Medtronic

Affera™

Ablation System:

HexaGen™ RF Generator

HexaPulse™ PF Generator

HexaFlow™ Irrigation Pump

User Manual

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

Explanation of Symbols

Refer to the package and product labels to see which symbols apply to this product and for product-specific information, such as the date of manufacture, manufactured-in location, and use-by date.


Refer to instruction manual/booklet


Caution

Warning: electricity

Alarm


Start/Stop button


Return electrode connection

Isolated high frequency patient circuit


Defibrillation-proof, type CF applied part


Catheter extension cable connection


System interconnect link


Auxiliary PF


nput connection


Output connection


Serial data connection


System communication connection

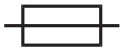

oot pedal connection

 Equipotential cable connection

 Direct current

 Alternating current

 Non-ionizing electromagnetic radiation

 Fuse

Medical device

Model number

Serial number

Catalog number

Lot number

Unique Device Identifier

 Manufacturer

 Date of manufacture

Authorized Representative in the European Community

 WEEE (Waste from electrical and electronic equipment)

 Do not use if package is damaged

 Use-by date

 Consult instructions for use

Consult instructions for use at this website

CE Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.

Importer

IPX8 Ingress protection rating for foot pedal (protected against the effects of continuous immersion in water)

TÜV SÜD NRTL Mark

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

Manufactured in

Package contents

Generator

rrigation pump

System components

Product documentation

Contents

1 Definitions

Table 1. Abbreviations and terms

Term	Definition
CIU	Catheter interface unit
EMC	Electromagnetic compatibility
PF	Pulsed field
PF	exaPulse™ PF generator
Pump	HexaFlow™ irrigation pump
RF	Radiofrequency
RF	exaGen™ RF generator

2 About the Affera ablation system

The Affera ablation system is comprised of the Hexa en radiofrequency (RF) generator, the HexaPulse pulsed field (PF) generator, and the HexaFlow irrigation pump and is designed for use with compatible ablation catheters (such as the Sphere-9™ catheter) to treat cardiac arrhythmias.

The Affera ablation system is also designed for integrated operation with the Affera mapping system, which is provided separately.

The RF generator (RFG) is specialized medical electrical equipment designed to supply RF energy for ablation treatment of cardiac arrhythmias. It is used in conjunction with a compatible ablation catheter and one or more dispersive pads that serve as return electrodes (also called indifferent or neutral electrodes) to create a monopolar electrical circuit capable of delivering controlled RF energy to ablate cardiac tissue.

The RFG monitors temperature sensors on a compatible ablation catheter and can adjust the RF energy output to maintain a desired sensor temperature. The RFG also monitors the ablation circuit impedance.

The PF generator (PFG) is specialized medical electrical equipment designed to supply PF energy for the ablation treatment of cardiac arrhythmias. It is connected in series with the RFG to provide PF energy using the same compatible ablation catheter, extension cable, and return electrodes as the RF .

The irrigation pump is a peristaltic pump designed to provide irrigation solution to a compatible ablation catheter. The pump is operated with a custom single-use tubing set to deliver accurate flow rates at the anticipated backpressure of the compatible catheter. The pump employs a bubble detector to prevent infusion of air into the patient.

The RFG communicates with the irrigation pump to monitor and control irrigation flow rate as appropriate during ablation.

The Affera ablation system is intended for use only by medical personnel trained and experienced in the techniques of electrophysiology who have been appropriately familiarized with the use of this equipment. Before using this system for the first time in a clinical application, the user should thoroughly read this user manual.

Figure 1. The Affera ablation system: HexaGen RF generator (top right), HexaPulse PF generator (middle right), and HexaFlow irrigation pump (left) (shown with the Affera mapping system, HexaMap™ CIU and the system cart)

3 Functional principles

3.1 RF application

The RF generator (RFG) applies RF current through the ablation electrode on a compatible ablation catheter. The current delivered by the RF is transmitted through the tissue in contact with the ablation electrode, causing localized heating in the tissue. The current disperses through the patient's body and is returned to the R through 4 return electrodes placed on the patient's skin.

3.2 PF application

The PF generator applies low energy high voltage PF pulses to the ablation electrode on a compatible therapeutic catheter to cause irreversible electroporation of the local cardiac tissue. The non-thermal PF pulses form pores in the cell membranes of target tissue, resulting in tissue apoptosis or necrosis. The current from these pulses is dispersed through the patient's body and is returned to the ablation system through 4 return electrodes placed on the patient's skin

3.3 Temperature feedback

The Affera ablation system is designed for use with a compatible ablation catheter that includes multiple surface temperature sensors that can ensure the surface temperature is appropriately monitored during RF application. The RF generator is designed to modulate the RF energy in response to feedback from the temperature sensors and limit the energy delivered, which may reduce the likelihood of char, coagulum, or steam pop. The Affera ablation system also monitors feedback from the temperature sensors during PF ablation, but unlike during RF delivery, temperature is not used to titrate PF energy delivery.

3.4 Ablation circuit impedance

The Affera ablation system measures the impedance of the ablation circuit between the ablation electrode and the return electrodes in real time. Ablation circuit impedance may provide information regarding the formation of the lesion during RF application.

3.5 Return electrodes

The Affera ablation system operates with 4 return electrodes. The return electrode adapter is connected to the front of the PF generator and connects to the RF generator via the ablation return link cable.

The Affera ablation system is designed for use with “split plate” return electrodes. When used with “split plate” return electrodes, the ablation system employs a contact quality monitoring system to monitor the impedance between the two halves of each return electrode and warns the user of any change in impedance consistent with poor contact quality. Colored indicators on the RFG front panel above the ablation return link connection indicate which return electrodes are connected and their status (*Table 4*).

To prevent excessive heating under the return electrodes, the R monitors the RF energy delivered through each return electrode. The RF will terminate or prevent initiation of RF delivery to ensure the energy delivered through each return electrode remains below a safe threshold.

See *Section 7.2* for proper return electrode placement and connection instructions.

3.6 Peristaltic irrigation

The irrigation pump is used with the tubing set to deliver irrigation solution to the compatible ablation catheter. The irrigation pump has a bubble detector to stop flow in the event that air is detected in the line. The irrigation pump can deliver irrigation solution at a low flow rate during mapping and at a high flow rate during ablation. The irrigation pump is controlled remotely by the RF generator to automatically synchronize the flow rate with energy delivery.

3.7 Mapping system integration

The Affera ablation system is designed for use with the Affera mapping system, which is provided separately. The compatible ablation catheter is connected to the Affera ablation system via the HexaMap catheter interface unit (CIU) and the front panel generator link cable. A communication cable enables information sharing between the units. When properly connected, the Affera mapping system will display the real-time and historical ablation parameters and can use this information to display 3D ablation tags. The ablation catheter signals are not modified by the CIU. The Affera mapping system has no influence on the operation of the Affera ablation system, including delivery of RF or PF energy. See the *Affera Mapping System User Manual* for further information.

4 Intended use

4.1 Indications for use

Refer to the instructions for use accompanying the compatible ablation catheter for the specific indications for use.

4.2 Intended patient population

Refer to the instructions for use accompanying the compatible ablation catheter for the intended patient population.

4.3 Intended users

The intended users are physicians and nurses/EP technicians trained in interventional cardiac electrophysiology (EP).

4.4 Contraindications

Refer to the instructions for use accompanying the compatible ablation catheter for specific contraindications prior to use with the system.

4.5 Potential adverse effects

Refer to the instructions for use accompanying the compatible ablation catheter for potential adverse events associated with cardiac ablation procedures.

5 Safety information

5.1 Warnings: General Use

- Carefully read all system instructions before use. Observe all contraindications, warnings, and precautions noted in the directions. ailure to do so may result in patient complications. Review any applicable product information with the patient, including known risks and contraindications.
- Inspect all items for possible damage during shipment. Do not operate the Affera ablation system if any components appear damaged. f any items are damaged, do not use them and contact a Medtronic representative.
- Cardiac ablation procedures should only be performed by personnel trained in RF catheter ablation techniques.
- Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias. Defibrillation equipment must be available for immediate use in the case of a life-threatening arrhythmia.
- Use only the components provided with the system or supplied by the manufacturer. Use of unauthorized or unapproved components, or modification of components, can alter system performance and lead to damage or patient harm.
- Do not modify the Affera ablation system in any way.
- Ensure that the RF generator, PF generator, and CIU components are placed on a firm and stable surface, and ensure that airflow is not restricted to the air vents before initiating the case.
- Do not operate the Affera ablation system stacked on or in close proximity with other electrical equipment other than the Affera mapping system as it could result in improper operation. If adjacent or stacked use is necessary, the system should be observed before use to verify normal operation in the configuration in which it will be used.
- Ensure the patient cannot directly contact grounded metal components or metal components that have a large, grounded surface area, such as the operating table.
- Skin contact between the patient's appendages and body should be avoided by insertion of dry gauze or other means.
- Physiological monitoring electrodes without protective resistance or RF filters should be applied to the patient's body as far as possible from the ablation site and the return electrodes. The use of monitoring systems incorporating high frequency current limiting devices is recommended.
- Avoid using flammable anesthetics. Due to the risk associated with flammable liquids under the patient or in the patient's body cavities, wipe the liquid away in these places before starting a procedure, and allow time for flammable substances such as cleaning agents or solvents to evaporate. The use of non-flammable cleaning agents is recommended.

- mplanted pacemakers and cardioverters/defibrillators (ICDs) can be adversely affected by energy delivery. Temporary external sources of pacing and defibrillation must be made available during ablation procedures. It is advised to temporarily reprogram the pacing system to OFF mode or minimum output and to deactivate cardioverters/defibrillators during the ablation procedure to minimize the risk of inappropriate pacing or shock. t is important to perform a complete implantable device analysis on all patients after ablation.
- Electromagnetic radiation emitted by the system can interfere with the function of other electrical devices. Radiation from other electrical devices can affect the function of the system if operated near the generator.
- f error messages repeatedly appear and cannot be resolved, stop using the system and contact Medtronic.
- To avoid damage to the system, use only appropriate cleaning agents (see *Section 10.1*).
- The Affera ablation system contains no user-serviceable parts and must not be disassembled by anyone other than persons authorized by Medtronic. No modifications to this equipment are allowed.
- Electrodes and probes for monitoring and stimulation devices can be electrical conductors of RF current. Reduce the risk of burns by placing the electrodes and probes as far as possible from the site of ablation and from the return electrodes.
- The ablation catheter and the tubing set are intended for single patient use only. To avoid the risks of cross contamination or use of degraded products, do not reuse devices that are marked for single use.
- f a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.
- There is no special handling, including no special storage or transport conditions, required for this device. Standard storage conditions are sufficient to safeguard the device.

5.2 Warnings: System connections and safety

- The Affera ablation system is intended for use with compatible ablation catheters and cables only. Do not use with devices having a rated accessory voltage less than the maximum output voltage specified in this user manual.
- Use caution when connecting the ablation system to other medical electrical equipment. The operator is responsible for installation and operation that complies with IEC/EN 60601-1. All system components must comply with applicable requirements and standards.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- The Affera ablation system may be interfered with by other equipment, even if the other equipment complies with CISPR emission requirements. System operation may be temporarily interrupted if exposed to excessive external electromagnetic disturbance or ESD. In case system operation is interrupted, such as loss of signal acquisition or an error message, reboot the system by cycling mains power to fully restore system operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the Affera ablation system, including cables specified by the manufacturer. Refer to the information provided in *Table 10* to ensure minimum safe operating distance is observed otherwise degradation of the performance of this equipment could result.
- Do not use the system near a strong magnetic field such as MRI. The system has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The safety of the system in the MR environment is unknown (such as any heating, migration, or image artifacts). Scanning a patient during the use of these devices may result in patient injury.
- To avoid risk of electric shock, this equipment must be connected to a mains power supply with protective earth using the power cord supplied. Do not use an additional multiple socket outlet or extension cord unless provided by Medtronic. Ensure the system is not positioned in such a way as to make it difficult to readily disconnect the device from the mains power supply if required.
- Connecting electrical equipment to an incompatible multiple socket outlet effectively leads to creating a medical electrical system, and the result can be a reduced level of safety. For the requirements that are applicable to a medical electrical system, refer to IEC/EN 60601-1.
- Do not connect the ablation system ethernet ports to a hospital IT network or computing device other than those explicitly specified in this manual.
- Do not upload unauthorized software onto the device.
- Inspect cables for damage to insulation or other signs of damage. Inspect cable connectors for bent pins. Do not use cables that appear damaged.
- To avoid differences in potential between the ablation system components and other medical electrical equipment, potential equalization (equipotential) cables are provided for connection to a central ground in the operating room as specified in IEC/EN 60601-1.
- Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). urthermore, all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the 3Ed. of IEC/EN 60601-1). Any person connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above-mentioned requirements. If in doubt, contact Medtronic.

5.3 Warnings: Irrigation pump and tubing set operation

- Use the irrigation pump only with the tubing set. Use of unauthorized tubing in the pump may cause flow inaccuracy and other dangerous conditions. The irrigation pump is intended for use only with the Affera ablation system and compatible devices.
- Ensure the tubing set is placed properly in the bubble detector of the irrigation pump before connecting to the patient.
- Verify flow from the catheter before insertion into the patient.
- Verify the tubing is free of air bubbles before insertion of the catheter into the patient.
- When mounting the pump to an IV pole, ensure stability before starting that case. It is recommended that the pump be mounted on the IV pole provided with the system cart, or a 5-legged hospital grade IV pole may be used. To ensure stability, the pump should not be mounted higher than 135 cm above the base of the pole.
- The tubing set is intended to be connected directly to a compatible catheter. Do not use stopcocks or extend the length of tubing between the pump and the catheter using unauthorized tubing extension devices.
- When the **PUR E** button is pressed, the air bubble detector is disabled. Do not press the **PUR E** button or the **CATHETER PREPARATION SEQUENCE** button while the catheter is in the patient. Purge air from the irrigation tubing and catheter lumen before inserting the catheter into the patient.
- ollow the catheter preparation instructions in the catheter instructions for use in order to reduce the likelihood of accidental infusion of air.
- The irrigation pump stops flow automatically when air is detected in the line or in case of other operational errors. When the pump alarm indicates flow has stopped, ensure that energy delivery has been terminated. If irrigation flow cannot be restored immediately, remove the ablation catheter from the patient until irrigation flow is resumed.
- The pump and tubing set are intended for use with heparinized saline irrigation solution. Patient injury may result from excessive delivery of inappropriate fluids.
- Always maintain a constant infusion of heparinized saline to prevent formation of coagulation.

5.4 Warnings: Return electrode management

- Care should be taken in the placement of the return electrodes. Each return electrode should be placed at a similar distance and with a similar mass of tissue from the ablation site.
- The entire surface of the return electrodes must be as close as possible to the operating field and must have reliable contact with the patient's body. The skin surface must be free of excessive oil and body hair.
- Use only return electrodes with a surface area of ≥ 124 cm^2 that conform with IEC/EN 60601-2-2.

- The Affera ablation system employs a contact quality monitoring feature to ensure return electrode contact. Use of compatible split type indifferent return electrodes is recommended to ensure poor return electrode contact is detected, resulting in an audible alarm. Use of non-split plate return electrodes will prevent the contact quality monitoring circuitry from operating, and may increase the risk of patient skin burn.
- Read the instructions for use for the return electrodes carefully, and take special note of warnings and precautions. An unsuitable or incorrectly applied return electrode can lead to skin burns. Check the return electrode and the connection cable before use. Do not use a return electrode that is damaged or modified.
- Ensure that the return electrode contact surface is moist and not dry. Replace dry electrodes with a new electrode. Do not use contact gel with single-use return electrodes.
- A single-use return electrode cannot be reused. If the return electrode becomes loose or must be moved, use a new return electrode.
- All patient leads and cables should be positioned in such a way that contact with the patient or other leads is avoided.
- Do not position a return electrode in contact with or covering any other body surface electrode or location reference patch.

5.5 Warnings: During ablation

- To avoid possible injury to the patient or to the operator, do not start energy delivery until the catheter is positioned in the intended ablation site. Always select the lowest appropriate output ablation setting for the intended site.
- Avoid high catheter electrode temperatures. High electrode temperatures during ablation are associated with char and thrombus, the formation of which could lead to embolism.
- igh temperatures observed with low applied RF energy may indicate an obstruction of irrigation.
- Prevent contact between the ablation electrode and other electrically conductive devices or implants in the heart (e.g. diagnostic catheters or pacemakers) to avoid the possibility of shunting energy away from the target location.
- Monitor the ablation circuit impedance measurement during RF energy delivery, and immediately terminate RF delivery if an abrupt change is observed.
- In case of apparent low power output or failure to function as expected at the selected output setting, verify contact of the return electrodes and connections before increasing the power setting.
- A failure of the RF generator or PF generator could result in an unintended increase of output energy.

