ENO / TEO / OTO

MRI SOLUTIONS

Addendum to the ENO, TEO and OTO implant manuals

MicroPort™ CRM | SORIN

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1. GENERAL DESCRIPTION

This MRI Solutions manual concerns ENO, OTO and TEO (SR and DR), and they will be hereinafter called "MR Conditional Devices". This manual is an addendum to their device manuals and provides important information about conditions for use and contraindications of examination using Magnetic Resonance Imaging (MRI) of patients implanted with a pacemaker system. It is designed for cardiologists, physiologists or other healthcare professionals programming the MR Conditional Devices, as well as for radiologists, technologists or other healthcare professionals performing the MRI scanning.

NOTE: Refer to the device manual for the complete instructions for use available at www.microportmanuals.com.

The following symbols are related to the MRI environment. They are used to indicate the safety of devices and components in the MRI environment.

	**MR Safe Symbol**: A medical device which can safely remain with the patient during an MRI scanning without conditions and in any MRI environment.
	**MR Conditional Symbol**: A medical device which can safely remain with the patient during an MRI scanning under specific MRI conditions for use.
	**MR Unsafe Symbol**: A medical device known to pose hazards in all MRI environments. The Microport Programmer is MR Unsafe.

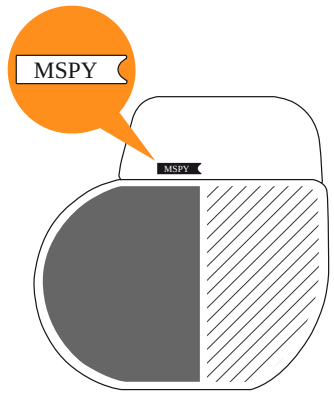
When implanted in combination with MR Conditional leads (listed below in "Overview of the MR Conditional products" section), the MR Conditional Devices constitute a Full Body MR Conditional pacing system. It is designed to allow patients to safely undergo an MRI scanning, when used according to specific MRI conditions for use.

2. OVERVIEW OF THE MR CONDITIONAL PRODUCTS

The MR Conditional Devices can be identified by the presence of 2 letters in the device serial number, or by the presence of a radio-opaque marker on the pacemaker head, visible with x-ray, mentioning MSPY:

Device model	Device serial number with	Radio-opaque marker with
ENO DR	CR	MSPY
ENO SR	CU	MSPY
TEO DR	CS	MSPY
TEO SR	CV	MSPY
OTO DR	CT	MSPY
OTO SR	CW	MSPY

MSPY specific X-ray marker



The following leads are MR Conditional when implanted with MR Conditional Devices:

Description		Lead name	Length
Active screw-in endocardial lead Atrial/Ventricular, Steroid		**BEFLEX RF45D**	52 cm
		BEFLEX RF46D	58 cm
		VEGA R45	45 cm
		VEGA R52	52 cm
		VEGA R58	58 cm
Passive endocardial lead	J-shaped	**XFINE JX24D**	45 cm
		XFINE JX25D	52 cm
	Straight	**XFINE TX25D**	52 cm
		XFINE TX26D	58 cm

CAUTION: Any combination of the MR Conditional Devices with pacing leads other than the ones listed above may result in a hazard to the patient during MRI scanning.

NOTE: Please note that the non-MRI lead is identical to the MRI lead (X-fine, Vega, Beflex). When used with "*MRI conditional pacemakers*", the previously implanted "non-MRI" lead **does not need to be explanted**. It will become part of the new *MRI conditional* system in combination with a *MRI conditional* pacemaker.

3. CONDITIONS FOR USE

When connected to an MR Conditional lead (see list in "Overview of the MR conditional products" section) the MR Conditional Devices enable a Full-Body MRI scanning under the following conditions.

