

# Medtronic

## DiamondTemp™

Catheter-to-RF Generator Cable

Instructions for Use

**Caution:** Investigational device. Limited by Federal law (USA) to investigational use.

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DiamondTemp™

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1 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard Title or Reference	Symbol Title/Reference Number	Explanatory Text
<b>Rx only</b>	21 CFR 801.109 <sup>a</sup>	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	EN 50419 <sup>b</sup>	Recycle: Electronic Equipment	Do NOT throw in trash.
	ISO 15223-1 <sup>d</sup>	Consult instructions for use (clause 5.4.3)	Indicates the need for the user to consult the instructions for use at this website: <a href="http://www.medtronic.com/manuals">www.medtronic.com/manuals</a>
	IEC 60601-1 <sup>c</sup>	Follow instructions for use (Table D2, Symbol 10)	Refer to instruction manual/booklet (blue symbol).
	ISO 15223-1 <sup>d</sup>	Date of manufacture (clause 5.1.3)	Indicates the date when the medical device was manufactured
	ISO 15223-1 <sup>d</sup>	Catalog number (clause 5.1.6)	Indicates the manufacturer's catalog number so the device can be identified
	ISO 15223-1 <sup>d</sup>	Batch code (clause 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1 <sup>d</sup>	Use by (clause 5.1.4)	Indicates the date after which the device is not to be used
	ISO 15223-1 <sup>d</sup>	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer
	ISO 15223-1 <sup>d</sup>	Keep Dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1 <sup>d</sup>	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened
	ISO 15223-1 <sup>d</sup>	Sterilized using ethylene oxide (clause 5.2.3)	Indicates a medical device that has been sterilized using ethylene oxide
	N/A	N/A	Device can be re-sterilized for the number of times indicated
	ISO 15223-1 <sup>d</sup>	Temperature limit (clause 5.3.7)	Indicates the temperature limits to which the medical device can be safely exposed
	N/A	Storage temperature limit	Indicates the required temperature range for storing the device
	N/A	Transit temperature limit	Indicates the required temperature range for transporting the device
	ISO 15223-1 <sup>d</sup>	Humidity limitation (clause 5.3.8)	Indicates the range of humidity to which the medical device can be safely exposed
	ISO 15223-1 <sup>d</sup>	Atmospheric pressure limitation (clause 5.3.9)	Indicates the range of atmospheric pressure to

Symbol	Standard/Standard Title or Reference	Symbol Title/Reference Number	Explanatory Text
	N/A	Package contents	which the medical device can be safely exposed Indicates the components included in the device package
	N/A	Catheter-to-RFG cable	Indicates that a cable is included in the device package
	ISO 7000 <sup>e</sup>	Product documentation	Indicates that product documentation is included in the device package
	ISO 15223-1 <sup>d</sup>	Sterile barrier	Single sterile barrier system

<sup>a</sup> 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

<sup>b</sup> EN 50419: Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

<sup>c</sup> IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

<sup>d</sup> ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

<sup>e</sup> ISO 7000: Graphical symbols for use on equipment

## 2 Device description

The Medtronic DiamondTemp catheter-to-RF generator (RFG) cable is part of the DiamondTemp ablation system, which also includes the DiamondTemp ablation catheter, DiamondTemp RF generator, DiamondTemp irrigation tubing set, DiamondTemp GenConnect cable, DiamondTemp EGM cable, and DiamondTemp irrigation pump.

The DiamondTemp ablation system is designed to deliver radiofrequency (RF) energy to the cardiac anatomy via the DiamondTemp catheter.

The Model CEDTC100 catheter-to-RFG cable is used to connect the DiamondTemp catheter to the RF generator. The distal end of the cable has a 19-pin connector that connects to the DiamondTemp catheter. The proximal end of the cable has a 26-pin connector that connects to the RF generator. The length of the cable is 2.5 m (8.2 ft).

## 3 Indications for use

The DiamondTemp catheter-to-RF generator cable is designed for use with the DiamondTemp ablation system. The cable provides connection between the DiamondTemp generator and the DiamondTemp catheter. Refer to the DiamondTemp catheter instructions for the indications for use. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the cable.

## 4 Contraindications

The contraindications listed in the DiamondTemp catheter instructions apply to the use of the DiamondTemp catheter-to-RFG cable. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the catheter-to-RFG cable.

## 5 Warnings and precautions

- Refer to the DiamondTemp catheter instructions for warnings and precautions related to the use of the DiamondTemp ablation system.
- Do not expose the cable to organic solvents.
- The cable is designed for use with the DiamondTemp catheter and generator only.
- Use of improper cables may cause errors in the operation of the generator and can result in hazards to the patient.
- The cable is supplied sterile, by ethylene oxide (EtO). Do not use if the sterile barrier is damaged. Use of non-sterile devices may result in patient injury.
- Use the cable before the “Use By” date on the device package. Do not use past the “Use By” date regardless of the number of times the cable has been resterilized.
- Do not pull on the cable to disconnect the cable from either the RF generator or the catheter.
- Sterilize after use; do not reuse without sterilizing. The cable may be resterilized up to ten (10) times via Autoclave sterilization (see section 9). Do not reuse more than ten times. Reusing the cable more than ten times may lead to device malfunction, resulting in failure to complete the procedure or possibly patient injury.
- Store in a cool, dry place.
- Before use, inspect the cable and packaging to verify that no damage has occurred. Do not use if the cable or packaging is damaged.

