Medtronic

PulseSelect™ PSCC100

Pulsed Field Ablation Loop Catheter

Technical Manual

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Explanation of symbols

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

LOT	Lot number
REF	Reorder number
	Use-by date
	Fragile, handle with care
	Pulsed Field Ablation Loop Catheter
STERILE R	Sterilized using irradiation
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Package contents
	Consult instructions for use
	Keep dry
	Product documentation
	Outside diameter
	Manufacturer
EC REP	Authorized representative in the European Community
CE	Conformité Européenne (European Conformity) This symbol means that the device fully complies with applicable European Union acts.
! USA	For US audiences only
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	Date of manufacture
MD	Medical device
#	Model number
	Manufactured in
	Importer
	Single sterile barrier system with protective packaging inside

1 Description

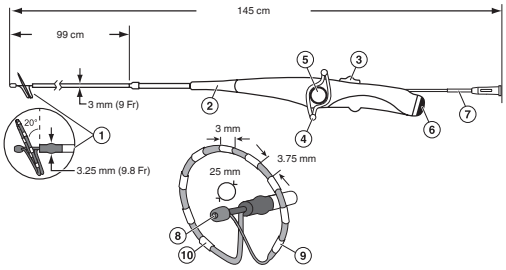
The Medtronic PulseSelect Pulsed Field Ablation (PFA) loop catheter is a sterile, single use, anatomically designed, multi-electrode catheter used to detect electrical signals, pace, and ablate the pulmonary veins (*Figure 1*). The catheter is provided sterile via electron beam (e-beam) sterilization. The catheter is used to perform cardiac tissue ablation through the mechanism of irreversible electroporation. The catheter is compatible with the Medtronic PulseSelect PFA system. The catheter is designed to be used together with an introducer sheath with a minimum inside diameter of 3.33 mm (10 Fr) and a 0.81 mm (0.032 in) J-tip guide wire.

The catheter has the following 2 control features:

1. A steering lever (4, *Figure 1*) that controls bidirectional deflection of the distal shaft.
2. A slide control (3, *Figure 1*) to extend or retract the guide wire lumen and distal tip (8, *Figure 1*) and change the catheter geometry from circular to spiral to a longitudinal shape.

The slide control also allows for extension of the distal portions of the catheter to allow capture of the distal array into the capture device that is used to deliver the catheter into the sheath. The catheter is inserted into the patient's vasculature, typically through an introducer sheath via the femoral vein, then advanced into the left atrium. Once in the sheath, the catheter and guide wire are advanced through the sheath with the guide wire being guided into one of the pulmonary veins. After the catheter array exits the sheath, it is deployed into a circular shape by pulling the slide control back. The catheter array is then placed in multiple sites for cardiac tissue ablation.

Figure 1. PulseSelect PFA loop catheter



1	Spiral array	6	Connector
2	Capture device	7	Luer
3	Slide control	8	Distal tip
4	Steering lever	9	Electrode 1
5	Steering lever tension control knob	10	Electrode 9

For details about the PulseSelect generator and how to use it with the catheter to perform ablation procedures, see the *PulseSelect Pulsed Field Ablation System Operator's Manual*.

1.1 Contents of package

The package contains the following:

- PulseSelect PFA loop catheter
- Product documentation

Carefully read all instructions before use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to read the instructions may result in less than expected outcomes.

Caution: Inspect the sterile packaging and catheter before use. If the sterile packaging or catheter is damaged, do not use the catheter. Contact your local Medtronic representative.

Caution: The catheter should be used only by, or under the supervision of physicians trained in left atrial ablation procedure~~s~~ TM using this catheter and the Medtronic PulseSelect PFA generator.

Pulsed Field Ablation (PFA) System

2 Indications for use

The PulseSelect ~~PFA loop catheter~~ is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year) ~~when used in conjunction with the PulseSelect PFA system~~.

3 Contraindications

The PulseSelect PFA loop catheter is contraindicated for use in patients with the following conditions:

- Active systemic infections
- A known sensitivity to Heparin
- Blood clotting abnormalities
- Permanently implanted metallic objects in the left atrium

The catheter is also contraindicated in conditions where the manipulation of the catheter within the heart would be unsafe, such as intracardiac mural thrombus.

The catheter is not recommended for use in patients who cannot undergo standard anticoagulation protocol for a left-sided cardiac procedure, or who have had a recent coagulopathy or embolic event.

4 Intended user

The intended user of this ablation system is a physician that performs cardiac ablation. Use of this device does not require specific qualifications or training beyond what is required per the applicable local, national, or federal regulations.

5 Intended patient population

The intended patient population for the PulseSelect PFA system includes adults (patients 18 years or older) who require or are candidates for cardiac ablation. For the most up-to-date medical consensus on additional considerations, refer to the applicable treatment guidelines.

6 Clinical studies

Information regarding clinical studies that are applicable to the PulseSelect PFA loop catheter 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 PulseSelect. The catheter technical manual and any applicable studies are listed. If 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.

7 Warnings and precautions

Ablation therapy hazards – To reduce the possibility of hazards associated with use of the PulseSelect PFA loop catheter:

- Use the catheter only in the recommended anatomical location.
- Maintain the catheter position during the ablation.

This will be removed when the content and eIFU part is created as part of implemtation on the eManuals website.

- If coughing occurs, reposition the catheter more proximally and review sedation management.
- Ensure electrodes are not in contact with any metal during ablations (for example the guide wire).
- Maintain substantially circular array to ensure uniform field distribution.
- If the electrode array is deployed to deliver ablation energy, avoid continuing to move the slide control forward to prevent the guide wire lumen from coming too close to the electrode array.

Air entrapment – It is recommended that the array be captured while it is submerged to help reduce the possibility of air becoming entrapped around the electrode array during capture and catheter insertion.

Anticoagulation therapy – Administer appropriate levels of anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures to minimize the risk of thromboembolic events. It is recommended to maintain therapeutic anticoagulation levels, per guidelines for patients undergoing cardiac ablation procedures.

Biohazard disposal – Discard all used catheters and sterile accessories in accordance with hospital procedures.

Catheter integrity – Use care to avoid damage to the catheter.

- Do not bend or kink the leading end of the catheter. Doing so could cause damage to the catheter lumen and make it unusable.
- Monitor the catheter throughout the procedure. If a flash is observed in the luer, replace the catheter immediately.

Do not resterilize – Do not resterilize this device for the purpose of reuse. Resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Electrode-electrode contact – Avoid contact between electrodes. Contact between electrodes may create a short circuit.

Embolism risk – Introducing any catheter or sheath into the circulatory system entails the risk of air, gas, or thromboembolism, which can occlude vessels and lead to tissue infarction with serious consequences.

- Avoid unnecessary catheter exchanges to minimize sheath-related embolic events.
- Always advance and withdraw components slowly to minimize the vacuum created and the risk of air embolism.
- Aspirate and flush the sheath frequently to help minimize the potential for embolic events resulting from the introduction of air or clot formation within the sheath.

Fluoroscopy use during catheter placement – The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Extensive exposure may result in acute radiation injury and increased risk for somatic and genetic effects. Only perform catheter ablation after giving adequate attention to the potential radiation exposure associated with the procedure, and taking steps to minimize this exposure. Give careful consideration before using the device in pregnant women.

For single use only – The PFA catheter is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize the PFA catheter. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Handling and placing catheters – Careful manipulation of the catheter is necessary to avoid cardiac damage, perforation, or tamponade.

- Do not use excessive force to advance, withdraw, or rotate the catheter, especially if resistance is encountered. Excessive force may lead to catheter damage and blood loss.
- Use imaging guidance during catheter advancement, manipulation, and placement.
- Vascular perforation is an inherent risk of catheter placement.
- Performing ablation with the PFA catheter array inside the sheath may result in damage to the array or the sheath and should be avoided.
- Performing steering manipulation with the PFA catheter array inside the sheath may result in damage to the catheter steering mechanism or the sheath and should be avoided.
- The PFA generator is capable of delivering significant energy. Do not touch the ablation electrodes of the PFA catheter while operating the generator.
- If the system is to be tested outside of the body, the electrode array must be immersed in saline solution in a plastic container. Never test PFA delivery in direct contact with skin.

Imaging for catheter placement – Use of imaging during catheter manipulation and placement is strongly advised. Manipulating the catheter without imaging may result in damage to cardiac and vascular structures.

Improper connection – Do not connect the PFA catheter to anything other than the PulseSelect PFA generator or use it to deliver non-PFA energy. This may cause catheter malfunction or patient injury.

Other devices, wires, or catheters – Avoid catheter entanglement with other devices, wires, or catheters, for example, intracardiac echo catheters. Failure to do so may increase the risk of entrapment of the array or damage to the array, which may affect retrieval of the device into the transseptal sheath.

Product literature – Do not operate the PFA system or connect a catheter to the generator before completely reading and understanding the product literature for the system.

Phrenic nerve injury – To reduce the potential for phrenic nerve injury, assess for proximity of the ablation catheter to the nerve using an appropriate technique such as pacing for local phrenic nerve capture or using the test pulse feature before ablation. Stop ablation immediately if phrenic nerve impairment is observed and assess for injury.

Required use environment – Cardiac ablation procedures should be performed only in a fully equipped electrophysiology laboratory.

Safety in magnetic resonance imaging (MRI) not evaluated – The PFA catheter has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The safety of the PFA 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.

