MRI-Ready Leadless Systems Manual

MRI Procedure Information for the MR Conditional Aveir™ Leadless Pacemaker

Model LSP112V, LSP202V, and LSP201A

Abbott

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Contents

Introduction

This manual explains the procedures and precautions that must be followed when scanning a patient who is implanted with an MR Conditional Aveir™ Leadless Pacemaker system.

It is important to read the information in this manual before conducting an MRI scan on a patient with an implanted MR Conditional Aveir Leadless Pacemaker system. Contact Technical Support if you have any questions (page 9).

Testing has demonstrated that the MR Conditional Aveir Leadless Pacemaker system is conditionally safe for use in the MRI environment when used according to the instructions in this manual.

Enable MRI Settings to turn on a mode of operation that allows a patient with an MR Conditional system to be safely scanned by an MRI scanner when used according to the instructions in this manual.

Refer to the appropriate device user's manual for a complete listing of device-specific indications, contraindications, warnings, precautions, potential adverse events, and directions for use. Refer to the Aveir Link Module Model LSL02 manual and the Merlin™ Patient Care System (PCS) Model 3650 manual for non-MRI related information.

Symbols

Table 1. MR Conditional symbols

Symbol	Description
	Device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

MR Conditional Leadless Pacemaker Models

Table 2. MR Conditional Models

Device	Model
Aveir™ leadless pacemaker	LSP112V
	LSP202V
	LSP201A

NOTE: The MR Conditional Aveir Leadless Pacemaker system may be a single-chamber pacing system with one device model or a dual-chamber system consisting of a LSP112V or LSP202V in the right ventricle and a LSP201A in the right atrium.

MRI Safety Information

A patient with this system may be safely scanned under the conditions given in this manual.

Scanning under different conditions may result in severe patient injury, death, or device malfunction.

3T MRI Scan Parameters for Aveir™ Leadless Pacemakers

When performing a 3T MRI scan on a patient with an MR Conditional Aveir™ Leadless Pacemaker system, the following scan parameters must be followed.

Table 3. 3T MRI scan parameters

Parameter	Setting
Item Name/Identification	Refer to the MR Conditional Models table (page 1)
Static Magnetic Field Strength and Type of Nuclei	3 Tesla/128 MHz excitation frequency (hydrogen atom only)
Magnet Type and Static Magnetic Field Orientation	Cylindrical-bore magnet, horizontal field orientation
Maximum Spatial Field Gradient	30 T/m (3000 Gauss/cm)
Maximum Gradient Slew Rate per axis	200 T/m/s
RF Transmit Conditions	First Level Controlled Operating Mode or Normal Operating Mode Integrated Whole Body RF Transmit Coil with RF excitation: ▪ Circularly polarized (CP), or ▪ Multichannel-2 (MC-2)
RF Receive Coil Type	Any receive coil may be used
Scan Duration	2 W/kg or 4 W/kg of whole-body average SAR for up to 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Region / Patient Landmarking Criteria	Full body scans allowed. Any landmark is acceptable
Patient Characteristics	Refer to Instructions for Cardiac Physicians and Clinicians to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 4) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 8) ▪ Perform the Scan and Monitor the Patient (page 9)
Patient Position in Scanner	Supine or prone; patient's arms must be at his or her sides
Device Configuration	MR Conditional labeling applies to single-chamber and dual-chamber configurations. If present, the LSP112V/LSP202V device must be implanted in the right ventricle. If present, the LSP201A device must be implanted in the right atrium.
Instructions to be followed before and after the MRI exam	Device programming is required for safe scanning: MRI Settings must be enabled before start of scan and disabled after completion of scan. Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 8)
MR Image Artifact	The presence of this system may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact.

1.5T MRI Scan Parameters for Aveir™ Leadless Pacemakers

When performing a 1.5T MRI scan on a patient with an MR Conditional Aveir™ Leadless Pacemaker system, the following scan parameters must be followed.