- The system monitors the energy delivered through each return electrode during the procedure to prevent heating. If the energy delivered to any return electrode exceeds the safe threshold, delivery will be stopped automatically. If the operator attempts to deliver energy that will cause the safe energy delivery limit to be exceeded, the system will not start the ablation and will present a message to wait until the selected energy can be safely delivered.
- Neuromuscular stimulation may occur during PF energy delivery. If patient movement occurs, verify the catheter position.
- Continuously monitor the patient and patient vital signs during ablation.
- Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias. Defibrillation equipment must be available for immediate use in the case of a life-threatening arrhythmia.
- Ensure a minimum flow of 4 mL/min heparinized saline throughout the entire procedure to prevent coagulation formation or occlusion of the catheter irrigation holes.
- Once the Start/Stop button is pressed, energy delivery will continue until the energy delivery sequence is completed or until the Start/Stop button is pressed a second time. Use caution manipulating the ablation catheter when delivering energy.
- Do not deliver energy near other intracardiac devices or when in contact with other cardiac catheters or pacing leads to avoid possible thrombus or inappropriate treatment location.

6 System overview and connections

6.1 Affera ablation system components

The components of the Affera ablation system are supplied as shown in *Table 2*, along with this user manual.

Table 2. Affera ablation system components

AFR-00004 HexaGen RF Generator (RF)	
ASM-00083	RF Generator Unit
CBA-00018	Generator Link Cable
ASM-00072	Return Electrode Adapter
SW -00014	oot Pedal
ASM-00102	HexaGen Remote Control
CBL-00104	Fiber Optic Communication Cable, 30 m
PWR-00018	Remote Control Power Supply
AFR-00008 HexaPulse PF Generator (PF)	
ASM-00094	PF Generator Unit
CBA-00018	Generator Link Cable
CBA-00119	Ablation Return Link Cable
CBA-00117	Generator Communication Cable (qty. 2)
AFR-00005 HexaFlow Irrigation Pump	
ASM-00077	rrigation Pump Unit
CBA-00139	RFG to Pump Communication Cable
PRT-00331	Pump Pole Clamp
Cables and Power Cords	
Various	Power Cord
CBL-00100	Equipotential Cable

These components of the Affera ablation system are supplied separately.

Table 3. Affera ablation system components (supplied separately)

AFR-00002	Tubing Set
AFR-00006	Catheter Extension Cable

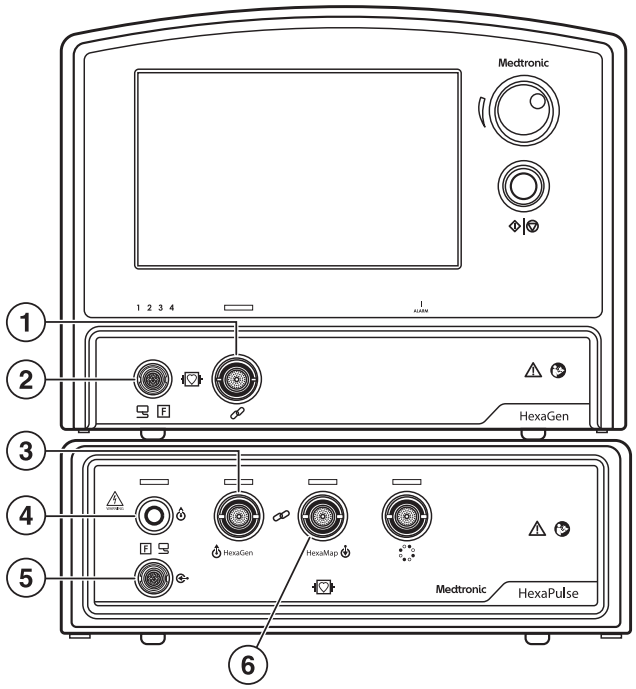
6.2 System connections

The Affera ablation system is designed for use in cardiac ablation procedures conducted in an appropriately equipped and qualified surgical suite. The system is intended to be used with a compatible mapping system and a compatible ablation catheter. Additional system connection information can be found in the *Affera Mapping System User Manual*.

Note: Product images shown in this manual are representative to show connections and ports; actual images may differ slightly.

6.2.1 Front panel connections

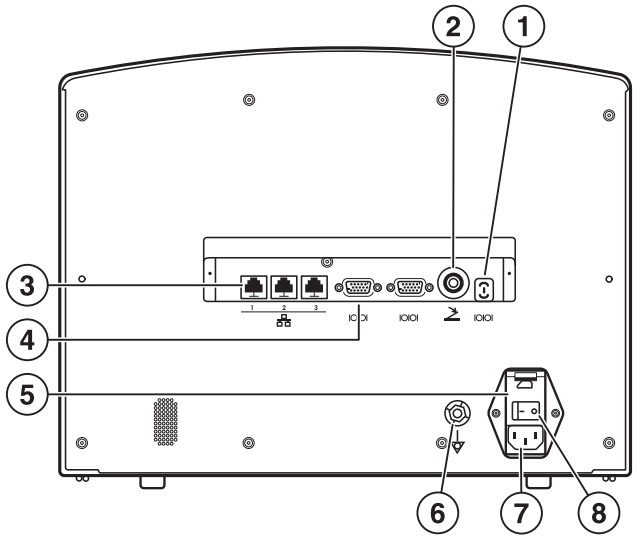
Figure 2. Front panel connections for the RF generator and PF generator



1 enerator link cable (to PF)
2 Ablation return link cable
3 enerator link cable (to RF)
4 Ablation return link cable
5 Return electrode adapter
6 enerator link cable (to CIU)

6.2.2 RF generator back panel

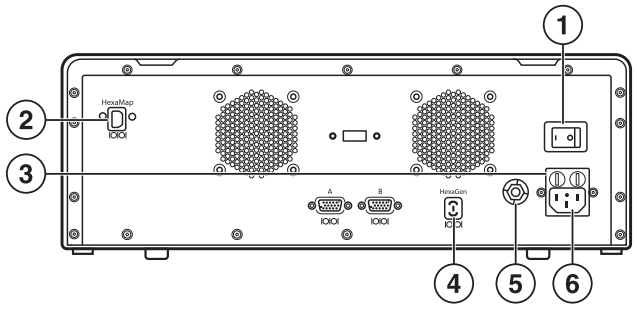
Figure 3. RF generator back panel



1 enerator communication cable (to PF)
2 oot pedal connection
3 System network communication
4 R to pump communication cable connection
5 use access
6 Equipotential cable connection
7 Mains power cord connection
8 Power switch

6.2.3 PF generator back panel

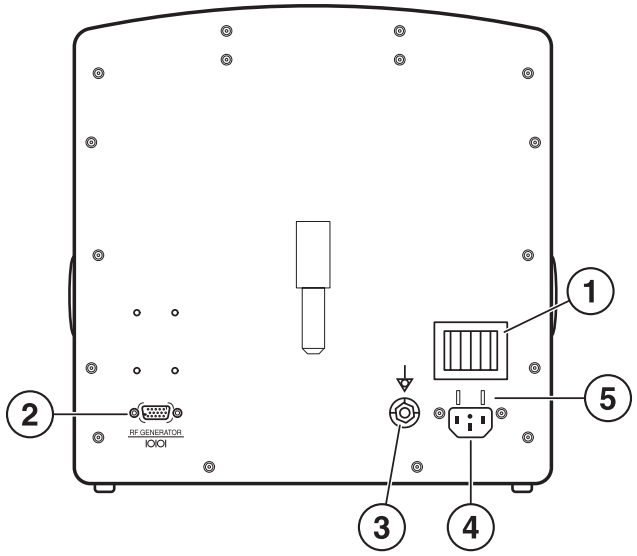
Figure 4. PF generator back panel



1 Power switch
2 enerator communication cable (to CIU)
3 use access
4 enerator communication cable (to RF)
5 Equipotential cable connection
6 Mains power cord connection

6.2.4 Irrigation pump back panel

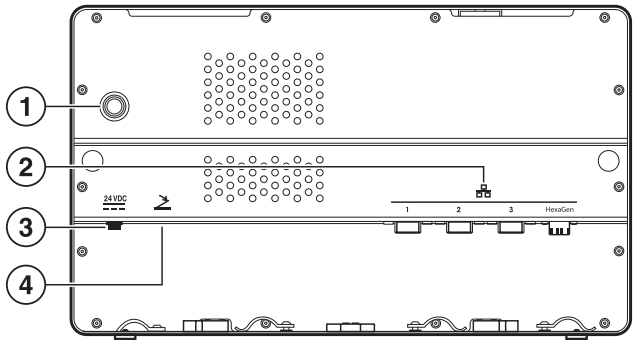
Figure 5. Irrigation pump back panel



1 Power switch
2 R to pump communication cable
3 Equipotential cable connection
4 Mains power cord connection
5 use access

6.3 Remote control back panel

Figure 6. HexaGen remote control back panel

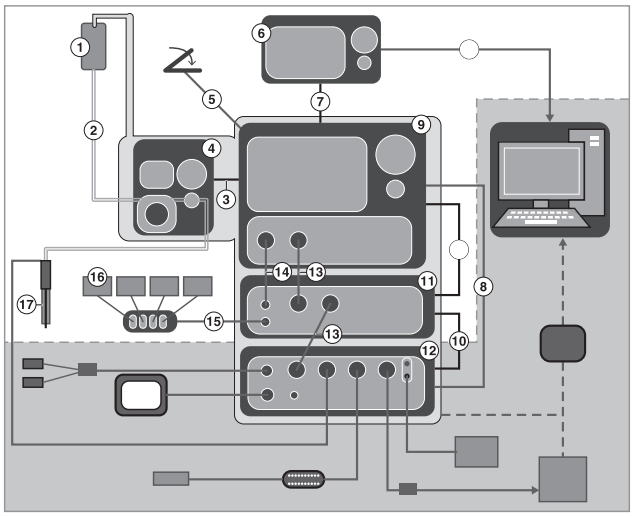


1 Power button
2 System network communication
3 Remote control power supply
4 oot pedal connection

6.4 System connection diagram

The Affera mapping system and the Affera ablation system are collectively referred to as the Affera mapping and ablation system, which is shown in *Figure 7*. The ablation system components are shown above the dotted line. (See the *Affera Mapping System User Manual* for a system diagram of the mapping system components, shown below the dotted line.)

Figure 7. Affera mapping and ablation system connection diagram

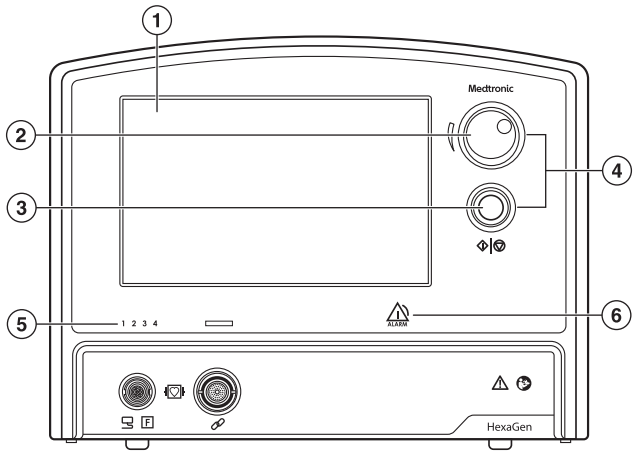


1 Saline bag
2 Tubing set (AFR-00002)
3 R to pump comm cable (CBA-00139)
4 rrigation pump unit (ASM-00077)
5 oot pedal (SW -00014)
6 Remote control (ASM-00102)
7 iber optic comm cable, 30 m (CBL-00104)
8 Ethernet cable (CBL-00101)
9 R unit (ASM-00083)
10 Generator comm cable (CBA-00117)
11 PFG unit (ASM-00094)
12 Affera mapping system CIU
13 Generator link cable (CBA-00018)
14 Ablation return link cable (CBA-00119)
15 Return electrode adapter (ASM-00072)
16 Return electrodes
17 Ablation catheter

6.5 System controls and indicators

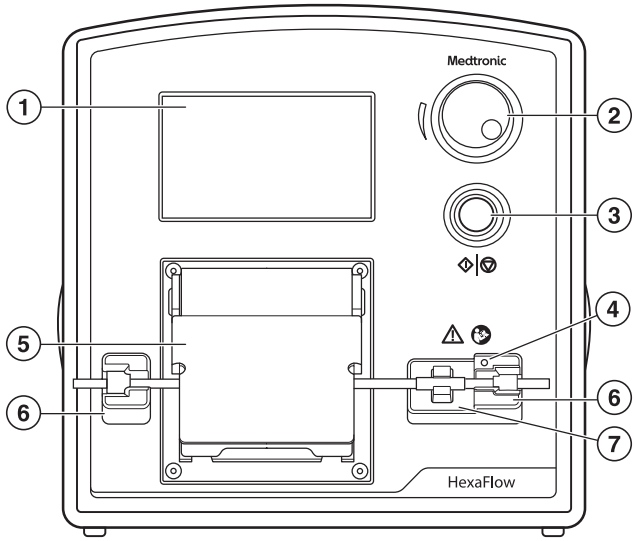
The Affera ablation system provides an intuitive user interface via touchscreen and rotary dial controls. Warning indicators are provided on the touchscreen and in some cases by dedicated indicators on the front panel. An optional remote control user interface is available with the same touchscreen, rotary dial, and Start/Stop button.

Figure 8. RF generator front panel controls and indicators



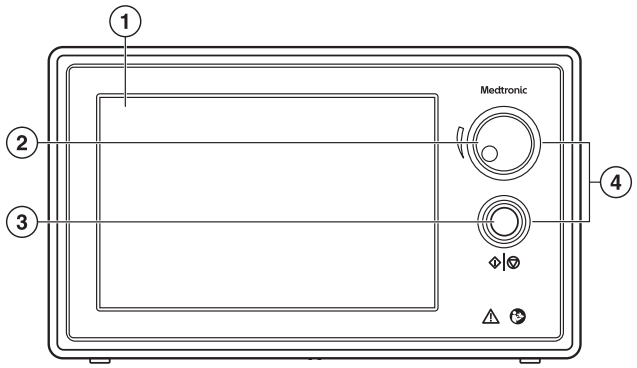
1 Touchscreen interface
2 Rotary dial
3 Start/Stop button
4 Ablation indicator lights
5 Return electrode status indicators
6 Error warning indicator

Figure 9. Irrigation pump front panel controls and indicators



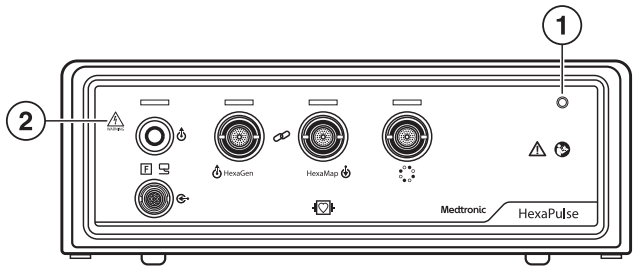
1 Touchscreen interface
2 Rotary dial
3 Start/Stop button
4 Bubble detected indicator
5 Door
6 Tubing mount
7 Bubble detector

Figure 10. Remote control front panel controls and indicators



1 Touchscreen interface
2 Rotary dial
3 Start/Stop button
4 Ablation indicator lights

Figure 11. PF generator front panel indicators



1 Power indicator
2 igh voltage indicator

7 System setup and operation

7.1 System setup

Warning: To avoid risk of electric shock, this equipment must be connected to a mains power supply with protective earth using the power cord supplied. Do not use an additional multiple socket outlet or extension cord unless provided by Medtronic. Ensure the system is not positioned in such a way as to make it difficult to readily disconnect the device from the mains power supply if required.

Warning: Connecting electrical equipment to an incompatible multiple socket outlet effectively leads to creating a medical electrical system, and the result can be a reduced level of safety. For the requirements that are applicable to a medical electrical system, refer to IEC/EN 60601-1.

or assistance with initial installation, setup, and operation, contact Medtronic.

1. Connect all mains power connections.

   Note: The HexaFlow irrigation pump is intended to be connected directly to mains power and is not to be connected to the multiple socket outlet on the system cart (AFR-00013).

