TALENTIA | ENERGYA

MRI SOLUTIONS

Addendum to the TALENTIA DR 3540 / VR 3240, ENERGYA DR 3440 / VR 3140 and TALENTIA 4LV SONR CRT D 3844 / ENERGYA 4LV CRT D 3744 implant manuals

MicroPort

Intended audience

This manual is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

Training for users

The following instructions for use are for informational purpose only. Each medical professional is responsible for their medical training and experience and should apply the following instructions according to the best clinical practices and patient condition.

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1. GENERAL DESCRIPTION

This MRI Solutions manual concerns TALENTIA | ENERGYA (VR, DR and CRT-D), 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 defibrillator 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 scan.

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 scan without conditions and in any MRI environment.
 MR Conditional	**MR Conditional Symbol**: A medical device which can safely remain with the patient during an MRI scan 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 scan, 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:

Device model	Device serial number with
TALENTIA VR DF4 3240	JQ
TALENTIA DR DF4 3540	JU
ENERGYA VR DF4 3140	JP
ENERGYA DR DF4 3440	JT
ENERGYA 4LV CRT D DF4/IS4 3744	JG
TALENTIA 4LV SONR CRT D DF4/IS4 3844	JH

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

Description	Lead name	Length
Active screw-in endocardial lead IS-1 atrial pacing lead	**BEFLEX RF45D**	52 cm
	BEFLEX RF46D	58 cm
	VEGA R45	45 cm
	VEGA R52	52 cm
	VEGA R58	58 cm
J-shaped passive endocardial lead	**XFINE JX24D**	45 cm
	XFINE JX25D	52 cm
Active endocardial IS-1 atrial pacing lead with contractility sensor	**SONRTIP PS55D**	52 cm
Active endocardial DF4 defibrillation and pacing ventricular lead	**INVICTA 1CR 58**	58 cm
	INVICTA 2CR 58	58 cm
	INVICTA 1CR 68	68 cm
	INVICTA 2CR 68	68 cm
Quadripolar IS4 left ventricular pacing lead	**NAVIGO 4LV 2D 78**	78 cm
	NAVIGO 4LV ARC 78	78 cm
	NAVIGO 4LV 2D 88	88 cm
	NAVIGO 4LV ARC 88	88 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: In case of replacement or upgrade, the already implanted lead labelled “non-MRI” in the table above, when used with “*MRI conditional defibrillators*”, becomes part of the *new MRI conditional* system. Thus, the already implanted lead labelled “non-MRI” **does not need to be explanted** as it is technically identical to the lead labeled “MRI”.

The MicroPort CRM MRI conditional systems are still MRI conditional when mounting a Third Party off-the-shelf plug, provided that the plug fulfills the following conditions:

- The plug is a CE marked IS-1 or DF4/IS4 plug,
- The plug is listed as part of an MRI conditional system for both 1.5T and 3T MR applications.

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 scan 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 (defibrillator 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.
- The MR Conditional Device and leads have been implanted for more than 6 weeks. The MR Conditional Device and leads implanted for less than 6 weeks have not been investigated by MicroPort CRM and are not recommended.

Additional requirements related to device parameters:

- The Recommended Replacement Time (RRT) is not reached.
- RA and RV pacing capture threshold are 2.5 V or less at a pulse width of 0.5 ms or less for pacing dependent patients.
- RA and RV leads impedance are between 200 Ω and 3000 Ω.
- Absence of diaphragmatic or pectoral stimulation as a result of a pacing output of 5.0 V and a pulse width of 1 ms in VOO or DOO mode.
- The MR Conditional Device is programmed to enable the MRI Mode during MRI examination (MRI Mode can be programmed to Manual or to Automatic).
- The MRI Mode Monitoring Period is long enough for the MRI scanning to be performed in the defined time window.
- Checklist item has to be 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: If MRI Mode is programmed to Auto, diaphragmatic or pectoral stimulation may not appear before the defibrillator switches to asynchronous pacing, when in a magnetic field. 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.

CAUTION: Left ventricle stimulation is deactivated during MRI mode.

CAUTION: Other implantation sites, such as abdominal implantation, have not been tested for MRI scanning safety. No data exist to support that MRI scanning in such cases is either safe or unsafe.