Table 4. 1.5T MRI scan parameters

Parameter	Setting
Item Name/Identification	Refer to the MR Conditional Models table (page 1)
Static Magnetic Field Strength and Type of Nuclei	1.5 Tesla/64 MHz excitation frequency (hydrogen atom only)
Magnet Type and Static Magnetic Field Orientation	Cylindrical-bore magnet, horizontal field orientation
Maximum Spatial Field Gradient	30 T/m (3000 Gauss/cm)
Maximum Gradient Slew Rate per axis	200 T/m/s
RF Transmit Conditions	First Level Controlled Operating Mode or Normal Operating Mode Integrated Whole Body RF Transmit Coil or Detachable RF Transmit-Receive coils (Head, Lower Extremity, or Upper Extremity) with RF excitation: ▪ Circularly polarized (CP)
RF Receive Coil Type	Any receive coil may be used
Scan Duration	2 W/kg or 4 W/kg of whole-body average SAR for up to 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Region / Patient Landmarking Criteria	Full body scans allowed. Any landmark is acceptable
Patient Characteristics	Refer to Instructions for Cardiac Physicians and Clinicians to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 4) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 8) ▪ Perform the Scan and Monitor the Patient (page 9)
Patient Position in Scanner	Supine or prone; patient's arms must be at his or her sides
Device Configuration	MR Conditional labeling applies to single-chamber and dual-chamber configurations. If implanted, the LSP112V/LSP202V device must be implanted in the right ventricle. If implanted, the LSP201A device must be implanted in the right atrium.
Instructions to be followed before and after the MRI exam	Device programming is required for safe scanning: MRI Settings must be enabled before start of scan and disabled after completion of scan. Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 8)
MR Image Artifact	The presence of this system may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact.

Instructions for Cardiac Physicians and Clinicians

NOTE: Radiologists and MRI technologists should see Instructions for Radiologists and MRI Technologists (page 8).

The role of cardiac physicians and clinicians in preparing a patient for an MRI scan is to:

- Confirm that the Patient has an MR Conditional Device (page 4)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 4)
- Review the Potential Adverse Events (page 4)
- Generate a Report of the Patient's Permanently Programmed Parameters (page 4)
- Select and Save MRI Settings (page 4)
- Review the MRI Checklist and Program MRI Settings (page 6)
- Disable MRI Settings (page 6)

I. Confirm that the Patient has an MR Conditional Device

1. Review the patient's ID card or a printed report generated by the Merlin™ PCS to obtain the model number for the implanted device(s).
2. Check that each model number is MR Conditional (page 1).

II. Confirm that No Adverse Conditions to MRI Scanning are Present

If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- The device is at End-of-Service
- The LSP112V or LSP202V device (if implanted) is implanted at a site other than the right ventricle
- The LSP201A device (if implanted) is implanted at a site other than the right atrium
- Patients with unstable capture thresholds
- Patients with capture threshold values of >2.5 V at a pulse width of 0.5 ms
- Complaints of diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI Settings are enabled
- Patients with additional cardiac hardware (eg. abandoned leads)

  NOTE:

  - Scanning patients who have other MR Conditional devices that are not implanted in cardiac tissue is acceptable provided all MR Conditional requirements for each implanted device are met.
  - Scanning patients who have abandoned MR Conditional leadless pacemaker devices in the same chamber is also acceptable provided all MR Conditional requirements for each leadless pacemaker are met. Abandoned leadless pacemaker devices must be deactivated.