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

Sheath and guide wire required – Do not attempt to advance or withdraw the catheter through the vasculature without the use of a sheath and guide wire, as it may result in damage to cardiac and vascular structures.

Sterile package inspection – Inspect the sterile packaging and catheter before use. If the sterile packaging or the catheter is damaged, do not use the catheter and contact your local Medtronic representative.

Storage and transport – 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.

Use by date – Do not use the device after the “Use by” date on the package label.

Using PFA energy near implanted devices – Implanted devices, such as pacemakers and implantable cardioverter-defibrillators (ICDs), may be adversely affected by PFA energy.

- Keep external sources of pacing and defibrillation available during ablation.
- Program pacemaker sensing parameters to asynchronous pacing to ensure that PFA energy is not sensed as an intrinsic event.
- Deactivate ICD detection during the delivery of PFA energy.
- Perform complete implantable device testing before and after ablation.

- Monitor surface and intracardiac electrograms or vital signs during PFA energy delivery to assess for device interaction. Take appropriate action if any interaction is detected.
- Refer to the appropriate implantable device technical manual for additional information.

8 Adverse events

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

- Access site complications (such as, bruising, ecchymosis, arteriovenous fistula, hematoma, pseudoaneurysm)
- Anemia
- Arrhythmias, proarrhythmia (such as, atrial flutter, bradycardia, heart block, tachycardia)
- Bleeding, possibly requiring transfusion
- Bruising
- Cardiopulmonary arrest
- Perforation of the heart or other organs during transseptal puncture or other procedures
- Cardiac tamponade
- Catheter entrapment in cardiac structures requiring intervention
- Cerebrovascular accident [such as stroke, transient ischemic attack (TIA)]
- Chest discomfort, pain, or pressure
- Collateral damage to the conduction system or coronary vasculature
- Cough
- Death
- Embolism
- Esophageal damage (including atrial esophageal fistula)
- Hemoptysis
- Hypotension
- Hypertension
- Infections (such as, sepsis)
- Myocardial infarction or ischemia
- Nerve injury or nerve damage (for example phrenic nerve injury)
- Pericarditis or endocarditis
- Pericardial effusion
- Pneumothorax
- Pulmonary edema
- Pulmonary vein dissection
- Pulmonary vein stenosis
- Radiation injury or damage and late malignancy
- Skin laceration or puncture
- Sore throat
- Unintended complete or incomplete atrioventricular node (AV-Node) or sinus node block or damage
- Valvular insufficiency or damage

9 Instructions for use

Caution: Inspect the sterile packaging and catheter before use. If the sterile packaging or catheter is damaged, do not use the catheter and contact your local Medtronic representative.

Caution: Verify that the catheter is within its expiration date. Do not use if the product use-by date has expired.

Notes:

- Check the activated clotting times (ACT) at 10 to 15 minute intervals until therapeutic anticoagulation is achieved and then at approximately 30 minute intervals during the procedure. The anticoagulation level is recommended to be maintained at an ACT of at least 350 seconds throughout the procedure.
- The PulseSelect PFA loop catheter is an over-the-wire catheter designed to be used with a 0.81 mm (0.032 in) J-tip guide wire at all times.

9.1 Prepare the PulseSelect PFA loop catheter and the transseptal sheath

Use a standard aseptic technique when removing the product from its sterile barrier and handling the catheter. During connection of the catheter, keep the connections dry at all times. Fluid incursion may lead to system malfunction.

1. Carefully remove the catheter from the packaging and inspect the catheter before use to verify that it has not been compromised during shipping or handling.
2. Use a sterile technique to connect the catheter interface cable to the connector located on the handle of the catheter (6, *Figure 1*).
3. Pass the other end of the catheter interface cable out of the sterile field and connect it to the front panel of the PulseSelect PFA generator. (For more detailed instructions, see the *PulseSelect Operator's Manual*).
4. Flush the guide wire lumen and insert the guide wire into the catheter via the guide wire luer. The guide wire must exit the proximal end of the catheter.
5. Prepare and manage a transseptal sheath with a minimum inner diameter of 3.33 mm (10 Fr) following the directions in the manufacturer's Instructions for Use (IFU).

   Notes:

   - Aspirate and flush the sheath while the sheath is in the right atrium.
   - After gaining access to the left atrium, maintain anticoagulation per hospital protocol.

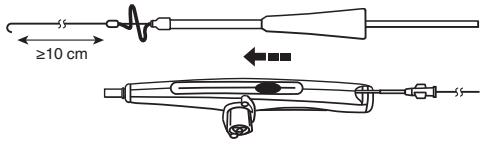
9.2 Capture the array with the capture device

1. Ensure the catheter is in a straight position with the array in a neutral position.

   Warning: The array must be captured while it is submerged in heparinized saline to wet the array and reduce the possibility of air bubbles adhering to the electrode array during capture and catheter insertion.
2. Remove the capture device from the handle and slide it up to the spiral array.
3. Verify that the guide wire extends at least 10 cm (3.9 in) from the distal tip.
4. While holding the capture device against the spiral array, slowly advance the slide control forward, as shown in *Figure 2*, while advancing the capture device.

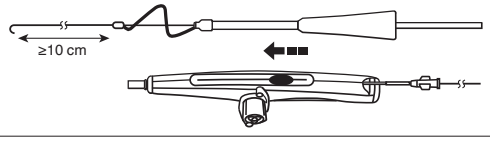
   Note: Do not advance the capture device beyond the end of the array.

   Figure 2. Advancing the capture device



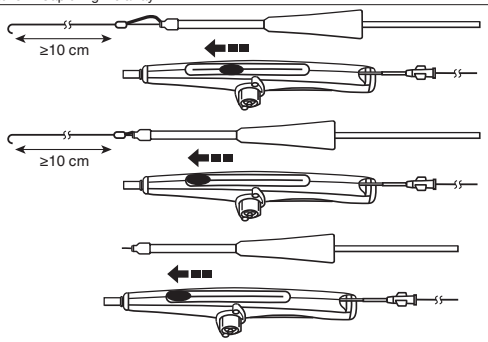
5. As the capture device is advanced forward, continue to advance the slide control forward (see *Figure 3*).

   Figure 3. Advancing the slide control while advancing the capture device



6. Hold the slide control in the forward position while capturing the tip of the spiral array (see *Figure 4*).
   Note: Ensure the slide control is fully forward before capturing the distal tip to prevent kinking.

Figure 4. Capturing the array

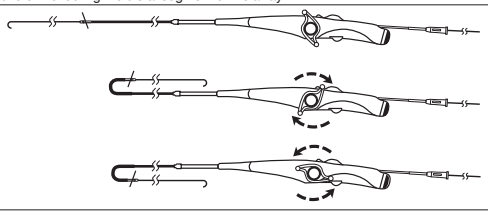


9.3 Insert the catheter and deploy the array

Warning: Avoid unnecessary catheter exchanges to minimize sheath-related embolic events. Catheter exchanges follow the same steps as catheter introductions.

1. Retract the guide wire to the distal tip of the catheter.
2. With the array contained, place the capture device against the hemostasis valve and advance the catheter array into the sheath.
3. Advance the array portion of the catheter into the sheath before replacing the capture device firmly onto the handle.
   Note: It is strongly advised to perform catheter manipulation under fluoroscopic guidance or other appropriate visualization techniques.
4. Advance approximately 10-20 cm of the guide wire length into the transseptal sheath.
5. Advance the catheter through the transseptal sheath until the guide wire and array enters the left atrium.
6. Before fully deploying the catheter, verify that the guide wire is positioned at least 5 cm past the ostium in 1 of the left pulmonary veins.
7. Continue to advance the catheter until the fourth electrode on the spiral array begins to exit the sheath.
8. Slowly pull back on the slide control while continuing to advance the catheter forward to deploy the spiral array.
9. To fully deflect the catheter, make sure the steering portion of the catheter is beyond the distal tip of the sheath. This will allow for full deflection of the distal segment of the catheter, as shown in *Figure 5*.
   Note: Do not attempt to steer the catheter within the sheath.

Figure 5. Deflecting the distal segment of the array



9.4 Pace and detect

Note: It is strongly advised to perform the remaining steps under fluoroscopic guidance or other appropriate visualization techniques.

1. Advance the guide wire into the selected pulmonary vein to support and stabilize the catheter.
2. Advance the array into position for performing diagnostic EGM recording or bipolar pacing from the electrode pairs.
3. The slide control may be advanced during pulmonary vein diagnostic recording or pacing, but it should not be advanced when performing therapeutic energy deliveries.
4. Detect pulmonary vein potentials. The generator is required to be powered on to pace or visualize electrograms when using the catheter.

9.5 Deliver therapy

To use the catheter for a pulsed field ablation procedure, follow these steps. For more detailed instructions, see the *PulseSelect Operator's Manual*.

