



GMREIS

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OPERATION MANUAL
MINIDRIVER SOLARIS

REV.00

Manufacturer:

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Product Registration:

Technical name: Surgical instrument motors and accessories/attachments.
Trade name: MINIDRIVER SOLARIS

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DEFINITIONS

-  **CAUTION:** Alerts the user to the possibility of injury or other adverse reaction associated with misuse of the equipment.
-  **ATTENTION:** Alerts the user to the possibility of a problem with the equipment associated with misuse, such as: malfunction, damage to the equipment, etc.

1. INTRODUCTION

The MINIDRIVER SOLARIS is a disposable, sterile, battery-powered medical device with an AO type quick-release coupling for drive accessories used in screw insertion and removal during surgical procedures. It features an ergonomically designed handle and forward/reverse drive buttons.

This operating manual must be read carefully to ensure correct use and maximum performance of the medical device.

IMPORTANT WARNINGS

- Never wet the medical device;
- Avoid turning on the medical device if it has been dropped or shows signs of mechanical damage;
- Do not expose the medical device to high temperatures;
- Do not reuse the medical device, it is a disposable, single-use product, sterilized with ethylene oxide;
- Upon receipt, check the integrity of the medical device. If there is any apparent damage, contact GMReis immediately for guidance;
- The MINIDRIVER SOLARIS uses RF energy only for its internal function. However, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment;
- Use of this equipment adjacent to or over other equipment should be avoided as it may result in improper operation. If such use is necessary, this and the other equipment should be observed to ensure they are operating normally;
- All parts and pieces that have come into contact with patient fluids are potentially contaminated and are therefore considered semi-critical material. All semi-critical material must undergo a high-level disinfection or sterilization process before disposal or be disposed of as potentially contaminated hospital waste;
- The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (IEC/CISPR 11, Class A). If used in a residential environment (for which IEC/CISPR 11, Class B is normally required), this equipment may not offer

adequate protection to radio frequency communications services. The user may be required to take mitigation measures, such as relocating or reorienting the equipment;

- The product should not be used in an oxygen-rich environment;
- The equipment is designed to operate in isolation, with its internal power supply and must not be connected to the external power grid.

WARNING

The MINIDRIVER SOLARIS is an electromedical device supplied ready for use and does not require any type of programming for operation. Modifications to the product may result in the loss of its functions, posing risks to the user.

WARNING

The MINIDRIVER SOLARIS is designed to insert and remove screws with a torque limit, activated by pressing the top buttons. The MINIDRIVER SOLARIS complies with electromagnetic safety standards; however, if it experiences an electromagnetic disturbance, the device may stop working.

2. GENERAL DESCRIPTION

The MINIDRIVER SOLARIS is a sterile, battery-powered, disposable medical device with a quick-connect type AO fitting for accessories used in the insertion and removal of screws in surgical procedures. It features an ergonomically designed handle and actuation buttons (direct/reverse).

ATTENTION

The MINIDRIVER SOLARIS cannot be recharged; discard after use.

3. INDICATION

The MINIDRIVER SOLARIS is indicated for the fixation of small bones (drilling and screwing).

4. CONTRAINDICATION

Not suitable for use on large bone fragments.

