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Medtronic

Attesta™ SR MRI SureScan™ ATSR01

Single chamber rate responsive pacemaker (AAIR/VVIR, AAI/VVI)

Device Manual

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1 CE mark of conformity

CE 0344

2 System overview

2.1 Introduction

About this manual – This document is primarily an implant manual. Regular patient follow-up sessions should be scheduled after implant. Follow-up procedures such as monitoring battery measurements and confirming therapy parameters are described in the product documentation that is included with the software that supports this device. To obtain additional copies of product documentation, contact a Medtronic representative.

This manual describes the Medtronic Attesta SR MRI SureScan model ATSR01 single chamber, multiprogrammable, rate-responsive implantable pulse generator (IPG), also referred to as a pacemaker.

Additional manuals and documents with information about the device:

MRI technical manual – This manual provides MRI-specific procedures and warnings and precautions.

Programming guide – This manual contains device programming procedures and patient follow-up guidelines. The programming guide applies to multiple models within a device family.

Reference manual – This manual contains feature descriptions, troubleshooting information, and other device reference information. The reference manual applies to multiple models within a device family.

Radio regulatory compliance information – This document provides compliance information related to the radio components of the device.

Explanation of symbols – This document defines the symbols that may appear on the device package. Refer to the package label to see which symbols apply specifically to this device.

Medical Procedure and EMI Warnings and Precautions Manual for Health Care Professionals – This manual provides warnings, precautions, and guidance for health care professionals who perform medical therapies and diagnostic procedures on cardiac device patients. The manual also provides patient education information related to sources of electromagnetic interference (EMI) at home, at work, and in other environments.

2.2 System description

The Medtronic Attesta SR MRI SureScan model ATSR01 single chamber implantable pulse generator (IPG) is a multi-programmable cardiac device that monitors and regulates the patient's heart rate by providing single chamber rate-responsive bradycardia pacing.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. Before performing an MRI scan, refer to the MRI technical manual.

The users of this device include medical professionals (physicians, nurses, technicians, and their supporting staff) trained in surgery, cardiology, radiology, and magnetic resonance (MR) technology (MR technology is not applicable for non-MR devices) and able to implement the procedures documented in the instructions for use for this device. Only physicians who have received appropriate training should implant a pacemaker.

Rate response – Rate response is controlled through an activity-based sensor.

Programmer and software – Use the appropriate Medtronic programmer and software to program this device. Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

For information about a specific programmer, go to www.manuals.medtronic.com to find the programmer manual.

Contents of sterile package – The package contains 1 implantable pulse generator and 1 torque wrench used to tighten setscrews.

2.2.1 Usage environments

The device is intended to be used in the following environments and conditions:

- The device will be implanted in a properly equipped, staffed, and sterile surgical environment. Implant will take place under standard surgical protocols and in the patient population for which the device is indicated.
- Post-surgical patient and device follow-up care will take place in a properly equipped and staffed cardiology clinic or office.
- MRI procedures for patients with this device will take place in a properly equipped and staffed MR facility, and in consideration of the conditions and requirements described in *Chapter 5, MRI conditions for use, page 6*.
- After having an implant, patients may resume their lives at home, at work, and in other environments with consideration of the advice and restrictions documented in the Medical Procedure and EMI Warnings and Precautions Manual for Health Care Professionals.

3 Indications

The Medtronic Attesta SR MRI SureScan model ATSR01 implantable pulse generator (IPG) is indicated for the following conditions:

- Accepted patient conditions warranting chronic cardiac pacing, which include:
  - Paroxysmal or permanent Type 2 second-degree or third-degree AV block
  - Symptomatic Type 1 second-degree AV block or block located at intra- or infra-His levels regardless of symptoms
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
  - Alternating bundle branch block
  - Bundle branch block with unexplained syncope and abnormal EPS or non-diagnostic evaluation
- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increase in activity

4 Contraindications

The Medtronic Attesta SR MRI SureScan model ATSR01 implantable pulse generator (IPG) is contraindicated for single chamber atrial pacing in patients with AV conduction disturbance.

5 MRI conditions for use

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a SureScan device with a Medtronic SureScan lead. Any other combination may result in a hazard to the patient during an MRI scan.

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan pacing system.

Note: The MRI SureScan mode cannot be programmed to On if the device is recommended for replacement.

Cardiology requirements

Patients and their implanted systems must be screened to meet the following requirements:

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
- The SureScan pacing system is implanted in the left or right pectoral region.
- The pace polarity parameters are set to Bipolar for programming the MRI SureScan mode to On.
- The SureScan device is operating within the projected service life.
- For patients whose device will be programmed to an asynchronous pacing mode when the MRI SureScan mode is programmed to On, no diaphragmatic stimulation is present when the paced lead has a pacing output of 5.0 V and a pulse width of 1.0 ms.

Caution: It is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms for pacemaker-dependent patients. A higher pacing capture threshold may indicate an issue with the implanted lead.

Notes:

- For radiology requirements, refer to the MRI technical manual.
- **Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.**

Patient monitoring and rescue requirements

- Continuous patient monitoring is required during the MRI scan.
- In the event that patient rescue is required, an external defibrillator must be immediately available.

6 Expected clinical benefit

The clinical benefits of pacemakers depend on the etiology and severity of patient bradycardia. These benefits may include the reduced incidence of syncope and extended survival. For many indicated patients, the clinical benefits may also include variable relief from the common symptoms of bradycardia, such as dyspnea and fatigue. The potential combination of these clinical benefits may improve the quality of life.

7 Summary of safety and clinical performance

The Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed. Search for the SSCP using the manufacturer and device name, and any of the following elements, as applicable: device model, reference number, catalog number, or the Basic Unique Device Identification (Basic UDI-DI) number — 0763000B00005387Y.

8 Intended purpose

Pacemakers are intended for long-term use to monitor and regulate the patient's heart rate. Pacemakers sense intrinsic electrical activity through lead electrodes, analyze heart rhythms based on programmed detection parameters, and deliver pacing pulses to treat bradyarrhythmias.

The software is intended to provide information which is used to make decisions with diagnostic or therapeutic devices.

9 Intended user

The users of this device include medical professionals (physicians, nurses, technicians, and their supporting staff) trained in surgery, cardiology, radiology, and magnetic resonance (MR) technology (MR technology is not applicable for non-MR devices) and able to implement the procedures documented in the instructions for use for this device. Only physicians who have received appropriate training should implant a pacemaker.

10 Intended patient population

The device is intended to treat indicated patients with bradyarrhythmias. Additional considerations should be made when pacing patients with the conditions identified below. Refer to the current European Society of Cardiology (ESC) and European Heart Rhythm Association (EHRA) guidelines on cardiac pacing for the most up-to-date medical consensus on pacemaker treatment for these specific conditions. The information for each condition listed below is summarized from these guidelines.

Pacing after acute myocardial infarction (MI) – There is no evidence that cardiac pacing improves the outcomes in patients with AV block that resolves spontaneously or in patients with anterior myocardial infarction that is complicated by new-onset bundle branch block and transient AV block.

Pacing after cardiac surgery, TAVI, and heart transplantation – Some bradyarrhythmias are transient and resolve after surgery. A period of clinical observation should be made prior to permanent pacemaker implant to determine if the bradyarrhythmia is transient.

Pregnancy – For women who have a junctional escape rhythm with a stable, narrow QRS complex, pacemaker implantation can be deferred until after delivery. However, women with complete heart block who exhibit an escape rhythm with a slow, wide QRS complex should undergo pacemaker implantation during pregnancy. The risks of pacemaker implantation are generally low and an implant can be performed safely, especially if the foetus is beyond 8 weeks' gestation. A pacemaker for the alleviation of symptomatic bradycardia can be implanted at any stage of pregnancy using echo guidance or electro-anatomic navigation to avoid fluoroscopy.

Children and congenital heart disease – Permanent pacing is indicated for congenital AV block and postoperative advanced second degree or complete AV block that does not resolve. Pacing is also indicated for symptomatic sinus node disease when there is a correlation between symptoms and bradycardia.