1. Select **START PROCEDURE** on the generator touchscreen display.
   Note: The therapy setup screen will display **1500 V** and a representation of the distal end of the 9-electrode **PFA Catheter**.
2. Confirm that the PFA Catheter is **Connected**. Connection of the catheter is indicated on the PulseSelect PFA generator touchscreen display.
3. The catheter array should first be placed to isolate each pulmonary vein ostium.
4. Deliver a test pulse.
   Notes:
   - The test pulse delivers a single sub-therapeutic stimulation pulse to the electrodes. A test pulse can indicate close proximity to the phrenic nerve via diaphragmatic stimulation. A delivery tone indicates when the R-wave synchronized test pulse has been delivered.
   - Deliver the test pulse while monitoring for stimulation of the diaphragm. The respiration cycle can move the catheter into or out of contact or proximity to the phrenic nerve.
   - If the test pulse produces diaphragm stimulation, reposition the catheter array.
5. Charge the system using the charge system button on the generator, optional remote, or the left actuator pad of the optional foot switch.
6. Deliver therapy using the deliver therapy button on the generator, optional remote, or the right actuator pad of the optional foot switch. Repeat applications for additional catheter placements as necessary to isolate the pulmonary vein ostium. One application is equivalent to four pulse trains delivered.
   Note: At any point the back button on the generator or optional remote can be used to return to the therapy setup screen.

7. Complete ablation of the associated pulmonary vein carina. Following isolation of the pulmonary vein ostium and carina, the catheter array should be repositioned antrally and four pulse trains delivered at each placement until an antral lesion pattern is achieved.
8. Repeat applications for additional catheter positions as necessary.

   Note: A minimum of 8 applications per vein is recommended to achieve ostial and antral ablation. Operators should use medical judgment to achieve a wide antral ablation for pulmonary vein isolation.

9.6 Pacing and navigation between pulmonary veins

1. Advance the guide wire to provide support for the catheter during maneuvers.

   Notes:
   - Do not attempt to steer the catheter within the sheath.
   - Use the steering lever tension control knob to maintain curve configuration.
2. Retract the catheter from the antrum of the vein.
3. Advance the slide control forward as required to detect electrical signals and check for pulmonary vein isolation.
4. Advance the spiral array into the vein while rotating it in a counter clockwise rotation.
5. Retract the slide control slightly to expand the spiral array against the inside surface of the vein.

   Note: Pacing is available through all electrodes on the catheter.
6. Repeat pulmonary vein isolation for additional pulmonary veins as necessary.

9.7 Removing the catheter

1. Disconnect the catheter from the catheter interface cable.
2. Verify that the steering lever is in a neutral position and at least 5 cm (1.97 in) of guide wire is inserted into one of the left pulmonary veins.
3. Slowly advance the slide control forward 1/4 of the travel distance and slowly pull back on the catheter shaft to retract the array into the transseptal sheath.

   Note: The catheter should only be pulled back to the right atrium through the transseptal puncture while fully inside the transseptal sheath.
4. Continue to slowly advance the slide control while simultaneously retracting the catheter, until the spiral array is completely inside the transseptal sheath.
5. Slowly withdraw the catheter halfway through the sheath.
6. Place the capture device against the hemostasis valve and continue retracting the catheter until the array is located in the capture device and the guide wire has been fully removed from the hemostasis valve.

9.8 Disposal

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

Caution: Discard all used catheters and sterile components in accordance with hospital procedures.

10 Specifications

Overall length	145 cm (57.09 in)
Effective length	99 cm (38.98 in)
Deflection angle	170 degrees
Catheter reach at 90 degree deflection	23 mm
Array configuration	Single circled array [25 mm (0.98 in) outside diameter]
Number of electrodes	9
Electrode spacing	3.75 mm (0.15 in)
Electrode length	3 mm (0.12 in)
Single use circuitry	Circuitry allows the generator to assess “single use”
Outside diameter at array to catheter shaft bond	3.25 mm (9.8 Fr; 0.13 in)
Outside diameter of shaft	3 mm (9 Fr; 0.12 in)
Compatibility:	
Generator	Medtronic PulseSelect PFA generator
Catheter interface cable	Medtronic PulseSelect PFA catheter interface cable
Introducer sheath minimum	3.33 mm (10 Fr; 0.13 in)
Guide wire	0.81 mm (0.032 in) J-tip
Operating environmental parameters	15 °C to 30 °C (59 °F to 86 °F) at humidity between 30% and 75%
Sterilization	Single use, sterile device, e-beam radiation

11 Medtronic limited warranty

For complete warranty information, see the accompanying limited warranty document.

12 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate telephone number or address listed on the back cover.

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Medtronic

PulseSelect™ PSG100

Pulsed Field Ablation Generator

Operator's Manual

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Explanation of packaging and product symbols

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Manufacturer

Authorized representative in the European community

Date of manufacture

Serial number

Reorder number

Keep dry

Fragile, handle with care

Mass

Caution

Follow instructions for use. Symbol appears blue on device.

Consult instructions for use

Product documentation

Alternating current

Equipotentiality (chassis ground)

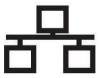
Indicates high or dangerous voltage

Defibrillation-proof, type CF applied part

Soft power button

Power off

Power on


Ethernet connector

USB connector

RS-232 connector

Canada ICES-001 (A) / NMB-001 (A)	Industry Canada Interference-Causing Equipment Standard (ICES-001).
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.
	Non-ionizing radiation symbol. Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems that may produce RF electromagnetic energy.
! USA	For US audiences only
RoHS	Indicates compliance to the RoHS directives.
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
IPX1	Indicates the level of particulate and fluid ingress protection as classified in IEC 60529.
IPX8	International Protection (IP) Code
	Fuse
	Package contents
	Power cord
	EGM cable
	Remote control
	Foot switch
	Catheter interface cable
	Do not resterilize
	Do not reuse
	Generator
	Single sterile barrier system
LOT	Lot number
	Use-by date
STERILE R	Sterilized using irradiation

	Do not use if package is damaged
	Temperature limit
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
	Medical device
	Model number
	Manufactured in
	System meets the applicable Canadian and U.S. electrical safety standards
	China e symbol for the restriction of the use of hazardous substances in electrical and electronic product
	Importer

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1 Description

The Medtronic PulseSelect Pulsed Field Ablation (PFA) generator delivers bipolar, biphasic pulsed electric fields through a compatible Medtronic catheter to perform cardiac tissue ablation through the mechanism of irreversible electroporation. The generator accepts trigger pulses from an external cardiac trigger monitor to synchronize the therapy delivery to an R wave.

The generator allows the user to:

- Charge the system in preparation for PFA delivery.
- Deliver a test pulse to identify phrenic nerve stimulation response to a low-voltage delivery.
- Initiate ablation.
- View system status and any notifications.

Ablation parameters such as PFA delivery status and faults are displayed on the generator's touchscreen display. The 1500 V displayed on the therapy setup screen represents the amplitude from baseline to peak of the pulsed field ablation waveform.

1.1 How supplied

The generator is supplied in a customized box. Medtronic PulseSelect PFA system accessories are supplied separately. See *Chapter 6* in this manual for detailed information and instructions for using compatible Medtronic accessories. The catheter, cardiac trigger monitor, and cardiac trigger monitor accessories are supplied separately and include instructions for use.

1.2 Indications

See the technical manual for the catheter you are using.

1.3 Contraindications

See the technical manual for the catheter you are using.

1.4 Intended user

The intended user of this ablation system is a physician that performs cardiac ablation. Use of this device does not require specific qualifications or training beyond what is required per the applicable local, national, or federal regulations.

1.5 Intended patient population

See the technical manual for the catheter you are using.

1.6 Warnings and precautions

These warnings and precautions apply in general to using the PFA system for cardiac ablation. Refer to the technical manual for system-compatible catheters for more information related to catheter use. Observe all contraindications, warnings, and precautions noted in the instructions for use. Review any applicable product information with the patient, including known risks and contraindications.

Biohazard disposal – Discard all used catheters and sterile accessories in accordance with hospital procedures.

Cable integrity – Do not use any cable if it is kinked or damaged. If a cable becomes kinked or damaged while in use, remove it and use a new cable.

Cable positioning – Position all cables associated with the generator so they do not come in contact with the patient or other leads. Electromagnetic interference may affect the ability to interpret patient EGMs.

Chassis ground – To avoid the risk of electric shock, do not make any connections to the chassis ground on the PFA system.

Do not resterilize – Do not resterilize the catheter interface cable for the purpose of reuse. Resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Electrical safety requirements – The PFA generator meets the requirements of IEC 60601-1. It is the user's responsibility after installation to verify and ensure that the generator meets the applicable local electrical safety requirements.

Electric shock – To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Electromagnetic interference (EMI) radiated – The generator emits energy during ablation at a frequency level that may cause EMI with unshielded electronic equipment. To minimize EMI, the generator should be moved away from any other electronic device. If EMI is apparent during the application of energy, EMI may be reduced by repositioning the generator or other equipment.

Electromagnetic interference (EMI) susceptibility – The generator has been designed to minimize electromagnetic interference (EMI). If interference should occur, move the generator away from the device generating the interference or place the generator at a different angle.

EP recording systems – The PFA system should only be used with EP recording systems that are approved for use in electrophysiology labs.

Equipment modification – No modification of this equipment is allowed. Modifications may reduce system effectiveness and impact patient health.

Equipment stability during use – Do not disturb or move the equipment, cardiac trigger monitor, or cables while the catheter is positioned within the patient, as patient injury may occur.

Fluid incursion – The generator may not function correctly if the electronic circuitry or the connectors are wet.

- Do not allow any fluid or moisture into the PFA system or the cables and cable connectors.
- Do not hang fluids above the system.
- Do not immerse the cables into fluids.

For single use only – The catheter interface cable is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize the device. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Generator placement – Place the generator on a level surface. Do not place other equipment on top of the generator. Do not place the generator on top of other equipment.

Handling PFA catheters outside the body – The PFA generator is capable of delivering significant energy. Do not touch the ablation electrode of the PFA catheter while operating the generator. Do not operate the generator when catheter is outside the body.