- All devices that are connected to the RF generator must be safe for patients per specifications in IEC 60601-1 and IEC 60601-2-2. Improper use may be dangerous for the patient.
- Position connecting cables to avoid contact with the patient and other electrical leads.
- If used in the presence of other electrical equipment, noise could be introduced into the cable. Position the cable as far away as possible from sources of potential electromagnetic interference.
- Do **not** clean the cable by using automated cleaning processes.
- Do not immerse the cable connectors in fluids.

## 6 Potential adverse events

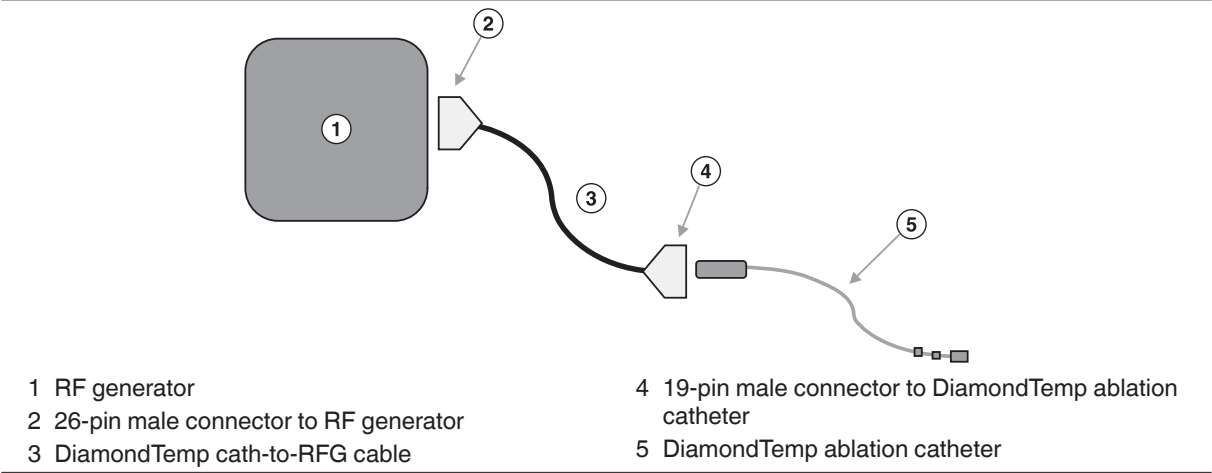
The potential adverse events that may be associated with ablation procedures can vary greatly in frequency and severity and may necessitate additional medical intervention, including surgery. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each DiamondTemp catheter, before using the DiamondTemp ablation system.

## 7 Directions for use

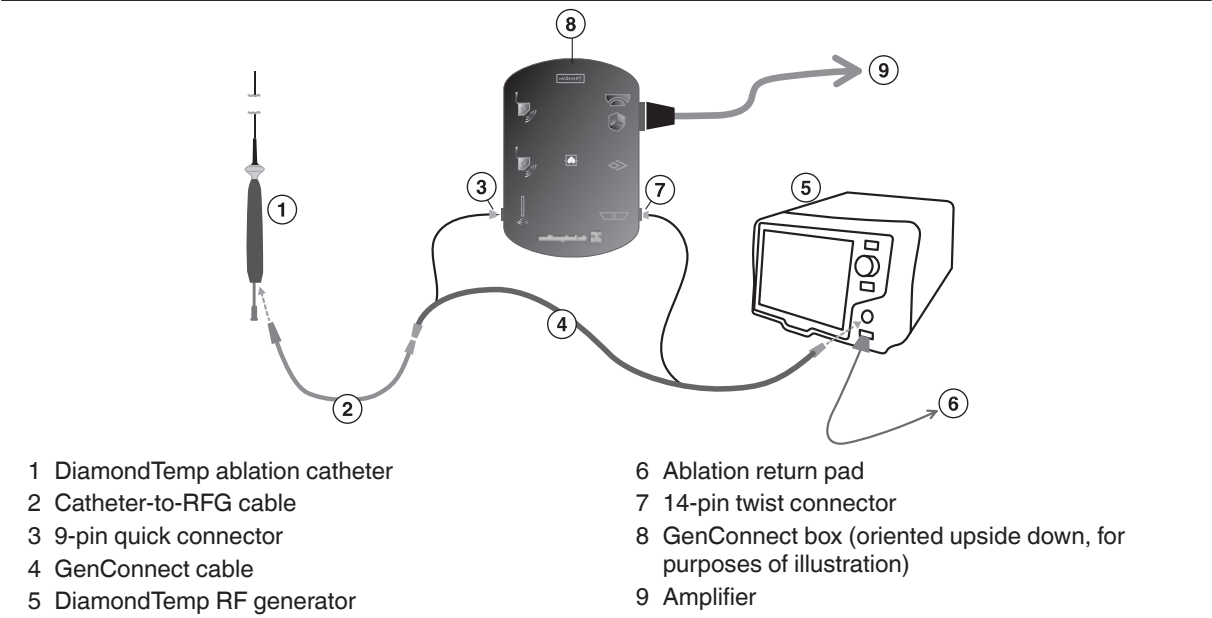
**Note:** Refer to the DiamondTemp catheter instructions for use and DiamondTemp RF generator user manual for detailed operating instructions of the DiamondTemp ablation system.