5. TECHNICAL SPECIFICATIONS

Electrical Power Supply

Working voltage 4.5V (3 1.5V AA alkaline batteries) - internally powered

Dimensions and Weight

Dimensions 185.0 x 40.0 x 48.0mm

Weight..... 205g

Operation

No-load speed 180 R.P.M

Nominal charging speed 150 R.P.M

Rated load torque 0.7N.m

Stop torque 1.2N.m

Coupling..... AO Type

Environmental conditions

Operation

Temperature 10° - 40°C

Humidity..... 30% - 75%UR

Pressure 700 – 1060hPa

Storage and transportation

Temperature -20° - 40°C

Humidity..... 10% - 75%UR

Pressure 500 – 1060hPa

Applied part..... BF Type

Degree of protection..... IPX0

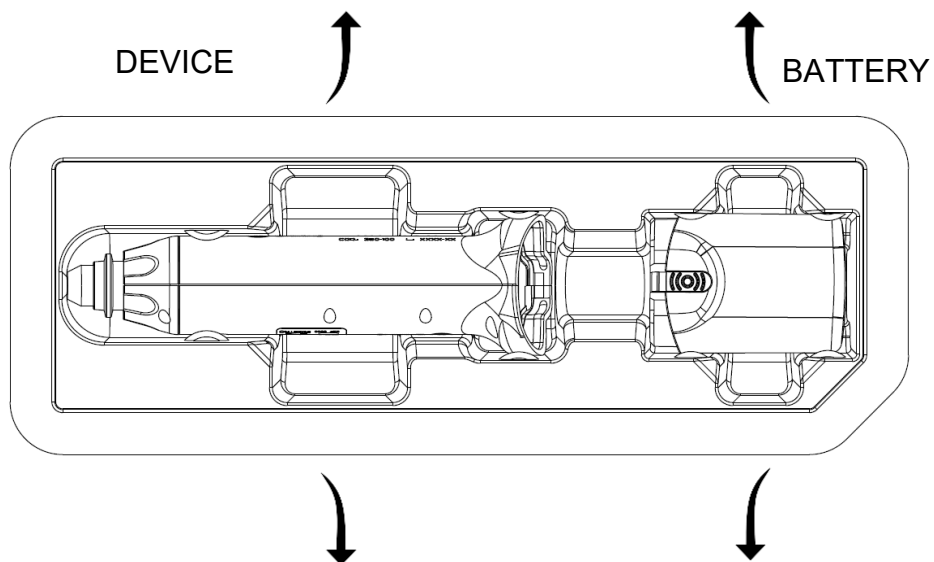
Operating mode CONTINUOUS OPERATION

6. OPERATING PRINCIPLE

The MINIDRIVER SOLARIS is a portable, disposable, and sterile battery-operated device for precise and rapid screw insertion and removal. It has 2 buttons allowing for forward and reverse operation.

7. OPERATING INSTRUCTIONS

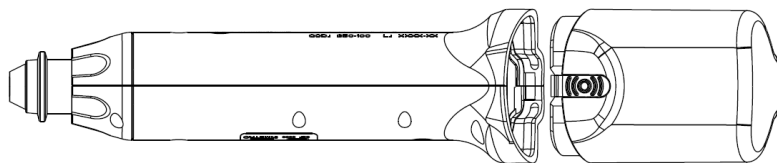
- a) Remove the device and battery from the packaging.;



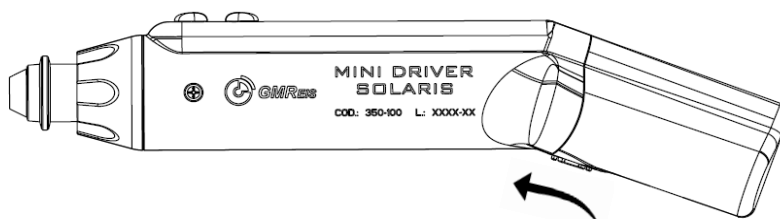
- b) Remove the protective sticker from the battery;



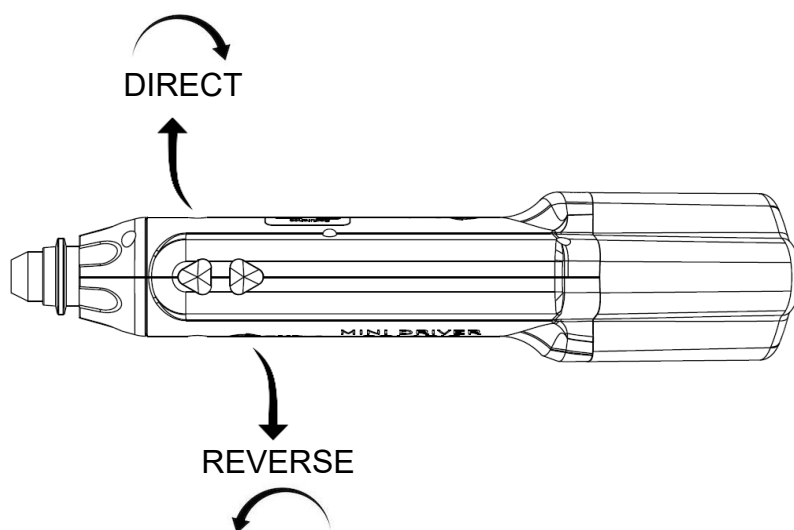
- c) Align the battery connector with the handle fitting;