3.1. FOR THE CARDIOLOGIST

Patients implanted with the MR Conditional pacing system can be safely scanned by an MRI system under the following conditions:

- The implanted system (pacemaker and leads) consists of a MR Conditional Device and MR Conditional lead(s) listed in "Overview of the MR conditional products" section.
- The MR Conditional Device is implanted in the left or right pectoral region. Other implantation sites, in particular abdominal implantations, have not been tested and are contraindicated for MRI.
- The MR Conditional Device and leads have been implanted for more than 6 weeks.
- The MR Conditional Device has a battery impedance of less than 5 kΩ. The Programmer carries out this test automatically.
- The MR Conditional Device is programmed to enable the MRI Mode during MRI examination (MRI Mode can be programmed to Manual or to Automatic).
- Pacing capture threshold is 2.0 V or less at a pulse width of 0.35 ms or less.
- Lead is bipolar and its impedance is between 200 Ω and 3000 Ω. The Programmer carries out this test automatically.
- There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- No other active or passive implants are permitted if they are not identified as MRI conditional by the manufacturer.
- The MRI Mode Monitoring Period is long enough for the MRI scanning to be performed in the defined time window.
- Checklist item is approved on Programmer Screen to enable the MRI feature.

All conditions must be fulfilled. In particular, any combination of MR Conditional Devices with pacing leads other than the ones listed above may result in a hazard to the patient during MRI scanning.

CAUTION: When the MRI Mode is programmed to VOO or DOO, patients may exhibit a diaphragmatic or pectoral stimulation, as a result of a pacing output of 5.0 V. If MRI Mode is programmed to Auto, this effect may not appear before the pacemaker switches to asynchronous pacing, when in a strong magnetic field. Caution should be taken to test such a pacing mode prior to programming the MRI Mode. It is recommended to test the MRI Mode by manual programming at the time of the follow-up. Patients with diaphragmatic or pectoral stimulation are more likely to move during MRI scanning or may feel uncomfortable, which may compromise the outcome of the MRI scanning.

3.2. FOR THE RADIOLOGIST

Patients implanted with the MR Conditional system can undergo an MRI scanning only under the following conditions:

- Magnetic resonance imaging of the hydrogen proton nucleus using a static magnetic field of 1.5T or 3T and, as a consequence, an excitation radiofrequency close to 64 MHz or 128 MHz.
- Horizontal cylindrical bore magnet, clinical MRI.
- For static magnetic field of 3T, whole Body Transmit Coil operating on Circularly Polarized (CP) RF excitation.
- Maximum spatial gradient of 20 T/m.
- Maximum gradient slew rate of 200T/m/s per axis and maximum amplitude of 50 mT/m per axis.
- Patient does not have fever or a compromised thermoregulation at time of scan.
- Patient lies in the supine or prone position.
- There are no restriction for receive-only local coils; Transmit-only and transmit-receive local coils must not be used.
- Proper patient monitoring is provided during the MRI scanning (use electrocardiography or pulse oxymetry or non-invasive blood pressure measurements).
- Whole body averaged specific absorption rate (SAR) as reported by the MRI equipment is 2.0 W/kg or less (3.2 W/kg or less for head scanning). This can be easily achieved by selecting the Normal Mode in the MRI scanning parameters.
- The total duration of radio-frequency exposure (or the MRI total scanning time, excluding pauses between sequences) is less than 40 minutes.

NOTE: If the device or lead(s) are within or near the field-of-view of the MRI image, quality may be degraded by ferromagnetic artifacts caused by the MR Conditional system.

CAUTION:

An external defibrillator must be available during the MRI scanning. If the patient's hemodynamic function is compromised during MRI scanning, discontinue the MRI scanning, remove the patient from the MRI room and take the proper measures to restore the patient's hemodynamic function.

Visual monitoring of the patient and verbal communication are mandatory during the MRI scanning.

4. CONTRAINDICATIONS

The patient shall be warned to inform the medical staff that he/she is implanted with an active implantable medical device before entering the MRI room and provide his/ her ID card if he/she received it.