11 Patient counseling information

In accordance with local regulations, healthcare providers should review the instructions for use for applicable information to be shared with the patient. A patient implant card, which contains identifying information about the implanted device, is included in the device package. After device implant, complete the patient implant card and provide it to the patient before they are discharged. Healthcare providers should communicate the following instructions to their patients:

- Always carry their implant card with them.
- Access additional information about their device on the website that is listed on their patient implant card.
  Note: If the patient is unable to access the website, the physician must provide the information from the website to the patient.
- Always inform any healthcare personnel that they have an implanted device before any procedure has begun.
- Contact their healthcare provider if they notice any new or changing symptoms.

12 Pre-implant considerations

Patient evaluation for the implant of the Model ATSR01 system should include the following consideration about a concomitant implant with a neurostimulator:

Concomitant neurostimulator and cardiac device implants – Some patients have medical conditions that require the implant of both a neurostimulator and a cardiac device (for example, a pacemaker, a defibrillator, or a monitor). In this case, physicians (for example, a neurologist, a neurosurgeon, a cardiologist, and a cardiac surgeon) involved with either device should contact their Medtronic representative before implanting the patient with the second device. Based on the particular devices that the physicians have prescribed, Medtronic can provide the necessary precautions and warnings related to the implant procedure. For information about how to contact Medtronic, see the telephone numbers and addresses provided on the back cover of this manual.

13 Warnings, precautions, and potential adverse events

SureScan System - A complete SureScan system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions.

A complete SureScan system only includes components that have been certified by Medtronic as being MR conditional.

13.1 Warnings and precautions to ensure intended device function

13.1.1 Device operation

Battery depletion – Carefully monitor device longevity by checking battery voltage and replacement indicators. Battery depletion eventually causes the device to stop functioning.

Capture Management – Capture Management does not program atrial outputs above 5.0 V or 1.0 ms. If the patient needs a pacing output higher than 5.0 V or 1.0 ms, manually program the amplitude and pulse width. If a lead dislodges partially or completely, Capture Management may not prevent loss of capture.

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators and implantable cardioverter defibrillators should generally be explanted.

Electrical isolation during implant – Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

Electrical reset – Electrical reset can be caused by exposure to temperatures below –18°C or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a partial reset occurs, pacing resumes in the programmed mode with many of the programmed settings retained. If a full reset occurs, the device operates in VVI mode at 65 min^{-1}. Electrical reset is indicated by a programmer warning message that is displayed immediately upon interrogation. To restore the device to its previous operation, it must be reprogrammed.

See *Section 19.1, Shipping, nominal, and electrical reset parameters, page 21* for a complete list of preserved and changed partial and full reset parameters.

Epicardial leads – Epicardial leads have not been determined appropriate for use with the Ventricular Capture Management feature. Program Ventricular Capture Management to Off if implanting an epicardial lead. **Note:** Epicardial leads compromise the ability to safely perform an MRI scan on the MRI SureScan pacing system. Patients with epicardial leads are contraindicated for an MRI scan.

Lead compatibility – Although Medtronic device connector modules conform to International Connector Standards, this device has not been tested for use with non-Medtronic leads. The known potential adverse consequences of using such a combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection.

Lead connection – Consider the following information when connecting the lead and the device:

- Cap abandoned leads to avoid transmitting electrical signals.
- Verify lead connection. A loose lead connection may result in inappropriate sensing and failure to deliver arrhythmia therapy.

Muscle stimulation – Muscle stimulation (for example, due to high-output unipolar pacing) may result in pacing at rates up to the Upper Sensor rate in rate responsive modes.

Pacing and sensing safety margins – Lead maturation (at least one month after implant) may cause sensing amplitudes to decrease and pacing thresholds to increase, which can cause undersensing or a loss of capture. Provide an adequate safety margin when selecting values for pacing amplitude, pacing pulse width, and sensitivity parameters.

Rate control – Decisions regarding rate control should not be based on the ability of the device to prevent atrial arrhythmias.

Rate-responsive modes – Do not program rate-responsive modes for patients who cannot tolerate rates above the programmed Lower Rate. Rate-responsive modes may cause discomfort for those patients.

Shipping values – Do not use shipping values or nominal values for pacing amplitude and sensitivity without verifying that the values provide adequate safety margins for the patient.

Single chamber atrial modes – Do not program single chamber atrial modes for patients with impaired AV nodal conduction. Ventricular pacing does not occur in these modes.

Tip contacts – When implanting a device, ensure that the tip setscrew is properly engaged and all electrical contacts are sealed to prevent possible electrical leakage. Also, ensure that electrical contacts are sealed when using a lead extender or adaptor. Electrical leakage may cause a loss of output. **Note:** A lead extender or lead adaptor compromises the ability to safely perform an MRI scan on the SureScan pacing system. Patients with a lead extender or lead adaptor are contraindicated for an MRI scan.

Torque wrench – Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew. Other torque wrenches (for example, a blue-handled or right-angled torque wrench) have torque capabilities greater than the lead connector can tolerate.

Twiddler's syndrome – Twiddler's syndrome, i.e., patient manipulation of the device after implant, may cause the patient to experience symptoms of loss of capture and/or extracardiac stimulation if the lead is dislodged.

13.1.2 Device system warnings and precautions for pacemaker-dependent patients

Asynchronous pacing modes – Asynchronous pacing modes (VOO, AOO) disable sensing. It is not appropriate to permanently program these pacing modes for pacemaker-dependent patients.

Diagnostic modes – Do not program diagnostic modes (OVO, OAO) for pacemaker-dependent patients. These modes disable pacing. Instead, use the programmer's inhibit function for brief interruption of outputs.

Polarity override – Do not override the polarity verification prompt with bipolar polarity when a unipolar lead is connected. Overriding the polarity verification prompt results in no pacing output.

Threshold Margin Test (TMT) and loss of capture – Be aware that loss of capture during a TMT at a 20% reduction in amplitude indicates an inadequate stimulation safety margin.

Underlying Rhythm Test – Use caution when using the Underlying Rhythm Test to inhibit pacing. The patient is without pacing support when pacing is inhibited.

13.1.3 External devices during implant

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during post implant testing.

External pacing instrument – Keep an external pacing instrument available for immediate use. When the lead is disconnected, pacemaker-dependent patients are without pacing support.

13.1.4 Handling and storage instructions

Follow these guidelines when handling or storing the device.

Avoid magnets – To avoid rapid battery depletion of the device, store the device in a clean area away from magnets, kits containing magnets, and any sources of electromagnetic interference.

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents.

Dropped device – Do not implant the device if it is dropped on a hard surface from a height of 30 cm or more after it is removed from its packaging.

Fluid immersion – Do not immerse the device in fluid or flush the connector ports at the time of implant. Doing so could adversely affect the performance of the device and lead system.

If the package is damaged – The device packaging consists of an outer tray and inner tray. Do not use the device or accessories if the outer packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

If the package information is damaged – If any information on the outer package or the sterile package is defaced or damaged so that you cannot read it, notify a Medtronic representative so that the device can be replaced.

If the printed manual is illegible – If this manual is supplied in its printed form and any part of it is illegible, contact a Medtronic representative to request a replacement manual.

Single use – This device is intended for single use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment.

Storage temperature – No specific temperature considerations are required for storage.

Transit temperature – Transport the package between –18°C and +55°C. Device reset can occur at temperatures below –18°C. Device longevity can decrease and performance may be affected at temperatures above +55°C.

"Use-by" date – Do not implant the device after the "Use-by" date because battery longevity could be reduced.

13.1.5 Explant and disposal

Consider the following information related to device explant and disposal:

- Explant the implantable device postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations. In addition, if subjected to incineration or cremation temperatures, the device may explode.
- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses.

13.2 Potential adverse events

The following are known potential adverse events associated with the use of this product.

Note: Implant and usage of this product may result in adverse events which may lead to injury, death, or other serious adverse reactions.