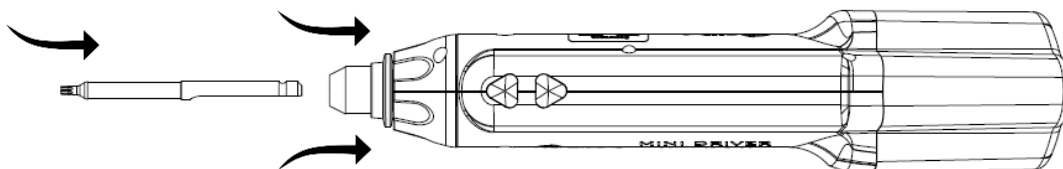
- d) Fit the battery into the handle, making sure the battery is locked in place;



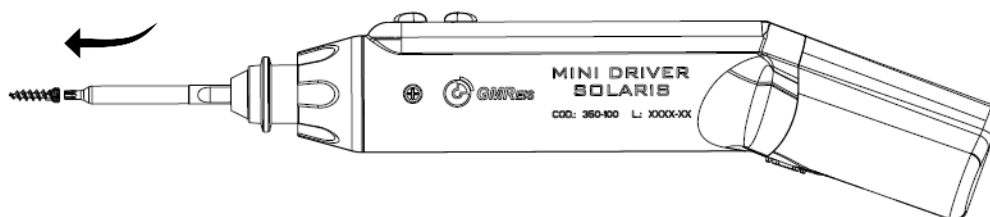
- e) Press the forward and reverse buttons to check operation;



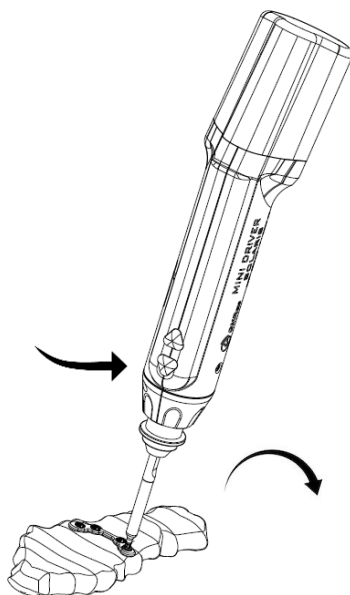
- f) Select the accessory to be used (compatible with AO fitting), press the latch and attach the accessory to the connector;



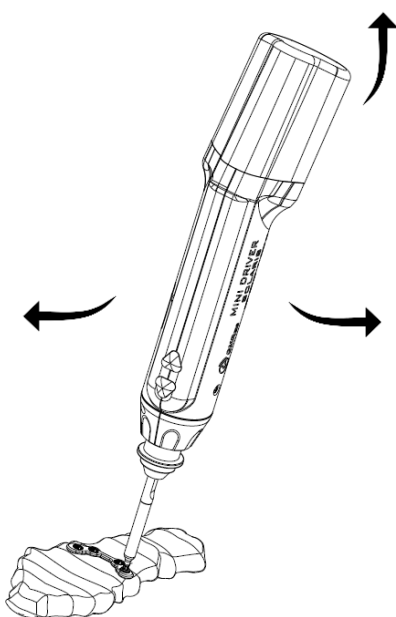
- g) Insert the wrench into the screw to be used;



- h)** Position the screw in the desired location and press the "Direct" button; the device will stop the operation when the screw reaches a force of 0.7 Nm;

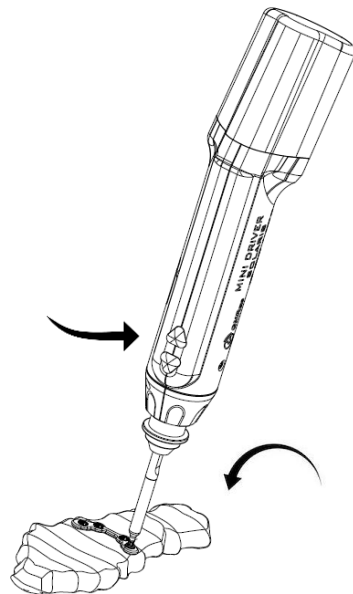


- i)** After tightening the screw, release the knob and make slight lateral movements to loosen the wrench;