1. Carefully remove the sterile cable from its packaging using standard hospital practices. Inspect the cable for damage or rough surfaces, sharp edges, or protrusions before use. Connect the sterile cable to the sterile catheter. To do this, align the blue strain-relief end of the catheter-to-RFG cable connector key to the catheter receptacle key, and then push the connector into the catheter receptacle firmly until it stops. Do not force connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
2. Pass the RF generator end of the cable out of the sterile field.
3. Connect the cable to the generator or GenConnect cable. To do this, align the green strain-relief end of the catheter-to-RFG cable connector key to the generator or catheter-to-RFG receptacle key, and then push the connector into the receptacle firmly until it stops. Do not force connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
4. Refer to the connectivity diagrams in *Figure 1* and *Figure 2*. *Figure 1* illustrates how to connect the cable to the catheter and directly to the RF generator. *Figure 2* illustrates how to connect the cable to operate the catheter and system in conjunction with a compatible mapping and navigation system (such as the Abbott EnSite™ system). Refer to the respective instructions for detailed information.
5. Connect the DIP electrode directly to the generator.

**Figure 1.** Connectivity diagram between catheter and RF generator



**Figure 2.** Connectivity diagram between catheter and RF generator when using a mapping and navigation system



Verify that the generator does not show any errors or warnings. When used with a mapping and navigation system, follow the respective instructions to confirm correct operation. Construct an anatomic map of the region of interest only after all mapping catheters, the DiamondTemp catheter, and all respective cables and neutral electrodes (including the ablation return pad) are completely and properly connected. The addition of catheters or electrodes may lead to inaccurate anatomic maps and may require re-mapping.

**8 Device removal and disposal**

At the end of the procedure, after removing the DiamondTemp catheter from the patient, disconnect the cable from the catheter by gently pulling on the outer housing of the connectors. Do not pull on the cabling, as this may damage the cable or the catheter.

Disconnect the cable from the generator by gently pulling on the outer housing of the RF generator connector. Do not pull on the cabling, as this may damage the cable or the generator.

After cleaning or decontamination, the cable may be resterilized and reused up to ten times or disposed of according to standard procedures for electrical cables and in accordance with local laws and regulations.

**9 Cleaning**

The cable should be cleaned by wiping with enzymatic concentrates, such as Prolystica 2x Concentrate, at 1/8 oz per gallon of tap water (0.94 g per 1 L).

1. If soiling is present on the external portion of the connector previously shielded by the receptacle, use clean, lint-free cloths to dip into the prepared detergent solution and wipe the area until all visible soil is removed.
2. Apply Parafilm over the connectors at both ends of the cable.
3. Use clean, lint-free cloths to dip into the prepared solution and wipe the cable until all visible soil is removed.
4. Thoroughly rinse the cable with reverse osmosis/deionized (RO/DI) water for a minimum of 30 s, ensuring the connectors remain dry.
5. Dry the cable with a clean, lint-free cloth. Remove the Parafilm.
6. Visually inspect each cable to ensure there is no visible soil.

**Note:** The cable connectors should not be immersed in fluids. Automated cleaning of the cable is not recommended.

**10 Resterilization**

The cable may be resterilized for reuse up to ten times. Medtronic recommends using autoclave sterilization methods. If using autoclave sterilization, the following method is recommended:

- Double wrap individual cables in sterile wraps.
- Condition using a prevacuum cycle of 4 pulses.
- Sterilize at 134°C for 3 to 18 min.
- Dry for 30 min.

## 11 How supplied

The cable is supplied separately from the generator, along with the required product documentation. The contents are sterile if the packaging is unopened and undamaged at the time of use. If the packaging is damaged, do not use the product and contact a Medtronic representative.

## 12 Storage

The cable should be stored in its original packaging before first use. Store in a cool and dry place, in a 15°C to 30°C (59°F to 86°F) noncondensing environment, according to standard hospital procedures for resterilized equipment after resterilization.

## 13 Limited warranty

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

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

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

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

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

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

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

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

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

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUNCTION OF THE Product, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

(2) This Limited Warranty is made only to the purchaser of the Product.

AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

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

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





# Medtronic

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# Medtronic

## DiamondTemp™ CEDTEGM100

EGM cable

Instructions for Use













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










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DiamondTemp™

# 1 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	ISO 15223-1 <sup>c</sup>	Consult instructions for use (clause 5.4.3)	Consult instructions for use at this website: <a href="http://www.medtronic.com/manuals">www.medtronic.com/manuals</a>
Rx only	21 CFR 801.109 <sup>a</sup>	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed health-care practitioner.
	EN 50419 <sup>b</sup>	Recycle: Electronic Equipment	Do NOT throw in trash.
	ISO 15223-1 <sup>c</sup>	Reorder/catalog number (clause 5.1.6)	Indicates the manufacturer's reorder number so the device can be identified
	ISO 15223-1 <sup>c</sup>	Batch code (clause 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1 <sup>c</sup>	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer
	ISO 15223-1 <sup>c</sup>	Date of manufacture (clause 5.1.3)	Indicates the date when the medical device was manufactured
	N/A	Manufactured in / manufacturing site	Indicates where the device was manufactured
	ISO 15223-1 <sup>c</sup>	Keep Dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1 <sup>c</sup>	Fragile, handle with care (clause 5.3.1)	Indicates the device is fragile and should be handled with care
	ISO 15223-1 <sup>c</sup>	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened
	N/A	Storage temperature limit	Indicates the required temperature range for storing the device
	N/A	Transit temperature limit	Indicates the required temperature range for transporting the device