- Allergic reaction
- Bradyarrhythmia
- Cardiac arrest
- Device migration
- Discomfort
- Dizziness
- Dyspnea
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation

- Fever
- Heart block
- Hematoma
- Hemodynamic compromise
- Hemorrhage
- Hiccups
- Hospitalization
- Inability to deliver therapy
- Infection
- Lethargy
- Loss of pacing
- Mental anguish
- Necrosis
- Nerve damage
- Onset of persistent AF
- Palpitations
- Physical injury
- Return of cardiac symptoms
- Seroma
- Skeletal muscle sensation/twitching
- Skin disorders
- Syncope
- Tachyarrhythmia
- Tissue trauma
- Toxic reaction
- Undersensing
- Undesirable impact to proximal medical equipment
- Wound dehiscence

Note: If the patient encounters a serious incident with the device, contact your Medtronic representative and the competent authority in your state or regulatory body.

14 Pacing mode information

Pacemaker modes are described using the NBG code. The five-letter NBG code, named after The North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG), describes the operation of implantable pulse generators. The NBG code, which supersedes the ICHD Code, is described in *Table 1*.

Table 1. The Revised NASPE/BPEG Generic Code for antibradycardia pacing

Position:	**I**	**II**	**III**	**IV**	**V**
Category:	Chamber(s) Paced	Chamber(s) Sensed	Response to Sensing	Rate Modulation	Multisite Pacing[a]
	O = None A = Atrium V = Ventricle D = Dual	O = None A = Atrium V = Ventricle D = Dual	O = None T = Triggered I = Inhibited D = Dual	O = None R = Rate modulation	O = None A = Atrium V = Ventricle D = Dual

Table 1. The Revised NASPE/BPEG Generic Code for antibradycardia pacing (continued)

Position:	I	II	III	IV	V
	(A + V)	(A + V)	(T + I)		(A + V)
Manufacturers' designation only:	S = Single[b] (A or V)	S = Single[b] (A or V)			

[a] Medtronic devices do not use the Multisite Pacing code.

[b] The programmer displays A or V (not S) for chambers paced and sensed.

15 Implant procedure

Proper surgical procedures and sterile techniques are the responsibility of the physician. The following procedures are provided for information only. Each physician must apply the information in these procedures according to professional medical training and experience.

15.1 Verify sufficient device longevity

Complete the following steps prior to opening the pacemaker box:

1. Check the use-by date printed on the package.
2. Place the programmer head over the box and start the application.
3. Interrogate the device.
4. Confirm the battery voltage is at least 2.75 V at room temperature using the Programming Guide instructions for viewing battery status.
5. Contact your Medtronic representative if the use-by date or battery voltage is out of range.

15.2 Verify lead and connector compatibility

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a SureScan device with a Medtronic SureScan lead. Any other combination may result in a hazard to the patient during an MRI scan.

Warning: Verify lead and connector compatibility before using a lead with this device. Using an incompatible lead may damage the connector, result in electrical current leakage, or result in an intermittent electrical connection.

A lead adaptor may be needed to connect the lead to the device. Contact a Medtronic representative for questions about lead adaptor compatibility.

Note: A bipolar or unipolar lead may be used with the Attesta SR MRI SureScan Model ATSR01 device, but if a lead other than a bipolar MRI SureScan lead is used, the system is contraindicated for MRI scans.

Note: Lead adaptors compromise the ability to safely scan the SureScan pacing system during an MRI scan. Patients with lead adaptors are contraindicated for an MRI scan.

Select a compatible lead. Refer to the following table.

Table 2. Lead and connector compatibility

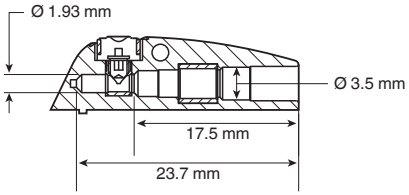
Connector port	Primary leads
A, V	IS-1[a] bipolar and IS-1 unipolar

[a] IS-1 refers to the international standard ISO 5841-3.

15.2.1 Connector dimensions

The following figure provides connector dimensions for the Attesta SR MRI SureScan model ATSR01 device.

Figure 1. Attesta SR MRI SureScan model ATSR01 IS-1 connector dimensions



15.3 Test the lead system

For lead testing procedures, refer to the technical manual supplied with the implant support instrument.

15.4 Connect the lead to the device

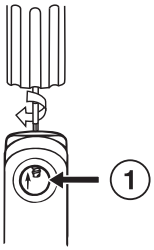
Warning: Verify that the lead connection is secure. A loose lead connection may result in inappropriate sensing, which can cause inappropriate arrhythmia therapy or a failure to deliver arrhythmia therapy.

Caution: Use only the wrench supplied with the device. The wrench is designed to prevent damage to the device from overtightening a setscrew.

Connect the lead to the device by performing the following steps:

1. Insert the wrench into the grommet on the connector port.
   a. Check that the setscrew is retracted from the connector port. If the connector port is obstructed, retract the setscrew to clear it. Do not disengage the setscrew from the connector block, see *Figure 2*.

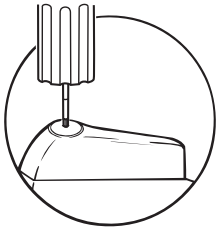
      Figure 2. Preparing the connector port setscrew

      1 IS-1 connector port, A or V

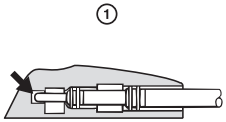
   b. Leave the wrench in the grommet until the lead is secure. This allows a pathway for venting trapped air when the lead is inserted, see *Figure 3*.

Figure 3. Wrench in the grommet



2. Push the lead connector pin into the connector port until the connector pin is visible in the lead viewing area. Sterile water may be used as a lubricant. Sealant is not required.

Figure 4. Inserting a lead into the device



1 ATSR01 with IS-1 BI lead – The lead pin is visible at the end of the viewing area.

3. Tighten the setscrew by turning the wrench to the right until the wrench clicks.
4. Gently pull on the lead to confirm the connection.

15.5 Test the device operation

Warning: Keep an external pacing instrument available for immediate use. When the lead is disconnected, pacemaker-dependent patients are without pacing support.

Verify device operation by reviewing an ECG. If pacing and sensing are not adequate, perform one or more of the following tasks for the lead, as needed:

- Verify that the pacing threshold margin is adequate at the time of implant (and at each patient follow-up session).
- Verify the connection of the lead to the device. Confirm that the lead connector pin appears in the viewing area.
- Disconnect the lead from the device. Visually inspect the lead connector and lead. Replace the lead if necessary.
- Retest the lead. Inadequate electrical signals may indicate lead dislodgment. If necessary, reposition or replace the lead.

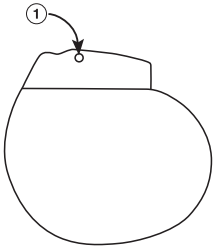
15.6 Position and secure the device

Note: Proper device placement can facilitate lead wrap and prevent muscle stimulation and device migration. The device may be implanted in right or left pectoral sites. Either side of the device may face the skin to facilitate excess lead wrap.

Note: Implant the device within 5 cm of the surface of the skin to optimize post-implant ambulatory monitoring.

1. Verify that the lead connector pin is fully inserted into the connector port and that the setscrew is tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length. Do not kink the lead body.
3. Place the device and lead into the surgical pocket.
4. Suture the device securely within the pocket. Use non-absorbable sutures. Secure the device to minimize post-implant rotation and migration. Use a surgical needle to penetrate the suture hole on the device.

Figure 5. Location of suture hole



1 Suture hole

5. Suture the pocket incision closed.

15.7 Program the device

1. If a unipolar lead is implanted, you may want to manually complete the Implant Detection process.
   a. Tap **Params**.
   b. Program the Pace Polarity and Sense Polarity parameters to Unipolar.
      Note: If the patient experiences muscle stimulation while being paced in the unipolar configuration, reduce the amplitude or narrow the pulse width. Maintain adequate stimulation safety margins.
   c. Tap **Additional Features…** and program the Implant Detection parameter to Off/Complete.
2. Verify that the pacing and detection parameters are programmed to values that are appropriate for the patient.
3. Enter the patient's information in the Patient Information screen.

   Note: Use the Patient Information screen to document complete information about the implanted lead and other hardware implanted in the patient, including abandoned devices, leads, lead extenders or adaptors. This information will be used in the future if the patient needs to be evaluated for an MRI scan. For more information, see the programming guide.