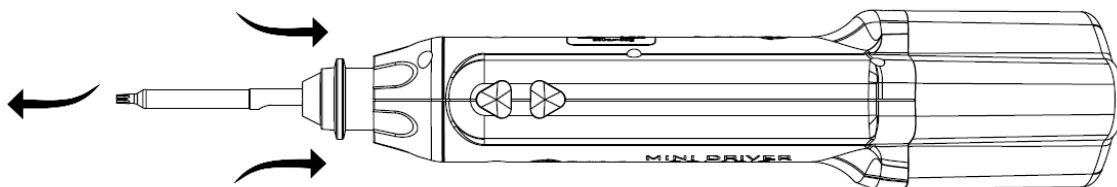


- j)** Repeat steps H and I to secure all necessary screws;

- k) To remove the screw, with the device switched off, insert the key into the screw and press the “Reverse” button until the screw comes out completely. If the button is pressed and the device does not rotate, manually rotate it counterclockwise to loosen it and then press the “Reverse” button;



- l) To remove the key from the coupling, press the coupling and remove the key.



⚠ ATTENTION

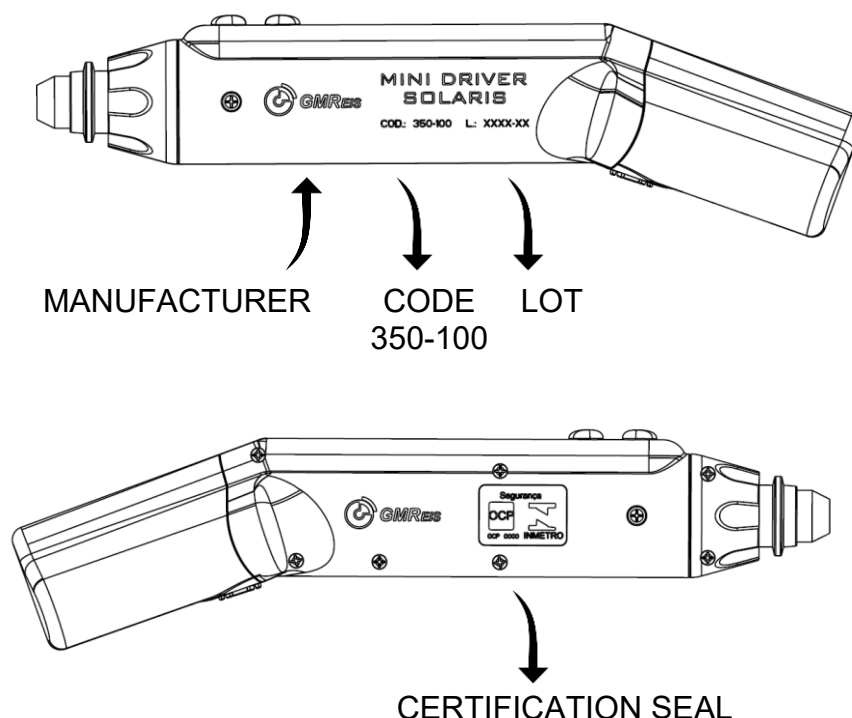
Do not use the equipment for any purpose other than inserting or removing screws.

⚠ ATTENTION

The equipment applies a preload of 0.7 Nm; it is recommended that after inserting the screws, the final tightening be performed with a click-type torque limiter.

8. IDENTIFICATION

The MINIDRIVER SOLARIS device is identified as shown in the diagram below:



9. STERILIZATION

The product is supplied sterilized by ethylene oxide (ETO), according to ISO 11135, and should be kept in its original packaging until the moment of use..

Instructions for opening the package

Before opening the medical device packaging, check that it is not damaged or broken, as this may affect the sterility of the product. Check the expiration date and verify that the selected model corresponds to the packaging to be opened.

Remove the polyolefin film and the safety seal to open the box and remove the medical device.

Special care must be taken when opening to ensure aseptic integrity during the removal of the medical device from its packaging.

Use dry hands and gloves.

Open the sterile envelope and remove the blister containing the product.

To open the blister, pull on the sealing side with continuous force.

With one hand, hold the packaging firmly and with the other hand remove the medical device for use;



CAUTION

Do not use the product if there is visible damage.