2. Mount the irrigation pump on the IV pole of the system cart or a suitable 5-leg IV pole and place the system components near the patient.
3. Connect the communication cables between the following components according to the system connection diagram in *Figure 7*:
   - exaGen RF generator
   - exaPulse PF generator
   - exaFlow irrigation pump
4. If used, connect the communication cables with the following additional components according to the system connection diagram in *Figure 7*:
   - exaGen remote control
   - exaMap CIU
   - Affera mapping system workstation
5. Power on each unit of the Affera ablation system using the power switch on the back panel, and ensure the self-test shown on the RF passes before continuing.

7.2 Return electrode placement and connections

1. Place return electrodes on the patient's skin as described below and connect them to the return electrode adapter. The system requires 4 return electrodes.

2. Ensure that return electrodes are within close proximity to the patient's heart and that there is secure contact between the entire electrode and the patient's skin. The chosen area should be prepared by removing hair or oils from the skin. Cleaning with saline and gauze is recommended.
3. After connecting the return electrodes, verify the contact quality monitoring status of each return electrode using the colored indicators on the RF front panel, above the ablation return link connection (*Table 4* and *Figure 8*). As described in *Section 3.5*, the Affera ablation system uses "split plate" return electrodes for contact quality monitoring.

Table 4. Contact quality monitoring status color codes

Color	Return Electrode Status
Green	Return electrode impedance is within expected range, indicating good contact quality
Red	Return electrode impedance is high, indicating a disconnected return electrode or poor contact quality
Yellow	Return electrode impedance is low, indicating an invalid contact quality measurement, which can be caused by using return electrodes without a "split plate" design

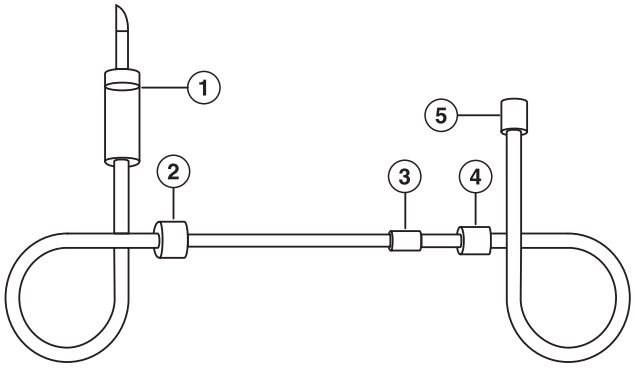
Warning: An unsuitable or incorrectly applied return electrode can lead to skin burns. Check the return electrode and the connection cable before use. Do not use a return electrode that is damaged or modified. Refer to the warnings in *Section 5.4*.

7.3 Tubing set installation

1. Using sterile technique, remove the tubing set (*Figure 12*) from the sterile package and place it into the sterile field.
2. The drip chamber and pump mounting section of the tubing set (1-4 in *Figure 12*) can be passed to nonsterile hands for installation into the irrigation pump (*Figure 9*) and connection to the irrigation source.
3. Place the large pump mounting block into the tubing mount receptacle to the left of the pump head.
4. With the pump door open, stretch the tubing under the pump head and insert the smaller pump mounting block into the tubing mount receptacle on the right side of the pump head.
5. Place the enlarged bubble detector feature into the bubble detector on the right side of the pump door. Ensure that the tubing is fully seated into the mounting block receptacles and bubble detector.
6. Close the pump door to engage the tubing.
7. Grasping the drip chamber, remove the spike cap, spike the irrigation source, and hang it from an IV pole.
8. Squeeze and release the drip chamber until it is a maximum of 25% full.

9. Fill the tubing set with heparinized saline irrigation solution by pushing the **PUR E** button on the irrigation pump (*Figure 20*). The **PUR E** button can also be found on either the RFG or the remote control (*Figure 13*). Hold the **PUR E** button until the bubble alarm is cleared.

Figure 12. Tubing set



1 Drip chamber
2 Large pump mounting block
3 Bubble detector feature
4 Small pump mounting block
5 Catheter luer connector

Warning: Inspect the tubing set to verify there are no air bubbles between the drip chamber and the luer connector before connecting to the catheter as air bubbles in the tubing may become emboli. Always verify flow from the tubing set before connecting to the catheter to ensure proper irrigation.

10. Connect the tubing set to the luer fitting of the compatible ablation catheter, and follow the instructions provided in the catheter instructions for use.

Caution: The tubing set should not be used with extension tubing or stopcocks.

11. As directed in the ablation catheter instructions for use, submerge the tip of the ablation catheter in a bowl of sterile saline, and press the **CATHETER PREPARAT ON SEQUENCE** button (*Figure 13* and *Figure 20*). Keep the ablation catheter tip submerged until the sequence is complete.
12. ollow the ablation catheter instructions for use regarding use of an insertion tool.
13. Ensure that irrigation fluid is flowing from the tip of the ablation catheter before inserting it into the patient.
14. Verify that there are no leaks from the tubing connections or catheter handle.

Caution: Ensure that there is a minimum flow of 4 mL/min heparinized saline throughout the entire procedure to prevent coagulation formation or occlusion of the catheter irrigation holes.

7.4 Bubble detection

f a bubble is detected in the tubing set, the irrigation pump will sound an audible warning and stop irrigation flow before the bubble is delivered to the ablation catheter. The air must be purged from the tubing set as described in this section before continuing irrigation.

1. Remove the ablation catheter from the body. It is recommended to disconnect the tubing set from the ablation catheter.

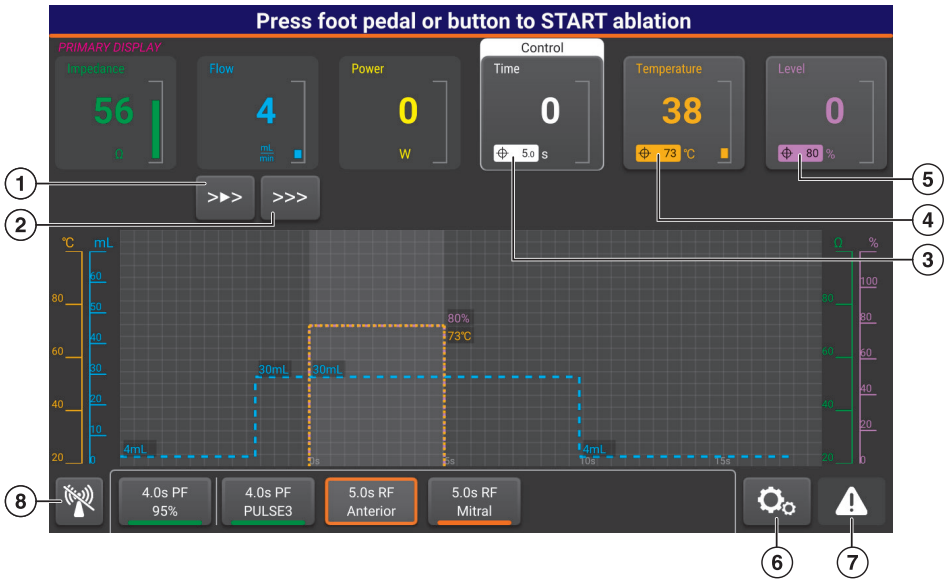
   Warning: When the **PUR E** button is pressed, the air bubble detector is disabled. Do not purge while the catheter is in the body.
2. Press and hold the **PUR E** button (*Figure 13* and *Figure 20*) until the air is purged from the tubing set (no air is visible) and the bubble alarm is automatically cleared. Reconnect the tubing set to the catheter, if disconnected.
3. Press and hold **PUR E** again (*Figure 13* and *Figure 20*), ensuring that there is no air in the tubing set and catheter.
4. Verify flow from the catheter tip before reinsertion.

   Warning: The irrigation pump stops flow automatically when air is detected in the line or in case of other operational errors. When the pump alarm indicates flow has stopped, ensure that energy delivery has been terminated. If irrigation flow cannot be restored immediately, remove the ablation catheter from the patient until irrigation flow is resumed.

7.5 Energy delivery

- Energy delivery parameters can be viewed and modified via the touchscreen on the RF generator (*Figure 8*). The RF home screen is shown in *Figure 13*.
- When the remote control is used, the touchscreen on the remote control presents the same user interface as the RF (*Figure 10*). Only one interface, called the primary interface, can be used to select and configure ablation parameters. The other interface, called the secondary interface, acts as a passive display.
- A set of ablation parameters can be selected from the list of saved presets. To select an ablation preset, touch one of the preset buttons at the bottom of the touchscreen. The selected preset will be highlighted with a colored border (*Figure 13*). A green border indicates PF energy. An orange border indicates RF energy.
- To adjust a parameter, touch that parameter. The rotary dial to the right of the touchscreen will illuminate in the color of the selected parameter. Rotate the dial and press to apply the adjusted parameter.
- Use the touchscreen and rotary dial to:
  - Set the **Level Limit** for either PF or RF ablation. PF **Level Limit** is expressed as a percentage of maximum current (A). R **Level Limit** is expressed as a percentage of maximum squared current (A^2).
  - Set the **Target Temperature** (°C) for temperature-controlled RF ablation.
  - Set the **Duration** (s) for RF ablation.

Figure 13. RF generator home screen with an RF ablation preset selected



1 Catheter preparation sequence button
2 Purge button
3 Target duration of selected preset
4 Target temperature of selected preset
5 Level limit of selected preset
6 Settings icon
7 Notifications icon
8 Deselect all presets

- The foot pedal can be used to toggle between two predefined presets. Press and release the foot pedal twice in rapid succession (double-tap) to toggle. Visually verify the settings on the screen before delivering energy.

  Note: When the Affera ablation system is ready for ablation, the rotary dial and the Start/Stop button are illuminated in green.

- Energy delivery can be started and stopped in one of two ways:
  - Press the Start/Stop button on the R (*Figure 8*) or the remote control (if connected and in use; *Figure 10*) once to initiate the delivery sequence. Energy delivery will continue up to the target duration. Press the Start/Stop button again to stop delivery of energy before the target duration has elapsed.
  - Depress and hold the foot pedal to initiate the delivery sequence, and release the foot pedal at any time to stop delivery of energy. With the foot pedal depressed, energy delivery will end automatically when the target duration is reached.

  Note: Once the delivery sequence has been initiated, the irrigation pump will play a sound indicating the sequence has started. The sound from the irrigation pump is unique for RF or PF ablation. When energy delivery begins, the RF will play a sound that is unique for RF or PF ablation.

Note: During energy delivery, the rotary dial and Start/Stop button are illuminated in blue. If energy delivery is terminated by the Affera ablation system for any reason, the rotary dial and Start/Stop button are illuminated in red.

Warning: Once the Start/Stop button is pressed, energy delivery will continue until the energy delivery sequence is completed or until the Start/Stop button is pressed a second time. Use caution manipulating the ablation catheter when delivering energy.

- Ablation parameters are displayed on a graph on the touchscreen interface during the energy delivery sequence, and remain on the screen until either the next delivery sequence is initiated or the touchscreen or rotary dial are used to change parameters. f in use, the remote control displays the same information.
- RF and PF energy delivery are differentiated by unique audible tones.

Warning: Neuromuscular stimulation may occur during PF energy delivery. f patient movement occurs, verify the catheter position.

7.6 System shutdown

- Ablation energy can be terminated during delivery by pressing the Start/Stop button on the RF generator (*Figure 8*) or the remote control (if connected and in use; *Figure 10*) or by pressing and releasing the foot pedal.
- rrigation delivery can be stopped by pressing the Start/Stop button on the irrigation pump (*Figure 9*).
- Power off each unit using the power switch on the back panel (*Section 6.2*). Power off the remote control by pressing the power button on the back panel (*Figure 6*).

8 Graphical user interface

8.1 HexaGen RF generator and remote control

The RF generator (RFG) provides a single user interface for controlling RF delivery, PF delivery, and irrigation.

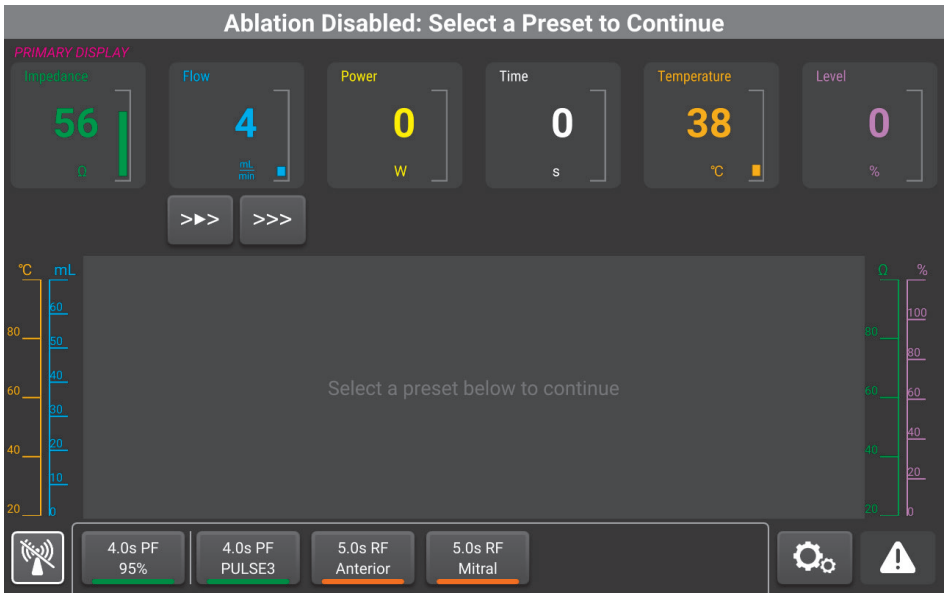
Note: The screen images shown in this user manual are representative of what is seen on-screen with the software; actual images may differ slightly. Bold text on software elements indicates that the term is referenced on-screen.

If the remote control is in use and connected, the remote control touchscreen presents the same user interface as the RF . The RFG and the remote control both display ablation settings and ablation-related measurements, but only one user interface may be defined as the primary interface, which can be used to modify ablation settings. The other user interface acts as a secondary interface for passive display. The user interface selected as the primary interface can be changed through the settings screen as further described in *Section 8.1.2*.

8.1.1 Home screen

The RF generator touchscreen interface home screen is shown in *Figure 14*. From this screen, the user can select ablation presets, manually adjust ablation parameters, view and clear notifications, and access the settings screen.

Figure 14. RF generator home screen



Status bar

The status bar at the top of the home screen displays the energy delivery state of the Affera ablation system (*Figure 13*, *Figure 14*). A colored border at the bottom of the status bar indicates the selected energy type (*Figure 13*), with orange indicating RF energy and green indicating PF energy. When energy is delivered, the status bar shows the progress through the energy delivery sequence.

Parameter displays and controls

Several ablation-related measurements, ablation settings, and controls are presented at the top of the home screen, below the status bar:

- **mpedance**: This element shows the real-time ablation circuit impedance (Ω) measured between the ablation electrode and the return electrodes. Impedance is displayed in green.
- **Flow**: This element shows the real-time flow rate (mL/min) being delivered by the irrigation pump. Flow is displayed in cyan (light blue).
  - ust below this element are buttons that can be used to initiate the **CATHETER PREPARATION SEQUENCE** and to **PUR E** .
- **Power**: During RF delivery, this element shows the real-time power (W) being delivered by the RF generator. Power is displayed in yellow. This element does not display a value during PF ablation.
- **Time**: This element shows the elapsed energy delivery duration (s). Time is displayed in white.
  - When a preset is selected, the target duration of the selected preset is shown at the lower left (see *Figure 13*).
  - When an RF ablation preset is selected, this element can be highlighted via the touchscreen interface, and the target duration can be adjusted using the rotary dial.
- **Energy**: At the conclusion of RF delivery, this element shows the energy delivered ( ). Energy is displayed in yellow. This element does not display a value during PF ablation.
- **Temperature**: This element shows the real-time temperature (°C) measured with the ablation catheter. For catheters with multiple temperature sensors such as the Sphere-9 catheter, the displayed temperature is the maximum across the multiple temperature sensors. Temperature is displayed in orange.
  - When an RF ablation preset is selected, the target temperature for the selected preset is shown in the lower left (see *Figure 13*). For more information on ablation presets, see *Section 8.1.2*.
  - When an RF ablation preset is selected, this element can be highlighted via the touchscreen interface, and the target temperature can be adjusted using the rotary dial.