15.8 Replace a device

To retain the ability to safely scan the SureScan pacing system during MRI scans, the MRI conditions for use in *Chapter 5, MRI conditions for use, page 6* must be followed. Refer to the Medtronic MRI technical manual for additional information.

Warning: A bipolar or unipolar lead may be used with the Attesta SR MRI SureScan Model ATSR01 device, but if a lead other than a bipolar MRI SureScan lead is used, the system is not approved for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI technical manual for additional information.

Warning: Abandoned leads or previously implanted non-MRI labeled leads compromise the ability to safely scan the SureScan pacing system during future MRI scans. When implanting a SureScan pacing system, consider the

risks associated with removing previously implanted leads before removing the leads to maintain the ability to safely scan the SureScan pacing system. Refer to the Medtronic MRI technical manual for additional information.

Warning: Keep an external pacing instrument available for immediate use. When the lead is disconnected, pacemaker-dependent patients are without pacing support.

Note: Any unused leads that remain implanted must be capped with a lead pin cap to avoid transmitting electrical signals. Contact your Medtronic representative for information about lead pin caps. Any capped or unused leads are considered abandoned leads in the MRI conditions for use, and their presence will contraindicate the system for MRI scanning.

See *Section 15.6, Position and secure the device, page 15* for additional warnings.

15.8.1 How to explant and replace a device

If you are replacing a previously implanted device, perform the following steps:

1. Program the device to a mode that is not rate responsive to avoid potential rate increases while explanting the device.
2. Dissect the lead and the device free from the surgical pocket. Do not nick or breach the lead insulation.
3. Use a torque wrench to loosen the setscrews in the connector port.
4. Gently pull the lead out of the connector port.
5. Evaluate the condition of the lead (see *Section 15.3, Test the lead system, page 14*). Replace the lead if the electrical integrity is not acceptable or if the lead connector pin is pitted or corroded. If you explant the lead, return it to Medtronic for analysis and disposal.
6. Connect the lead to the replacement device (see *Section 15.4, Connect the lead to the device, page 14*).
   Note: A lead adaptor may be needed to connect the lead to the replacement device (see *Section 15.2, Verify lead and connector compatibility, page 13*). Contact a Medtronic representative for questions about compatible lead adaptors.
   Note: Lead adaptors compromise the ability to safely perform an MRI scan on the SureScan pacing system in the future. Patients with lead adaptors are contraindicated for an MRI scan.
7. Use the replacement device to evaluate stimulation thresholds and sensing potentials.
8. After confirming acceptable electrical measurements, place the device in the surgical pocket and suture the pocket incision closed.
9. Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses.

16 Potential complications and emergency pacing

16.1 Potential complications

The pacemaker/lead system may operate inappropriately or fail completely due to several potential complications. Note the following potential complications.

- Pacing thresholds can change over time. Clinicians are advised to program a pacing threshold margin that will prevent loss of capture in case of an increase in pacing threshold.
- Potential effects of premature battery depletion are decreased output voltage, no pacing output, loss-of-capture, Recommended Replacement Time (RRT), Elective Replacement Indicator (ERI), and eventual erratic pacing.
- Potential effects of pacemaker component(s) failure are loss of pacing output, pacing rate and other parameter changes, reversion to asynchronous mode, loss-of-capture, loss of programming capability, Recommended Replacement Time (RRT), Elective Replacement Indicator (ERI), and erratic pacing.

- Potential effects of the activity sensor detecting muscle or mechanical stimulation may increase the pacing rate to levels higher than expected for a given patient activity. In addition, an open or shorted activity sensor may cause rate response pacing to cease operating.
- Potential effects of electromagnetic interference (EMI) on the pacemaker's circuitry are pacing output inhibition, reversion to asynchronous mode, pacing synchronized to the EMI source, and a partial or full electrical reset condition.
- Electromagnetic interference (EMI) from electrocautery and defibrillation may cause any of the following conditions:
  - pacing output inhibition
  - temporary pause in pacing
  - permanent loss of pacing output
  - reversion to asynchronous mode
  - pacing synchronized to the EMI source
  - Recommended Replacement Time (RRT)
  - Elective Replacement Indicator (ERI)
  - partial or full electrical reset
- Potential effects of poor connection of lead to pacemaker connector block are intermittent or continuous loss-of-capture, failure to sense properly or loss of sensing, and inhibition of pacing.
- Potential effects of displaced or fractured lead are intermittent or continuous loss-of-capture and/or sensing, and inhibition of pacing. Cardiac perforation may cause intermittent or continuous loss-of-capture and/or sensing, inhibition of pacing, cardiac tamponade, and muscle or nerve stimulation. Myocardial irritability at the time of lead insertion may cause fibrillation or flutter. Elevation of pacing thresholds may cause a loss-of-capture.

16.2 Emergency pacing

Emergency pacing provides VVI pacing at high output settings in emergency situations for pacemaker-dependent patients. *Table 3* lists the emergency settings.

Table 3. Emergency settings

Parameter	Setting
Mode	VVI
Pacing Rate	70 min^{-1}
Ventricular	
Amplitude	7.5 V
Pulse Width	1.5 ms
Sensitivity	2.8 mV
Pacing Polarity	Unipolar
Sensing Polarity	Unipolar
Lead Monitor	Monitor Only
Ventricular Refractory Period	330 ms
Single Chamber Hysteresis	Off
Capture Management	Off

17 Magnet operation and Elective Replacement Indicator (ERI)

Table 4. Magnet operation and Elective Replacement Indicator (ERI) status

Magnet operation		**Indicators of ERI status**	
Without magnet	With magnet	Without magnet	With magnet
VVI/AAI	VOO/AOO at 85 min^{-1} (705 ms / ±2 ms)	VVI at 65 min^{-1}	VOO at 65 min^{-1} (923 ms / ±2 ms)

Note: The device does not respond to the application of a magnet for one hour after the use of a programmer unless the session is ended with the command option to immediately clear data collected in the device. The default command for ending a session allows the device to retain collected data for one hour.

18 Measuring methods

Device parameters, such as pulse duration, pulse amplitude, and sensitivity (sensing threshold), are measured according to the standard ISO 14708-2 or EN 45502-2-1.

Pulse duration – Pulse duration is measured at 1/3 peak voltage levels according to the standard ISO 14708-2 or EN 45502-2-1. See *Figure 6*. (See *Figure 7* for definitions of amplitude measurements.)

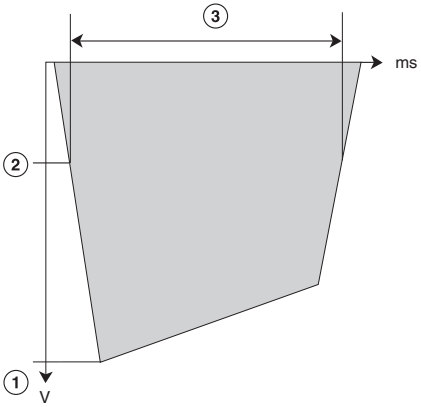
Pulse amplitude – The peak pulse amplitude is measured according to the standard ISO 14708-2 or EN 45502-2-1.

Sensitivity (sensing threshold) – Ventricular sensitivity is defined as the voltage amplitude of a standard ISO 14708-2 or EN 45502-2-1 test signal that is just sufficient to be sensed by the device. The signal from a test signal generator used for the exact determination of sensitivity (sensing threshold) is illustrated in *Figure 8*.

Notes:

- When measuring the pacing and sensing parameters with pacing system analyzers, considerable differences may be observed with the specifications presented in this manual. This is because the measuring methods employed by such systems may differ from those described above.
- Lead impedance measurement results may be distorted by electrocardiogram monitoring equipment.