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	ISO 15223-1 <sup>c</sup>	Humidity limitation (clause 5.3.8)	Indicates the range of humidity to which the medical device can be safely exposed
	EU MDR 2017/745 <sup>d</sup>	Medical device (Annex I, Chapter III)	Indicates the device is a medical device
	EU MDR 2017/745 <sup>d</sup>	Model number (Annex I, Chapter III)	Indicates the model number of the device
	EU MDR 2017/745 <sup>d</sup>	Unique device identifier (UD) (Article 27; Annex VI)	Indicates the unique identification number of the device
	N/A	Package contents	Indicates the components included in the device package
	ISO 7000 <sup>e</sup>	Product documentation	Indicates that product documentation is included in the device package
	N/A	EGM cable	Indicates that a cable is included in the device package
	EU medical device directive/regulation	CE mark of conformity	Signifies European technical conformity to applicable European Union acts
	ISO 15223-1 <sup>c</sup>	Authorized representative in European Community (clause 5.1.2)	Indicates the authorized representative in the European Community
.	N/A	For US audience only	Indicates that the information is only intended for the U.S.A.

<sup>a</sup> 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

<sup>b</sup> EN 50419: Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

<sup>c</sup> ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

<sup>d</sup> EU MDR 2017/745: European Union Medical Device Regulation

<sup>e</sup> ISO 7000: Graphical symbols for use on equipment

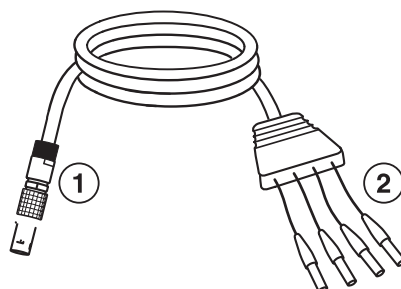
## 2 Device description

The Medtronic DiamondTemp CEDTEGM100 EGM cable connects the RF generator to a hospital's compatible EP recording system. This feature is used with the DiamondTemp ablation catheters. (**Note:** Any electronic recording or stimulation equipment used with the catheter must be compliant with the applicable standards, such as IEC 60601-1.)

The supplied EGM cable should be used only with the DiamondTemp ablation system.

**Figure 1.** Model CEDTEGM100 EGM cable

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1 Male, 9-pin connector

2 Male, 2.0 mm shrouded pin connectors (x4)

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### 3 Contents of package

The cable is supplied nonsterile. The package contains the following items:

- One model CEDTEGM100 EGM cable
- Product documentation

### 4 Indications for use and contraindications

Refer to the instructions for use for the compatible DiamondTemp catheter being used for the indications for use and contraindications.

### 5 Intended use

The CEDTEGM100 EGM cable is intended to connect the DiamondTemp RF generator to an external EP recording system.

### 6 Warnings and precautions

**Review the system documentation** – Because the cable is part of an ablation system, review all applicable documentation for warnings and precautions, adverse events, and instructions.

**Product compatibility** – For use only with the DiamondTemp RF generator. Use with other ablation systems has not been assessed, and may compromise patient or operator safety.

**Inspect the package** – Carefully inspect the package before opening. If the package has been damaged or opened, do not use and contact a Medtronic representative.

**Inspect the cable** – Inspect the cable thoroughly. Check for insulation damage, such as brittleness, cracking, or bare spots. Do not use the cable if it appears to be damaged.

**Connection to generator** – All devices that are connected to the RF generator must be safe for patients per specifications in IEC 60601-1 and IEC 60601-2-2. Improper use may be dangerous for the patient.

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

**Leakage current** – Use only isolated amplifiers, pacing equipment, and ECG equipment (IEC 60601-1 Type CF equipment or equivalent) or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 micro Amps ( $\mu\text{A}$ ) under any circumstances.

**Do not modify** – Do not modify this equipment. Modifications may reduce system effectiveness and impact patient health.

**Storage conditions** – Do not expose this component to storage temperatures below 15°C (59°F) or above 30°C (86°F).

**Standard grounding** – It is recommended that standard grounding precautions be followed when electrosurgical instruments are used.

**Sterilization and reuse** – The cable is provided nonsterile and is not intended for sterilization. The cable can be reused up to ten (10) times. Reusing the cable more than ten times may lead to device malfunction, resulting in failure to complete the procedure or possibly 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.

**Technical manual information** – If you find information in this manual that is incorrect or illegible, contact your Medtronic representative or your local competent medical authority.

## 7 Directions for use

**Note:** Inspect the cable before use. Do not use this cable if it appears to be damaged.

To connect the EGM cable, use the following steps:

1. Insert the connector on the cable into the EGM output (ECG/Pace) on the DiamondTemp RF generator.
2. Connect the four 2 mm shrouded pins on the end of the cable to the EP recording system.

To disconnect the cable, pull back on the locking ring to release the cable and then detach the cable from the generator.

For additional instructions on using the cable with the RF generator, see the *DiamondTemp RF Generator User Manual*.

## 8 Cleaning and disposal

After use, the cable may be reused (up to 10 times) or disposed per standard procedures for electrical cables and in accordance with local laws and regulations.

The cable is not required to be cleaned before use, but it may be cleaned between uses. To clean the cable, use the following steps:

1. Clean the cable by wiping it with a damp cloth. If necessary, use a mild detergent solution.  
**Caution:** Do not immerse the cable. Do not allow any fluid or moisture into any connector. The cable and attached devices may not function correctly if the connectors get wet.  
**Caution:** Do not clean the cable with aggressive solvents or the cable may be damaged.
2. Dry thoroughly.  
**Caution:** Inspect this component thoroughly after cleaning and before reuse. Check for insulation damage, such as brittleness, cracking, or bare spots. Do not use this component if it appears to be damaged.