- **Level**: This element shows the real-time current level (%) being delivered by the RF generator or the PF generator. During RF ablation, level is reported as a percentage of the maximum current squared (A^2). During PF ablation, level is reported as a percentage of the maximum current (A). Level is displayed in purple.
  - When a preset is selected, the level limit is shown in the lower left (see *Figure 13*). or more information on ablation presets, see *Section 8.1.2*.
  - When a preset is selected, this element can be highlighted via the touchscreen interface, and the level limit can be adjusted using the rotary dial.

When using the rotary dial to adjust a highlighted ablation parameter, the rotary dial must be pressed to apply the new value. If the rotary dial is not pressed, the new value will not be applied.

Note that modifying an ablation parameter on the home screen automatically updates the manual preset to match the modified ablation parameters and activates the manual preset. See the following sections for more information regarding presets.

Parameters displayed at the top of the home screen, including measured and control values, are provided to the connected compatible mapping system for secondary display.

Ablation graph

The ablation graph is a visual display of ablation-related parameters over time. The ablation graph appears in the middle of the home screen. When an ablation preset is selected, an outline of anticipated values (target or maximum) for control parameters is displayed on the graph. When ablation is started, measured values are plotted in real time. our parameters are graphed in real time in this graph:

- **Temperature** (°C) is plotted in orange, with a vertical axis to the far left of the ablation graph. or catheters with multiple temperature sensors such as the Sphere-9 catheter, the maximum sensor temperature is plotted in bright orange, and the other sensor temperatures are plotted in dark orange.
- **Flow** (mL/min) is displayed in cyan (light blue), with a vertical axis directly to the left of the ablation graph (units abbreviated to " mL").
- **mpedance** (Ω) is displayed in green, with a vertical axis directly to the right of the ablation graph.
- **Level** (%) displayed in purple, with a vertical axis to the far right of the ablation graph.

Information in the ablation graph is also provided to the connected compatible mapping system for secondary display.

Presets

Presets allow the user to apply a set of predefined ablation parameters. Selectable presets are displayed at the bottom of the home screen. RF presets have a dark orange bottom border and are outlined in the same dark orange color when active. PF presets have a green bottom border and are outlined with the same green color when active.

Presets can be selected in two ways:

- Press the corresponding button at the bottom of the home screen on the touchscreen interface, activating the selected preset. This can only be done using the primary interface.
- Press and release the foot pedal twice in rapid succession (double-tap) to toggle between two predefined presets labeled with the foot pedal symbol (*Figure 16*). Presets available for toggling with the foot pedal are defined in the preset settings (*Section 8.1.2*).

Up to five predefined presets can be displayed at the bottom of the home screen. The presets displayed on the home screen – and therefore available for use – are defined in the preset settings (*Section 8.1.2*).

In addition to predefined presets, an additional manual preset is always displayed at the far left of the presets on the home screen. When a predefined preset is active, if any parameters are modified using the controls on the home screen, the predefined preset is deactivated, and the manual preset becomes active. This allows the user to select the modified parameters again at a later time. Note that selecting another predefined preset and modifying the parameters will overwrite the manual preset.

The button at the far bottom left of the home screen deselects all presets, disabling ablation. In order to ablate, a preset must be selected as described above.

Notifications

Affera ablation system notifications are displayed at the bottom right of the Home Screen. The RF generator touchscreen interface displays notifications from the RFG, the P , and the irrigation pump. Affera ablation system notifications are also provided to the connected compatible mapping system for secondary display.

Pressing the notifications button at the bottom right corner of the home screen displays the active notifications. There are three color-coded notification categories:

- Critical notifications are displayed with a red background.
- Warning notifications are displayed with a yellow background.
- Information notifications are displayed with a blue background.

Each notification is initially displayed with a short title. Pressing a notification expands it to reveal more details and troubleshooting steps. f a notification is resolved or does not require further action, it can be cleared by pressing the reset warnings button.

8.1.2 Settings screen

The settings screen can be accessed by pressing the settings icon at the bottom of the home screen, to the right of the presets. This screen displays system information and allows adjustment of system settings including limits, ablation control parameters, display brightness, audio volume, and the primary interface. The settings screen is comprised of several tabs, each of which is described in more detail in the following section.

Note: Ablation is disabled while the settings screen is open.

To modify a user-adjustable parameter in any of the settings screen tabs, start by pressing the current value. If the parameter has only two states, pressing it toggles the parameter value. If the parameter is a text field, a keyboard will open on the touchscreen interface to allow text to be entered. If the parameter is a numeric value, the value can be increased or decreased by pressing the arrow buttons; alternatively, pressing the value again will open a keypad for direct entry of the new value. Note that parameter values that are outside the minimum or maximum range allowed by the system cannot be entered.

General tab

The **General** tab of the settings screen is shown in *Figure 15*. This tab includes two sections:

- **Limits** define the impedance and temperature ranges within which ablation delivery is allowed. Parameters and limits are listed in *Table 5*.
- **Axis Settings** define the vertical axis ranges for the ablation graph. Parameters and limits are listed in *Table 6*.

All user-configurable settings on the **General** tab can be reset to default values using **Reset to Factory** on the **System** tab (*Figure 19*).

Figure 15. RF generator settings screen - **General** tab

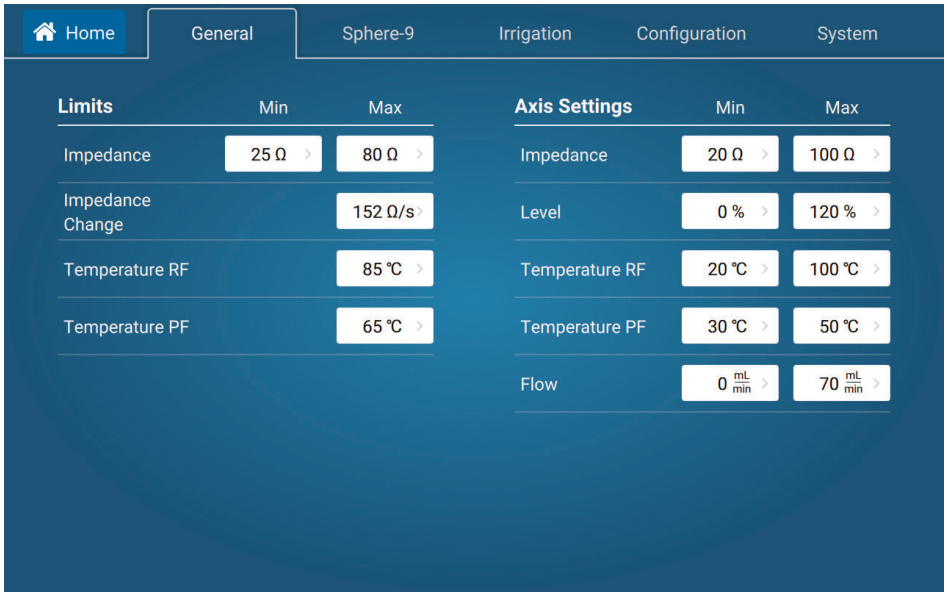


Table 5. RF generator settings screen - **General** tab - **Limits**

Parameter	Description	Lower Limit	Upper Limit

Table 5. RF generator settings screen - **General** tab - **Limits** (continued)

Minimum **mpedance** (Ω)	Energy delivery is stopped or prevented when the ablation circuit impedance is outside the range of values selected for minimum and maximum.	25 Ω	60 Ω
Maximum **mpedance** (Ω)		60 Ω	80 Ω
mpedance Change (Ω/s)	Energy delivery is stopped if the ablation circuit impedance changes faster than the rate selected between these values.	0 Ω/s	300 Ω/s
Temperature RF (°C)	RF delivery is stopped if the maximum catheter temperature measurement exceeds the value selected within this range.	40 °C	85 °C
Temperature P (°C)	PF delivery is stopped if the maximum catheter temperature measurement exceeds the value selected within this range.	40 °C	65 °C

Table 6. RF generator settings screen - **General** tab - **Axis Settings**

Parameter	Description	Lower Limit	Upper Limit
mpedance (Ω)	Ablation graph axis range for impedance	0 Ω	150 Ω
Level (%)	Ablation graph axis range for level	0%	150%
Temperature R (°C)	Ablation graph axis range for temperature during RF ablation	0 °C	100 °C
Temperature P (°C)	Ablation graph axis range for temperature during PF ablation	0 °C	100 °C
Flow (mL/min)	Ablation graph axis range for flow	0 mL/min	80 mL/min

Sphere-9 preset tab

The preset tab is used to view and configure ablation presets. All ablation presets, including the manual preset, are listed along the left side of the tab. Except for the manual preset, all presets can be re-ordered in the vertical list by pressing and dragging the three horizontal lines next to the preset name. A preset can be selected for editing by pressing the item in the list.

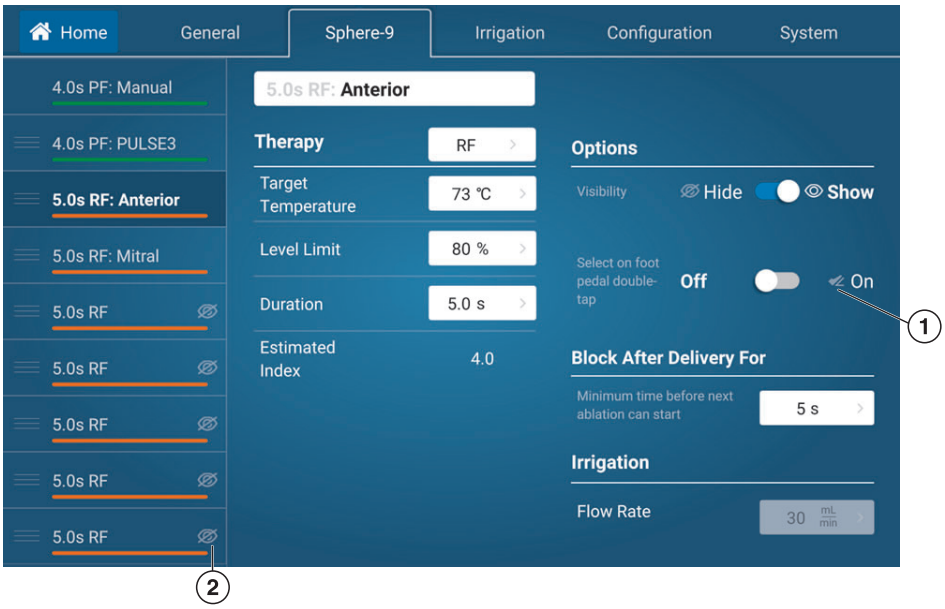
The preset labels on the left side of this tab provide basic information about each corresponding preset including delivery duration and energy type (RF or P). ollowing the duration and energy type, the user-defined preset label is shown. To the right of the user-defined label, icons indicate if the preset is hidden from the home screen or can be selected using foot pedal double-tap (*Figure 16*). (Presets without one of these icons are shown on the home screen and cannot be selected using foot pedal double-tap.) PF presets are underlined in green, while RF presets are underlined in orange.

Ablation parameters and user interface options are displayed to the right for the selected preset (*Figure 16*). The Affera ablation system comes with factory default ablation presets, which can be restored at any time using **Reset to Factory** on the **System** tab (*Figure 19*). Some preset parameters can be configured by the user.

Preset parameters include the following:

- The preset label can be edited at the top.
- **Therapy** includes energy delivery parameters such as **Duration**, **Level Limit**, and **Target Temperature** (for RF only).
- **Options** includes a control for preset visibility on the home screen and the option to select with foot pedal double-tap. Note that only five presets can be visible on the home screen, and only two presets can be toggled with the foot pedal. If the controls for visibility or foot pedal selection are disabled, it may be necessary to disable the corresponding option on another preset.
- **Block After Delivery or** specifies the minimum time after energy delivery ends before the next ablation sequence can begin. This is also the minimum duration over which increased irrigation flow is maintained after energy delivery ends.
- **rrigation** shows the irrigation flow rate during energy delivery.

Figure 16. RF generator settings screen - Sphere-9 preset tab



1 oot pedal symbol

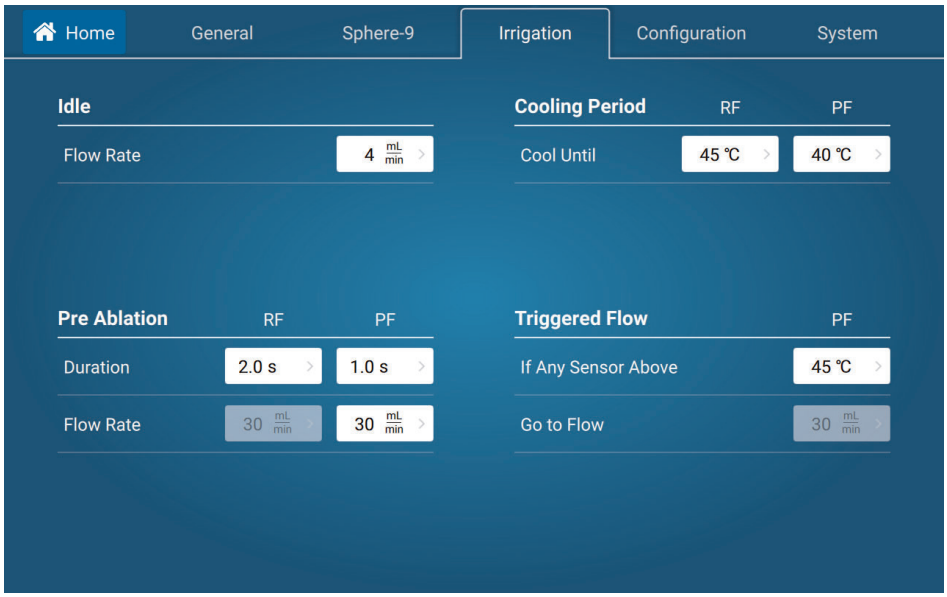
2 con indicating preset is hidden from home screen

rrigation tab

The **rrigation** tab (*Figure 17*) is used to view and configure irrigation pump parameters that apply to all ablation presets. This tab includes the following parameters:

- **dle Flow Rate** is the flow rate of the irrigation pump when not ablating (mL/min).
- **Cooling Period** maintains the irrigation rate from the end of energy delivery, past the minimum period specified in **Block After Delivery or**, until the temperature measured by the compatible ablation catheter falls below the **Cool Until** threshold (°C). The next ablation sequence cannot begin until the temperature falls below the **Cool Until** threshold.
- **Pre Ablation** is the time period after the ablation sequence has been initiated but before energy delivery begins. During this period, which is specified by **Duration** (s), the irrigation rate of the irrigation pump is increased to the rate specified in **Flow Rate** (mL/min).
- **Triggered Flow** increases the irrigation rate during energy delivery if the specified criterion is met. If the temperature measured by any temperature sensor on the compatible ablation catheter exceeds the value in **If Any Sensor Above** (°C), the irrigation rate increases to the value in **Go to Flow** (mL/min). Once triggered, the increased irrigation is maintained through the rest of the ablation sequence.

Figure 17. RF generator settings screen — **rrigation** tab



Configuration tab

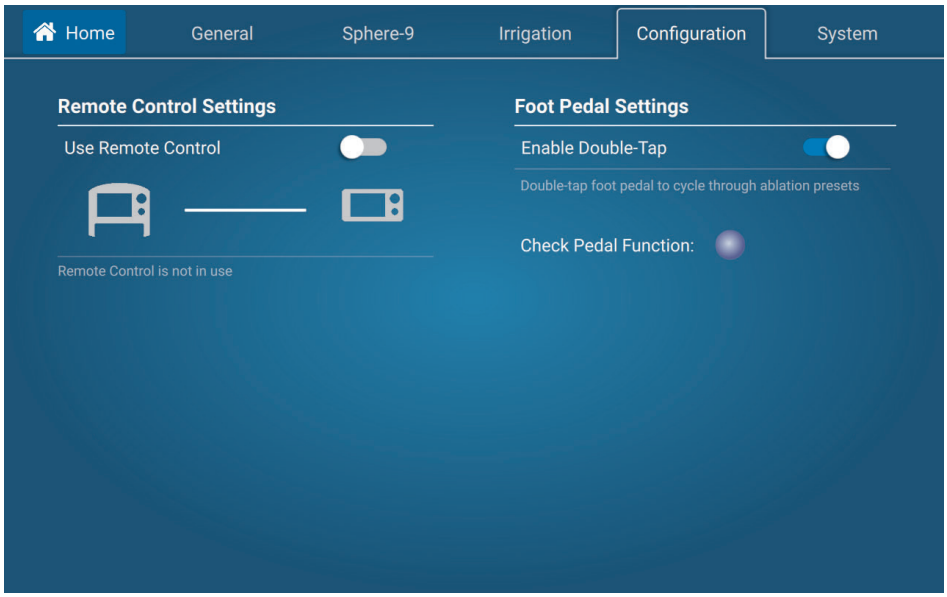
The **Configuration** tab (*Figure 18*) is used to view and configure settings related to the remote control and the foot pedal:

- **Remote Control Settings** includes controls for enabling use of the remote control (by toggling **Use Remote Control** on the RF generator) and, once enabled, for becoming the primary interface. The control for becoming the primary interface is only available when **Use Remote Control** is enabled on the RF and the remote control is communicating with the RF . The control for becoming the primary interface appears on the unit that is currently the secondary interface; the primary interface does not have a control for becoming the secondary interface.