Figure 6. Measurement of pulse duration



1 Maximum amplitude
2 1/3 maximum amplitude
3 Pulse duration

Figure 7. Measurement of pulse amplitude

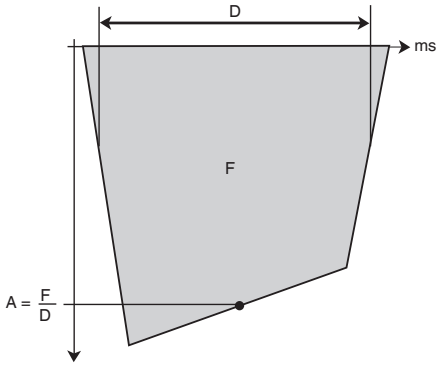
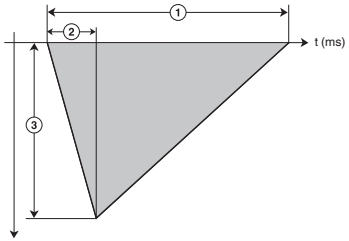


Figure 8. Measurement of sensitivity



1 T = 15 ms ±1 ms
2 t = 2 ms ±0.2 ms
3 Signal amplitude A_T

Note: The signal may be either positive or negative.

19 Device parameters

19.1 Shipping, nominal, and electrical reset parameters

Notes:

- "Unchanged" indicates that the programmed setting is unaffected by nominal programming or an electrical reset event. "Adaptive" indicates that the parameter is adapted during operation.
- The shipping parameters for some features are not applied until the 30-minute Implant Detection period is complete.
- After certain serious device errors, the pacemaker will recover as a model SES01. If this occurs, contact a Medtronic representative.

Table 5. Mode and rates

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
Mode and rates				
Mode	VVIR	VVIR	Unchanged	VVI
Lower Rate	60 min^{-1} (1000 ms)	60 min^{-1} (1000 ms)	Unchanged	65 min^{-1} (923 ms)
Upper Sensor Rate	130 min^{-1}	130 min^{-1}	Unchanged	120 min^{-1}

Table 6. Rate Response

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
ADL Rate	95 min^{-1}	95 min^{-1}	Unchanged	95 min^{-1}
Rate Profile Optimization	On	On	Unchanged	Off
ADL Response	3	3	3	3
Exertion Response	3	3	3	3
ADL Setpoint	15	Unchanged	15	15
UR Setpoint	40	Unchanged	40	40
Activity Threshold	Medium/Low	Unchanged	Medium/Low	Medium/Low

Table 6. Rate Response (continued)

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
Acceleration	30 s	Unchanged	30 s	30 s
Deceleration	Exercise	Unchanged	Exercise	Exercise

Table 7. Atrial Lead

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset (VVI mode)
Amplitude[a]	—	3.5 V	Unchanged	5.0 V
Pulse Width[a]	—	0.4 ms	Unchanged	0.4 ms
Sensitivity	—	0.5 mV (Adaptive)	Unchanged	2.80 mV
Sensing Assurance	On	On	Unchanged	Off
Pacing Polarity	Configure	Unchanged	Unchanged	Configure[b]
Sensing Polarity	Configure	Unchanged	Unchanged	Configure
Lead Monitor	Configure	Unchanged	Unchanged	Configure
Notify if <	200 Ω	200 Ω	200 Ω	200 Ω
Notify if >	4000 Ω	4000 Ω	4000 Ω	4000 Ω
Monitor Sensitivity	8	8	8	8

[a] The shipping and full reset pacing modes are ventricular. Atrial amplitude and pulse width have no shipping or full reset values.

[b] Bipolar models revert to Implant Detection during which polarity is automatically configured.

Table 8. Ventricular lead

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
Amplitude	3.5 V (Adaptive)	3.5 V (Adaptive[a])	Unchanged	5.0 V
Pulse Width	0.4 ms (Adaptive)	0.4 ms (Adaptive[a])	Unchanged	0.4 ms
Sensitivity	2.8 mV (Adaptive)	2.8 mV (Adaptive[a])	Unchanged	2.8 mV
Sensing Assurance	On	On	Unchanged	Off
Pacing Polarity	Configure	Unchanged	Unchanged	Configure[b]
Sensing Polarity	Configure	Unchanged	Unchanged	Configure[b]
Lead Monitor	Configure	Unchanged	Unchanged	Configure
Notify if <	200 Ω	200 Ω	200 Ω	200 Ω
Notify if >	4000 Ω	4000 Ω	4000 Ω	4000 Ω
Monitor Sensitivity	8	8	8	8

[a] Value from which adaptive adjustment begins when nominals are programmed.

[b] Bipolar model reverts to Implant Detection during which polarity is automatically configured.

Table 9. Ventricular Capture Management

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
Ventricular Capture Management	Adaptive	Adaptive	Unchanged	Off
Amplitude Margin	2x (times)	2x (times)	Unchanged	2x (times)
Minimum Adapted Amplitude	2.0 V	2.0 V	Unchanged	2.0 V
Capture Test Frequency	Day at Rest	Day at Rest	Day at Rest[a]	Day at Rest
Capture Test Time	None	None	None[a]	None
Acute Phase Days Remaining	112 days	Unchanged	112 days	112 days
Sensing During Search[b]	Adaptive	Adaptive	Adaptive	Adaptive

[a] If values differ from nominal, the Capture Test Time will be set to occur every Day at… 12 hours after electrical reset time.

[b] Bipolar model.

Table 10. Refractory/Blanking

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset (VVI mode)
Atrial Refractory Period[a]	—	250 ms	400 ms	—
Atrial Blanking Period[a]	—	180 ms	180 ms	—
Ventricular Refractory Period	330 ms	330 ms	330 ms	330 ms

[a] Atrial modes only.

Table 11. Additional Features

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
Sleep Function	Off	Off	Off	Off
Sleep Rate	50 min^{-1}	50 min^{-1}	50 min^{-1}	50 min^{-1}
Bed Time	22:00	22:00	22:00	22:00
Wake Time	08:00	08:00	08:00	08:00
Single Chamber Hysteresis	Off	Unchanged	Unchanged	Off
Implant Detection	On/Restart	Unchanged	Unchanged	On/Restart

Table 12. Interventions

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
Conducted AF Response	Off	Off	Unchanged	Off
Maximum Rate	110 min^{-1}	110 min^{-1}	110 min^{-1}	110 min^{-1}

Table 13. MRI SureScan

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
MRI SureScan	Off	Off	Off[a]	Off[a]

[a] The MRI SureScan parameter cannot be programmed until the reset has been cleared.

Table 14. Telemetry Features

Parameter	Shipping	Medtronic nominal	Partial electrical reset	Full electrical reset
Transtelephonic Monitor	Off	Unchanged	Unchanged	Off
Extended Telemetry	Off	Unchanged	Off	Off
Extended Marker	Standard	Unchanged	Standard	Standard

19.2 Programmable parameters

Caution: Do not program device parameters before implant.

19.2.1 Pacing parameters

Caution: Do not program Rate Response until after Implant Detection is complete.

Note: In the event of a component failure, the runaway rate limit is held to 200 min^{-1} (±20 min^{-1}), and is not an adjustable parameter. Rate limit is automatically overridden in temporary single chamber modes for high-rate pacing.

Table 15. Mode and rates

Parameter	Settings	Notes
Mode	VVIR: VVI; VVT; VOOR; VOO; AAIR; AAI; AAT; AOOR; AOO; OVO; OAO	
Lower Rate[a]	30; 35; 40 … 120 min^{-1} (±1 min^{-1}) 125; 130; 130 … 170 min^{-1} (except 65 and 85 min^{-1}) (±2 min^{-1})	
Upper Sensor Rate	80; 90; 95; 100 … 180 min^{-1} (±2 min^{-1})	

[a] The corresponding Lower Rate Interval can be calculated as follows: Lower Rate Interval (ms) = 60,000/Lower Rate.