CAUTION

The MINIDRIVER SOLARIS must be kept in its original packaging and should not be opened until the moment of use. Before use, the packaging must be examined for damage and tampering to ensure the sterility of the product. If the packaging is damaged or tampered with, the product should not be used and should be discarded.

Before use, handle the product in its packaging following procedures that ensure asepsis.

10. REUSE

Single-use product.

Do not reuse or re-sterilize.

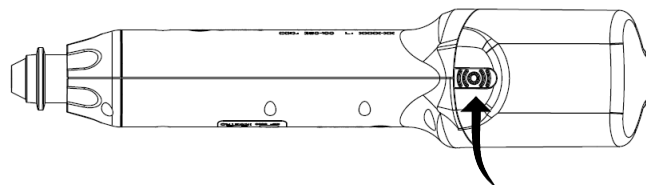
Reprocessing of the product is not permitted, even if it appears to be in perfect condition, as the product may lose its physical and mechanical properties, failing to perform as intended and potentially endangering the health of patients and healthcare professionals.

11. ECORESPONSIBILITY

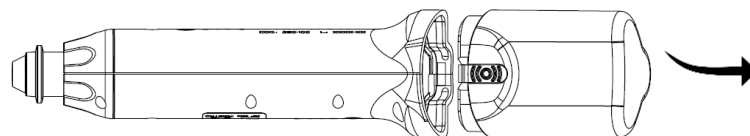


The MINIDRIVER SOLARIS uses 3 AA alkaline batteries for operation; these should be removed from the product for proper disposal, following the instructions below:

- Press the battery release latch.



- Remove the battery and dispose of it properly.



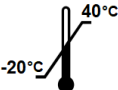
Dispose of the remaining material according to the hospital's own recommendations, in accordance with medical-hospital procedures and/or local legislation, or as instructed by the Hospital Infection Control Committee (CCIH).

CAUTION

Contaminated materials must be decontaminated before disposal.

12. SYMBOLS

The graphic symbols used on the medical device and labeling comply with ABNT NBR ISO 15223-1, as follows:

Symbol	Meaning	Description
	Manufacturer	Indicates the manufacturer of the medical device.
	Manufacturing date	Indicates the date a medical device was manufactured.
	Batch number	Indicates the manufacturer's shipping code so that the shipment or batch can be identified.
	Use by date	Indicates the date after which the medical device can no longer be used.
	Sterilized by Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	Single Use Product Do not reuse	Indicates a medical device intended for single use only.
	Não reesterilizar	Indicates a medical device that cannot be sterilized.
	Consult the user manual or electronic user instructions.	Indicates the need for the user to consult the instructions for use.
	Consult the instruction manual/booklet.	Indicates the need for the user to consult the instructions for use.
	Caution	This indicates that caution is needed when operating the product or control near where the symbol is placed, or that the current situation requires operator attention or action to avoid undesirable consequences.
	Protect from sunlight	Indicates a medical device that needs protection from light sources.
	Do not use it if the packaging is damaged and consult the instructions for use.	This indicates that a medical device should not be used if the packaging is damaged or open, and that the user should consult the instructions for use for further information.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Fragile, handle with care.	Indicates a medical device that may break or be damaged if not handled carefully.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

	Moisture limit	Indicates the humidity range to which the medical device can be safely exposed.
	Atmospheric pressure limit	Indicates the atmospheric pressure ranges to which the medical device can be safely exposed.
	Do not dispose of it in regular trash	Indicates the separate disposal of waste batteries and accumulators.
	Type BF applied part	Identify a BF type part applied in accordance with IEC 60601-1.
IPX0	Protection rating	Indicates the degree of protection or sealing effectiveness of appliances against the ingress of objects, water, dust or accidental contact in accordance with IEC 60529.
	Radio frequency	It indicates a radio frequency generating unit.

13. SPECIFIC GUIDELINES FOR REPORTING ADVERSE EVENTS AND TECHNICAL COMPLAINTS

If the MINIDRIVER SOLARIS presents a specific unforeseen risk, is outside its specifications, or is causing any dissatisfaction, please notify GMReis Customer Service (SAC) directly. The product must be sent clean and packaged in a plastic bag, properly identified and with a description of the non-conformity, to the following address: Av. Pierre Simon de Laplace, 600 – Lote 3 – Quadra F – Quarteirão 9677 – CEP 13069-320 – Condomínio Technopark - Campinas, SP, Brazil or notify directly by phone: (0XX19) 3765-9900 / Email: sac@gmreis.com.br.