III. Review the Potential Adverse Events

The Aveir™ Leadless Pacemaker system has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MRI environment:

- Device heating resulting in tissue damage leading to loss of capture or sensing or both
- Induced currents resulting in continuous capture, VT/VF, hemodynamic collapse, or all three
- Damage to the functionality or mechanical integrity of the device resulting in the inability to communicate with the device
- Damage to the device causing it to fail to detect or treat irregular heartbeats, or to treat the patient's condition incorrectly
- Movement or vibration of the device
- Device dislodgement
- Competitive pacing and potential for VT/VF induction due to asynchronous pacing when MRI Settings are enabled
- Syncope due to loss of pacing

Potential interactions between the MRI scanner and the MR Conditional device include:

- The magnetic material of an implanted device may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. These effects have been shown to be minimal in the Aveir leadless pacemaker system.
- The gradient magnetic and RF fields produced by an MRI scanner could potentially interact with the MR Conditional device and cause unintended stimulation of the heart. When all conditions outlined in this manual are met, the currents induced on the device are limited so that the potential for capturing the heart is minimized.
- If a dual-chamber system is implanted and programmed to MRI DOO⇄VOO mode, the gradient magnetic and RF fields produced by an MRI scanner will cause the pacing support to temporarily switch from MRI DOO mode to MRI VOO mode during the MRI scan to avoid i2i interference. Gradient magnetic and RF fields may occasionally cause individual pacing cycle variations.
- The RF fields generated by an MRI scanner could potentially interact with the device, resulting in heating. This heating could damage the surrounding tissue and compromise pacing and sensing thresholds at that site. When all conditions outlined in this manual are met, the Aveir leadless pacemaker system has been tested and shown to limit heating and to minimize thermal damage of the surrounding cardiac tissue.

IV. Generate a Report of the Patient's Permanently Programmed Parameters

CAUTION: Do not bring any external control devices, such as a Merlin™ PCS or Aveir™ Link Module, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.

1. Interrogate the patient using the Aveir Link Module and the Merlin PCS.
2. If needed, perform capture and sense tests.
3. Select the Print button to print the Parameter report and any other relevant reports.
   The Merlin PCS will print to the default printer (internal printer, external printer or PDF).

   NOTE: With the exception of i2i diagnostic data, device diagnostic data will be suspended when MRI Settings are enabled. For any device, it is recommended that the clinician performs a complete follow-up prior to the MRI procedure to save all diagnostic data.

V. Select and Save MRI Settings

The MRI parameter settings are selected at the physician's discretion.

The default MRI parameter settings are automatically stored in the MR Conditional device.

Table 5. Default MRI Settings for dual-chamber leadless pacemaker systems

Parameter	Setting
MRI Mode	DOO⇄VOO
MRI Base Rate	85 bpm
MRI Paced AV Delay	120 ms
MRI Pulse Amplitude	5.0 V
MRI Pulse Width	1.0 ms
MRI Electrode Configuration	Bipolar

NOTE: MRI DOO⇄VOO MRI Mode will temporarily switch from MRI DOO mode to MRI VOO mode during the MRI scan to avoid i2i interference. If selecting MRI DOO⇄VOO, be sure to test both MRI DOO and MRI VOO modes before programming MRI Settings.

Table 6. Default MRI Settings for single-chamber leadless pacemakers

Parameter	Setting
MRI Mode	VOO or AOO
MRI Base Rate	85 bpm
MRI Pulse Amplitude	5.0 V
MRI Pulse Width	1.0 ms
MRI Electrode Configuration	Bipolar

If you change MRI Settings you must save the modified MRI Settings in the device as described below.

Refer to the Merlin™ PCS on-screen help for information on selecting, testing, and saving the MRI parameter settings.

1. After you interrogate the device with the Merlin PCS and Aveir™ Link Module, select the Parameters button on the right to open the Parameters window. Then, select the MRI Settings tab. This opens the MRI Settings window.
2. From this window, you can modify the MRI parameters that are in effect when MRI Settings are enabled.