## 9 Specifications

Length	3.0 m (9.8 ft)
Environmental parameters	
Operational conditions	15°C to 30°C (59°F to 86°F), 30% to 75% relative humidity (non-condensing)
Storage temperature	15°C to 30°C (59°F to 86°F)

## 10 Limited warranty

The following limited warranty applies to customers within the United States only:

A. This limited warranty provides the following assurance to the customer of the Medtronic DiamondTemp RF generator, irrigation pump, GenConnect cable, and EGM cable, with reusable parts (foot switch, ethernet cable, and power cord), hereafter collectively referred to as the DiamondTemp ablation system. Subject to the limitations herein, Medtronic warrants the DiamondTemp ablation system sold to the customer will be free from defects in materials and workmanship under normal usage for a period of 12 months from the delivery date at the customer's facility.

B. Should the DiamondTemp ablation system fail to meet the above warranty, Medtronic will at its option, repair or replace such DiamondTemp ablation system, or any portion thereof. For the limited warranty to apply, the following conditions must be met:

(1) Medtronic must be notified of and confirm the failure of the alleged defect within 60 days after discovery of the defect.

(2) The DiamondTemp ablation system must not have been repaired or altered outside of authorized personnel at Medtronic.

(3) THE DIAMONDTEMP ABLATION SYSTEM MUST BE USED IN ACCORDANCE WITH LABELING AND NOT ALTERED OR SUBJECTED TO MISUSE, ABUSE, IMPROPER HANDLING, OR ACCIDENT, INCLUDING, BUT NOT LIMITED TO, FIRE, FLOOD OR NATURAL DISASTERS.

C. At the discretion of Medtronic, parts or assemblies used or installed as part of the DiamondTemp ablation system may be either new or rebuilt of equal or improved quality. All parts removed or replaced during maintenance become the property of Medtronic.

D. This limited warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this limited warranty, MEDTRONIC EXPRESSLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WHETHER AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER MATTER. THE REMEDIES SET FORTH IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE TO THE CUSTOMER OR ANY THIRD PARTY FOR BREACH OF WARRANTY. MEDTRONIC SHALL HAVE NO LIABILITY TO ANY PERSON FOR INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES OF ANY DESCRIPTION, WHETHER ARISING OUT OF WARRANTY, OTHER CONTRACT, TORT, OR OTHERWISE.

(2) Except as expressly provided by this limited warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, MALFUNCTION, OR FAILURE OF THE DEVICE TO FUNCTION WITHIN NORMAL TOLERANCE, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

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

F. No person has any authority to bind Medtronic to any representation, condition, or warranty except this limited warranty.

G. This limited warranty is not applicable to accessories or products used with the DiamondTemp ablation system unless specifically noted.



# Medtronic

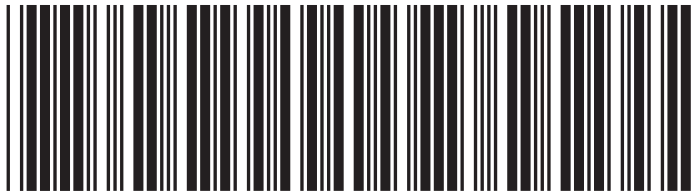
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# Medtronic

DiamondTemp™  
GenConnect Cable

Instructions for Use

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

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## 1 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	ISO 15223-1 <sup>d</sup>	Consult instructions for use (clause 5.4.3)	Consult instructions for use at this website: <a href="http://www.medtronic.com/manuals">www.medtronic.com/manuals</a>
<b>Rx only</b>	21 CFR 801.109 <sup>a</sup>	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	EN 50419 <sup>b</sup>	Recycle: Electronic Equipment	Do NOT throw in trash.
	IEC 60601-1 <sup>c</sup>	Follow instructions for use (Table D2, Symbol 10)	Refer to instruction manual/booklet (blue symbol)
	ISO 15223-1 <sup>d</sup>	Catalog number (clause 5.1.6)	Indicates the manufacturer's catalog number so the device can be identified
	ISO 15223-1 <sup>d</sup>	Batch code (clause 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1 <sup>d</sup>	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer
	ISO 15223-1 <sup>d</sup>	Date of manufacture (clause 5.1.3)	Indicates the date when the medical device was manufactured
	ISO 15223-1 <sup>d</sup>	Keep Dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1 <sup>d</sup>	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened
	ISO 15223-1 <sup>d</sup>	Temperature limit (clause 5.3.7)	Indicates the temperature limits to which the medical device can be safely exposed
	N/A	Storage temperature limit	Indicates the required temperature range for storing the device
	N/A	Transit temperature limit	Indicates the required temperature range for transporting the device
	ISO 15223-1 <sup>d</sup>	Humidity limitation (clause 5.3.8)	Indicates the range of humidity to which the medical device can be safely exposed
	ISO 15223-1 <sup>d</sup>	Atmospheric pressure limitation (clause 5.3.9)	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	N/A	Package contents	Indicates the components included in the device package
	N/A	GenConnect cable	Indicates that a GenConnect cable is included in the device package
	ISO 7000 <sup>e</sup>	Product documentation	Indicates that product documentation is included in the device package

<sup>a</sup> 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

<sup>b</sup> EN 50419: Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

<sup>c</sup> IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

<sup>d</sup> ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

<sup>e</sup> ISO 7000: Graphical symbols for use on equipment

## 2 Device description

The Medtronic DiamondTemp GenConnect cable is part of the DiamondTemp ablation system, which also includes the DiamondTemp ablation catheter, DiamondTemp RF generator, DiamondTemp irrigation tubing set, DiamondTemp catheter-to-RF generator (RFG) cable, DiamondTemp EGM cable, and DiamondTemp irrigation pump.