  Note: If the remote control is being used and communication with the remote control is lost, a notification will appear on the RF generator, and ablation will be disabled.

- **oot Pedal Settings**:
  - A switch allows the user to **Enable Double-Tap** for toggling ablation presets.
  - The **Check Pedal Function** indicator is used for testing the foot pedal. If it is connected and functioning properly, pressing the foot pedal will cause the indicator to turn green.

Figure 18. RF generator settings screen — **Configuration** tab

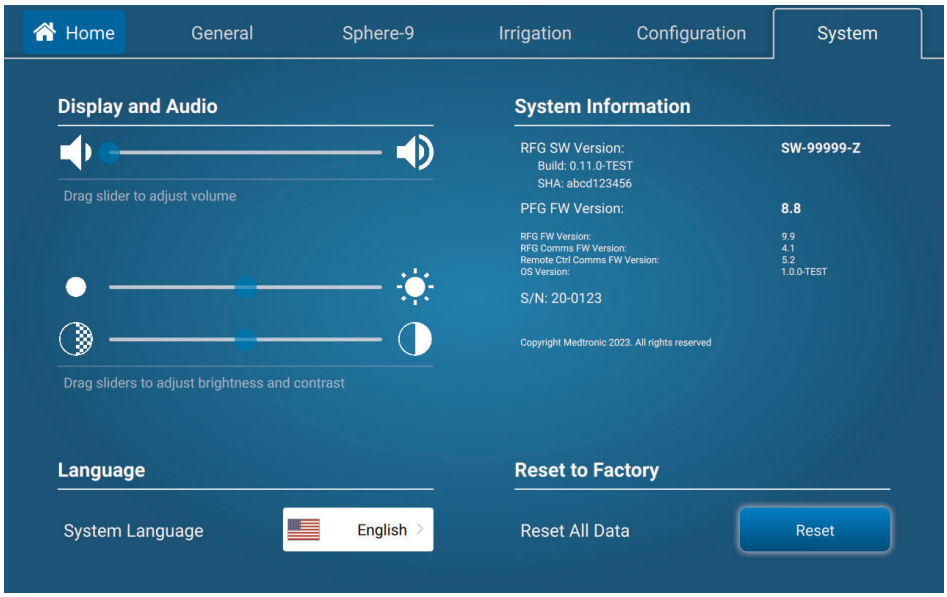


System tab

The **System** tab allows display and configuration of local system information and settings:

- **Display and Audio** includes controls for audible notification volume as well as display brightness and contrast. These settings apply only to the unit on which they are shown; they do not apply to other components of the Affera ablation system.
- **System Information** shows the software versions that are currently installed on the RF generator, the remote control, and the PF generator.
- **Language** is used to choose the language for the generator touchscreen interface.
- **Reset to Factory** can be used to reset all manually configured settings within the generator. Settings are restored to the factory default state. This includes but is not limited to presets, foot pedal settings, volume, and brightness.

Figure 19. RF generator settings screen — **System** tab



8.2 HexaFlow irrigation pump

The irrigation pump provides a touchscreen user interface that can be used for setting up the pump and tubing set at the beginning of the procedure.

8.2.1 Home screen

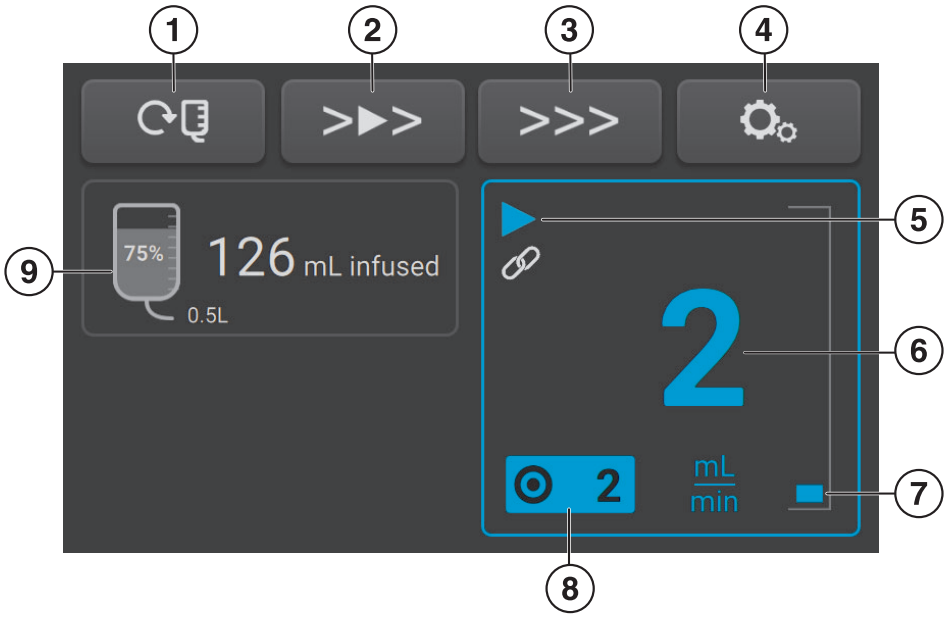
The irrigation pump home screen is shown in *Figure 20*. rom this screen, the user can reset the bag volume counter, start the catheter preparation sequence, run at purge speed, view notifications, and access the settings screen.

8.2.2 Settings screen

The irrigation pump settings screen is shown in *Figure 21* and includes two tabs:

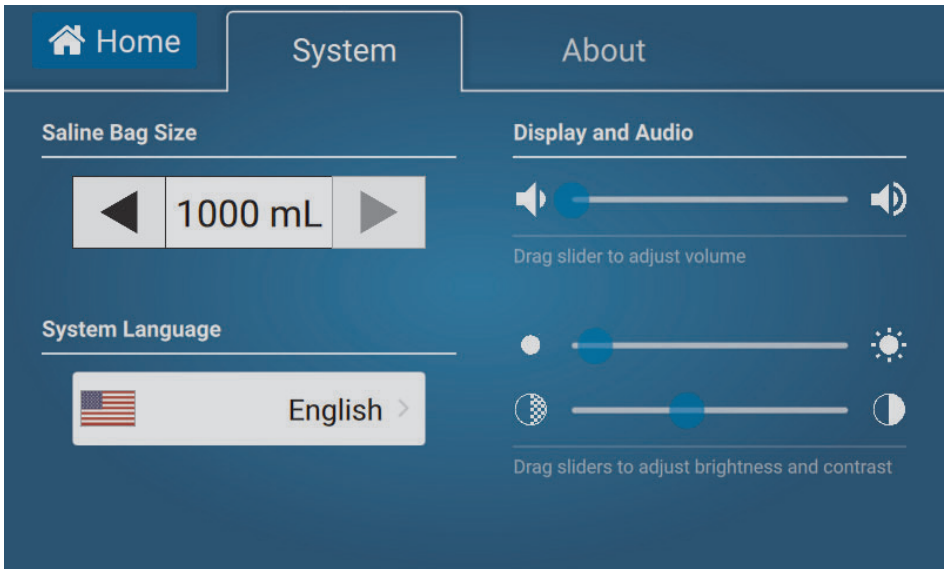
- The **System** tab includes controls for changing the **Saline Bag Size** (used for the bag volume counter on the home screen), configuring the touchscreen display contrast and brightness, and adjusting audible notification volume.
- The **About** tab shows the software version that is currently installed on the irrigation pump.

Figure 20. Irrigation pump home screen



1 Volume counter reset
2 Catheter preparation sequence button
3 Purge button
4 Settings screen
5 Status: running, connected
6 low rate, numeric
7 low rate, graphical
8 Target flow rate
9 Display volume infused, and remaining

Figure 21. Irrigation pump settings screen



9 Security and privacy

9.1 Overview

The Affera ablation system is a closed system that is not intended for external connection to other systems within the hospital environment.

Caution: Do not connect ethernet ports of the Affera ablation system to the hospital network or to another computing device other than those explicitly specified in this manual.

9.2 Networking

The ethernet connections on the Affera ablation system may be used exclusively for the following purposes:

- for connection between the HexaGen remote control or RF generator components per *Section 6.4*
- for connection to a compatible Affera mapping system per *Section 6.4*
- by authorized Medtronic service personnel to deliver software updates to the ablation system

The ethernet connections on the Affera ablation system are protected by a firewall with all unnecessary ports closed and open ports requiring authentication. Ethernet communication packets between the RF generator and remote control are encrypted.

9.3 Pin codes

Access to the system requires a 4-digit pin code entry on the RF generator touchscreen that prevents unauthorized access. The pin code can be configured by Medtronic personnel to be unique for the site, according to the Field Service Manual.

9.4 Patient records

The Affera ablation system does not collect or process patient records. When connected to an Affera mapping system via ethernet, ablation data is transmitted to the mapping system. Ablation system logs capture errors, maintenance, and general system performance. The logs are transmitted to the mapping system when connected. or further information on how such telemetry or logs may be stored as a patient record in the mapping system, refer to the Affera Prism-1 Mapping Software Manual.

9.5 Security events

If you experience a security event, contact Medtronic customer support. If you believe that you have identified a potential security vulnerability involving the Affera ablation system, consult the Medtronic Coordinated Disclosure Process website at www.medtronic.com/security to report your concerns.

10 Periodic maintenance and service

10.1 System cleaning

Before cleaning, all components of the system must be turned off and disconnected from mains power.

If cleaning is needed or desired, use a dry microfiber cloth to clean the touch screen of the RF generator, the remote control, and the irrigation pump.

Use a dampened, lint-free cloth to clean the housing of the RF generator, the remote control, the PF generator, and the irrigation pump. Common hospital cleaning solutions may be used, such as 2% glutaraldehyde solution, green soap, 10% bleach solution, or 70% isopropyl alcohol. Ensure no liquid penetrates the inside of the RF generator, the remote control, the PF generator, or the irrigation pump.

10.2 Periodic maintenance

The Affera ablation system requires no periodic maintenance. An electrical safety inspection must be performed at least once every two years in regions where local regulations require periodic inspections, and must be performed after any repair, in accordance with IEC/EN 60601-1 and IEC/EN 62353.

10.3 Service and repairs

The Affera ablation system has no user-serviceable parts other than fuses described on the unit back panel.

The system should no longer be used when material or performance degradation is identified or suspected. Contact Medtronic for service.

To ensure safe operation of the Affera ablation system, repairs may only be performed by those authorized by Medtronic. Contact Medtronic for service.

10.4 Disposal

To dispose of any electronic or electrical components from the system, contact Medtronic customer support for the appropriate disposal procedure.

11 Technical description

11.1 Technical specifications

Table 7. Affera ablation system technical specifications

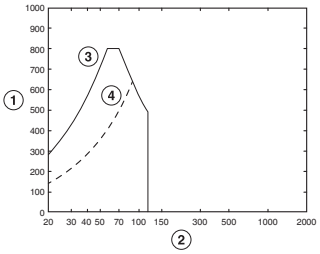
Technical Specifications	
HexaGen RF Generator	
RF power output frequency	488 kHz
RF output voltage	0 - 240 V_{RMS}
RF output current	0 - 3.75 A_{RMS}
RF impedance operating range	20-120 Ω
RF impedance monitoring	8.5 µA, 488 kHz
RF impedance display accuracy	10%
Return electrode contact quality monitoring	9 µA, 61 kHz
Temperature operating range	20-100 °C
Temperature measurement display accuracy	20-60 °C ± 1 °C 61-100 °C ± 2 °C
RF power display accuracy	10%
RF energy display accuracy	10%
RF level (% of max I^2) display accuracy	8%
Mains power	100-240 VAC, 50/60 Hz, 1200 VA
Weight	17 kg
Operational limits	Continuous operation at 50% output level; operation at 100% output level and 50% duty cycle
Ingress protection rating	PX0 (non-protected)
HexaPulse PF Generator	
PF output voltage (peak)	3333 Vpeak
PF output current (peak)	57 A
PF impedance operating range	20 - 120 Ω
PF level (% of max Ip-p) display accuracy	10%
Mains power	100-240 VAC, 50/60 Hz 300 VA
Weight	11 kg
Operational limits	Continuous operation at 50% output level; operation at 100% output level and 50% duty cycle
Ingress protection rating	PX0 (non-protected)

Table 7. Affera ablation system technical specifications (continued)

Technical Specifications	
HexaFlow Irrigation Pump	
Flow rate	0-55 mL/min
Air bubble detection	≥2 µL
Maximum output pressure (occlusion)	110 psi
Flow rate accuracy	2-5 mL/min ± 1 mL/min 6-30 mL/min -5% / +15% 31-55 mL/min ± 25%
Mains power	100-240 VAC, 50/60 Hz 150 VA
Weight	11 kg
Ingress protection rating	PX0 (non-protected)
HexaGen Remote Control Power Supply	
Remote control power supply input	100-240 VAC, 50/60 Hz 60 VA
Remote control power supply output	24 VDC 2.5 A Medical grade isolation
Environmental Conditions	
Ambient environmental operating conditions	15 °C to 30 °C 30% to 75% relative humidity (non-condensing)

11.2 RF output characteristics

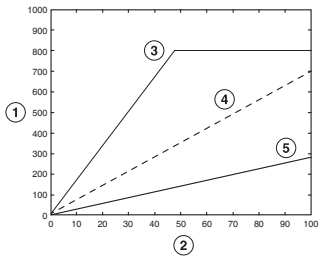
Figure 22. RF generator output power vs. load impedance



1 Output power [W]
2 Load impedance [Ω]
3 Level = 100%
4 Level = 50%

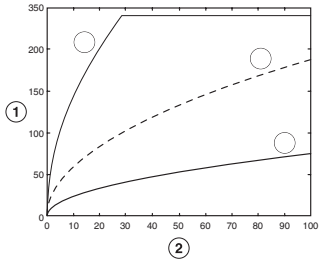
Note: Power delivery is prevented above 120 Ω.

Figure 23. RF generator output power vs. control setting



1 Output power [W]
2 Level [%]
3 Load = 120 Ω
4 Load = 50 Ω
5 Load = 20 Ω

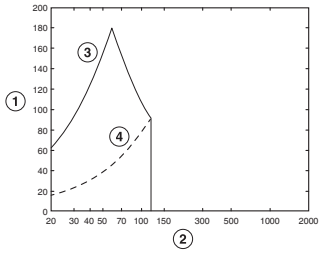
Figure 24. RF generator output voltage vs. control setting



1 Peak output voltage [V]
2 Level [%]
3 Load = 120 Ω
4 Load = 50 Ω
5 Load = 20 Ω

11.3 PF output characteristics

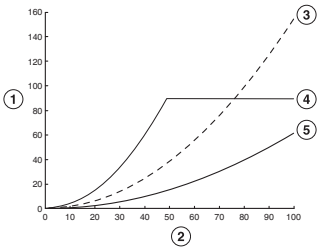
Figure 25. PF generator output power vs. load impedance



1 Output power [W]
2 Load impedance [Ω]
3 Level = 100%
4 Level = 50%

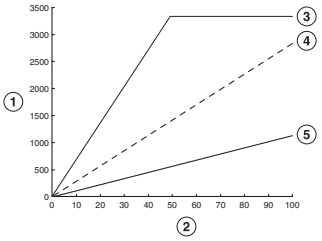
Note: Power delivery is prevented above 120 Ω.

Figure 26. PF generator output power vs. control setting



1 Output power [W]
2 Level [%]
3 Load = 50 Ω
4 Load = 120 Ω
5 Load = 20 Ω

Figure 27. PF generator peak output voltage vs. control setting



1 Peak output voltage [V]
2 Level [%]
3 Load = 120 Ω
4 Load = 50 Ω
5 Load = 20 Ω

11.4 Use environment and electromagnetic compatibility (EMC)

The Affera ablation system is intended for use in a cardiac catheterization laboratory or surgical suite environment by trained personnel only. The Affera ablation system can be stacked with the Affera mapping system HexaMap CIU on the system cart.