The patient should be warned of the potential risks of pacemaker malfunction if he/she is exposed to external magnetic, electrical, or electromagnetic signals.

All conditions detailed in "Conditions for use" section must be fulfilled.

5. POTENTIAL ADVERSE EVENTS

The MR Conditional system has been designed and tested to minimize potential interactions with the MRI scanner. By programming the MRI Mode prior to MRI scanning, the following adverse events should be avoided but however may still occur in the MRI environment:

Mechanical Interactions:

The presence of ferromagnetic materials interacting with the static and gradient fields may induce force and vibration to the system.

Thermal Interactions:

Gradient and RF fields may induce warming of the device can and lead contact electrodes, which may damage the adjacent tissues, and eventually affect the lead pacing and sensing function.

Therapy Interactions:

The collected energy from gradient and RF fields may induce unintended cardiac stimulation and negatively affect the behavior of the device.

Residual potential interactions may still occur and the patient may feel physical sensations such as warm sensation, slight pulling or vibration at the implantation site which can lead to patient discomfort.

Artifacts may be observed if the implanted system is within the field of view (FOV) of the MRI scanner.

6. MRI MODE

The MRI Mode is a pacing mode which is intended to be applied during MRI scanning.

CAUTION: MRI Mode is an asynchronous pacing at 5.0 V, 1ms pacing output, with a user-defined pacing rate or no pacing. Carefully consider the patient's condition before enabling MRI Mode.

6.1. PROGRAMMABLE PARAMETERS

MRI Mode:

Programmable values: Auto, Manual, Off.

This parameter enables/disables the MRI Mode feature. Depending on specific needs, this parameter can be programmed to enable the MRI Mode automatically (triggered by the detection of a strong magnetic field) or manually.

MRI Mode set to Auto indicates that immediately after clicking on the [PROG] button, the MRI Mode is enabled, but not applied right away. The MR Conditional Device enters a monitoring phase. The programmer header bar displays "**MRI MODE: MONITORING**". As soon as a strong magnetic field is detected, the MR Conditional Device switches to "**MRI MODE: ACTIVE**" phase: MRI parameters are applied and pacing is either asynchronous (AOO, DOO or VOO) or suspended (OOO).

MRI Mode set to Manual indicates that immediately after clicking on the [PROG] button the device enters in MRI mode and all MRI parameters become active. The programmer header bar displays "**MRI MODE: ACTIVE**".

MRI Pacing Mode:

Programmable values: DOO, AOO, VOO, OOO.

This parameter indicates the pacing modality applied during the phase "MRI MODE: ACTIVE".

NOTE: Only asynchronous pacing or absence of pacing is permissible during an MRI scanning. The electromagnetic interferences caused by the MRI equipment could induce noise in the MR Conditional Device. Allowing the pacemaker to sense atrial or ventricular contractions in such a noisy environment could lead to inappropriate pacing or inhibition of pacing.

MRI Pacing Rate:

Programmable values: 50-55-60-65-70-75-80-85-90-95-100-105-110-115-120.

Default value = basic rate + 20 min^{-1}.

If an asynchronous pacing mode is selected, MRI Pacing Rate should be sufficiently high to avoid competitive pacing.

MRI Monitoring Period:

Programmable values: 2h, 4h, 6h, 12h, 24h, 48h, 3 days, 7 days, 10 days.

When MRI Mode is set to Auto, this parameter defines the time window for the detection of a strong magnetic field which will trigger the asynchronous pacing mode (or absence of pacing when OOO is selected).

When MRI Mode is set to Manual, this parameter defines the time during which pacing will be asynchronous (AOO, VOO or DOO) or suspended (OOO).

NOTE:

Re-interrogation allows the interruption of the MRI Mode at any time before the end of the MRI Monitoring Period.

NOTES:

— DOO is available on MR Conditional Devices DR only.