Table 16. Rate Response

Parameter	Settings	Notes
ADL Rate	60; 65; 70 … 120 min^{-1} (±1 min^{-1}) 125; 130; 135 … 175 min^{-1} (±2 min^{-1})	
Rate Profile Optimization	On; Off	
ADL Response	1; 2; 3; 4; 5	
Exertion Response	1; 2; 3; 4; 5	
ADL Setpoint	5; 6; 7 … 40; 42; 44; 46 … 80	Programmable from the Exercise test only
UR Setpoint	15; 16; 17 … 40; 42; 44; 46 … 80; 85; 90; 95 … 180	Programmable from the Exercise test only
Activity Threshold	Low; Medium/Low; Medium/High; High	

Table 16. Rate Response (continued)

Parameter	Settings	Notes
Acceleration	15 s (+8/–2 s); 30 s (+13/–3 s); 60 s(+19/–3 s)	
Deceleration	2.5 min (+0.6/–0.2 min); 5 min (+1.1/–0.5 min); 10 min (+1.1/–1.0 min); Exercise	

Table 17. Atrial Lead[a]

Parameter	Settings	Notes
Amplitude[b,c]	0.5; 0.75; 1.0 … 4.0; 4.5; 5.0; 5.5; 6.0; 7.5 V	
Pulse Width[d]	0.12; 0.15 ms (±10 µs) 0.21; 0.27; 0.34; 0.40; 0.46; 0.52; 0.64; 0.76; 1.00; 1.25; 1.50 ms (±25 µs)	
Sensitivity[e]	0.25; 0.35 mV (±60%) 0.5; 0.7; 1.0; 1.4; 2.0; 2.8; 4.0 mV (±40%)	0.25 and 0.35 mV apply to bipolar atrial sensing only
Sensing Assurance	On; Off	
Pacing Polarity	Bipolar; Unipolar; Configure	Configure is displayed but is not selectable.
Sensing Polarity	Bipolar; Unipolar; Configure	Configure is displayed but is not selectable.
Lead Monitor	Off; Configure; Monitor Only; Adaptive	
Notify if < (less than)	200 Ω	Non-programmable.
Notify if > (greater than)	1000; 2000; 3000; 4000 Ω	
Monitor Sensitivity	2; 3; 4 … 16	

[a] Applies when the device is set on atrial mode.

[b] Tolerance for amplitudes from 0.5 V through 6.0 V is ±10% and for 7.5 V is –20/+0%. Tolerances are based on 37°C and a 500 Ω load. Amplitude is determined 200 µs after the leading edge of the pace.

[c] When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 240 Ω load, tolerance for pulse amplitude is –20/+0%. When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 500 Ω load, tolerance for pulse amplitude is ±10%. When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 1000 Ω load, tolerance for pulse amplitude is –6/+14% and for 2000 Ω load, tolerance for pulse amplitude is –4/+16%.

[d] When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 240 Ω load, tolerance for pulse width 0.12 ms and 0.15 ms is ±10 µs, from 0.21 ms through 1.25 ms is ±25 µs and for 1.50 ms is –224/+0 µs. When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 500 or 1000 Ω load, tolerance for pulse width 0.12 ms and 0.15 ms is ±10 µs and from 0.21 ms through 1.50 ms is ±25 µs. When measurements are performed using ISO 14708-2 at 2000 Ω load, tolerance for pulse width 0.12 ms and 0.15 ms is –10/+20 µs and from 0.21 ms through 1.50 ms is –25/+35 µs.

[e] **Warning:** Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its most sensitive setting. When susceptibility to interference is tested under the conditions specified in ISO 14708-2, EN 45502-2-1, or ISO 14117, the device is more susceptible to electromagnetic interference. The device will meet standard requirements when the bipolar atrial sensitivity threshold is programmed to 0.5 mV or higher, the unipolar atrial sensitivity threshold is programmed to 2.8 mV or higher, or the bipolar or unipolar ventricular sensitivity threshold is programmed to 2.8 mV or higher.

Table 18. Ventricular Lead[a]

Parameter	Settings	Notes
Amplitude[b,c] (with Ventricular Capture Management)	0.5; 0.75; 1.0 … 4.0; 4.5; 5.0 V	0.625, 0.875, 1.125, 1.375, 1.625, and 1.875 V can be set by Ventricular Capture Management. Values are displayed but are not selectable.
Amplitude[b,c] (without Ventricular Capture Management)	0.5; 0.75; 1.0 … 4.0; 4.5; 5.0; 5.5; 6.0; 7.5 V	
Pulse Width[d] (with Ventricular Capture Management)	0.12; 0.15 ms (±10 µs) 0.21; 0.27; 0.34; 0.40; 0.46; 0.52; 0.64; 0.76; 1.00 ms (±25 µs)	Settings lower than 0.40 ms can be programmed, but Capture Management adjusts them to 0.40 ms.
Pulse Width[d] (without Ventricular Capture Management)	0.12; 0.15 ms (±10 µs) 0.21; 0.27; 0.34; 0.40; 0.46; 0.52; 0.64; 0.76; 1.00; 1.25; 1.50 ms (±25 µs)	
Sensitivity[e]	1.0; 1.4; 2.0; 2.8; 4.0; 5.6; 8.0; 11.2 mV (±40%)	
Sensing Assurance	On; Off	
Pacing Polarity	Bipolar; Unipolar; Configure	Configure is displayed but is not selectable.
Sensing Polarity	Bipolar; Unipolar; Configure	Configure is displayed but is not selectable.
Lead Monitor[f]	Off; Configure; Monitor Only; Adaptive	
Notify if < (less than)	200 Ω	Non-programmable.
Notify if > (greater than)	1000; 2000; 3000; 4000 Ω	
Monitor Sensitivity	2; 3; 4 … 16	

[a] Applies when the device is set on ventricular mode.

[b] Tolerance for amplitudes from 0.5 V through 6.0 V is ±10% and for 7.5 V is -20/+0%. Tolerances are based on 37°C and a 500 Ω load. Amplitude is determined 200 µs after the leading edge of the pace.

[c] When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 240 Ω load, tolerance for pulse amplitude is –20/+0%. When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 500 Ω load, tolerance for pulse amplitude is ±10%. When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 1000 Ω load, tolerance for pulse amplitude is –6/+14% and for 2000 Ω load, tolerance for pulse amplitude is –4/+16%.

[d] When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 240 Ω load, tolerance for pulse width 0.12 ms and 0.15 ms is ±10 µs, from 0.21 ms through 1.25 ms is ±25 µs and for 1.50 ms is –224/+0 µs. When measurements are performed using ISO 14708-2 or EN 45502-2-1 at 500 or 1000 Ω load, tolerance for pulse width 0.12 ms and 0.15 ms is ±10 µs and from 0.21 ms through 1.50 ms is ±25 µs. When measurements are performed using ISO 14708-2 at 2000 Ω load, tolerance for pulse width 0.12 ms and 0.15 ms is –10/+20 µs and from 0.21 ms through 1.50 ms is –25/+35 µs.

[e] **Warning:** Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its most sensitive setting. When susceptibility to interference is tested under the conditions specified in ISO 14708-2, EN 45502-2-1, or ISO 14117, the device is more susceptible to electromagnetic interference. The device will meet standard requirements when the bipolar atrial sensitivity threshold is programmed to 0.5 mV or higher, the unipolar atrial sensitivity threshold is programmed to 2.8 mV or higher, or the bipolar or unipolar ventricular sensitivity threshold is programmed to 2.8 mV or higher.

[f] Lead Monitor is available only for the paced chamber.

Table 19. Ventricular Capture Management

Parameter	Settings	Notes
Ventricular Capture Management	Off; Monitor Only; Adaptive	
Amplitude Margin	1.5x; 2x; 2.5x; 3x; 4x (times)	
Minimum Adapted Amplitude	0.5; 0.75; 1.0 … 3.5 V	
Capture Test Frequency	15 min; 30 min; 1 hour; 2 hours; 4 hours; 8 hours; 12 hours; Day at rest; Day at…; 7 Days at…	For Day(s) at …, next parameter specifies the time of day.
Capture Test Time	00:00; 01:00 … 23:00	Applies only for Day(s) at … parameter.
Acute Phase Days Remaining[a]	Off; 7; 14 … 84; 112; 140; 168; 196; 224; 252 days	
Sensing During Search	Unipolar; Bipolar; Adaptive	

[a] If the acute phase is completed, the Acute Phase Completed time and date are indicated below Acute Phase Days Remaining.