Caution: The Affera ablation system conforms to the requirements of the EMC standard IEC/EN 60601-1-2:2014: AMD:2020 and is qualified for operation in an environment in which radiated RF disturbances are controlled. The limits are designed to provide reasonable protection against interference; however, interference by other equipment in close proximity may occur, resulting in errors that may delay the procedure. If interference from other equipment is suspected, or if interference from the Affera ablation system is suspected to affect other equipment, relocate the Affera ablation system to maximize its distance from other equipment.

Table 8. Electromagnetic emissions environment

The Affera ablation system is intended for use in the electromagnetic environment specified below. Users should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR11	Group 2	The Affera ablation system must emit RF energy for its intended function. Nearby electronic equipment may be affected. If necessary, increase the distance between the Affera ablation system and the affected electronic equipment to reduce interference.
RF emissions CISPR11	Class A	The emissions characteristics of the Affera ablation system make it suitable for use only in industrial areas and hospitals.
armonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

The Affera ablation system generates the following frequencies for its operation:

- 488 kHz patient impedance monitoring between the catheter and return electrodes
- 61 kHz return electrode contact quality monitoring

Table 9. Electromagnetic immunity environmental guidance

The Affera ablation system is intended for use in the electromagnetic environment specified below. Users should assure that it is used in such an environment.			
Immunity Test	**EC 60601 Test Level**	**Compliance Result**	**Electromagnetic Environment - uidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 15 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV on AC mains 1 kV on signal and control lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV Differential 2 kV Common	Complies	Mains power quality should be that of a typical commercial or hospital environment.

Table 9. Electromagnetic immunity environmental guidance (continued)

Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	Drop to 0 V for 0.5 Cycle Drop to 0 V for 1 Cycle 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Complies	Mains power quality should be that of a typical commercial or hospital environment. f the use of the Affera ablation system requires continued operation during power mains interruptions, it is recommended that system be powered from an uninterruptible power supply or battery. Tested at 100 VAC/60 Hz and 240 VAC/50 Hz
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	30 A/m	Complies	Magnetic fields should be that of a typical location in a typical hospital environment. IF electromagnetic interference (EMI) occurs, it may be necessary to position the Affera ablation system further from sources of magnetic fields or to install magnetic shielding.
Proximity magnetic fields IEC 61000-4-39	30 kHz, 8 A/m, CW 134.2 kHz, 65 A/m, Pulse (2.1 kHz square wave) 13.56 MHz, 7.5 A/m, Pulse (50 kHz square wave)	Complies[1]	

[1] Not tested at 30 kHz as that test level is only applicable to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

Warning: The Affera ablation system may be interfered with by other equipment, even if the other equipment complies with CISPR emission requirements. System operation may be temporarily interrupted if exposed to excessive external electromagnetic disturbance or ESD. In case system operation is interrupted, such as loss of signal acquisition or an error message, reboot the system by cycling mains power to fully restore system operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the Affera ablation system, including cables specified by the manufacturer. Refer to the information provided in *Table 10* to ensure minimum safe operating distance is observed otherwise degradation of the performance of this equipment could result.

Table 10. Recommended separation distances between portable and mobile R communications equipment

The Affera ablation system is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Affera ablation system as recommended below, according to the maximum output power of the communications equipment.

Immunity Test	**EC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - uidance**
Conducted RF IEC 61000-4-6	3 V_{RMS}, 6 V_{RMS} from 150 kHz to 80 MHz 80% AM at 1 kHz	Complies	Portable and mobile RF communications equipment should be separated from the Affera ablation system by no less than the recommended separation distances calculated/listed below: $D = (3.5/3)\sqrt{P}$ 150 kHz to 80 MHz $D = (3.5/3)\sqrt{P}$ 80 M z to 800 M z $D = (7/3)\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum power rating in watts and *D* is the recommended separation distance in meters.
Radiated R IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	Complies	
Radiated R proximity fields IEC 61000-4-3	See *Table 11*	See *Table 11*	

Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less that the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter, which is marked by the following symbol:

Maximum Output Power of Adjacent Communications Equipment (W)	**Recommended Separation Distances** (m)		
	150 kHz to 80 MHz $D = 1.1667\sqrt{P}$	80 to 800 MHz $D = 1.1667\sqrt{P}$	800 MHz to 2.5 GHz $D = 2.3333\sqrt{P}$
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.378
100	11.667	11.667	23.333

Table 11. Radiated RF Frequency Proximity IEC 61000-4-3 Immunity Levels

Spot Frequencies	**mmunity Test Level (V/m)**	**Modulation Parameters**	**Compli-ance Result**
385 MHz	27	Pulse (18 Hz)[1]	Complies
450 MHz	28	Pulse (18 Hz)[1]	Complies

Table 11. Radiated RF Frequency Proximity IEC 61000-4-3 Immunity Levels (continued)

Spot Frequencies	mmunity Test Level (V/m)	Modulation Parameters	Compli-ance Result
710, 745, 780 MHz	9	Pulse (217 Hz)[1]	Complies
810, 870, 930 MHz	28	Pulse (18 Hz)[1]	Complies
1.720, 1.845, 1.970, 2.450 GHz	28	Pulse (217 Hz)[1]	Complies
5.240, 5.500, 5.785 GHz	9	Pulse (217 Hz)[1]	Complies

[1] The carrier shall be modulated using a 50% duty cycle square wave signal.

11.5 Essential performance

The essential performance of the Affera ablation system is defined as the following:

RF generator and PF generator:

- The essential performance of the RF and PFG is to ensure no unacceptable temperature occurs under the return electrodes by monitoring the heating factor and limiting the current through each return electrode and preventing operation in a high current mode.

rrigation pump:

- The essential performance of the pump depends on the bubble detection scheme to ensure no air is delivered to the patient.

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Medtronic

AFR-00006

Catheter Extension Cable

Instructions for Use

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

Explanation of symbols

Refer to the package and product labels to see which symbols apply to this product and for product-specific information, such as the date of manufacture, manufactured-in location, and use-by date.

MD	Medical device
STERILE EO	Sterilized using ethylene oxide
	Single sterile barrier system
	Do not reuse
	Do not resterilize
	Keep dry
	Do not use if package is damaged
	Use-by date
	Package contents
	Consult instructions for use
www.medtronic.com/manuals	Consult instructions for use at this website
AUS	or Australia/New Zealand audiences only
LOT	Lot number
REF	Catalog number
#	Model number
EC REP	Authorized Representative in the European Community
	Manufacturer
	Date of manufacture
	Manufactured in
CE	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
	mporter
	Catheter extension cable

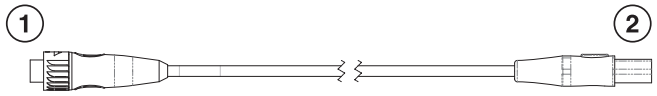
Product documentation

Rx only Caution: ederal law (USA) restricts this device to sale by or on the order of a physician.

Device description

The Medtronic catheter extension cable (A R -00006) is designed to connect a compatible catheter to the exaMap™ catheter interface unit (CIU) and Affera™ ablation system.

Figure 1. Catheter extension cable



1 Circular 52-pole connector (to Affera equipment)
2 Oblong edge card connector (to compatible catheter)

Contents of package

The catheter extension cable is supplied sterile. The package contains the following items:

- 1 model A R -00006 catheter extension cable
- Product documentation

Indications for use

Refer to the instructions for use accompanying the compatible electrophysiology catheter for the specific indications for use.

Contraindications

There are no known contraindications for the use of this cable. Refer to contraindications of the compatible electrophysiology catheter.

ntended users

The intended users are physicians and nurses/EP technicians trained in interventional cardiac electrophysiology (EP).

ntended patient population

Refer to the instructions for use accompanying the compatible electrophysiology catheter for the intended patient population.

Warnings and precautions

- Carefully read all instructions for use of the Affera ablation system, Affera mapping system, and compatible catheter before use. Observe all contraindications, warnings, and precautions noted in the directions. ailure to do so may result in patient complications. Review any applicable product information with the patient, including known risks and contraindications.
- Visually inspect all sterile-barrier packaging before use. f the device is damaged or if the integrity of the sterile barrier has been compromised, do not use the product. Contact your Medtronic representative for return information.
- Position connecting cables to avoid contact with the patient and other electrical leads
- There is no special handling, including no special storage or transport conditions, required for this device. Standard storage conditions are sufficient to safeguard the device. Store the device in the original packaging at room temperature in a dry place.
- The catheter extension cable is packaged and sterilized for single patient use only. Do not reuse, reprocess, or resterilize the device. The device has not been qualified for reuse, reprocessing, or resterilization. Reuse, reprocessing, or resterilization can cause patient infection and compromise device performance and functionality.
- The catheter extension cable is sterilized with ethylene oxide (EO) gas. The pouch contents are sterile unless the package has been damaged or opened.
- The catheter extension cable must be used by the Use-by date printed on the package label. The product and package have been tested to demonstrate sterility and performance if used before the Use-by date printed on the package label. Do not use the cable after the Use-by date.
- The catheter extension cable is intended for use only with compatible Medtronic devices and equipment.
- Cardiac mapping and ablation procedures are to be performed only by physicians trained in electrophysiology procedures in a fully equipped electrophysiology laboratory.
- Do not submerge the cable connectors in any liquid. f the cable connector is wet, do not use the cable.
- Do not expose the device to organic solvents such as alcohol.
- I f you find information in this manual that is incorrect or illegible, contact your Medtronic representative or your local competent medical authority.

- If a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

Potential adverse events

Refer to the instructions for use of the compatible electrophysiology catheter for potential complications and adverse events associated with cardiac mapping and ablation procedures.

Directions for use

On the catheter extension cable (*Figure 1*), the circular 52-pole connector is intended for connection to compatible Affera equipment. To connect, align the key and press the connector into the receptacle. To remove, rotate the outer ring counterclockwise to release the locking mechanism and pull the connector from the receptacle.

The oblong edge card connector is intended for connection to the compatible catheter. Properly orient the connector and press into the catheter handle until the locking mechanism clicks into place. To remove, press the thumb activated release button and pull the connector from the catheter handle.

Note: Refer to the instructions for use or user manual of the compatible catheter and equipment to verify connectivity before use.

Disposal

Dispose of the device and its packaging in accordance with applicable local laws and regulations.

Device compatibility

Use only with the following devices.

Compatible Device	Catalog Number
Sphere-9™ catheter	AR-00001
Affera mapping system	AR-00003
exa en™ RF generator	AR-00004
exaPulse™ PF generator	AR-00008

Specifications

The following table provides the product s physical and performance characteristics.

Length	2 m
Environmental conditions	Store in a cool and dry place. Refer to the *Affera Ablation System User Manual* for the operating environmental parameters of the system.
Sterilization	Single use, sterile device, ethylene oxide

Medtronic warranty

The following Limited Warranty applies to customers within the United States only:

A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic accessory, hereafter referred to as “Product”:

(1) Should the Product fail to function within normal tolerances due to a defect in materials or workmanship on or before its “Use By” or "Use Before" date, Medtronic will at its option: (a) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement product or (b) provide a functionally comparable replacement product at no charge.

(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement product.

B. To qualify for this Limited Warranty, these conditions must be met:

(1) The Product must be used on or before its “Use By” or "Use Before" date.

(2) The Product must be returned to Medtronic within 60 days and shall be the property of Medtronic.

(3) The Product must not have been used for any other patient.

(4) The Product must be used in accordance with the labeling and not altered or subjected to misuse, abuse, accident, or improper handling.

C. This Limited Warranty is limited to its express terms. n particular:

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC S NOT RESPONS BLE FOR ANY DIRECT, NCIDENTAL, OR CONSEQUENT AL DAMA E S BASED ON ANY DEFECT, A LURE, OR MALFUNCTION OF THE Product, WHET ER THE CLA M S BASED ON WARRANTY, CONTRACT, TORT, OR OTHERW SE.

(2) This Limited Warranty is made only to the purchaser of the Product. AS TO ALL OT ER S, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR MPLIED, NCLUDING, BUT NOT LIM TED TO, ANY MPLIED WARRANTY OF MERCHANTABILITY, OR TNESS FOR A PART CULAR PURPOSE WHET ER ARIS NG FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERW SE. NO EXPRESS OR MPLIED WARRANTY TO THE PAT ENT S ALL EXTEND BEYOND THE PERIOD SPECIFIED N A(1) ABOVE. T S LIM TED WARRANTY S ALL BE THE EXCLUSIVE REMEDY AVA LABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. f any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Medtronic to any representation,condition, or warranty except this Limited Warranty. This Limited Warranty is provided by Medtronic, nc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. t applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

General warning

Medtronic accessories are used in the extremely hostile environment of the human body. These Products may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of the Product will not occur, or that the body will not react adversely to the Product, or that medical complications will not follow.

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Medtronic

Sphere-9™ A R -00001

Catheter

nstructions for Use

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

Explanation of symbols

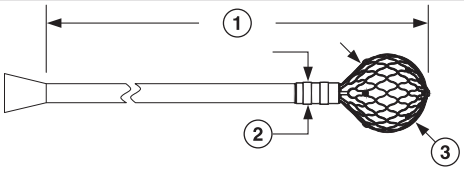
Refer to the package and product labels to see which symbols apply to this product and for product-specific information, such as the date of manufacture, manufactured-in location, and use-by date.

MD	Medical device
STERILE EO	Sterilized using ethylene oxide
	Single sterile barrier system
#	Model number
	Diameter
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Use-by date
	Consult instructions for use
www.medtronic.com/manuals	Consult instructions for use at this website
AUS	or Australia/New Zealand audiences only
LOT	Lot number
REF	Catalog number
	Date of manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
	Keep dry
Rx only	Caution: ederal law (USA) restricts this device to sale by or on the order of a physician.
CE	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
	mporter
	Package contents
	Manufactured in
	Catheter
	Product documentation

Device description

The Sphere-9 catheter (A R -00001) is a steerable, irrigated, multi-electrode catheter with a bidirectional deflecting tip intended for intracardiac mapping and ablation.

Figure 1. Sphere-9 Catheter



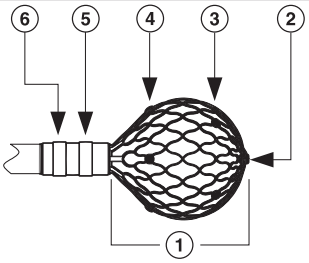
1 Catheter shaft length: 115 cm
2 Catheter diameter: 2.7 mm (8 r)
3 Expandable ablation electrode diameter (expandable to 9.3 mm in the cardiac chamber)

The expandable ablation electrode fits a 2.7 mm (8 r) straight introducer sheath or a 2.8 mm (8.5 r) curved or deflectable sheath, and expands to a 9.3 mm diameter in the cardiac chamber.

The catheter is supplied with an insertion tool that must be used to aid in collapsing the expandable ablation electrode for insertion into an introducer or guiding sheath.

The expandable ablation electrode (electrode E1) contains 9 mini surface electrodes mounted on its surface with roughly 5 mm spacing to collect local electrograms and monitor local impedance. The mini surface electrodes also contain sensors for monitoring local temperature.

Figure 2. Catheter electrodes



1 Expandable ablation electrode “E1”
2 Tip mini surface electrode “t”
3 4 distal mini surface electrodes “d1” - “d4”
4 4 proximal mini surface electrodes “p1” - “p4”
5 Ring electrode “E3”
6 Ring electrode “E4”

A reference electrode (not shown, referred to as electrode “c”) is mounted in the center of the sphere to provide an electrogram reference.

The shaft contains two 2.7 mm (8 Fr) ring electrodes (electrodes E3 and E4) mounted proximal to the expandable ablation electrode with 2 mm center-to-center spacing.

Contents of package

The Sphere-9 catheter is supplied sterile. The package contains the following items:

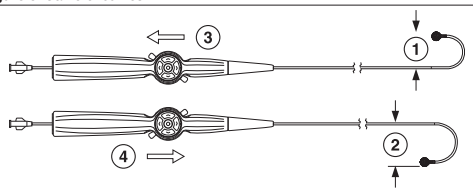
- 1 Sphere-9 catheter with insertion tool
- Product documentation

Performance characteristics

The torque response of the catheter shaft provides the ability to steer the electrodes to any desired location within the heart. The handle provides steering wings to deflect the tip with the thumb and forefinger. Asymmetrical curves are provided.

With the friction control knob facing away from the palm, pulling the steering wings with the right thumb creates a small "D" curve, while pushing the steering wings with the right thumb creates a large "F" curve.