Information technology equipment – All information technology equipment that is attached to the PFA system must be approved by a third party to the requirements of UL 1950 or EN 60950.

Leakage current from connected devices – Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the PFA system and catheters or patient injury or death may occur. Do not allow leakage current from any connected devices to the patient to exceed 10 microamperes (μA) under any circumstances.

Monitoring systems – The PFA system should only be used with monitoring systems that are approved for use in electrophysiology labs. Monitoring electrodes should be placed as far as possible from surgical electrodes. Needle monitoring systems are not recommended.

Overheating the generator – Do not place the generator near heat-generating equipment. Do not block cooling inlets or outlets on the generator.

Patient metal contact – The patient should not come into contact with metal parts which are grounded or have an appreciable capacitance to ground (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.

Power supply – The power cord may be used to disconnect the device from electrical power. Do not position the device so that it is difficult to remove the power cord.

Product literature – Do not operate the PFA system or connect a catheter to the generator before completely reading and understanding the product literature for the system.

Pulsed field ablation near flammable materials – The risk of igniting flammable gases or other materials is inherent in pulsed field ablation and cannot be eliminated by device design. Take precautions to restrict flammable materials and substances from the ablation site.

Flammable materials may come in the following forms:

- Anesthetics or skin preparation agents
- Flammable anesthetic mixture with air or with oxygen or with nitrous oxide
- Chemicals originating in surgical drapes or other materials

Required use environment – Cardiac ablation procedures should be performed only in a fully equipped electrophysiology laboratory.

Reusable accessories – Regularly inspect and test reusable cables and accessories. Do not use any cable or accessory that appears to be damaged.

- Inspect for insulation damage, such as brittleness, cracking, thinning, or bare spots.
- Replace damaged cables and accessories.

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

Sterile package inspection – Visually inspect all sterile-barrier packaging before use. If 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.

Storage and transport – There are 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.

System compatibility – Use only compatible Medtronic catheters and compatible accessories. The safety and use of other catheters or accessories has not been tested.

Unintentional patient burns – To avoid unintentional burns to the patient during therapy delivery, minimize skin-to-skin contact between parts of the patient's body by covering these areas with dry gauze.

Unintentional power output – Failure of the ablation equipment can result in an unintentional power output increase. An unintentional power output increase may impact patient safety.

Use by date – Do not use the catheter interface cable after the "Use by" date on the package label.

X-ray and fluoroscopic exposure – Minimize x-ray and fluoroscopic exposure. Due to the x-ray beam intensity and the duration of the fluoroscopic imaging during ablation procedures, patients and laboratory staff may be subjected to acute radiation injury and increased risk for somatic and genetic effects. Take all appropriate measures to minimize x-ray exposure to both patients and clinical staff. The long-term effects of protracted fluoroscopy have not been established.

1.7 Adverse events

See the technical manual for the catheter you are using.

1.8 The generator, its accessories, and the catheter

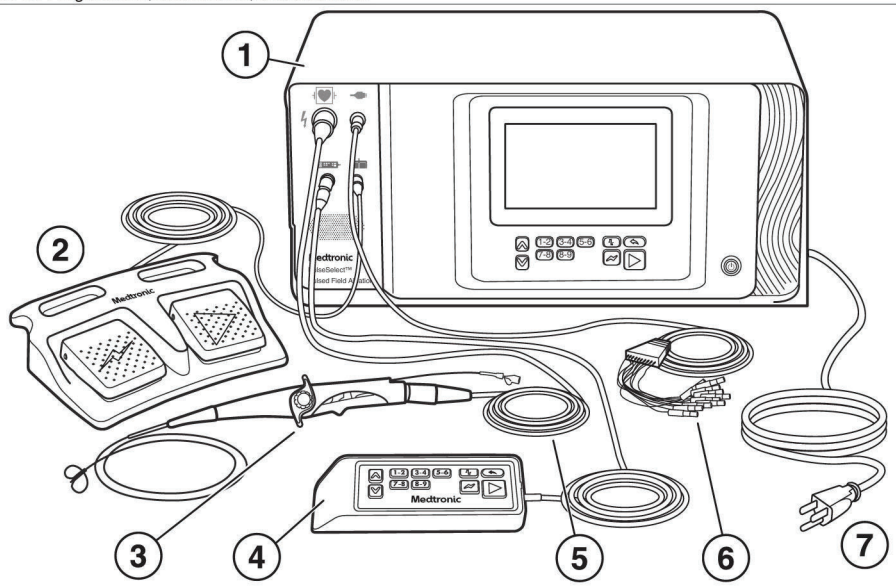
The generator is intended for use with compatible Medtronic catheters. For information about these devices, see their respective technical manuals.

For information about the sterile and nonsterile Medtronic accessories, see *Chapter 6*.

For information about setting up the PFA system for a procedure, see *Chapter 2*.

The PFA system including generator, accessories, and a compatible catheter are shown in *Figure 1*.

Figure 1. PFA generator, accessories, and a catheter



1 Generator
2 Foot switch
3 Catheter
4 Remote control
5 Catheter interface cable
6 Electrogram (EGM) cable
7 Power cord

2 Using the PFA system

Inspect all system accessories for visible damage before use. Do not use any cable or accessory that appears to have damage, including damage to cable insulation (for example, brittleness, cracking, thinning, or bare spots). Replace any damaged accessories. See *Chapter 6* for instructions for using compatible Medtronic accessories.

Audible indicators, visual indicators, and informational messages with codes are sounded out or displayed on the touchscreen display of the generator.

2.1 Place the nonsterile equipment

Place the generator outside the sterile field on a level, nonconductive surface. Do not place other equipment on top of the generator and ensure the fan on the back of the generator is not obstructed. The generator must be protected from moisture, contamination, and contact with flammable or explosive substances.

Other placement requirements include:

- The generator should be close to the operating field so that the catheter interface cable reaches from the generator to the sterile patient access field where the PFA catheter will be located.
- The generator should be close to the EP recording system to enable the electrogram (EGM) cable connection between the front panel of the generator (2, *Figure 2*) and an EP recording system.
- The generator should be close to the cardiac trigger monitor to enable a connection between the cardiac trigger monitor cable and the R-in connection on the back panel of the generator (5, *Figure 3*).

  Note: The cardiac trigger monitor should be visible to the operator to monitor R-wave detection.

2.2 Connect the system

Use only the cables, accessories, and catheters provided or recommended. Refer to *Section 5.1* for a list of compatible accessories and devices.

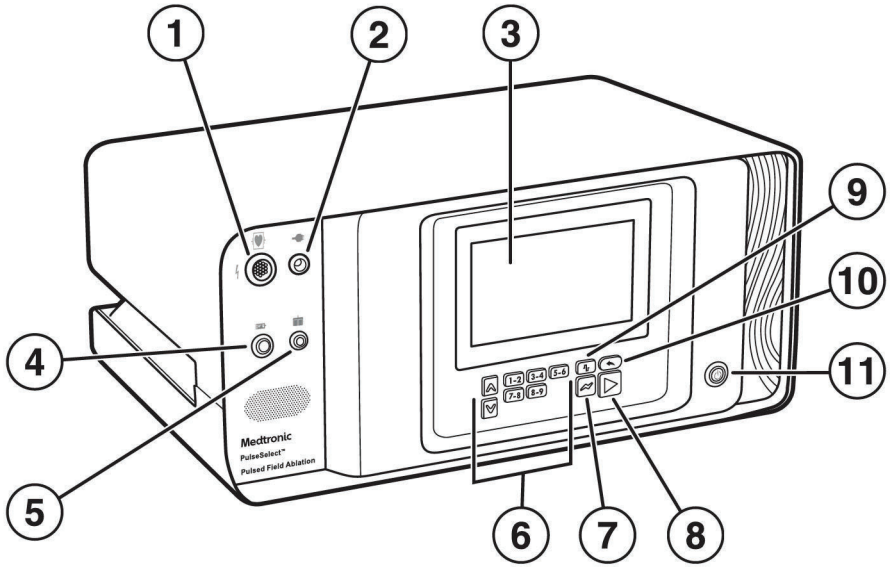
1. Connect required attachments to the generator:
    - Plug the generator power cord into the power cord connector on the back panel of the generator (6, *Figure 3*).
    - Plug the connected generator power cord into a wall outlet.
    - Plug the EGM cable into the port on the front of the generator (2, *Figure 2*).
    - Connect the shielded EGM pins from the EGM cable to the EP recording system pin block.
    - Connect the cardiac trigger monitor cable to the R-in connection on the back panel of the generator (5, *Figure 3*).

      Note: Follow the manufacturer's instructions for use supplied with the cardiac trigger monitor.
2. Connect optional accessories to the generator:
    - Plug the remote control into the port on the front panel of the generator (4, *Figure 2*).

      Note: The optional remote control is not a sterile device. Should the physician choose to control the equipment with the remote, the remote should be placed under a clear drape or wrapped in a sterile protective barrier to avoid compromising the sterile field.
    - Plug the foot switch into the port on the front panel of the generator (5, *Figure 2*).
    - Connect an external monitor, if desired, to the HDMI port (12, *Figure 3*).