   NOTE: For a dual chamber leadless pacemaker system that includes a leadless pacemaker with a serial number prior to 1316238, you must select the Save MRI Settings button to ensure MRI Settings are updated and in effect prior to testing. To activate the Save MRI Settings button, complete the following steps:

   i. Temporarily modify MRI Mode e.g. to VOO.
   ii. Select the “Save MRI Settings” button.
   iii. You can then modify the MRI parameters to your desired settings.
   iv. Continue by Testing MRI Settings in Step 3.
3. You can temporarily test the settings by selecting the Test MRI Settings button. Use this function to evaluate the patient’s hemodynamic status with the proposed MRI parameter settings.

   NOTE:

   - If selecting MRI DOO⇄VOO, be sure to test both MRI DOO and MRI VOO modes before programming MRI Settings.
   - For MRI DOO⇄VOO mode during Test DOO MRI Settings, loss of i2i communication markers will appear during each pace cycle on the RV marker channel. See figure below, Loss of i2i communication markers on the RV marker channel during each pace cycle.
   - For MRI DOO⇄VOO mode during Test VOO MRI Settings, loss of i2i communication markers will appear during each pace cycle on both the RV and RA marker channels and atrial pacing withheld markers will appear during each pace cycle on the RA marker channel. See figure below, Loss of i2i communication markers on the RV and RA marker channels, and atrial pacing withheld event markers on the RA marker channel during each pace cycle.

Figure 1. Loss of i2i communication markers on the RV marker channel during each pace cycle

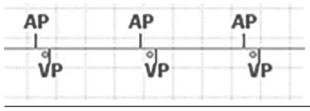
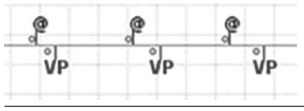


Figure 2. Loss of i2i communication markers on the RV and RA marker channels, and atrial pacing withheld event markers on the RA marker channel during each pace cycle



4. Select the Cancel Test button to return to permanently programmed settings.

   CAUTION: Failure to Cancel Test, or loss of communication with device before canceling test, can unintentionally leave the device programmed with MRI Settings.
5. Select the Save MRI Settings button to save any changed parameters.
6. When you are satisfied with MRI Settings, select the Setup for MRI Now button to open the MRI Checklist.

   CAUTION: Regardless of the programmed permanent pacing mode, sensed events are ignored by the device when MRI Settings are enabled. Determine whether or not pacing support is needed during the MRI scan. When pacing support is needed, set the MRI Mode to an asynchronous pacing mode (DOO⇄VOO, VOO, or AOO). When pacing support is not needed, set the MRI Mode to Pacing Off.

   Some patients may be susceptible to cardiac arrhythmia induced by competitive pacing when an asynchronous MRI Mode is selected. For these patients, it is important to select an appropriate MRI pacing rate to avoid competitive pacing and then minimize the duration of the asynchronous pacing operation.

VI. Review the MRI Checklist and Program MRI Settings

Figure 3. An example of the MRI Checklist screen for single-chamber leadless pacemakers on the Merlin™ PCS

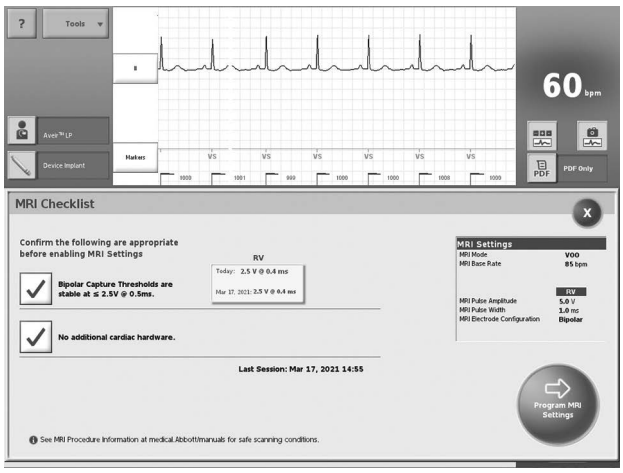
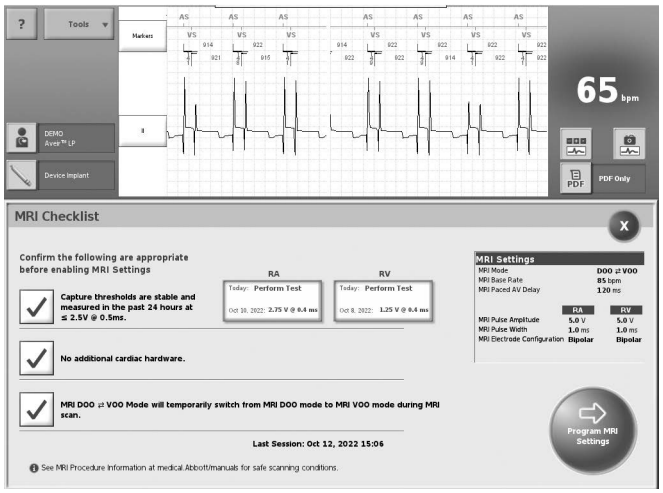