CAUTION: If the pulse generator is implanted in a patient who has other devices implanted in the chest area, MRI may be performed if the following conditions are fulfilled:

— All the other implanted devices are identified as MRI conditional or MRI safe by the respective manufacturers;

— The pulse generator and the leads are farther than 2 cm from the other implanted devices.

3.2. FOR THE RADIOLOGIST

Patients implanted with the MR Conditional system can undergo an MRI scan 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) or Multichannel-2 (MC-2) RF excitation.

— Maximum static B0 spatial gradient of 20 T/m.

— Maximum gradient slew rate of 200T/m/s per axis.

— There are no restriction for receive-only local coils; Transmit-only and transmit-receive local coils must not be used.

Examination procedure requirements

— 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).

— Patient lies in the supine or prone position.

— Proper patient monitoring is provided during the MRI scanning (use electrocardiography or pulse oxymetry or non-invasive blood pressure measurements).

— Patient does not have fever or a compromised thermoregulation at time of scan.

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.

NOTE: No limitations on scan duration or wait time between scans.

CAUTION:

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

After external defibrillation, check for proper device function.

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

4. INDICATIONS

MR conditional systems are listed above in "Overview of the MR Conditional products" section.

Please refer to the device user manuals for more details.

5. 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 defibrillator malfunction if he/she is exposed to external magnetic, electrical, or electromagnetic signals.

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

6. ADVERSE EVENTS, RISKS AND SIDE-EFFECTS

The MR Conditional system has been designed and tested to minimize potential interactions with the MR system when programmed in MRI Mode prior a MR examination. Such interactions may cause following adverse events:

- Mechanical force and vibration to the system, which may damage the pocket tissues, and cause patient discomfort such as slight pulling or vibration at the implantation site.
- Heating of lead electrodes adjacent tissues, which may affect the lead pacing and sensing function, as well as device therapies.
- Heating of the device case, which may damage the pocket tissues, and cause patient discomfort such as warm sensation.
- Induced unintended cardiac stimulation, which may induce tachycardia or fibrillation.
- Damage of the device or the leads, which may result in the inability to deliver therapy, or in the delivery of unintended therapy.
- Damage of the device, which may result in the inability to further communicate with the programmer.
- MR image artefacts may be observed if the implanted system is within the field of view (FOV) of the MRI scanner.

Potential Adverse Events specific to MRI Mode

The following potential adverse events are specific to the use of MRI Mode: Failure to treat spontaneous patient tachyarrhythmias, because the device therapies (ATP and shocks) are suspended while MR Mode is active.

7. 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. Therapies (shocks and ATP) and left ventricle stimulation are deactivated during MRI mode. Carefully consider the patient's condition before enabling MRI Mode.

7.1. 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 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 magnetic field is detected, the MR Conditional Device switches to "**MRI MODE: ACTIVE**" phase: MRI parameters are applied, pacing is either asynchronous (DOO or VOO) or suspended (OOO) and therapies are deactivated (no ATP, no shock).

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, 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 defibrillator 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:

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

Programmable values: 2h-4h-6h-12h-1day-2days-3days-7days-10days.

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

Programmable values: 2h-4h-6h-12h-1day-2days

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 and CRT-D only.

— When programmed to Automatic MRI Mode, MRI mode is maintained for 5 minutes before resuming normal programming after the magnetic field is no longer detected. 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 defibrillator will wait for 5 minutes before resuming normal programming mode.Therapies are reactivated.

7.2. ENABLING MRI MODE

CAUTION: The Programmer and telemetry head are MR Unsafe and shall 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 Monitoring Period
   — MRI Pacing Mode
   — MRI Pacing Rate
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 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,

— if impedance of one of the leads is out of the permissible range.

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)

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

— Atrial / Ventricular width = 1ms

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.

CAUTION: When MRI Mode set to Auto, the device may switch to MRI Mode due to the exposure to magnetic sources other than the MR scanner (e.g. anti-theft gate, induction cook top). Patient should be informed to avoid close proximity of the device to significantly larger than commonly observed magnetic fields (greater than 1 mT) until the end of the MRI Monitoring period.

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.

7.3. 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 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.

8. EXPLANATION OF SYMBOLS

The symbols on product labeling have the following meaning:

General symbols	Explanation of symbols
	Manufacturer
	MR Conditional and Full Body
	MR Conditional
	Full Body
	Instructions for use on the website
	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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