approximately 36Kg (80 pounds). These units are considered to both be 2 person lifts.

Ensure that the Coil is placed on a level surface during use. Ensure that the Power Unit is placed on a level surface.

The JTS MLE is not suitable for use in an oxygen rich environment. Only to be serviced/maintained by qualified personnel.

Warnings & Precautions

⚠ Ensure to position the equipment so that it is not difficult to disconnect the mains supply plug.

⚠ The main limitation of the procedure is the size of the patient's leg. The opening in the Coil is 16cm in diameter (approx. 50cm circumference), if the patient's limb is bigger than this they will be unable to position the prosthesis correctly in the magnetic field.

⚠ Booster switch to only be used by qualified service personnel.

⚠ If the drive unit requires disposing of, contact Onkos Surgical.

⚠ WARNING: JTS Drive Unit only to be used with supplied Coil (Coil and drive unit must have matching serial numbers). Use of non-paired Coil may lead to trauma to the patient.

⚠ WARNING: To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

⚠ WARNING: No modification of this equipment is allowed.

⚠ WARNING: The drive unit must only be used with a Onkos Surgical JTS non-invasive extendible implant.

Cleaning & Maintenance

Routinely remove dust using a soft cloth. Do not use solvent of any kind. If required wipe the Drive Unit with Universal Wipes and allow it to dry naturally before use. The Drive Unit should be cleaned after each use and between patients.

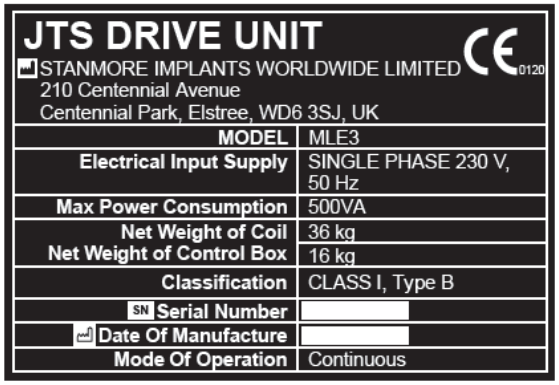
The equipment should be checked annually for performance, by an approved person. Please contact your local representative or Onkos Surgical directly for details.

Technical Specifications

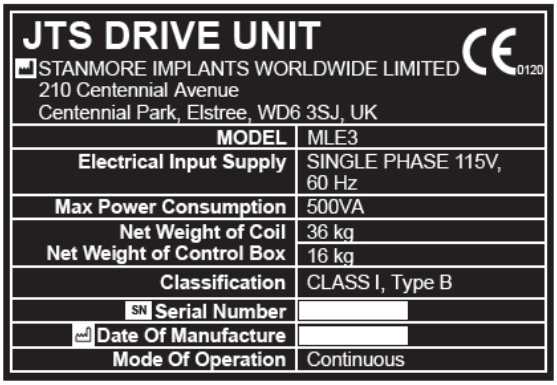
Wiring schematics are available on request from Onkos Surgical

MODEL	MLE3
ELECTRICAL INPUT SUPPLY (230V Systems)	Single Phase 230V, 50Hz
ELECTRICAL INPUT SUPPLY (115V Systems)	Single Phase 115V, 60Hz
MAINS FUSE RAITING	Double T-5 Amps-AH
SECONDARY CIRCUIT FUSE RATING	T-1.6 Amps-AL
MAX POWER CONSUMPTION	500VA
NET WEIGHT OF COIL	36kg
NET WEIGHT OF POWER UNIT	16kg
ELECTRICAL CLASSIFICATION	Class 1 Coil—Applied Part—?—Type B
MODE OF OPERATION	Continuous
MAXIMUM MAGNETIC FLUX INTENSITY	100 milli-Tesla RMS
MEANS USED TO DISCONNECT MAINS	Mains plug
OPERATION ENVIRONMENTAL CONDITIONS (TRANSPORT & STORAGE)	Temperature: 10°C–32°C (-10°C–50°C) Humidity: 30%–75% (10%–90%) Atm. Pressure: 70.0kPa–106.0kPA (50kPa–106kPa)
SOFTWARE REVISION	QF-133 Issue 2
CALIBRATION & INSTALLATION available upon request.	Installation, calibration and testing documentation
SERVICING	Equipment only to be serviced and repaired by approved Onkos Surgical manufacturer. Work Instructions held by approved manufacturer

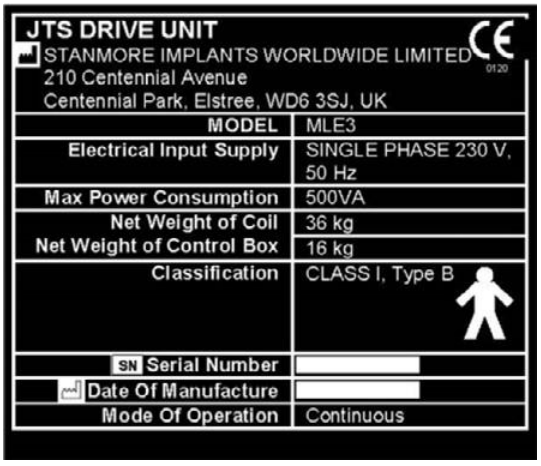
Label Specification



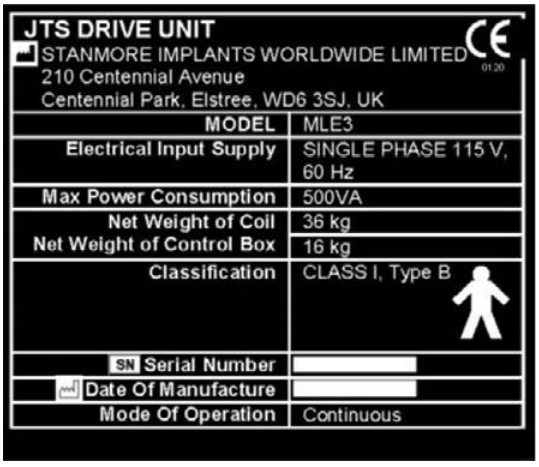
Power Unit Main Label (230V Systems)