Table 20. Refractory/Blanking

Parameter	Settings	Notes
Ventricular Refractory Period	150; 160; 170 … 500 ms (±9 ms)	
Atrial Refractory Period	180; 190; 200 … 500 ms (±9 ms)	
Atrial Blanking Period	130; 140; 150 … 350 ms (±9 ms)	

Table 21. Temporary parameters

Parameter	Settings	Notes
Chamber	Atrium; Ventricle	Setting determines available modes.
Mode	VVI; VVT; VOO; AAI; AAT; AOO; OVO; OAO	Availability of modes is dependent on programmed mode.
Lower Rate	30; 35; 40 … 120 min^{-1} (except 65 and 85 min^{-1}) (±1 min^{-1}) 125; 130; 135 … 180 min^{-1} (±2 min^{-1}) 190; 200; 210 … 250 min^{-1} (±3 min^{-1}) 260; 270; 280; 300; 310; 320; 330; 350; 370; 380; 400 min^{-1} (±5 min^{-1})	Rates above 180 min^{-1} are available by selecting the enable button.
Amplitude[a]	0.25; 0.375 … 2.0; 2.25; 2.50; 2.75 … 4.0; 4.5; 5.0; 5.5; 6.0 V (±10%) 7.5 V (+0/-20%)	
Pulse Width	0.03; 0.06; 0.09 … 0.15 ms (±10 µs) 0.21; 0.27; 0.34; 0.40; 0.46; 0.52; 0.64; 0.76; 1.00; 1.25; 1.50 ms (±25 µs)	
Atrial Sensitivity	0.25; 0.35 mV (±60%) 0.5; 0.7; 1.0; 1.4; 2.0; 2.8; 4.0 mV (±40%)	
Ventricular Sensitivity	1.0; 1.4; 2.0; 2.8; 4.0; 5.6; 8.0; 11.2 mV (±40%)	

[a] The amplitude values in 0.125 V increments apply only to the Capture Management and Temporary Tests.

19.2.2 Additional features

Table 22. Additional rate therapies

Parameter	Settings	Notes
Sleep Function	On; Off	
Sleep Rate	30; 35; 40 … 90 min^{-1} (except 65 and 85 min^{-1}) (±1 min^{-1})	
Bed Time	00:00; 00:15; 00:30 … 23:45 (±10 min)	
Wake Time	00:00; 00:15; 00:30 … 23:45 (±10 min)	
Single Chamber Hysteresis	Off; 40; 50; 60 min^{-1} (±1 min^{-1})	

Table 23. MRI SureScan parameters

Parameter	Programmable values	Notes
MRI SureScan	On; Off	
MRI Pacing Mode	AOO; VOO; OAO; OVO	
MRI Pacing Rate	60; 70; 75; 80; 90; 95; 100 … 120 min^{-1}	

Table 24. Telemetry Features

Parameter	Settings	Notes
Transtelephonic Monitor	On; Off	
Extended Telemetry	On; Off	
Extended Marker[a]	Standard; Therapy Trace	

[a] Therapy Trace markers cannot be displayed or printed on the programmer.

Table 25. Implant detection

Parameter	Settings	Notes
Implant Detection	On/Restart; Off/Complete	If Implant Detection is completed, the time and date of completion are indicated below the Off/Complete setting.

Table 26. Status (reset) parameters

Parameter	Settings	Notes
Atrial Lead Status	Reset Indicator	
Ventricular Lead Status	Reset Indicator	
RRT/ERI or POR Reset	Reset	Listed under Additional Features

19.2.3 Interventions

Table 27. Arrhythmia interventions

Parameter	Settings	Notes
Conducted AF Response	On; Off	Continuously on in VVIR mode
Maximum Rate	80; 85; 90; 95 …130 min^{-1} (±2 min^{-1})	

19.3 Automatic and clinician-selectable diagnostics

Table 28. Automatic Diagnostics

Parameter	Settings
Heart Rate Histograms[a] (Short and Long Term, Atrial and Ventricular)	
Include Refractory Senses	Include; Exclude
Sensor Indicated Rate Profile	
Atrial High Rate Episodes[b]	
Detection Rate	80; 85; 90 … 180; 200; 220; 240 … 320; 330; 350; 370; 380; 400 min^{-1}
Detection Duration[c]	1; 2; 3 … 20; 25; 30 … 50; 55; 60 s
Termination Beats	5; 6; 7 … 20 beats
Collection Method[d]	Frozen; Rolling
Ventricular High Rate Episodes	
Detection Rate	80; 85; 90 … 180; 200; 220; 240 … 320; 330; 350; 370; 380; 400 min^{-1}
Detection Duration	2; 3; 4 … 198; 199; 200 beats
Termination Beats	5; 6; 7 … 20 beats
Collection Method	Frozen; Rolling
Atrial Arrhythmia Trend	
Atrial Arrhythmia Durations	
Chronic Lead Trends	
Lead Monitor Counters	
Sensitivity Trends	Monitors chambers with Sensing Assurance
Ventricular Capture Management Trend	
Key Parameter History	

[a] Heart Rate Histograms are available for the paced chamber. Heart Rate Histograms can be programmed to include or exclude refractory sensed events.

[b] High Rate Detail is available for the paced chamber.

[c] Detection duration is 2 to 200 beats.

[d] Collection Method applies to Atrial High Rate Episodes and Ventricular High Rate Episodes.

Table 29. Clinician-Selectable Diagnostics

Diagnostic and parameters	Parameter settings
Custom Rate Trend	
Duration	Beat-to-Beat; 1 Hour; 24 hours
Collection Method	Frozen; Rolling
Include Refractory Senses?	Include; Exclude
Ventricular Capture Management Detail	
EGM Collection	Off; EGM
High Rate Detail[a, b]	
EGM Type	Off; EGM
Allocation (Collection Method[c] = Frozen)	1 for 0/48; 1 for 48/0; 1 for 24/24; 2 for 0/24; 2 for 24/0; 2 for 12/12; 4 for 0/12; 4 for 12/0; 4 for 6/6; 8 for 0/6; 8 for 6/0; 8 for 3/3 (number of episodes for pre-onset seconds/post onset seconds collected)

Table 29. Clinician-Selectable Diagnostics (continued)

Diagnostic and parameters	Parameter settings
Allocation (Collection Method[c] = Rolling)	1 for 24/0; 1 for 12/12; 1 for 0/48; 2 for 16/0; 2 for 8/8; 2 for 0/24; 4 for 8/0; 4 for 4/4; 4 for 0/12; 8 for 4/0; 8 for 2/2; 8 for 0/6 (number of episodes for pre-onset seconds/post onset seconds collected)
Pre-detection Timeout	1; 2; 3 … 12; 14; 16 …24 weeks

[a] High rate detection rate, detection duration, and termination criteria are set by parameters for the automatic diagnostic.

[b] High Rate Detail is available for the paced chamber.

[c] Collection Method is set in the High Rate automatic diagnostic.

19.4 Nonprogrammable parameters

Table 30. Nonprogrammable parameters

Parameter	Value
Magnet rate	
Magnet rate	85 min^{-1} (±2 min^{-1})
Magnet rate at ERI	65 min^{-1} (±2 min^{-1})
Hardware parameters	
Pacing rate limit (protective feature)	200 min^{-1} (±30 min^{-1})
Input impedance	150 kΩ minimum
Effective pacing capacitance	5 µF (±10%)
Recommended Replacement Time (RRT) and Elective Replacement Indicator (ERI)	
Battery Voltage Threshold	≤ 2.5 V, or ≤ 2.59 V and battery impedance at ≥ 3000 Ω
Operating period between RRT and ERI	90 days
Operating period between ERI and End of Service (EOS)[a]	90 days

[a] EOS is set when the first pace fails to deliver at programmed pacing parameters because of depleted battery power.

20 Device information

20.1 Physical characteristics

The following table and figure provide physical characteristics for the Attesta SR MRI SureScan model ATSR01 device.

Table 31. Physical characteristics: Model ATSR01

Volume[a]	9.7 cm^3
Mass	21.5 g
H x W x D[b]	40.2 mm x 42.9 mm x 7.5 mm
Surface area of titanium	26.9 cm^2
Radiopaque ID[c]	PHX

Table 31. Physical characteristics: Model ATSR01 (continued)

Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber, silicone rubber adhesive
Battery	Single-cell lithium-iodine

[a] Volume with connector hole unplugged.