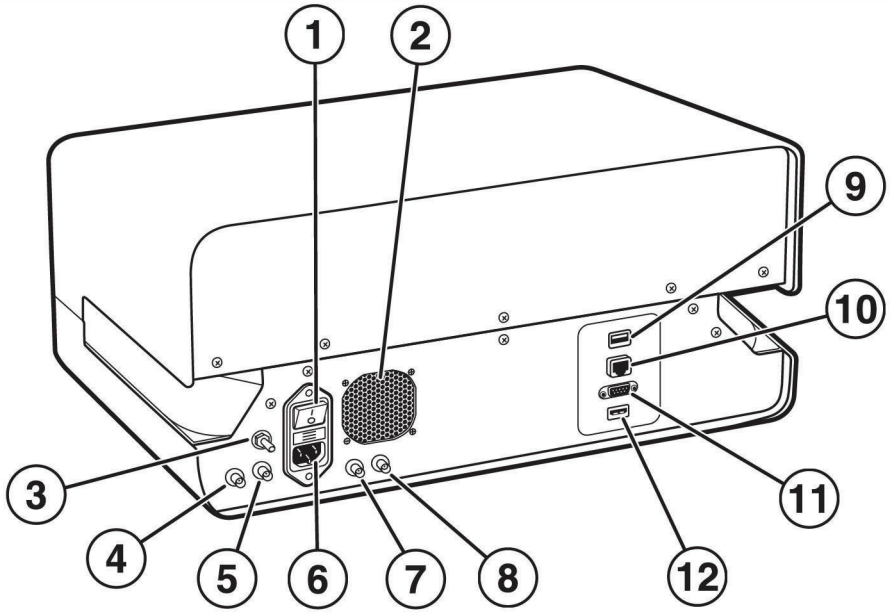
      Note: Connection to an external monitor via the HDMI port will duplicate the generator display.

Figure 2. Generator front connection and control panel



1 Catheter interface cable connector
2 EGM cable connector
3 Touchscreen display
4 Remote control connector
5 Foot switch connector
6 These buttons are not functional
7 Charge system button
8 Deliver therapy button
9 Test pulse button
10 Back button
11 Soft power button

Figure 3. Generator rear connection panel



1 Power switch
2 Fan
3 Chassis ground (not for clinical use)
4 R-out
5 R-in
6 Power cord connector
7 Sync (not for clinical use)
8 Waveform (not for clinical use)
9 USB (Port can be used by Medtronic support teams for accessing log files stored on the generator.)
10 Ethernet (Port can be used by Medtronic service to provide updates and complete service maintenance on the generator. Do not connect to network.)
11 RS-232 (not for clinical use)
12 HDMI

2.3 Prep the patient

1. Connect 3 electrocardiogram (ECG) patches to the patient.
2. Follow the manufacturer's instructions for use to connect the ECG limb lead cable to the cardiac trigger monitor.
3. Plug the cardiac trigger monitor into a wall outlet.
4. Power on the cardiac trigger monitor and follow the manufacturer's instructions for use to configure monitor.
5. Confirm R wave detection and that the displayed heart rate on the cardiac trigger monitor is appropriate.
   Note: Troubleshoot the cardiac trigger monitor by following the manufacturer's instructions for use.
6. Move the system to the appropriate location for the procedure.

2.4 Connect the catheter

Read the complete compatible catheter technical manual for detailed catheter preparation and placement instructions.

1. Before insertion of the catheter, use sterile technique to connect the catheter interface cable to the connector located on the handle of the catheter.
2. Pass the other end of the catheter interface cable out of the sterile field and connect it to the front panel of the generator (1, *Figure 2*).
   Notes:
   - The catheter must be used within 8 hours of initial connection to the generator via the catheter interface cable.
   - If a system notice appears unexpectedly while using a compatible catheter, disconnect and reconnect the catheter interface cable. If the issue persists, contact your Medtronic representative.

2.5 Start the system

1. Ensure that the power cord is plugged in to the supply mains. Only connect the power cord to a hospital-grade grounded power outlet and to the rear power cord connector shown in *Figure 3*.
2. Turn the power switch at the rear of the generator to the on position (1, *Figure 3*).

3. To start the generator, press the soft power button on the lower-right front panel of the generator (11, *Figure 2*). A black screen will display Medtronic as the generator is powering on.

2.6 System setup

System setup information can be entered or revised by following these steps.

1. After power on and initialization, open the menu in the top-right corner of the generator touchscreen display and select **SETTINGS**.
2. On the **Settings** screen, use the dropdown menus to set the **Language**, **Current Time**, and **Time Zone**.
3. If applicable, select the checkbox to **Adjusts clock for daylight saving time**.
4. Make a selection for the **Clock Type** (**12-Hour** or **24-Hour**) and **Date Format** (**DD MM YYYY** or **MM DD YYYY**).
5. Open the menu in the top-right corner of the generator touchscreen display and select **HOME** to save setup information.

2.7 Perform pulsed field ablation therapy

Read the complete compatible catheter technical manual for detailed ablation procedure steps.

1. Select **START PROCEDURE** on the generator touchscreen display.
   Note: The therapy setup screen will display **1500 V** and a representation of the distal end of the 9-electrode **PFA Catheter**.
2. Confirm that the **PFA Catheter** is **Connected**. Connection of the catheter is indicated on the generator touchscreen display.
3. Confirm detection of an R wave on the generator touchscreen display (*Table 2*). Detection of an R wave is indicated by the R wave detection icon in the upper-right corner of the generator touchscreen display blinking green (first state) and white (second state). When no R wave is detected, an R wave error state is indicated by an orange R wave detection icon on the generator touchscreen display.
   Note: If an R wave error state is detected, confirm that the cardiac trigger monitor is connected correctly to both the patient and generator. Troubleshoot the cardiac trigger monitor as appropriate by following the manufacturer's instructions for use.
4. If applicable, confirm the optional remote control and foot switch accessories are connected. Connection of these accessories is indicated on the generator touchscreen display (*Table 2*).
   Note: The remote control and generator front panel buttons can be used to deliver a test pulse, initiate a charge, and deliver pulsed field ablation. The foot switch can be used to initiate a charge and deliver pulsed field ablation. The generator touchscreen display is not used for these functions.
5. A test pulse does not require charging the system and can be used at any time during a procedure to detect proximity of the catheter to the phrenic nerve. The test pulse is a single low-voltage pulse that is delivered by pressing the test pulse button (). An audible tone will sound, and the system status will display **Delivering test pulse**.
   Note: If the test pulse produces diaphragm stimulation, consider repositioning the catheter.
6. Charging the system for therapy delivery is initiated by pressing the charge system button () on the generator, remote control, or the left actuator pad of the foot switch (2, *Figure 5*).
   - A tone will sound, the system status will display **Charging**, and the charge system button on the generator and remote control will blink while the system is charging.
   - The charge system button on the generator and remote control will stop blinking and will not be illuminated. The deliver therapy, back, and test pulse buttons will be illuminated when the system is fully charged and prepared for ablation.

   Note: Once a delivery has been performed using the generator, remote control, or foot switch, subsequent deliveries must be performed using the same source until one application (four pulse trains) has been delivered or the user has pressed the back button.
7. The therapy delivery screen is visible when the system is charged.
   - The system status **Charged** will appear at the bottom of the screen.
   - The therapy delivery screen displays **0 of 4 pulse trains**.

     Note: If therapy is not delivered within 30 seconds after the system is charged, users will be returned to the therapy setup screen.
8. Position the catheter and press the deliver therapy button (). An audible tone will sound each time therapy is delivered.
9. After each delivery, the number of delivered **pulse trains** will increase, and the system status will display **Ready** when another pulse train can be delivered. An application is completed when 4 consecutive pulse trains have been delivered, and the system status will display **Complete**. Users are returned to the therapy setup screen at the completion of four consecutive pulse trains.
   Note: At any point the back button () can be pressed to return to the therapy setup screen.

Table 1. PFA generator and remote control buttons and descriptions

Button	Description
	Charge system button
	Test pulse button
	Deliver therapy button

Table 1. PFA generator and remote control buttons and descriptions (continued)

Button	Description
	Back button
	These buttons are not functional

Table 2. PFA touchscreen display icons and descriptions

Icon	Description
	Menu
	HOME / START PROCEDURE
	SETTINGS
	LOGS
	SERVICE
	SYSTEM DATA
	ABOUT
(green)	R-wave detection first state
(white)	R-wave detection second state
(orange)	R-wave error state
	Remote control connected
	Remote control disconnected
	Foot switch connected
	Foot switch disconnected
	Error
	Disconnected / invalid catheter authentication
	Locked
	Exit procedure

2.8 End a procedure

1. Select the end procedure icon (⏎) in the top-left corner of the therapy setup screen.
   Note: To end a procedure before four pulse trains have been delivered, press the back button () to return to the therapy setup screen.
2. The **End Procedure** dialog box asks users to confirm end of procedure. Select **END PROCEDURE** to return to the start screen or **CANCEL** to remain on the therapy setup screen.

2.9 Powering down the PFA generator

1. Following the final delivery of PFA energy, power down the generator by first pressing the soft power button on the lower-right front panel of the generator (11, *Figure 2*).
2. A dialog box will ask users to confirm system shut down. Select **SHUT DOWN** to shut down the system or **CANCEL** to return to the previous screen.

Note: If software is unresponsive during system shut down, hold soft power button for at least 3 s to force a system shut down or use the power switch on the back panel of the generator to completely power off the generator.

3. When the touchscreen display returns to a black screen, the generator may be completely powered off by switching the power switch on the rear panel of the generator (1, *Figure 3*).