USER ALERT

This user manual is available in digital format through the manufacturer's website: <http://www.gmreis.com.br/produtos/IFU> and can be searched using the trade name and ANVISA registration number found on the product packaging label. Always verify that the version in the user manual matches the version indicated on the label. The user manual provided will always be the latest version available. If the user is interested, a printed copy of the user manual can be obtained at no additional cost. Request it free of charge by emailing: sac@gmreis.com.br.

ELECTROMAGNETIC EMISSIONS		
The MINIDRIVER SOLARIS is intended for the electromagnetic environment specified below. The user must ensure that it is used in such an environment.		
Emissions	Compliance	Electromagnetic environment – Guidance
RF Emissions CISPR 11	Group 1	The MINIDRIVER SOLARIS uses RF energy only for its internal functions. However, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The emission characteristics of the MINIDRIVER SOLARIS make it suitable for use in industrial areas and hospitals (IEC/CISPR 11, Class A). If used in a residential environment (for which IEC/CISPR 11, Class B is normally required), this equipment may not provide adequate protection for radio frequency communication services. The user may need to take mitigation measures, such as relocating or reorienting the equipment.
Harmonic emissions IEC61000-3-2	Class A	

ELECTROMAGNETIC IMMUNITY			
The MINIDRIVER SOLARIS is intended for the electromagnetic environment specified below. The user must ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should not be used near any part of the MINIDRIVER SOLARIS, including cables, other than at the minimum recommended distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6Kv - contact +/- 8Kv - air	In Compliance	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	In Compliance	The energy frequency magnetic fields should be at levels characteristic of a typical location in a doctor's office, commercial environment, or typical hospital.
Radiated RF IEC 61000-4-3	3 V/m (80 MHz to 2.7 GHz)	In Compliance	$d=0.35 \sqrt{P}$ 80 MHz to 2.5 GHz Where P is the maximum transmitter output power in watts (W) according to the transmitter manufacturer, and d is the recommended distance in meters (m).

Portable and mobile RF communications equipment should not be used near any part of the MINIDRIVER SOLARIS, including cables, other than at the minimum recommended distance calculated from the equation applicable to the frequency of the transmitter.
The field intensities of fixed RF transmitters, as determined by an electromagnetic survey of the site, must be less than the compliance level in each frequency band.

Interference may occur in the vicinity of equipment marked with the following symbol:



The intensity of fields from fixed transmitters (e.g., cordless telephone base stations, land mobile radios, amateur radio, AM or FM radio broadcasting, and television broadcasting) cannot be predicted theoretically with accuracy. To assess the electromagnetic environment produced by fixed RF transmitters, an electromagnetic site survey should be considered. If the field strength measured at the location of use of the MINIDRIVER SOLARIS is greater than the RF compatibility level indicated above, observe whether the MINIDRIVER SOLARIS functions normally. If the MINIDRIVER SOLARIS does not function properly, other measures may be necessary, such as changing its position or location.

In the frequency range from 150 kHz to 80 MHz, the field strength must be less than 10 V/m.

RECOMMENDED SEPARATION DISTANCE			
The MINIDRIVER SOLARIS should be used in an electromagnetic environment where radiated RF disturbances are controlled.			
Electromagnetic interference can be avoided by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below according to the maximum output power of the communications equipment.			
Maximum output power (W) of the transmitter	Separation distance (m) according to transmitter frequency		
	150kHz to 80 MHz	80MHz to 800 MHz	800MHz to 2,7GHz
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	23.00

For transmitters with a maximum output power not listed above, the recommended separation distance (d in meters (m)) can be estimated using the equation applicable to the transmitter frequency, where P is the maximum output power of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE:

- For 80 MHz and 800 MHz, the separation distance for the higher frequency band applies.

- These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- An additional factor of 10/3 is used when calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if inadvertently brought into patient areas.

 CAUTION

Accessory combinations not listed in the instruction manual may only be used if they are intended exclusively for a specific use and do not affect the performance, safety, and EMC characteristics of the medical device.