Figure 4. An example of the MRI Checklist screen for dual-chamber leadless pacemakers on the Merlin™ PCS



1. After you have selected the appropriate MRI Settings, from the MRI Settings window on the Merlin™ PCS, select the Setup for MRI Now button. The MRI Checklist window will open.
2. Review each condition on the checklist and check off each one that applies. You will not be able to program MRI Settings until all boxes are checked.
3. Once you have completed the checklist, select the Program MRI Settings button to enable MRI Settings. Next, MRI Settings: Active window appears. This window confirms the programmed changes.

   NOTE:

   - If the Merlin PCS emergency VVI hard button is selected when MRI Settings are enabled, the system will disable MRI Settings and display the emergency VVI dialog box. Restore MRI Settings before scanning the patient.
   - When MRI Settings are active in MRI DOO⇄VOO mode, loss of i2i communication markers will appear during each pace cycle on the RV marker channel when the device is pacing in MRI DOO or MRI VOO mode. Additionally, if the system is in i2i Noise Reversion, loss of i2i communication markers and atrial pacing withheld event markers will appear during each pace cycle on the RA marker channel.
4. Select Print MRI Report button to print the report.
5. Select End Session.
6. Remove ECG electrodes from the patient prior to entering the MRI scan.

The Patient is now ready for the MRI scan.

CAUTION: The patient must be hemodynamically monitored and an external defibrillator must be available during the MRI scan.

Be sure to disable MRI Settings as soon as the MRI scan is complete.

VII. Disable MRI Settings

CAUTION: Do not bring any external control devices, such as a Merlin™ PCS or Aveir™ Link Module, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.

Immediately following the MRI procedure, the patient's device management physician or clinician must:

1. Interrogate the device using the Aveir Link Module and the Merlin PCS.

   NOTE: When MRI Settings are active in MRI DOO⇄VOO mode, loss of i2i communication markers will appear during each pace cycle on the RV marker channel when the device is pacing in MRI DOO or MRI VOO mode. Additionally, if the system is in i2i Noise Reversion, loss of i2i communication markers and atrial pacing withheld event markers will appear during each pace cycle on the RA marker channel.

2. Disable MRI Settings by selecting the Disable MRI Settings button. This restores the permanently programmed settings.

- Confirm the permanently programmed settings are appropriate.

- Check the pacing capture thresholds after the scan is complete and ensure that the pacing parameters are programmed adequately for the patient based on the threshold.

Refer to the Merlin PCS on-screen help for information on selecting and programming parameter settings.

Instructions for Radiologists and MRI Technologists

NOTE: Cardiac physicians and clinicians should see Instructions for Cardiac Physicians and Clinicians (page 4)

The role of the radiologist or MRI technologist is to:

- Confirm that the Patient has an MR Conditional Device (page 8)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 8)
- Review the Potential Interactions (page 8)
- Select the Correct Scan Parameters (page 8)
- Check MRI Settings Status (page 9)
- Perform the Scan and Monitor the Patient (page 9)

I. Confirm that the Patient has an MR Conditional Device

1. Review the patient's ID card or the MRI Summary Report (generated by the Merlin™ PCS) to obtain the model number of the implanted device(s).
2. Check that the model number is MR Conditional (page 1).