— AOO is available on MR Conditional Devices SR only, when set for the atrial cavity.

— When programmed to Automatic MRI Mode, after the magnetic field is no longer detected, MRI mode is maintained for a few minutes before resuming normal programming. In case the patient has to go back into the MRI equipment, the MRI mode will be applied as long as the MRI Mode Monitoring Period is not over and a magnetic field is detected.

— When programmed to MRI Mode, if the MRI Monitoring Period expires while the patient is still in the MRI environment, MRI mode is maintained until the magnetic field is no longer sensed. Then, the pacemaker will wait for a few minutes before resuming normal programming mode.

6.2. ENABLING MRI MODE

CAUTION: The Programmer is MR Unsafe and should never be taken inside the MRI room.

Apply the following steps to enable the MRI Mode:

1. In “Advanced Parameters” section of the “Parameters” tab, select "MRI parameters".
2. Set MRI Mode to Manual or Auto.
3. Adjust values for parameters:
   — MRI Pacing Mode
   — MRI Pacing Rate
   — MRI Monitoring Period
4. Program the MRI parameters by clicking on the [PROG] button.
5. A message is displayed with an MRI check list. Verify and click the check box to confirm all conditions are met.
6. The MRI Mode is enabled and MRI parameters will apply, either immediately (Manual) or when a strong magnetic field is detected (Auto). When interrogating the MR Conditional Device, the Programmer header bar will either display “MRI MODE: ACTIVE” (Manual) or “MRI MODE: MONITORING” (Auto).

NOTE: Depending on measurements carried out automatically, it is possible that MRI Mode cannot be enabled:

— when the device is too close to RRT (ERI),

— if bipolar impedance of one of the leads is out of the permissible range (or if a lead is unipolar).

In such a situation, an error message will be displayed on the Programmer user interface.

During phase **"MRI MODE: ACTIVE"**, the following parameters are set as follows:

— AV Delay = programmed Rest AV Delay (AV Delay extension = 0), the minimum AV Delay is 95 ms.

— Atrial / Ventricular amplitude = 5V or current programmed value if higher

— Atrial / Ventricular width = 1ms

— Atrial / Ventricular sensing polarity = Bipolar

— Atrial / Ventricular pacing polarity = Bipolar

Restrictions

During phase **"MRI MODE: ACTIVE"**, the Magnet Mode is replaced by the MRI Mode and all other features are deactivated or suspended due to asynchronous mode.

CAUTION: If the nominal mode is requested, for example by pushing the button on the telemetry head, the MRI mode is disabled.

NOTES:

— When the Programmer displays **"MRI MODE: ACTIVE"**, it is not possible to change device parameters. The only possible changes are to disable the MRI mode or to apply the nominal mode.

— It is possible to disable the MRI mode manually before the end of the MRI Monitoring period.

6.3. DISABLING MRI MODE

When MRI Mode is programmed to Auto, asynchronous pacing or absence of pacing programmed as MRI parameters automatically reverts to the initial configuration approximately five minutes after the MR Conditional Device ceases to measure a strong magnetic field. It is preferable to keep the patient in a controlled medical environment until this mode switch has happened.

When MRI Mode is programmed to Manual, the MR Conditional Device automatically returns to the initial configuration at the end of the MRI Monitoring Period. However it is recommended to manually disable MRI Mode, in the programmer parameters screen by selecting value "OFF" for MRI mode, in order to avoid keeping the patient in asynchronous pacing or absence of pacing for an extended period of time.

At the end of the MRI Monitoring Period or after MRI Mode is manually disabled, the magnet mode becomes active again.

7. EXPLANATION OF SYMBOLS

The symbols on product labeling have the following meaning:

General symbols	Explanation of symbols
	Manufacturer
	MR Conditional
	Full Body
	Conformité Européenne (European Conformity)
	This icon is used to call your attention to a particularly important point.
	This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.

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