The DiamondTemp ablation system is designed to deliver radiofrequency (RF) energy to the cardiac anatomy via the DiamondTemp catheter.

The distal end of the nonsterile GenConnect cable (model CEDTGC100) has a 26-pin female connector that connects to the catheter-to-RFG cable and the proximal end has a 26-pin male connector that connects to the generator. The length of the cable is 1.8 m (6.0 ft).

### 3 Indications for use

The DiamondTemp GenConnect cable is designed for use with the DiamondTemp ablation system. The cable operates in conjunction with the DiamondTemp generator and an external GenConnect box (or similar connection box). Refer to the DiamondTemp catheter instructions for the indications for use. Carefully review the specific indications, contraindications, warnings, precautions, adverse events, included with the DiamondTemp catheter before using the cable.

### 4 Contraindications

The contraindications listed in the DiamondTemp catheter instructions apply to the use of the DiamondTemp GenConnect cable. Carefully review the specific indications, contraindications, warnings, precautions, adverse events, included with the DiamondTemp catheter before using the GenConnect cable.

### 5 Warnings and precautions

- Refer to the DiamondTemp catheter instructions for warnings related to use of the DiamondTemp ablation system.
- Do not expose the GenConnect cable to organic solvents.
- The GenConnect cable is not sterile and should not be used in a sterile field.
- The GenConnect cable is not intended to be sterilized. Use appropriate cleaning and disinfection techniques to clean this cable before reusing.
- The GenConnect cable is designed for use with the DiamondTemp ablation system.
- Use of improper cables may cause errors in the operation of the generator and can result in hazards to the patient.
- Do not pull on the GenConnect cable to disconnect the cable from the generator, the GenConnect box, or the catheter.
- Store in a cool, dry place.
- Before use, inspect the GenConnect cable and packaging to verify that no damage has occurred. Do not use if the cable or packaging is damaged.
- All devices that are connected to the RF generator must be safe for patients per specifications in IEC 60601-1 and IEC 60601-2-2. Improper use may be dangerous for the patient.
- Position connecting cables to avoid contact with the patient and other electrical leads.
- If used in the presence of other electrical equipment, noise could be introduced into the cable. Position the cable as far away as possible from sources of potential electromagnetic interference.
- Do not clean the GenConnect cable by using automated cleaning processes.
- Do not immerse the GenConnect cable connectors in fluids.
- The GenConnect cable is used only in conjunction with a GenConnect box (or similar connection box) with a compatible mapping and navigation system (such as the Abbott EnSite™ Cardiac Mapping System).
- Consult the respective instructions to ensure correct connectivity and usage.
- If a serious incident related to the device occurs, immediately report the incident to the manufacturer and the applicable competent authority or regulatory body.
- If you find information in this manual that is incorrect or illegible, contact your Medtronic representative.

### 6 Potential adverse events

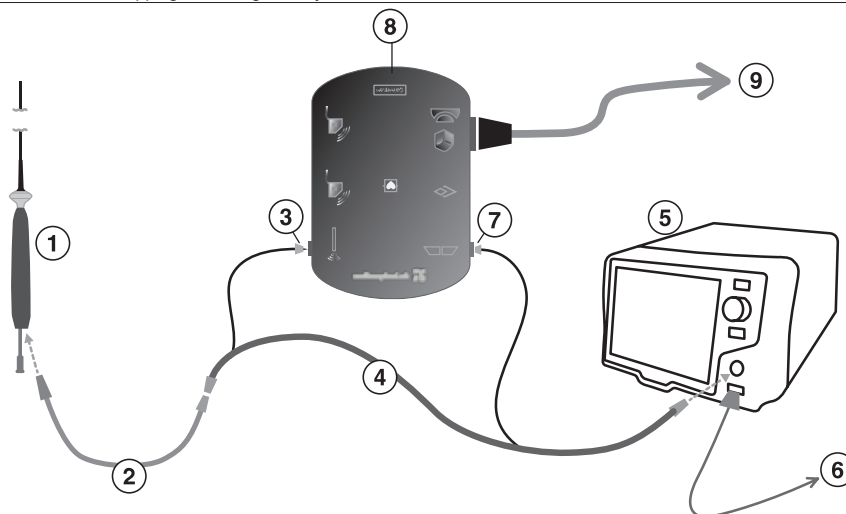
The potential adverse events that may be associated with ablation procedures can vary greatly in frequency and severity and may necessitate additional medical intervention, including surgery. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each DiamondTemp catheter before using the DiamondTemp ablation system.

### 7 Directions for use

**Note:** Refer to the DiamondTemp catheter instructions for use and DiamondTemp RF generator user manual for detailed operating instructions of the DiamondTemp ablation system.