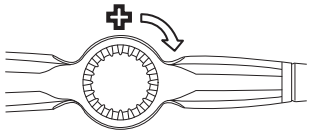
Figure 3. Catheter curves



1 “D” curve
2 “F” curve
3 Pulling steering wings with right thumb creates the smaller “D” curve
4 Pushing steering wings with right thumb creates the larger “F” curve

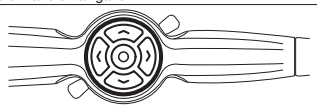
The friction control knob allows adjustable friction on the deflection mechanism to retain deflection as desired. Rotate the knob clockwise to increase friction.

Figure 4. Friction control knob



The handle also provides navigation control buttons which allow remote control of the compatible Affera™ mapping system navigation screen and features.

Figure 5. Catheter handle navigation



The catheter is used in conjunction with a compatible Affera ablation system and appropriate return electrode pads for ablation. All catheter electrodes may be used for recording or stimulation.

A compatible HexaFlow™ irrigation pump and tubing set are used to provide a flow of heparinized saline through the irrigation lumen via a standard luer connector. The flow provides irrigation to the ablation site from a nozzle mounted within the expandable ablation electrode.

The catheter is fitted with electromagnetic location sensors to enable visualization of the catheter tip and deflected curve on the compatible mapping system. The catheter connects to the system via the compatible catheter extension cable.

The mini surface electrode temperature sensors are used by the compatible ablation generator to display local temperature. Refer to the *Affera Ablation System User Manual* for temperature range and accuracy specifications.

Indications for use

The Sphere-9 catheter is indicated for use in cardiac electrophysiological mapping (stimulation and electrogram recording) and for treatment of drug refractory, recurrent, symptomatic persistent atrial fibrillation (episode duration less than 1 year) and radiofrequency ablation of cavotricuspid isthmus dependent atrial flutter when used with the Affera mapping system.

Contraindications

Do not use this device under the following circumstances:

- In patients with an active systemic infection.
- In patients who have had cardiac surgery in the preceding eight weeks, as the risk of perforation may increase.
- In patients with intracardiac thrombus or myxoma, as the catheter may precipitate an embolus.

- In coronary vessels with diameter smaller than the expandable ablation electrode, as the catheter may damage the coronary vessels.
- In patients with prosthetic valves, as the catheter may damage the prosthesis.
- Using the transaortic retrograde approach in patients who have had aortic valve replacement.
- Using the transseptal approach in patients with an interatrial baffle or patch, as the opening could persist and result in an iatrogenic atrial shunt.

ntended users

The intended users are physicians and nurses/EP technicians trained in interventional cardiac electrophysiology (EP).

ntended patient population

The intended patient population is adult patients (patients 18 years or older) undergoing cardiac mapping and ablation procedures.

Warnings and precautions

- The Sphere-9 catheter is intended for single patient use only. Do not reuse, reprocess, or resterilize the device. Reuse, reprocessing, or resterilization of single use devices can cause patient infection and compromise catheter functionality.
- Failure to carefully read all instructions before use, and observe all contraindications, warnings, and precautions provided in these instructions may result in complications. Review any applicable product information with the patient, including known risks and contraindications.
- The catheter is sterilized with ethylene oxide gas and must be used by the Use-by date printed on the package label. Do not use the catheter after the Use-by date.
- Do not attempt to insert the catheter into a sheath without using the insertion tool and following the directions for use provided, as damage to the expandable ablation electrode assembly and/or air embolism may occur.
- Always place the steering wings in the central position to straighten the catheter tip before insertion or withdrawal of the catheter.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Catheter manipulation should be performed under appropriate imaging guidance (e.g., intracardiac echocardiography and/or fluoroscopy) in order to avoid cardiac tissue damage, perforation, or tamponade, especially when used in combination with a long sheath.
- It is recommended to verify compatibility between the sheath and catheter before placing them in the body. The catheter is not compatible with straight sheaths less than 2.7 mm (8 r) in diameter, or fixed curve or deflectable sheaths less than 2.8 mm (8.5 r) in diameter.
- The expandable ablation electrode assembly expands when deployed. To reduce the possibility of tissue damage, retract the expandable ablation electrode assembly into the introducer or guiding sheath before attempting to move the catheter into or out of a chamber or introduction site.
- The use of conventional localization means, such as imaging guidance and electrogram data, to monitor catheter location during manipulation is critical to minimizing the risk of tissue injury. Do not rely solely on the electromagnetic navigation system display.
- The use of heparin is referenced throughout this document with the assumption that when the use of heparin is contraindicated, an acceptable alternative will need to be substituted per institutional guidelines.
- Always maintain a constant infusion of heparinized saline to prevent the formation of coagulation within the lumen of the catheter. Purge air from the irrigation tubing and catheter lumen before inserting the catheter into the patient. Do not purge while the catheter is in the body.
- Intravenous heparin must be used to reduce the likelihood of thromboemboli developing during the procedure. Anticoagulation treatment should adhere to consensus guidelines, including pre- and post-procedure anticoagulation management and administering intravenous heparin during the procedure. Achieve and maintain a minimum active clotting time (ACT) of at least 350 s prior to catheter insertion and throughout the procedure. Monitor the ACT regularly during the procedure.
- Inspect the irrigation supply and tubing for air bubbles before connecting to the catheter. Air bubbles in the irrigation supply may become emboli.
- Monitor the patient s fluid intake to avoid fluid volume overload. Patients with congestive heart failure or renal insufficiency and the elderly are susceptible to complications. dentify the patient s risk of volume overload before the start of the procedure.
- Avoid steering the Sphere-9 catheter in close proximity to other catheters to reduce the possibility of the catheters becoming entangled. Do not use catheters with a tip smaller than 2 mm in diameter in the same chamber as the Sphere-9 catheter.
- Implanted pacemakers and cardioverters/defibrillators (ICDs) can be adversely affected by energy delivery. Temporary external sources of pacing and defibrillation must be made available during ablation procedures. t is advised to temporarily reprogram the pacing system to OFF mode or minimum output and to deactivate cardioverter/defibrillators during the ablation procedure to minimize the risk of inappropriate pacing or shock. t is important to perform a complete implantable device analysis on all patients after ablation.
- Exercise extreme caution when manipulating the catheter in close proximity to pacing and defibrillation leads to avoid damage or displacement of leads.
- Do not deliver energy near other intracardiac devices or when in contact with other cardiac catheters or pacing and defibrillation leads to avoid possible thrombus or inappropriate treatment location.
- Carefully observe the recommended settings in the instructions for use to reduce the risk of delivering excessive energy and causing excessive heating or collateral damage. Excessive ablation duration may also lead to excessive heating or collateral damage.
- Continuously monitor the patient and patient vital signs during the procedure.
- Coagulum formation may not be accompanied by an increase in system impedance. Adherence to ACT goals throughout the procedure is important. f thrombus/coagulum are noted through imaging modalities (ICE for example) the catheter should be removed and inspected.
- Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias. Defibrillation equipment must be available for immediate use in the case of a life-threatening arrhythmia.
- The long-term effects of exposure to ionizing radiation have not been established. Therefore, careful consideration should be given to pregnant patients. Minimize X-ray exposure during the procedure, as significant X-ray exposure could result in acute radiation injury as well as increased risk for somatic and genetic effects to both patients and laboratory staff.
- Cardiac ablation procedures are to be performed only by physicians trained in electrophysiology procedures in a fully equipped electrophysiology laboratory.
- To reduce the risk of shock to the patient, connect the catheter to the system via the extension cable before inserting the catheter into the body.
- If energy delivery is interrupted due to a sudden temperature or impedance rise, the catheter should be removed and inspected.

- Do not scrub or twist the expandable ablation electrode.
- Visually inspect all sterile-barrier packaging before use. f the device is damaged or the integrity of the sterile barrier has been compromised, do not use the product. Contact your Medtronic representative for return information.
- Do not immerse the catheter handle or cable connector in fluids.
- Do not expose the device to organic solvents such as alcohol.
- The Sphere-9 catheter is used in conjunction with a compatible ablation generator capable of delivering significant electrical power. Patient or operator injury can result from improper catheter handling and return electrode placement. During energy delivery, ensure that the patient does not come into contact with grounded metal surfaces.
- Care should be taken when ablating near sensitive structures such as the sino-atrial and atrioventricular nodes, or in locations near adjacent anatomical structures susceptible to collateral damage. Take precautions to avoid collateral damage including pacing to identify the location of the phrenic nerve and using only PF energy near the phrenic nerve or esophagus (along the posterior wall of the left atrium).
- P ablation in areas adjacent to coronary arteries may lead to coronary artery spasm
- I f high catheter impedance or low power delivery is experienced during energy delivery, or if another failure of the ablation system occurs at normal settings, check for faults and verify the proper application and function of the return electrode pads and other electrical cables before continuing power delivery.
- The Sphere-9 catheter has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The safety of the catheter in the MR environment is unknown (such as any heating, migration, or image artifact). Scanning a patient during the use of this device may result in patient injury.
- F lammable gas for anesthesia or other flammable materials must be restricted from the electrosurgical suite to reduce the inherent risk of ignition in electrosurgery.
- Electromagnetic interference (EM) may be emitted from the device when used in conjunction with an ablation generator during normal operation and may adversely affect the performance of other equipment.
- Place surface electrodes and probes for monitoring and stimulation devices as far as possible from the ablation site and from the return electrode pads.
- R catheter ablation in the coronary artery has been associated with myocardial infarction.
- The Sphere-9 catheter is designed for use only with compatible devices. Do not use the catheter with devices other than those listed in the device compatibility table in the *Directions for use, page 7*.
- Manual bending or shaping of the deflectable tip section of the device may cause damage to the internal components or compromise catheter performance and must be avoided.
- Catheter entrapment within the heart is a possible complication of cardiac ablation procedures that could necessitate surgical intervention. There is an increased potential for catheter entrapment when the catheter is positioned in the chordae tendineae.
- When using a deflectable guiding sheath, the sheath must be straight before advancing the catheter through the sheath or retracting the catheter back into the sheath.
- There is no special handling, including no special storage or transport conditions, required for this device. Standard storage conditions are sufficient to safeguard the device. Store the device in the original packaging at room temperature in a dry place.
- I f a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.
- Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

Potential adverse events

Potential adverse events associated with catheter ablation and mapping procedures include, but are not limited to, the following conditions:

Access site complications (e.g. hematoma, laceration, arterio-venous fistula)	ypotension
Allergic reaction (including anaphylaxis)	H ypoxia
Anemia	ncreased creatine phosphokinase (CPK) level
Anesthesia complications	nfection
Arrhythmia (worsening, or outside of diagnosis, or life-threatening)	Myocardial infarction
Atrioesophageal fistula	Muscle pain / soreness
Asymptomatic cerebral ischemia	Perforation
Bleeding	Pericardial effusion
Bradycardia	Pericarditis
Bronchial injury	Peripheral nerve injury
Cardiac perforation / tamponade	Phrenic nerve palsy / paralysis
Cardiac or respiratory arrest	Pleural effusion
Catheter entrapment	Pneumonia
Cerebrovascular accident (CVA) / stroke	Pneumothorax
Chest pain	Pseudoaneurysm
Conduction system injury	Pulmonary edema
Coronary artery spasm / occlusion / stenosis	Pulmonary hypertension
Damage / dislodgement to CD or implantable pacemaker	Pulmonary vein stenosis
Death	Radiation injury
Deep vein thrombosis	Renal failure
Embolism	Respiratory insufficiency
Endocarditis	Skin burn, irritation or rash
Esophageal ulceration / erythema	Stiff left atrial syndrome
luid volume overload	Transient ischemic attack
astric hypomotility	Vagal nerve injury
eart failure	Valve damage
emoptysis	Vasovagal reactions
ematoma	Vessel dissection
emothorax	

Clinical studies

nformation regarding clinical studies that are applicable to Sphere-9 are available on the Medtronic Manual Library website:

1. Point your browser to www.medtronic.com/manuals.
2. Select the geography and language, and then search by product name for Sphere-9. The catheter technical manual and any applicable studies are listed. f you do not have web access, you can order printed copies of the clinical study

summaries from your Medtronic representative or by calling the toll-free number located on the back cover.

Directions for use

Connection and operation for ablation

The Sphere-9 catheter must be connected to the appropriate input connector of the catheter interface unit (CIU) of the compatible Affera mapping system using the compatible catheter extension cable. The compatible Affera ablation system is connected to the catheter through the CIU.

To complete the ablation circuit, return electrode pads are placed on the patient s skin. Verify that the ablation circuit impedance displayed by the compatible Affera ablation system is less than 80 Ω and the catheter temperature sensors are reading near 37 °C before starting ablation.

Warning: Achieve and maintain a minimum active clotting time (ACT) of at least 350 s prior to catheter insertion and throughout the procedure. Monitor the ACT regularly during the procedure.

rrigation is intended to be provided by the compatible irrigation pump and tubing set, connected to the luer connector mounted on the catheter handle. A minimum of 4 mL/min of heparinized saline must be continuously infused to reduce the risk of coagulation during use. igher flow rates are required during RF ablation and are outlined in this section.

Refer to the *Affera Ablation System User Manual* for system operating instructions.

Preparing the catheter for use

Note: Before introducing the catheter into the patient, test the deflection mechanism on the handle to ensure it is operational.

1. Create a vascular access in a large central vessel using standard aseptic techniques, and place a compatible sheath.

   Warning: Verify compatibility of the sheath to be used before inserting into the patient. Use only 2.7 mm (8 r) or larger straight sheaths or 2.8 mm (8.5 r) or larger curved or deflectable sheaths to prevent damage to the expandable ablation electrode during insertion.
2. Once the sheath is inserted into the vasculature and the dilator is removed, aspirate with a syringe on the sheath side port before flushing or infusion.
3. f using a deflectable sheath, ensure that the sheath deflection is adjusted straight (no deflection) before introducing the catheter.
4. Remove the catheter from the sterile packaging.
5. Connect the catheter to the Affera mapping and ablation system using the catheter extension cable.
6. ill the tubing set with heparinized saline by pressing and holding the purge button on the irrigation pump.

   Warning: When the purge button is pressed, the air bubble detector is disabled. Do not purge while the catheter is in the body.
7. Visually inspect the tubing set to verify there are no air bubbles between the drip chamber and the luer connector before connecting to the catheter.
8. Connect the tubing set directly to the luer fitting of the catheter. Do not use a stopcock.
9. Verify that there are no leaks from the tubing connections or the handle and that irrigation solution is flowing from the catheter tip.
10. Advance the insertion tool so it is near the distal tip.
11. Submerge the expandable ablation electrode into a bowl of heparinized saline.
12. nitiate the catheter preparation sequence on the irrigation pump.
13. Keep the expandable ablation electrode submerged until the catheter preparation sequence completes.
14. To dislodge any trapped air, tap the distal catheter shaft while keeping the entire expandable ablation electrode submerged.
15. Advance the insertion tool distally to collapse the expandable ablation electrode while keeping the expandable ablation electrode fully submerged.
16. To avoid air ingress, adjust the handle of the sheath such that the level of the hemostasis valve is below the level of the patient s heart.
17. Stop flow to the sheath side port.
18. Carefully lift the insertion tool out of the bowl of heparinized saline.
19. Verify that heparinized saline is flowing.
20. Ensuring the insertion tool remains filled with heparinized saline and that the hemostasis valve remains below the level of the patient s heart, push the insertion tool through the hemostasis valve of the sheath.
21. Advance the expandable ablation electrode into the sheath, just past the hemostasis valve.
22. Once the expandable ablation electrode has passed the hemostasis valve, retract the insertion tool from the hemostasis valve by sliding it proximally along the catheter shaft to the catheter handle.
23. Lift and adjust the sheath handle so that the side port is pointed up, so that any trapped air is easily aspirated through the side port.
24. Aspirate through the sheath side port while tapping on the sheath to dislodge any trapped air.
25. Apply positive pressure to the sheath with a pressure bag or a syringe connected to the sheath side port, and slowly advance the catheter until the expandable ablation electrode is fully expanded in the cardiac chamber.
26. Restore flow to the side port, and maintain a continuous infusion of heparinized saline through the sheath side port throughout the entire procedure.
27. Ensure a minimum flow of 4 mL/min heparinized saline through the catheter throughout the entire procedure.

Steering and control

1. Once deployed from the sheath with at least 7 cm of the shaft extending, the catheter tip can be deflected by pressing the steering wings with the thumb and forefinger. The friction knob can be tightened to maintain deflection.
2. Use both imaging guidance (e.g., fluoroscopy or intracardiac echocardiography) and electrograms to aid in proper positioning.
3. The navigation control buttons on the catheter handle provide functionality on the compatible Affera mapping system. Refer to the *Affera Mapping System User Manual* for more information.