3 Safety shutdown conditions

The PFA generator performs a safety shutdown to prevent an unsafe operating condition. During a safety shutdown, energy delivery stops and cannot be initiated again until the condition that caused the safety shutdown is resolved.

The following occurs during a safety shutdown:

1. A system fault message explaining the reason for the safety shutdown appears on the generator touchscreen display.
2. All therapy controls become inactive until the safety shutdown condition is resolved.

The following sections present possible causes of, and possible solutions for, several safety shutdown messages.

If the ablation system does not operate properly after taking the steps listed in the tables or listed in the message itself, contact your local Medtronic representative.

3.1 System notices and troubleshooting

Table 3. PFA system notices

Error message title	Description and actions to take
No R wave Detected	Confirm the trigger monitor is connected and detecting the R wave.
Catheter Disconnected	The catheter has been disconnected. Connect the catheter to continue delivering therapy.
Catheter Electrical Current Error	A catheter electrical current error occurred. Check the catheter and guide wire positioning. Inspect the catheter cable. If the issue persists, restart the system or replace the guide wire, catheter cable, and/or catheter.
Catheter Expired	The catheter in use has expired. Connect a new catheter to continue. If the issue persists, contact Medtronic.
System Error	A system error has occurred. Restart the system. The procedure cannot be started until the error is resolved. If the issue persists, contact Medtronic.
Invalid Catheter	Connect a valid catheter to continue or select the back button to clear this message. If the issue persists, contact Medtronic.
System Timeout	The system timed out before completing your request.
Remote Control Disconnected	The remote control has been disconnected. Connect the remote to continue using it to deliver therapy.
Foot Switch Disconnected	The foot switch has been disconnected. Connect the foot switch to continue using it to deliver therapy.
Stuck Remote Control Button	The system has detected that the test pulse, charge system, back, or deliver therapy button is stuck on the remote control. Try to unstick the button, disconnect the remote, or use an alternate mode of control. If the issue persists, contact Medtronic.
Stuck Generator Button	The system has detected that the test pulse, charge system, back, or deliver therapy button is stuck on the generator. Try to unstick the button or use an alternate mode of control. If the issue persists, contact Medtronic.
Therapy timeout	User will be navigated back to the therapy setup screen.
Failed to Export	Check USB connection and retry.
Failed to Delete	Select retry to continue deletion process.
USB Not Compatible	Connect a new USB to continue.

Table 4. PFA system troubleshooting

Observed issue	Description and actions to take
Flashing remote LED	This may indicate the system cannot communicate with remote. Try to disconnect and reconnect the remote. Use front panel buttons if the preferred optional accessory is not working. If the issue persists, contact Medtronic.
Foot switch not working	This may indicate the system cannot communicate with foot switch. Try to disconnect and reconnect the foot switch. Use front panel buttons if the preferred optional accessory is not working. If the issue persists, contact Medtronic.
Generator tones not working	Check HDMI (secondary display) cable connection. If HDMI is not being used, restart the PFA generator. If the issue persists, contact Medtronic.

4 Testing and maintaining the PFA system

Wipe off the generator with a damp cloth after each use. If necessary, use a mild detergent solution. Dry generator and accessories thoroughly. Do not immerse the system in water. Do not wipe or service the generator or accessories while in use.

If there is blood or fluid ingress to the cable connections on the generator, please return the generator to Medtronic.

Caution: Do not wipe the PFA generator or reusable accessories with aggressive solvents because the equipment may be damaged.

Caution: Avoid wiping down connectors on the equipment. There should be no fluid or cleaning product applied directly to connectors. Use air to remove debris in connectors.

4.1 Functional tests and system information

The PFA system performs an internal self-check during the power on sequence. As part of this self-check, a tone will sound and the control buttons on the front panel of the generator and the optional remote control will blink. Should the system repeatedly fail to complete a successful check, the system will not be able to provide its essential performance, and the unit should be returned to Medtronic.

Voltage and current results from the internal self-check can be accessed on the **System Data** screen. Voltage and current are evaluated each time the system is powered on.

The **About** screen provides the generator serial number and relevant version numbers for software and firmware.

4.2 Maintenance

The PFA system does not contain any field serviceable parts. There is no recommended annual maintenance for this device. For service or repairs, return the unit to Medtronic.

Caution: If the PFA generator, foot switch, or the remote control is cracked or if any connectors are damaged, contact Medtronic. If there is damage to the power cord, catheter interface cable, or accessory cables, contact Medtronic.

The PFA system does not support hospital network or other Ethernet connectivity. Do not connect the system to a network or other devices via Ethernet to avoid unintended system or network behavior. Software updates are to be installed on the PFA system by authorized Medtronic service personnel only. Do not install any software on the system to avoid unintended system behavior.

4.3 Product support and returns

Contact your Medtronic representative for product support or to initiate a return of the PFA system.

A serial number is printed on the back of the generator. This serial number should be referenced in any correspondence.

4.4 Security and privacy

The PulseSelect PFA system is a non-network medical system. The generator's Ethernet connection can be used by service to deliver software updates. Do not connect the PFA system to the hospital network using the generator's ports. To prevent unauthorized access to the PFA generator's maintenance screens, these screens are accessible only by Medtronic personnel. System data can be transferred to USB for the purpose of troubleshooting system errors. This data is encrypted, can only be read by Medtronic personnel, and contains no patient information.

The PFA system does not collect or process patient records. The system does contain logs needed for errors, maintenance, and general system performance. These logs may include serial numbers of single use catheters. To learn more about what data may be collected, contact your institution or email Medtronic at rs.globaldataprivacyoffice@medtonic.com.

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

4.5 Export or delete procedure data

1. Open the menu in the top-right corner of the generator touchscreen display and select **LOGS**.
2. If exporting procedure data, insert a USB flash drive (9, *Figure 3*).
   Note: To ensure the integrity and security of patient health information, use USB flash drives that are dedicated to storing generator data only.
3. Select procedures to export or delete by dates listed on the **Logs** screen. A green check mark will indicate selected dates.
4. Select **DELETE** to delete procedure data or **EXPORT TO USB** to export procedure data.
5. When **DELETE** is selected, a dialogue box will ask users to confirm deletion of the selected logs. Select **CANCEL** to return to the Logs screen or **DELETE** to delete the selected logs.
6. When **EXPORT TO USB** is selected, an **Exporting** dialogue box will appear with a status bar. Users can also select **CANCEL** to cancel the export of selected logs.
7. A dialogue box will indicate **Export Complete** when the files have been exported to a USB.
   Note: Logs exported from the generator are encrypted and intended for use by Medtronic only. This data is encrypted, can only be read by Medtronic personnel, and contains no identifiable patient information.
8. Select **CLOSE**.
9. Remove the USB and provide the USB to your Medtronic representative.

5 Technical specifications

The generator is class II medical equipment, type CF (defibrillation proof), 2 kV common mode per IEC 60601-2-2.

The recovery time of the generator in the event of a defibrillation is 0 s. Therefore, there is no loss of basic safety or essential performance of the generator in such an event.

Table 5. Generator specifications

Description	Specification
Height	28.73 cm, 11.31 in
Depth	43.10 cm, 16.97 in
Width	60 cm, 23.75 in
AC power requirement	100 - 240 VAC ~ 4-2 A 50 Hz / 100 - 220 VAC ~ 4-2 A 60 Hz
Fuse rating	250 V (6.3 A)
Operating environmental parameters	15 °C to 30 °C (59 °F to 86 °F) at humidity of between 30% and 75%
Power cord type	Hospital grade with a retainer clip pattern that matches the PFA generator power cord connector. Refer to *Section 6.3* for more information about the applicable power cords.

5.1 Compatible accessories and devices

- PulseSelect PFA remote control (optional, supplied separately)
- PulseSelect PFA foot switch (optional, supplied separately)
- Power cord (supplied separately)
- PulseSelect PFA catheter interface cable (supplied separately)
- PulseSelect PFA electrogram (EGM) cable (supplied separately)
- PulseSelect PFA loop catheter (supplied separately)
- Cardiac trigger monitor and cardiac trigger monitor accessories (supplied separately)
  Note: Compatible cardiac trigger monitors must have a BNC connector and + 5 V transistor to transistor logic (TTL).

5.2 Disposal regulations

End-of-service instructions and information are available for Medtronic products that are within the scope of the European Union Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC.

Requirements for waste collection, reuse, recycling and recovery programs vary by regulatory authority at your location. Contact your sales representative for complete end-of-service information on applicable products.

Caution: Discard all used catheters and sterile accessories in accordance with hospital procedures.

6 Generator accessory information

This chapter includes detailed information about the nonsterile and sterile accessories of the PulseSelect PFA system.

For information about connections between the accessories and the generator, see *Section 1.8*.

Warnings and precautions

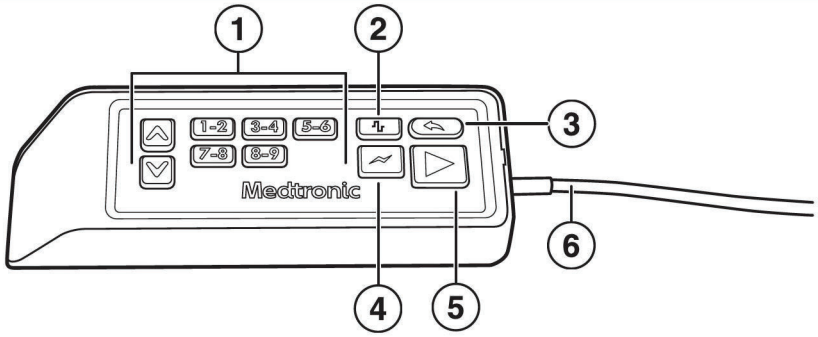
See *Section 1.6* for important information related to the generator accessories.