[b] Grommet may protrude slightly beyond the can surface.

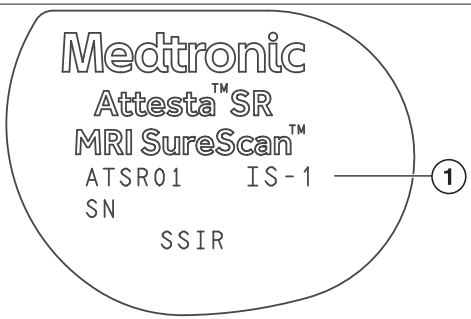
[c] The radiopaque ID can be viewed in a fluoroscopic image of the device.

[d] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

The Model ATSR01 shield graphics are shown in *Figure 9*.

IS-1 marking in *Figure 9* refers to the International Connector Standard (see Document No. ISO 5841-3) whereby pulse generators and leads so designated are assured of meeting the electrical and mechanical parameters specified in the IS-1 International Standard.

Figure 9. Shield graphics: Model ATSR01



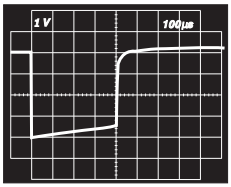
1 IS-1 marking

20.2 Electrical specifications

20.2.1 Output waveform

The output waveform for the pacemaker is shown in *Figure 10*.

Figure 10. Output waveform at nominal conditions (resistive load: 500 Ω)[1]



20.2.2 Battery information

Information about the battery used in the Attesta SR MRI SureScan model ATSR01 device is provided in the following table.

Note: Usable capacity is defined from the Beginning of Service (BOS) to the End of Service (EOS).

Table 32. Battery characteristics

Manufacturer	Medtronic Energy and Component Center
Model	Sigma 213
Number of battery cells	1
Type	Single-cell lithium-iodine
Nominal voltage	2.8 V
Usable capacity	0.92 Ah
Residual capacity at RRT	0.06 Ah

Table 33. Current consumption for model ATSR01

Current consumption (at 100% pacing)[a]	17.31 µA
Current consumption (at 100% inhibition)[b]	12.93 µA

[a] Current consumption when pacing into 500 Ω ± 1% loads at the Beginning of Service in VVIR mode at 60 min^{-1}, 2.5 V, 0.4 ms.

[b] Current consumption when at the Beginning of Service in VVIR mode at 60 min^{-1}, 2.5 V, 0.4 ms.

20.2.3 Variation with temperature

Basic rate, test pulse rate, pulse duration, and pulse amplitude remain within expected tolerances when the device temperature is between 20°C to 43°C. Sensitivity at nominal conditions as measured at 37°C can vary up to ±1% per°C, from 22°C to 45°C.

[1] Amplitude and pulse width measured per ISO 14708-2.

20.3 Projected service life

20.3.1 Projected service life for Model ATSR01

Table 34. Model ATSR01 Projected service life from implant to RRT, in years

Pacing	A Amplitude, V Amplitude	Rate, Pulse Width	Lead impedance	
			500 Ω	1000 Ω
			Longevity (years)	
SSIR or SSI, 0%	2.0 V	60 min^{-1}, 0.4 ms	11.3	11.3
	2.5 V		10.4	10.4
	3.5 V		11.1	11.1
SSIR or SSI, 50%	2.0 V	60 min^{-1}, 0.4 ms	10.4	10.8
	2.5 V		9.5	9.9
	3.5 V		9.0	9.9
SSIR or SSI, 100%	2.0 V	60 min^{-1}, 0.4 ms	9.6	10.4
	2.5 V		8.7	9.5
	3.5 V		7.5	8.9
SSIR or SSI, 0%	2.5 V	70 min^{-1}, 0.5 ms	10.3	—
	5.0 V		10.2	—
SSIR or SSI, 100%	2.5 V	70 min^{-1}, 0.5 ms	8.0	—
	5.0 V		4.6	—
SSIR or SSI, 100%	5.0 V	70 min^{-1}, 1.0 ms	3.1	—
SSIR or SSI, 100%	5.0 V	100 min^{-1}, 1.0 ms	2.3	—

20.4 Prolonged service period

At most programmed settings, approximately 95% of pacemakers have a prolonged service period of at least 90 days between RRT and ERI, and 90 days between ERI and EOS.

The prolonged service period between RRT and EOS meet the following conditions, in conformance with ISO 14708-2:

- 100% pacing in VVI mode
- 60 min^{-1} pacing rate
- 2.5 V pulse amplitude / 0.4 ms pulse width
- 600 Ω pacing load

The mean prolonged service period is 253 days.

Note: After ERI, pacing parameters including mode and rate can be reprogrammed, however this may shorten the ERI-to-EOS period.

20.4.1 Features disabled at RRT

The following features are disabled at RRT and cannot be programmed to On:

- MRI SureScan mode
- EP Studies

20.4.2 Features disabled at ERI

The following features are disabled at ERI and cannot be programmed to On:

- Single Chamber Hysteresis
- Sleep Function
- Ventricular Capture Management
- Atrial Sensing Assurance
- Ventricular Sensing Assurance

20.5 Feature summary

This section describes the features available with the Attesta SR MRI SureScan model ATSR01 pacemaker.

Automatic Polarity Configuration – This feature uses Lead Monitor to automatically configure pacing and sensing polarities for bipolar devices during Implant Detection.

Conducted AF Response – The feature regularizes the ventricular rhythm during AT/AF by modifying the pacing rate on a beat-by-beat basis to achieve pacing of just over 50% of ventricular events.

EP Studies – EP (Electrophysiologic) Studies uses the patient's implanted pacemaker to noninvasively deliver high-rate cardiac stimulation. Programmable mode, interval, and delay parameters allow set up of protocols to deliver either programmed electrical stimulation (PES) or burst stimulation.

Implant Detection – You can only perform EP Studies when the lead polarities are set to Unipolar or Bipolar. During Implant Detection you can manually configure the lead polarities if you choose, or you can wait for Implant Detection to configure the lead polarities.

Lead Monitor – This feature measures lead impedances during the life of the implanted device and controls automatic configuration of lead polarities at implant. If Lead Monitor is programmed to Adaptive, the device automatically switches bipolar pacing and sensing to unipolar pacing and sensing if the integrity of a bipolar lead is compromised.

MRI SureScan – This feature allows patients with an implanted MRI SureScan system, including the device and lead, to have a safe MRI procedure if the requirements provided in the MRI technical manual are followed.

Pacing mode and rate programming after ERI – The pacing mode and rate parameters can be re-programmed after the Elective Replacement Indicator (ERI) pacing mode and rate parameters have been set.

Rate Profile Optimization – The goal of Rate Profile Optimization is to ensure that the rate response remains appropriate for the full range of patient activities. This feature monitors the patient's daily and monthly sensor rate profiles and adjusts the rate response curves over time to achieve a prescribed target rate profile.

Rate-responsive pacing – This feature varies the pacing rate in response to the patient's physical motion as detected by the activity sensor of the device.

Rate Response User Interface – This feature provides a graphical display to aid in programming rate response. When Rate Profile Optimization parameters are programmed, rate response undergoes an immediate change.

Sensing Assurance – This feature automatically monitors the peak amplitude of sensed signals and adjusts atrial and ventricular sensitivities within defined limits to maintain adequate sensing margins. Sensing Assurance is enabled at the completion of Implant Detection.

Single Chamber Hysteresis – This feature enables tracking of the patient's intrinsic rhythm below the programmed Lower Rate to prevent pacing during extended periods of inactivity, such as when a patient is sleeping.

Sleep Function – This programmable feature suspends the programmed Lower Rate and replaces it with a Sleep Rate during a specified sleep period.

Ventricular Capture Management – This feature provides automatic monitoring of ventricular pacing thresholds. Ventricular Capture Management may be programmed to automatically adjust the ventricular Amplitude and Pulse Width settings to maintain capture.

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
+31 45 566 8000

Canada
Medtronic Canada ULC
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
1 800 268 5346

Technical manuals
www.medtronic.com/manuals

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