Ablation

t is recommended that RF and PF energy be used as follows for atrial ablation:

- Only PF energy should be delivered on or near the posterior wall of the left atrium.
- Only PF energy should be delivered around the antrum of the left inferior PV (LIPV).
- Only PF energy should be used when ablating near a location where pacing captures the phrenic nerve.

  Warning: PF ablation in areas adjacent to coronary arteries may lead to coronary artery spasm.

  Warning: Do not deliver energy near other intracardiac devices or when in contact with other cardiac catheters or pacing and defibrillation leads to avoid possible thrombus or inappropriate treatment location.

Note: The Sphere-9 catheter should not be used to intentionally create reversible PF lesions.

The following Affera ablation system settings are recommended.

RF Settings	Duration	Current Limit	Temp. Target	rrigation Rate
RF-ANTERI-OR	5 s	80%	73°C	30 mL/min
RF-M TRAL	5 s	90%	73°C	30 mL/min
PF Setting	**Duration**	**Current Limit**		**rrigation Rate**
PULSE3	4 s	95%		15 mL/min

The RF-M TRAL ablation setting is recommended only for endocardial ablation along the mitral isthmus between the left inferior pulmonary vein and the mitral valve. The RF-ANTERIOR setting is recommended for all other RF ablation.

Warning: Application of high RF energy settings (e.g., long duration, high level, or high temperature) may increase the likelihood of excessive tissue heating and collateral damage.

Warning: RF catheter ablation in the coronary artery has been associated with myocardial infarction.

Warning: Repeated RF energy delivery in nearby locations may also increase the likelihood of excessive tissue heating and collateral damage.

Note: Use a luminal esophageal temperature probe to monitor esophagus temperature when delivering RF energy near the esophagus.

Note: Use pacing maneuvers to identify the location of the phrenic nerve before ablating near the right superior pulmonary vein, the superior vena cava, or the left atrial appendage.

1. Ensure stable ablation electrode positioning before starting energy delivery.
2. Ensure the irrigation flow rate is automatically increased by the Affera ablation system to an appropriate high flow rate before energy delivery.
3. Monitor the temperature and impedance displays on the Affera ablation system. Stop energy application if temperature or impedance changes abruptly or exceeds the desired value.
   Note: The temperature sensors on the Sphere-9 catheter are intended to measure tissue surface temperature when in contact with tissue. Temperature sensors that are not in contact with tissue during ablation may not reflect tissue surface temperature and may not reach the target temperature.
4. f energy delivery is terminated due to excessive temperature or impedance rise, it is advised to withdraw the catheter to inspect the expandable ablation electrode.
   Caution: Do not scrub or twist the expandable ablation electrode.

Catheter removal

1. Before removing the catheter, move the catheter away from tissue and straighten the deflectable tip of the Sphere-9 catheter completely by moving the steering wings to the neutral position. When using a deflectable sheath, straighten the sheath as well.
2. Retract the expandable ablation electrode into the sheath.
3. Advance the insertion tool into the hemostasis valve of the introducer sheath.
4. Slowly retract the Sphere-9 catheter through the sheath and then into the insertion tool.
5. Do not pull the expandable ablation electrode out through the insertion tool.
6. Remove the insertion tool containing the expandable ablation electrode from the hemostasis valve.
7. Leave the expandable ablation electrode inside the insertion tool in order prevent potential contamination and to facilitate reinsertion.

Device compatibility

Use only the following compatible devices.

Catalog No.	Compatible Device
A R -00003	Affera mapping system
A R -00002	Tubing set
A R -00006	Catheter extension cable
A R -00004	exa en™ RF generator
A R -00008	exaPulse™ PF generator
A R -00005	exa low irrigation pump

Disposal

Once used, the device must be handled and disposed of as contaminated hospital waste. Dispose of the device and its packaging in accordance with applicable local laws and regulations.

Specifications

Significant physical and performance characteristics are included in the following table.

Catheter shaft outer diameter	2.7 mm (8 r)
Catheter effective length (without insertion tool)	115 cm
Number of electrodes	9 mini-electrodes, 1 center electrode, 2 ring electrodes
Expandable ablation electrode diameter	Up to 9.3 mm in cardiac chamber
Sheath compatibility	2.7 mm (8 r) straight introducer 2.8 mm (8.5 r) curved or deflectable
Environmental operating conditions	15 °C to 30 °C, at non-condensing humidity
Sterilization	Single use, sterile device, ethylene oxide (EO) gas

Medtronic warranty

The following Limited Warranty applies to customers within the United States only:

A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic catheter, hereafter referred to as Product:

(1) Should the Product fail to function within normal tolerances due to a defect in materials or workmanship on or before its “Use By” or "Use Before" date, Medtronic will at its option: (a) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement product or (b) provide a functionally comparable replacement product at no charge.

(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement product.

B. To qualify for this Limited Warranty, these conditions must be met:

(1) The Product must be used on or before its “Use By” or "Use Before" date.

(2) The Product must be returned to Medtronic within 60 days and shall be the property of Medtronic.

(3) The Product must not have been used for any other patient.

(4) The Product must be used in accordance with the labeling and not altered or subjected to misuse, abuse, accident, or improper handling.

C. This Limited Warranty is limited to its express terms. n particular:

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC S NOT RESPONS BLE FOR ANY DIRECT, NCIDENTAL, OR CONSEQUENT AL DAMA E S BASED ON ANY DEFECT,FA LURE, OR MALFUNCTION OF T E Product, WHET ER THE CLA M S BASED ON WARRANTY, CONTRACT, TORT, OR OTHERW SE.

(2) This Limited Warranty is made only to the purchaser of the Product. AS TO ALL OT ER S, MEDTRON C MAKES NO WARRANTY, EXPRESS OR MPLIED, NCLUDING, BUT NOT LIM TED TO, ANY MPLIED WARRANTY OF MERCHANTABILITY, OR TNESS FORA PART CULAR PURPOSE WHET ER ARIS NG FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERW SE. NO EXPRESS OR MPLIED WARRANTY TO THE PAT ENT S ALL EXTEND BEYONDTHE PERIOD SPECIFIED N A(1) ABOVE. T S LIM TED WARRANTY S ALL BE THE EXCLUSIVE REMEDY AVA LABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. f any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Medtronic to any representation,condition, or warranty except this Limited Warranty. This Limited Warranty is provided by Medtronic, nc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. t applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

General warning

Medtronic catheters are used in the extremely hostile environment of the human body. Catheters may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of the catheter will not occur, or that the body will not react adversely to the catheter, or that medical complications will not follow.

Medtronic

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M051218C001

Medtronic

A R -00002

Tubing Set

nstructions for Use

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

Explanation of symbols

Refer to the package and product labels to see which symbols apply to this product and for product-specific information, such as the date of manufacture, manufactured-in location, and use-by date.

MD	Medical device
STERILE EO	Sterilized using ethylene oxide
	Single sterile barrier system
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Use-by date
	Consult instructions for use
www.medtronic.com/manuals	Consult instructions for use at this website
AUS	or Australia/New Zealand audiences only
LOT	Lot number
REF	Catalog number
	Date of manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
	Keep dry
#	Model number
UDI	Unique Device dentifier
	Package contents
	Keep away from sunlight
	Temperature limit
Rx only	Caution: ederal law (USA) restricts this device to sale by or on the order of a physician.
CE	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.

mporter

Manufactured in

Tubing set

Product documentation

Device description

The Medtronic tubing set (A R -00002) is a sterile, single-use, disposable peristaltic tubing set used with the compatible exa low™ irrigation pump to provide heparinized saline irrigation to a compatible ablation catheter. The tubing set contains unique features for mounting into the irrigation pump and for interfacing with the pump s bubble detector. t employs a standard V spike and drip chamber to interface with common irrigation bags, and it connects to the catheter via a standard luer connector. Refer to the *Affera Ablation System User Manual* for irrigation pump performance characteristics and specifications.

Contents of package

The tubing set is supplied sterile. The package contains the following items:

- 1 model A R -00002 tubing set
- Product documentation

Indications for use

Refer to the instructions for use accompanying the compatible ablation catheter for the specific indications for use.

Contraindications

The tubing set is not for use in patients with an active systemic infection. Refer to the instructions for use accompanying the compatible ablation catheter for additional contraindications related to the catheter.

ntended users

The intended users are physicians and nurses/EP technicians trained in interventional cardiac electrophysiology (EP).

ntended patient population

Refer to the instructions for use accompanying the compatible ablation catheter for the intended patient population.

Potential adverse events

Refer to the instructions for use accompanying the compatible ablation catheter for potential complications and adverse events associated with cardiac ablation procedures.

Warnings and precautions

- Carefully read all instructions for use of the Affera™ ablation system and compatible catheter before use. Observe all contraindications, warnings, and precautions noted in the directions. ailure to do so may result in patient complications. Review any applicable product information with the patient, including known risks and contraindications.
- The tubing set is intended for single patient use only. Do not reuse, reprocess, or resterilize the device. Reuse, reprocessing, or resterilization of single use devices can cause patient infection and compromise device performance and functionality.
- The tubing set is sterilized with ethylene oxide gas and must be used by the Use-by date printed on the package label. Do not use the tubing set after the use-by date.
- Visually inspect all sterile-barrier packaging before use. f the device is damaged or if the integrity of the sterile barrier has been compromised, do not use the product. Contact your Medtronic representative for return information.
- The tubing set is intended for use only with the exa low irrigation pump and direct connection to a compatible ablation catheter. Do not use stopcocks or extend the length of tubing between the pump and the catheter using unauthorized tubing extension devices.
- Ensure the tubing set is properly placed in the bubble detector of the irrigation pump before connecting to the patient.

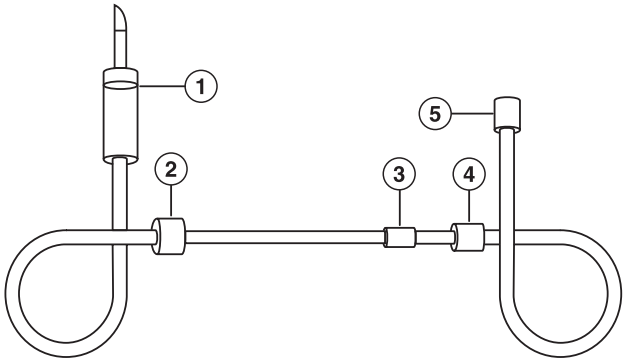
- •I nspect the irrigation supply and tubing for air bubbles before connecting to the catheter. Verify the tubing is free of air bubbles before inserting the catheter into the patient. Air bubbles in the irrigation supply may become emboli.
- Verify flow from the tubing set before connecting to the catheter.
- The use of heparin is referenced throughout this document with the assumption that when the use of heparin is contraindicated, an acceptable alternative will need to be substituted per institutional guidelines.
- The pump and tubing set are intended for use with heparinized saline irrigation solution. Patient injury may result from excessive delivery of inappropriate fluids.
- Always maintain a constant infusion of heparinized saline to prevent formation of coagulation within the lumen of the catheter. Purge air from the irrigation tubing and catheter lumen before inserting the catheter into the patient. Do not purge while the catheter is in the body.
- •I ntravenous heparin must be used to reduce the likelihood of thromboemboli developing during the procedure. Anticoagulation treatment should adhere to consensus guidelines, including pre- and post-procedure anticoagulation management and administering intravenous heparin during the procedure. Achieve and maintain a minimum active clotting time (ACT) of at least 350 s prior to catheter insertion and throughout the procedure. Monitor the ACT regularly during the procedure.
- Monitor the patient s fluid intake to avoid fluid volume overload. Patients with congestive heart failure or renal insufficiency and the elderly are susceptible to complications. dentify the patient s risk of volume overload before the start of the procedure.
- Cardiac ablation procedures are to be performed only by physicians trained in electrophysiology procedures in a fully equipped electrophysiology laboratory.
- Do not expose the device to organic solvents such as alcohol.
- •I f you find information in this manual that is incorrect or illegible, contact your Medtronic representative or your local competent medical authority.
- •I f a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.
- There is no special handling, including no special storage or transport conditions, required for this device. Standard storage conditions are sufficient to safeguard the device. Store the device in the original packaging at room temperature in a dry place.

Directions for use

Preparing the tubing set for use

1. Using sterile technique, remove the tubing set from the sterile package and place it into the sterile field.

Figure 1. Tubing Set



1 Drip chamber
2 Large mounting block
3 Enlarged detector section
4 Small mounting block
5 Luer lock end

2. The drip chamber (1) and pump mounting section of the tubing set (2-4) can be passed to nonsterile hands for installation into the pump and connection to the irrigation source.
3. Place the large mounting block (2) into the receptacle to the left of the pump head.
4. With the pump door open, stretch the tubing under the pump head and insert the smaller mounting block (4) into the receptacle on the right side of the pump head.
5. Place the enlarged detector section (3) into the bubble detector on the right side of the pump door. Ensure the tubing is fully seated into the mounting block receptacles and bubble detector.
6. Close the pump door to engage the tubing.
7. rasping the drip chamber, remove the spike cap, spike the heparinized saline bag, and hang it from an V pole.
8. Squeeze and release the drip chamber until it is approximately 25% full.
9. ill the tubing set with heparinized saline by pushing the purge button on the irrigation pump. old the purge button until the bubble alarm is cleared.

Warning: nspect the tubing for air bubbles before connecting to the catheter as air bubbles in the tubing may become emboli. Always verify flow from the tubing set before connecting to the catheter to ensure proper irrigation.

10. Connect the luer lock end of the tubing set (5) to the luer fitting of the catheter.
11. ollow the directions provided in the instructions for use accompanying the compatible ablation catheter to complete catheter preparation.

Disposal

Once used, the device must be handled and disposed of as contaminated hospital waste. Dispose of the device and its packaging in accordance with applicable local laws and regulations governing the disposal of medical waste.

Device compatibility

Use only with the following devices:

Compatible Device	Catalog Number
exa low irrigation pump	A R -00005
Sphere-9™ catheter	A R -00001

Specifications

The following table provides the product s physical and performance characteristics.

Length	V bag interface to peristaltic pump head: >120 cm
	Bubble sensor to luer lock: >150 cm
Environmental operating conditions	Store in a cool and dry place.
	Refer to the *Affera Ablation System User Manual* for the operating environmental parameters of the system.
Sterilization	Single use, sterile device, ethylene oxide

Medtronic warranty

The following Limited Warranty applies to customers within the United States only:

A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic accessory, hereafter referred to as “Product”:

(1) Should the Product fail to function within normal tolerances due to a defect in materials or workmanship on or before its “Use By” or "Use Before" date, Medtronic will at its option: (a) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement product or (b) provide a functionally comparable replacement product at no charge.

(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement product.

B. To qualify for this Limited Warranty, these conditions must be met:

(1) The Product must be used on or before its “Use By” or "Use Before" date.

(2) The Product must be returned to Medtronic within 60 days and shall be the property of Medtronic.

(3) The Product must not have been used for any other patient.

(4) The Product must be used in accordance with the labeling and not altered or subjected to misuse, abuse, accident, or improper handling.

C. This Limited Warranty is limited to its express terms. n particular:

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC S NOT RESPONS BLE FOR ANY DIRECT, NCIDENTAL, OR CONSEQUENT AL DAMA E S BASED ON ANY DEFECT, A LURE, OR MALFUNCTION OF THE Product, WHET ER THE CLA M S BASED ON WARRANTY, CONTRACT, TORT, OR OTHERW SE.

(2) This Limited Warranty is made only to the purchaser of the Product. AS TO ALL OT ER S, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR MPLIED, NCLUDING, BUT NOT LIM TED TO, ANY MPLIED WARRANTY OF MERCHANTABILITY, OR TNESS FOR A PART CULAR PURPOSE WHET ER ARIS NG FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERW SE. NO EXPRESS OR MPLIED WARRANTY TO THE PAT ENT S ALL EXTEND BEYOND THE PERIOD SPECIFIED N A(1) ABOVE. T S LIM TED WARRANTY S ALL BE THE EXCLUSIVE REMEDY AVA LABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. f any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid.

This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Medtronic to any representation,condition, or warranty except this Limited Warranty. This Limited Warranty is provided by Medtronic, nc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. t applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

General warning

Medtronic accessories are used in the extremely hostile environment of the human body. These Products may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of the Product will not occur, or that the body will not react adversely to the Product, or that medical complications will not follow.

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