II. Confirm that No Adverse Conditions to MRI Scanning are Present

If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- Any patient position in the scanner other than supine or prone, with patient's arm at his or her sides
- Patients with additional cardiac hardware (eg. abandoned leads)

NOTE:

- Scanning patients who have other MR Conditional devices that are not implanted in cardiac tissue is acceptable provided all MR Conditional requirements for each implanted device are met.
- Scanning patients who have abandoned MR Conditional leadless pacemaker devices in the same chamber is also acceptable provided all MR Conditional requirements for each implanted device are met. Abandoned leadless pacemaker devices must be deactivated.

III. Review the Potential Interactions

Potential interactions between the MRI scanner and the MR Conditional device include:

- The magnetic material of an implanted device may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. These effects have been shown to be minimal in the Aveir™ Leadless Pacemaker system.
- The gradient magnetic and RF fields produced by an MRI scanner could potentially interact with the MR Conditional device and cause unintended stimulation of the heart. When all conditions outlined in this manual are met, the currents induced on the device are limited so that the potential for capturing the heart is minimized.
- If a dual-chamber system is implanted and programmed to MRI DOO⇄VOO mode, the gradient magnetic and RF fields produced by an MRI scanner will cause the pacing support to temporarily switch from MRI DOO mode to MRI VOO mode during the MRI scan to avoid i2i interference. Gradient magnetic and RF fields may occasionally cause individual pacing cycle variations.
- The RF fields generated by an MRI scanner could potentially interact with the device, resulting in heating. This heating could damage the surrounding tissue and compromise pacing and sensing thresholds at that site. When all conditions outlined in this manual are met, the Aveir leadless pacemaker system has been tested and shown to limit heating and to minimize thermal damage of the surrounding cardiac tissue.

IV. Select the Correct Scan Parameters

Refer to the MRI scan parameters table (3T MRI table (page 2) or 1.5T MRI table (page 3)) for the applicable scan parameter settings.

V. Check MRI Settings Status

CAUTION: Do not bring any external control devices, such as a Merlin™ PCS or Aveir™ Link Module, into the scanner magnet room (Zone VI). These devices are considered MR Unsafe.

1. Refer to the MRI Summary Report generated by the Merlin PCS.
2. Confirm these settings with the device management physician or clinician.

Table 7. MRI Settings for leadless pacemakers [1]

Parameter	Setting
MRI Mode	DOO⇄VOO, VOO, AOO, or Pacing Off
MRI Base Rate	30 - 120 bpm
MRI Paced AV Delay	40-120 ms
MRI Pulse Amplitude	5.0 V
MRI Pulse Width	1.0 ms
MRI Electrode Configuration	Bipolar

VI. Perform the Scan and Monitor the Patient

Proper patient monitoring must be provided during the MRI scan. This includes continuous monitoring of the patient's hemodynamic function. Since the MR environment may interfere with the patient monitoring system, it is recommended that more than one of the following systems be used:

- electrocardiography
- pulse oximetry
- noninvasive blood pressure measurements

If the patient's hemodynamic function is compromised during the MRI scan, discontinue the MRI scan and take the proper measures to restore the patient's hemodynamic function.

Verbal communication with the patient during the MRI scan is recommended.

Keep an external defibrillator available during the MRI scan.

Once the MRI scan is complete, MRI Settings must be disabled by the patient's device management physician or clinician using the Merlin™ PCS and Aveir™ Link Module.

Technical Support

Abbott Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.

Any serious incident related to a device should be reported to Abbott Medical and the FDA.

[1] This is the entire range of all possible settings for each parameter.

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