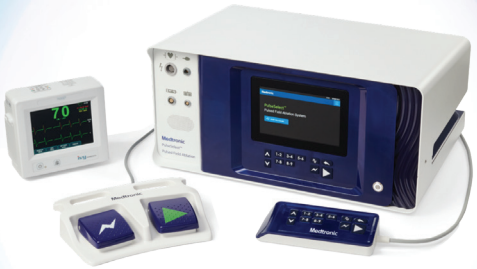
Medtronic

PulseSelect™ Pulsed Field Ablation

Generator components



PulseSelect™ PFA Generator

The PulseSelect pulsed field ablation generator is designed for simple lab installation, intuitive usability, and offers flexible user control.

Ordering information

Order number	
PSG100	PulseSelect™ PFA Generator

Specifications

Input voltage	250 V/The system can be plugged into standard hospital mains power using the provided geography specific cable.
Output voltage	1,500 V (baseline to peak) Bipolar, biphasic waveform
Weight	< 55 lbs/< 25 kgs
Height	11.3 in/28.73 cm
Depth	16.9 in/43.10 cm
Width	23.6 in/60 cm
Operating & storage temperature	15–30 C/59–86 F
Operating humidity	30–75%

Accessories

External monitor	Duplicate generator display via HDMI port
PulseSelect PFA remote control	
PulseSelect PFA foot switch	
PulseSelect PFA electrogram (EGM) cable	
PulseSelect PFA cart	
Cardiac trigger monitor and accessories	

The PulseSelect PFA remote control enables flexible user control of the system.

The PulseSelect PFA foot switch enables hands-free control of therapy delivery.

PulseSelect PFA Remote Control

Ordering information

Order number	
PSRC100	PulseSelect PFA remote control – 10 ft
PSRC101	PulseSelect PFA remote control – 25 ft

Specifications

Length (remote to connector)	Model PSRC100: 10 ft/3.01 m Model PSRC101: 25 ft/7.62 m
Height	1.87 in/4.75 cm
Depth	3.5 in/8.89 cm
Width	9.12 in/23.16 cm
Operating & storage temperature	59–86 F/15–30 C
Operating & storage humidity	30–75%
Ingress protection	IPX1

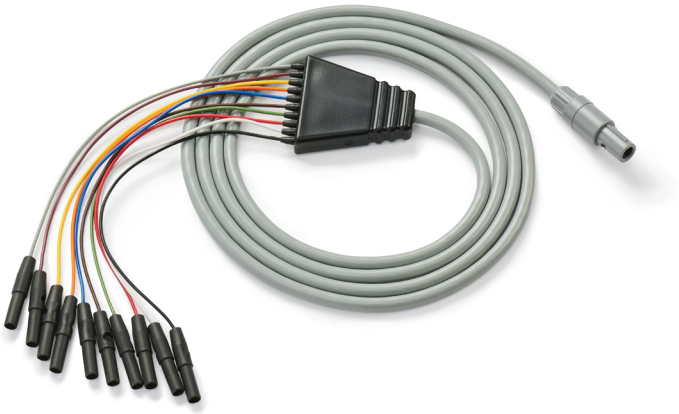
PulseSelect PFA Foot Switch

Ordering information

Order number	
PSFS100	PulseSelect PFA foot switch

Specifications

Cable length	10 ft/3.05 m
Height	2.01 in/5.12 cm
Depth	8.42 in/21.39 cm
Width	11.44 in/29.06 cm
Connector	Keyed, locking
Operating & storage temperature	59–86 F/15–30 C
Operating & storage humidity	30–75%



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

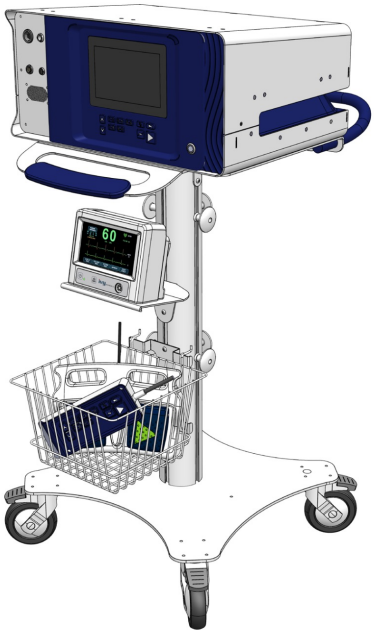
PulseSelect PFA EGM cable

Ordering information

Order number	
PSEGM100	PulseSelect PFA EGM cable

Specifications

Length (pin to connector)	77 in/1.96 m
Connector 1 (single-tip end)	Male, 14-pin connector
Connector 2	Male, shrouded pin connectors x10
Operating & storage temperature	59–86 F/15–30 C
Operating & storage humidity	30–75%



PulseSelect PFA Cart

Ordering information

Order number	
2103098	PulseSelect PFA Cart

Specifications

Height	41 in/104.1 cm
Depth	33 in/83.82 cm
Width	26 in/66.04 cm
Weight (unloaded)	< 75 lbs/< 34 kg

Features:

- 4 wheels with foot locks
- Platform for PulseSelect PFA generator with fasteners
- Platform for cardiac trigger monitor
- Basket for PulseSelect PFA system accessories

Cardiac trigger monitor and accessories kit

Ordering information

Order number

7600EP

The cardiac trigger monitor precisely detects the peak of the patient's ECG R-wave enabling synchronized PFA delivery with the PulseSelect PFA system.

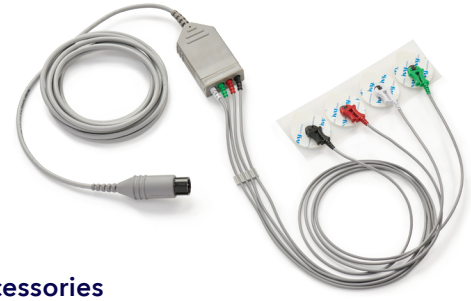
Cardiac trigger monitor – Model 7600EP

Specifications

Range	10–300 BPM
Accuracy	± 1% ± 1 BPM
Resolution	1 BPM
Height	7.49 in/19.02 cm
Width	7.94 in/20.17 cm
Depth	5.18 in/13.16 cm
Weight	3.9 lbs/1.80 kg
Screen Size	6.5 in/16.5 cm diagonal
Operating temperature	41–104 F/5–40 C
Operating humidity	0–90% noncondensing
Storage temperature	-40–158 F/-40–70 C
Storage humidity	5–95%
Voltage input	200–230 V
Ingress protection	IPX1
ECG configuration	4-lead system
Trigger lead selection	I, II, III, or AUTO
Synch output	BNC-BNC interface cable; Provides trigger pulse output synch to ECG R-wave peak

Product manufactured by Ivy Biomedical distributed by Medtronic. Please refer to the 7600EP Operator Manual.

ECG Lead



Compatible accessories

Order number 590494	ECG Electrodes, AccuScan-EG, Adult, 10x4/pkg, 10% KCl
Order number 590449	ECG lead wires, metallic, IEC, 36"
Order number 590478	ECG Trunk Cable, LN, 4 Lead, Universal AHA/IEC, 10'

PulseSelect™ Pulsed Field Ablation (PFA) System Brief Statement
Indications (or Intended Use): The PulseSelect™ Pulsed Field Ablation (PFA) System 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).
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.
Warnings and Precautions: 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. • 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. 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. 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. 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 – 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. 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. 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. 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. 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. 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. 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. 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. 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.
Potential Adverse Events or Potential Complications: 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.
Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.
Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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