6.1 Remote control

6.1.1 Description

The model PSRC100 series PulseSelect PFA remote control is an optional, nonsterile accessory that allows the operator to charge the system and deliver energy to perform ablation. The remote control connects to the PFA generator via a cable and allows the user to charge the system in preparation for PFA delivery, deliver a test pulse to identify phrenic nerve stimulation response to a low-voltage delivery, and to initiate PFA delivery. The remote control can be placed within the user's reach, either outside of the sterile field or inside once it has been draped in accordance with appropriate sterile techniques.

Figure 4. Remote control



1 These buttons are not functional
2 Test pulse button
3 Back button
4 Charge system button
5 Deliver therapy button
6 Generator connection cable

6.1.2 Contents of package

The package contains the following:

- PulseSelect PFA remote control
- Product documentation

Carefully read all instructions before use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to read the instructions may result in less than expected outcomes.

6.1.3 Intended user

The intended user of this ablation system is a physician that performs cardiac ablation. Use of this device does not require specific qualifications or training beyond what is required per the applicable local, national, or federal regulations.

6.1.4 Adverse events

Adverse events associated with the use of the remote control in conjunction with the compatible catheter are included in the catheter instructions for use.

6.1.5 Instructions for use

To use the remote control, complete the following steps:

1. Plug the remote control cable into the connector (4, *Figure 2*) on the front panel of the generator.
   Note: The optional remote control is not a sterile device. Should the physician choose to control the equipment with the remote, the remote should be placed under a clear drape or wrapped in a sterile protective barrier to avoid compromising the sterile field.
2. Confirm that the remote control is connected as indicated in the upper-right corner of the generator touchscreen display. See *Table 2*.
3. See *Section 2.7* to find detailed instructions for using the remote control as part of the PFA system.
4. Remove the remote control by unplugging its cable from the connector on the front panel of the generator.

6.1.6 Care and storage

After use, perform the following steps:

1. Wipe the remote control and cable with a damp cloth. If necessary, use a mild detergent solution.
   Caution: Do not immerse the remote control or cable. Do not allow any fluid or moisture into the connector. The remote control may not function correctly if the connector gets wet.
   Caution: Do not wipe the remote control or cable with aggressive solvents or they may become damaged.
2. Dry the remote control and cable thoroughly.

Store the remote control at room temperature in a dry place.

6.1.7 Disposal

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

6.1.8 Specifications

Table 6. Remote control specifications

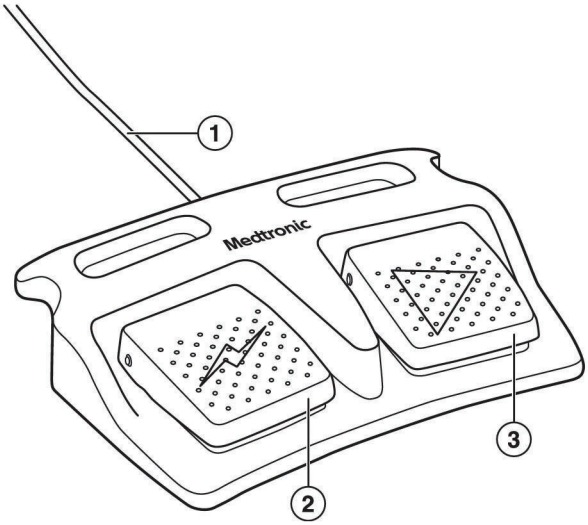
Model	Description	Specification
PSRC100	Length (remote to connector)	3.01 m (10 ft)
PSRC101	Length (remote to connector)	7.62 m (25 ft)
PSRC100, PSRC101	Height	4.75 cm (1.87 in)
PSRC100, PSRC101	Depth	8.89 cm (3.5 in)
PSRC100, PSRC101	Width	23.16 cm (9.12 in)
PSRC100, PSRC101	Connector	Keyed, latching
PSRC100, PSRC101	Operating and storage environmental parameters	15 °C to 30 °C (59 °F to 86 °F) at humidity of between 30%and 75%
PSRC100, PSRC101	Fluid ingress protection	IPX1

6.2 Foot switch

6.2.1 Description

The model PSFS100 PulseSelect PFA foot switch is an optional, nonsterile accessory that allows the operator to charge the system and deliver energy to perform ablation. The foot switch is connected to the PulseSelect PFA generator.

Figure 5. PFA foot switch



1 Connection cable
2 Charge system actuator pad
3 Deliver therapy actuator pad

The foot switch has the following parts:

- **Connection cable** – A permanently attached cable connects to the port on the back of the generator.
- **Foot switch** – The foot switch unit contains two foot actuator pads. The left pad charges the PFA system. The right pad delivers PFA therapy.

6.2.2 Contents of package

The package contains the following:

- PulseSelect PFA foot switch
- Product documentation

Carefully read all instructions before use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to read the instructions may result in less than expected outcomes.

6.2.3 Intended user

The intended user of this ablation system is a physician that performs cardiac ablation. Use of this device does not require specific qualifications or training beyond what is required per the applicable local, national, or federal regulations.

6.2.4 Adverse events

Electric shock, possibly resulting in arrhythmia or death, is a potential adverse event related to the use of the foot switch. For additional adverse events associated with the use of the product in conjunction with the compatible catheter, see the catheter instructions for use.

6.2.5 Instructions for use

To use the foot switch, complete the following steps:

1. Plug the foot switch cable into the connector (5, *Figure 2*) on the front panel of the generator.
2. Position the foot switch where a person cannot inadvertently step on or trip over it.
3. Confirm that the foot switch is connected as indicated in the upper-right corner of the generator touchscreen display. See *Table 2*.
4. See *Section 2.7* to find detailed instructions for using the foot switch as part of the PFA system.
5. Remove the foot switch by unplugging its cable from the connector on the front panel of the generator.

6.2.6 Care and storage

After use, perform the following steps:

1. Wipe the foot switch and cable with a damp cloth. If necessary, use a mild detergent solution.
   Caution: Do not immerse the foot switch. Do not allow any fluid or moisture into any connector. The foot switch and attached devices may not function correctly if the connectors get wet.
   Caution: Do not wipe the foot switch with aggressive solvents or it may become damaged.
2. Dry the foot switch thoroughly.

Store the foot switch at room temperature in a dry place.

6.2.7 Disposal

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

6.2.8 Specifications

Table 7. Foot switch specifications

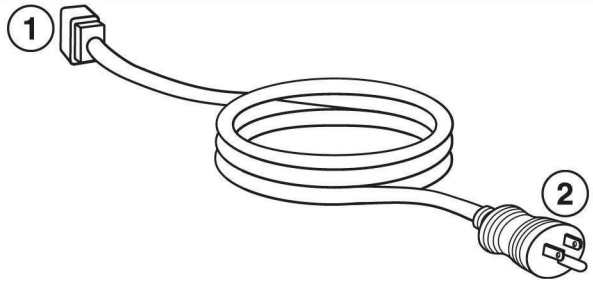
Description	Specification
Cable length	3.05 m (10 ft)
Height	5.12 cm (2.01 in)
Depth	21.39 cm (8.42 in)
Width	29.06 cm (11.44 in)
Connector	Keyed, locking
Safety information	Complies to IEC 60601-2-2 for resistance to water or particulate ingress
Operating environmental parameters	15 °C to 30 °C (59 °F to 86 °F) at humidity of between 30% and 75%

6.3 Power cord

6.3.1 Description

The power cord models PWC101, PWC201, PWC202, PWC203, PWC204, PWC205, PWC206, PWC207, PWC208, PWC209, PWC210, PWC211, PWC212, and PWC213 supply electricity to the PFA generator via hospital mains during clinical use. The power cord connects to the specified inlet on the back of the generator and a source of line power. Different power cords will be used per local compatibility requirements.

Figure 6. Power cord



1 Generator connector
2 Electrical power connector

6.3.2 Contents of package

The package contains the following:

- PulseSelect power cord
- Product documentation

Carefully read all instructions before use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to read the instructions may result in less than expected outcomes.

6.3.3 Intended user

The intended user of this ablation system is a physician that performs cardiac ablation. Use of this device does not require specific qualifications or training beyond what is required per the applicable local, national, or federal regulations.

6.3.4 Adverse events

Electric shock, possibly resulting in arrhythmia or death, is a potential adverse event related to the use of the power cord. For additional adverse events associated with the use of the product in conjunction with the compatible catheter, see the catheter instructions for use.

6.3.5 Instructions for use

To use the power cord, complete the following steps:

Note: Inspect the power cord before use. Do not use the power cord if it appears to be damaged.

1. Before turning on the generator, first connect the power cord to the back panel of the generator (6, *Figure 3*), then connect it to a wall outlet.
2. After you perform the proper shutdown procedure (see *Section 2.9*), you may leave the power cord attached to the generator.

6.3.6 Care and storage

After use, perform the following steps:

1. Wipe the power cord with a damp cloth. If necessary, use a mild detergent solution.
   Caution: Do not immerse the power cord. Do not allow any fluid or moisture into any connector. The power cord and attached devices may not function correctly if the connectors get wet.
   Caution: Do not wipe the power cord with aggressive solvents or the power cord may become damaged.
2. Dry the power cord thoroughly.