1. Carefully remove the GenConnect cable from its packaging using standard hospital practices, and inspect the cable for damage or rough surfaces, sharp edges, or protrusions before use.
2. Refer to *Figure 1* for illustration of how to connect to and operate the DiamondTemp catheter and system in conjunction with a compatible mapping and navigation system and GenConnect box. Refer to the respective instructions for detailed information.
3. Connect the distal end (26-pin female receptacle) of the GenConnect cable to the DiamondTemp catheter-to-RFG cable. To do this, align the green connector end of the catheter-to-RFG cable to the green receptacle key of the GenConnect cable, and then push the connector into the receptacle firmly until it stops. Do not force the connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
4. Connect the proximal end (26-pin male connector) of the GenConnect cable to the DiamondTemp generator. To do this, align the green strain-relief end of the GenConnect cable connector key to the generator receptacle key, and then push the connector into the receptacle firmly until it stops. Do not force connectors or pin damage can occur. To disconnect, pull the connector body until it separates from the receptacle.
5. Connect the grey 9-pin connector to the catheter input of the mapping system.
6. Connect the black 14-pin connector to the RF generator output of the GenConnect box.
7. Confirm correct connectivity with the mapping system.
8. Connect the return pad directly to the generator.

**Figure 1.** DiamondTemp Generator Connection to Mapping and Navigation System





- 1 DiamondTemp ablation catheter
- 2 Catheter-to-RFG cable
- 3 9-pin quick connector
- 4 GenConnect cable
- 5 DiamondTemp RF generator

- 6 Ablation return pad
- 7 14-pin twist connector
- 8 GenConnect box (oriented upside down, for purposes of illustration)
- 9 Amplifier

## 8 Device removal and disposal

At the end of the procedure, after removing the DiamondTemp catheter from the patient, disconnect the GenConnect cable from the catheter by gently pulling on the outer housings of the connectors. Do not pull on the cabling, as this may damage the cable or the catheter.

Disconnect the GenConnect cable from the generator by gently pulling on the outer housing of the generator connector. Do not pull on the cabling, as this may damage the GenConnect cable or the generator.

After cleaning, disinfection, or decontamination, the GenConnect cable may be reused or disposed per standard procedures for electrical cables and in accordance with local laws and regulations.

## 9 Cleaning

The GenConnect cable should be cleaned by wiping it with enzymatic concentrates, such as Prolystica 2x Concentrate, at 1/8 oz per gallon of tap water (0.94 g in 1 L). The connectors should not be immersed in fluids. Automated cleaning of the cable is not recommended.

To disinfect, use broad spectrum disinfectants like phenolics, aldehydes, or alcohols. Recommended disinfectants are Glutaraldehyde 1%, 70% Isopropyl Alcohol (IPA), sodium hypochlorite (0.1%), or equivalent. Follow the manufacturer's instructions for use to use the disinfectant.

Wipe dry with a clean, soft nonlinting cloth.

Do not immerse the GenConnect cable in any liquid and do not expose it to steam autoclave or ethylene oxide (EtO) sterilization.

## 10 How supplied

The GenConnect cable is supplied nonsterile along with the required product documentation. If the packaging is damaged, do not use the product and contact a Medtronic representative.

## 11 Storage

The GenConnect cable should be stored in its original packaging before first use. Store in a cool and dry place, in a 15°C to 30°C (59°F to 86°F) noncondensing environment, per standard hospital procedures for nonsterile equipment.

## 12 Limited warranty

The following limited warranty applies to customers within the United States only:

A. This limited warranty provides the following assurance to the customer of the Medtronic DiamondTemp RF generator, irrigation pump, and GenConnect cable, with reusable parts (foot switch, ethernet cable, and power cord), hereafter collectively referred to as the DiamondTemp ablation system. Subject to the limitations herein, Medtronic warrants the DiamondTemp ablation system sold to the customer will be free from defects in materials and workmanship under normal usage for a period of 12 months from the delivery date at the customer's facility.

B. Should the DiamondTemp ablation system fail to meet the above warranty, Medtronic will at its option, repair or replace such DiamondTemp ablation system, or any portion thereof. For the limited warranty to apply, the following conditions must be met:

(1) Medtronic must be notified of and confirm the failure of the alleged defect within 60 days after discovery of the defect.

(2) The DiamondTemp ablation system must not have been repaired or altered outside of authorized personnel at Medtronic.

(3) THE DIAMONDTEMP ABLATION SYSTEM MUST BE USED IN ACCORDANCE WITH LABELING AND NOT ALTERED OR SUBJECTED TO MISUSE, ABUSE, IMPROPER HANDLING, OR ACCIDENT, INCLUDING, BUT NOT LIMITED TO, FIRE, FLOOD OR NATURAL DISASTERS.

C. At the discretion of Medtronic, parts or assemblies used or installed as part of the DiamondTemp ablation system may be either new or rebuilt of equal or improved quality. All parts removed or replaced during maintenance become the property of Medtronic.

D. This limited warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this limited warranty, MEDTRONIC EXPRESSLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WHETHER AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER MATTER. THE REMEDIES SET FORTH IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE TO THE CUSTOMER OR ANY THIRD PARTY FOR BREACH OF WARRANTY. MEDTRONIC SHALL HAVE NO LIABILITY TO ANY PERSON FOR INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES OF ANY DESCRIPTION, WHETHER ARISING OUT OF WARRANTY, OTHER CONTRACT, TORT, OR OTHERWISE.

(2) Except as expressly provided by this limited warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, MALFUNCTION, OR FAILURE OF THE DEVICE TO FUNCTION WITHIN NORMAL TOLERANCE, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

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

F. No person has any authority to bind Medtronic to any representation, condition, or warranty except this limited warranty.

G. This limited warranty is not applicable to accessories or products used with the DiamondTemp ablation system unless specifically noted.