Power Unit Main Label (115V Systems)



Coil Main Label (230V Systems)



Coil Main Label (115V Systems)

Mains Power

Air Vent Label

Mains Input Label (230V Systems)

Mains Input Label (115V Systems)

Mains Input Label (230V Systems)

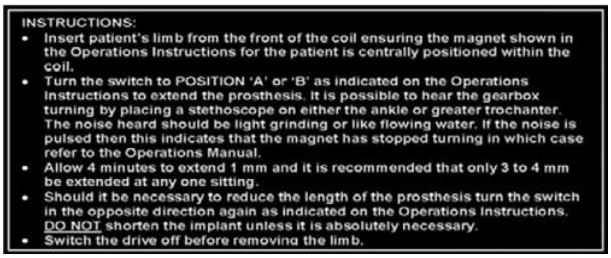
Mains Input Label (115V Systems)

Label Specification

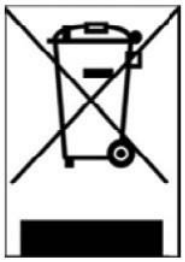
Front Label

Patient Specific Label

Directional Control Switch Label



Patient Specific Label



Do Not Trash Label

Directional Control Switch Label

Stanmore Implants Label

Patient Orientation Indicator in Relation to Limb Entry Point

Limb Entry Point

Testing Notes
(EN60601-1-2:2007)

Special Instructions / Notes regarding the MLE3 JTS Drive unit and Electromagnetic compatibility (EMC) testing to EN60601-1-2:2007

The MLE3 has been tested regarding it's ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure the MLE3 is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the MLE3.

As the MLE3 intentionally radiates electromagnetic energy to provide its intended function, it could in some cases interfere with the operation of other equipment. If the MLE3 is believed to interfere with the normal operation of other equipment, the user should try disconnecting the MLE3 from the mains supply (to establish if the MLE3 is the cause of the problem). If the MLE3 is found to interfere with other equipment, the user is encouraged to increase the physical distance between the MLE3 and the susceptible equipment.

Despite the testing of the MLE3 that has been undertaken, normal operation of the MLE3 can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the MLE3 is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the MLE3 is configured and installed/put into service, in ac- cordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

The MLE3 has been tested (and should be used only with) the Coil output cable supplied.

If the MLE3 is used with a cable other than the one supplied, this may result in in- creased emissions or decreased immunity of the MLE3 in relation to EMC performance.

It should be noted that the cables provided with the MLE3 should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

The MLE3 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the MLE3 and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2, the MLE3 has an essential performance. This es- sential performance is that the Coil output should remain on.

Testing Notes (continued)

(EN60601-1-2:2007)

Guidance & Manufacturer's Declaration—Electromagnetic Emissions

The MLE3 is intended for use in the electromagnetic environment specified below.
The customer or the user of the MLE3 should assure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT—GUIDANCE
RF emissions CISPR 11	Group 2	The MLE3 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The MLE3 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

Guidance & Manufacturer's Declaration—Electromagnetic Immunity

The MLE3 is intended for use in the electromagnetic environment specified below.
The customer or the user of the MLE3 should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT—GUIDANCE
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines input/output line tests are not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MLE3 requires continued operation during power mains interruptions, it is recommended that the MLE3 be powered from an uninterruptable power supply or a battery.
Power frequency (50Hz) Magnetic field IEC61000-4-8	3 A/m	3 A/m	If incorrect operation occurs, it may be necessary to position the MLE3 further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Testing Notes (continued)
(EN60601-1-2:2007)

Guidance & Manufacturer's Declaration—Electromagnetic Immunity

The MLE3 is intended for use in the electromagnetic environment specified below.
The customer or the user of the MLE3 should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT—GUIDANCE
Conducted RF IEC61000-4-6	3Vrms 150kHz – 80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the MLE3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance (*d*) *d* = 1.2 P *d* = 1.2 P 80MHz–800MHz *d* = 2.3 P 800MHz–2.5GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3Vrms 80MHz – 2.5GHz	3V/m	

Note 1: At 80MHz and 800MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed 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 theoret- ically with accuracy. To assess the electromagnetic environment due to fixed RF transmissters, an electro- magnetic site survey should be considered. If the measured field strength in the location in which the MLE3 is used exceeds the applicable RF compliance level above, the MLE3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientat- ing or relocating the MLE3.

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

Testing Notes (continued)
(EN60601-1-2:2007)

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MLE3

The MLE3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MLE3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MLE3 as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER M		
	150KHz–80MHz $d = 1.2\ P$	80MHz–800MHz $d = 1.2\ P$	800MHz–2.5GHz $d = 1.2\ P$
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.30

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 80MHz and 800MHz, the separation distance for 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.

If further information is required, please contact Onkos Surgical

Notes

Notes

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