Store the power cord at room temperature in a dry place.

6.3.7 Disposal

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

6.3.8 Specifications

Table 8. Power cord specifications

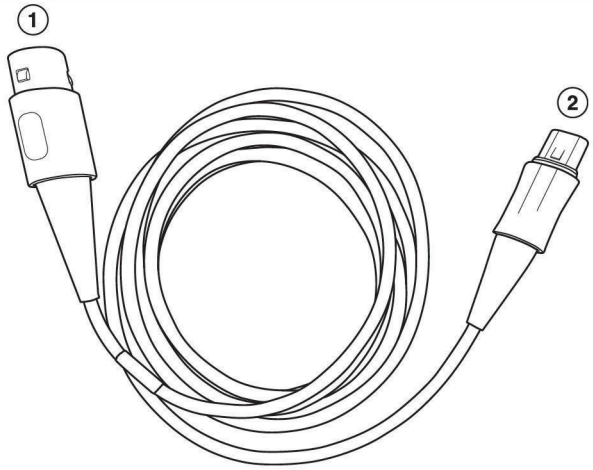
Description	Specification
Length (all models)	2.5 m (8.2 ft)

6.4 Catheter interface cable

6.4.1 Description

The model PSCIC101 PulseSelect PFA catheter interface cable (CIC) is a sterile, single use cable that provides a means for connecting the catheter to generator using a custom locking connector. This cable is provided sterile via electron beam (e-beam) sterilization.

Figure 7. Catheter interface cable



1 Generator connector
2 Catheter connector

The catheter interface cable connects the catheter to the PFA generator.

6.4.2 Contents of package

The package contains the following:

- PulseSelect PFA catheter interface cable
- Product documentation

Carefully read all instructions before use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to read the instructions may result in less than expected outcomes.

6.4.3 Intended user

The intended user of this ablation system is a physician that performs cardiac ablation. Use of this device does not require specific qualifications or training beyond what is required per the applicable local, national, or federal regulations.

6.4.4 Adverse events

Adverse events associated with the use of the catheter interface cable with the compatible catheter are included in the catheter instructions for use.

6.4.5 Instructions for use

1. Unpack the catheter interface cable.
2. Connect the catheter interface cable to the catheter.
3. Plug the catheter interface cable into the connector (1, *Figure 2*) on the front panel of the generator.
4. After procedure is complete, disconnect the catheter interface cable from the catheter handle and the generator.

6.4.6 Care and storage

Prior to use, store the catheter interface cable in the original packaging at room temperature in a dry place.

The catheter interface cable is a sterile component intended for single use. Do not attempt to clean it.

6.4.7 Disposal

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

6.4.8 Specifications

Table 9. Catheter interface cable specifications

Description	Specification
Length (generator to catheter)	251.46 cm (99 in)
Fluid ingress protection	IPX4

Table 9. Catheter interface cable specifications (continued)

Description	Specification
Operating environmental parameters	15 °C to 30 °C (59 °F to 86 °F) at humidity of between 30% and 75%
Sterilization	Single use, sterile, e-beam radiation

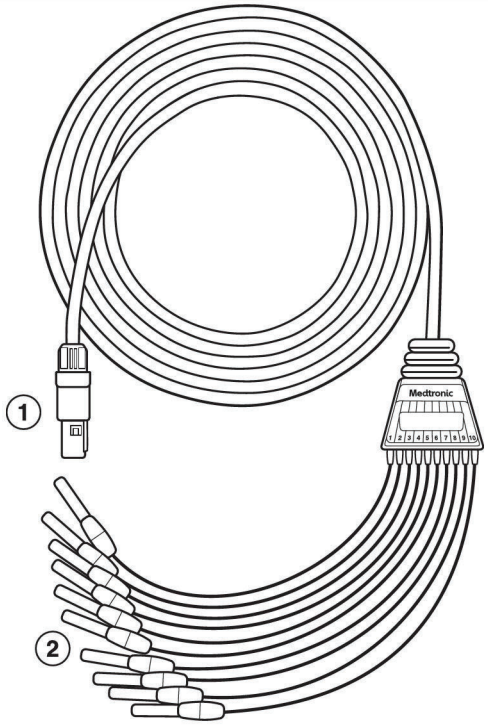
6.5 Electrogram (EGM) cable

6.5.1 Description

The model PSEGM100 PulseSelect PFA electrogram (EGM) cable is a nonsterile, reusable cable that connects the PFA generator to an external EP recording system and/or pacing equipment.

Note: Any external EP recording system and/or pacing equipment used with the PFA system must be compliant with the applicable standards.

Figure 8. EGM cable



1 Single-tip end
2 Shrouded pin connectors

The EGM cable connects to:

- **The EP recording system** – Ten 2 mm shielded connectors connect to a compatible EP recording system.
- **The PFA generator** – The single-tip end connects to the corresponding port of the PFA generator.

6.5.2 Contents of package

The package contains the following:

- PulseSelect PFA EGM cable
- Product documentation

Carefully read all instructions before use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to read the instructions may result in less than expected outcomes.

6.5.3 Intended user

The intended user of this ablation system is a physician that performs cardiac ablation. Use of this device does not require specific qualifications or training beyond what is required per the applicable local, national, or federal regulations.

6.5.4 Adverse events

Electric shock, possibly resulting in arrhythmia or death, is a potential adverse event related to the use of the EGM cable. For additional adverse events associated with the use of the product in conjunction with the compatible catheter, see the catheter instructions for use.

6.5.5 Instructions for use

To connect the EGM cable, complete the following steps:

1. Plug the single-tip end of the EGM cable to the connector (2, *Figure 2*) on the front panel of the generator.
2. Connect the 10 shielded-tip jacks to the EP recording system.

To disconnect the EGM cable, unplug it from the PFA generator and from the EP recording system.

6.5.6 Care and storage

After use, perform the following steps:

1. Wipe the EGM cable with a damp cloth. If necessary, use a mild detergent solution.
   Caution: Do not immerse the EGM cable. Do not allow any fluid or moisture into any connector. The EGM cable and attached devices may not function correctly if the connectors get wet.
   Caution: Do not wipe the EGM cable with aggressive solvents or it may be damaged.
2. Dry the EGM cable thoroughly.

Store the EGM cable at room temperature in a dry place.

6.5.7 Disposal

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

6.5.8 Specifications

Table 10. EGM cable specifications

Description	Specification
Length (pin-to-connector)	1.96 m (77 in)
Connector 1 (single-tip end)	Male, 14-pin connector
Connector 2	Male, shrouded pin connectors x10 (connects to the hospital's compatible EP recording system)
Operating environmental parameters	15 °C to 30 °C (59 °F to 86 °F) at humidity of between 30% and 75%

7 Appendix: EMI/EMC declaration of conformity

Guidance and manufacturer's declaration – electromagnetic emissions		
The Medtronic PFA system is intended for use in the electromagnetic environment specified in this section. This intended use of this equipment is compatible with the high frequency surgical equipment standard 60601-2-2 during high frequency. The operator of the system should ensure that it is used in such an environment. **Notes:** • The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment. • There are no special instructions for maintaining basic safety and Essential Performance with regard to Electromagnetic disturbances for the expected service life of this equipment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 2	The PFA system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The PFA system is suitable for use in establishments other than domestic and those directly connected to the public low-voltage power supply network, which supplies power to buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Medtronic PFA system is intended for use in the electromagnetic environment specified in this section. The operator of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**

Guidance and manufacturer's declaration – electromagnetic immunity			
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	
Surge IEC 61000-4-5	±0.5, ±1, ±2 kV differential mode ±0.5, ±1, ±2 kV common mode	±0.5, ±1, ±2 kV differential mode ±0.5, ±1, ±2 kV common mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle 0% U_T for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 250 cycles	0% U_T for 0.5 cycle 0% U_T for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 250 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	If electromagnetic interference (EMI) occurs, it may be necessary to position the PFA system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note: U_T is the AC mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 V_{RMS} (volts root-mean-square)	3 V_{RMS}	Portable and mobile RF communications equipment should be used no closer to any part of the PFA system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** for geographies compliant to IEC 60601-1-2 3rd edition where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). $d = 1.2\sqrt{P}$ (150 kHz to 80 MHz) $d = 1.2\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3\sqrt{P}$ (800 MHz to 2.5 GHz) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[a]. For geographies compliant to IEC 60601-1-2 4th edition, minimum separation distance is 30 cm[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
	IEC 60601-1-2 4th edition Table 5	6 V	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
	IEC 60601-1-2 4th Edition Table 9	Meets all the field strength	
Note: At 80 MHz and 800 MHz, the higher frequency range applies. **Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PFA system is used exceeds the applicable RF compliance level above, the generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the generator.

[b] Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PFA system (This table is applicable to IEC 60601-1-2 3rd Ed.)
The Medtronic PFA system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The operator of the generator can help prevent electromagnetic interference by maintaining a minimum distance

Recommended separation distances between portable and mobile RF communications equipment and the PFA system (This table is applicable to IEC 60601-1-2 3rd Ed.)			
between portable and mobile RF communications equipment (transmitters) and the generator as recommended in this table, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. **Note:** This warning is intended to make patients and operators aware of the minimum separation distance that should be maintained between portable RF communications equipment and ME equipment and ME systems in order to avoid potential performance degradation and compromise of basic safety and essential performance.			

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