# Medtronic

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# Medtronic

## DiamondTemp™

Irrigation Pump

User Manual

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

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DiamondTemp™

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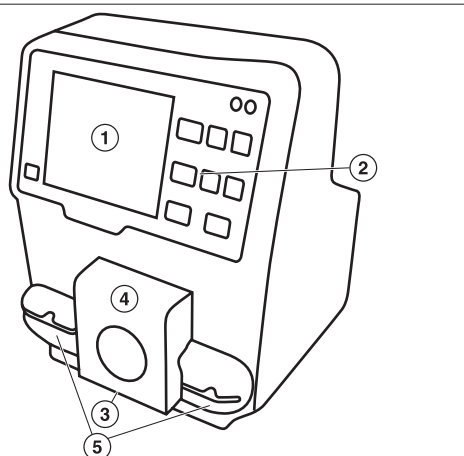
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## 1 Device description

The Epix Therapeutics DiamondTemp irrigation pump is part of the DiamondTemp ablation system, which also includes the DiamondTemp ablation catheter, DiamondTemp RF generator (RFG), DiamondTemp catheter-to-RF generator (RFG) cable, DiamondTemp GenConnect cable, DiamondTemp EGM cable, and DiamondTemp irrigation tubing set.

The DiamondTemp ablation system is designed to deliver radiofrequency (RF) energy to the cardiac anatomy via the DiamondTemp catheter. The DiamondTemp irrigation pump (*Figure 1*) delivers saline (0.9%) with Heparin at 1 IU/mL to the catheter when used in conjunction with the DiamondTemp tubing set. The irrigation pump (model CEDTP100) has a touch-screen display and flow control button that controls a two-flow-rate feature for easy selection of the appropriate irrigation flow rate. The rate can be changed between a low flow rate (1-5 mL/min) and a high flow rate (6-30 mL/min). Large numbers on the touch-screen display and an LED light on the flow control button indicate the flow rate selected. The irrigation pump communicates with the DiamondTemp generator and may be operated independently or under control of the generator.

**Figure 1.** Irrigation Pump



- 1 Touch Screen Display
- 2 Flow-Rate Control Buttons
- 3 Pump Head

- 4 Pump Head Door
- 5 Air Bubble Sensors

A transparent pump head door (4, *Figure 1*) protects the rotating pump head (3, *Figure 1*), while allowing visibility of the entire tubing set during pump operation.

The tubing set is placed in the path and around the pump head for operation. The irrigation pump uses twin ultrasonic air bubble detectors (5, *Figure 1*) for added safety in preventing air infusion.

Audible or visual indicators and informational messages displayed on the touch-screen panel (1, *Figure 1*) warn of air in the tubing, an open pump head door, or other operational conditions.

## 2 Indications for use

The DiamondTemp irrigation pump is designed for use with the DiamondTemp ablation system. Refer to the DiamondTemp catheter instructions for the indications for use. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the irrigation pump.

## 3 Principle of operation

The irrigation pump delivers normal saline to the catheter through a tubing set by a peristaltic mechanism employing rollers and mechanical fingers that push fluid through the tubing set.

The irrigation pump is intended to be used in an electrophysiology (EP) lab. It is not sterile and is intended to reside outside the sterile field.

## 4 Contraindications

The contraindications listed in the DiamondTemp catheter instructions apply to the use of the DiamondTemp irrigation pump. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the irrigation pump.



## 5 Warnings and precautions

- Refer to the DiamondTemp catheter instructions for warnings and precautions related to the use of the DiamondTemp ablation system.
- The irrigation pump is designed for use only with the DiamondTemp irrigation tubing set. Fluid extension lines should not be used with the irrigation pump. Use of an inappropriate tubing set could cause conditions in the operation of the pump that may result in improper irrigation or air induction into the patient.
- The DiamondTemp tubing set is specially designed to minimize the noise that may be induced on electrograms by the triboelectric charge caused by the peristaltic motion of the irrigation pump head. The irrigation pump should not be used with any tubing other than the DiamondTemp tubing set.
- The irrigation pump is designed for use only with sterile heparinized normal saline solution. Specified flowrate accuracy may not be maintained when used with incompatible fluids or delivery devices.
- The irrigation pump is designed to terminate the flow of saline when certain operating conditions occur. Read all informational messages carefully. Some steps require user action before continuing the procedure.
- It is the responsibility of hospital personnel to monitor and track the total saline load delivered to the patient to prevent overinfusion of saline to the patient.
- To avoid the risk of electric shock, the irrigation pump must only be connected to a supply mains with protective earth ground.
- The irrigation pump should be placed on a hard, level surface and not be stacked on other equipment.
- Do not mount the irrigation pump on an IV pole.
- The air bubble detector is disabled during irrigation pump priming and purging functions. Do not prime or purge the catheter when it is inserted in the vasculature of the patient.
- Do not remove the irrigation tubing set from the irrigation pump while the tubing set is in line with a catheter that is inside the patient.
- The irrigation pump materials are not compatible with magnetic resonance imaging (MRI).
- Do not modify the irrigation pump.
- Carefully load the tubing set into the pump head. Do **not** attempt to remove the electrostatic discharge (ESD) pink sleeve positioned over the tubing set.
- The tubing set uses an ESD pink sleeve to reduce triboelectric-charge artifacts. The ESD pink sleeve is located on the outer surface between the retention clips. This section of the tubing set must be seated smoothly under the pump head rollers, with no bends, twists, or kinks.
- The irrigation pump should not be connected to other infusion systems.
- To avoid the risk of explosion, do not use the irrigation pump in the presence of flammable anesthetics or gases.
- To avoid the risk of electrical shock or fire, do not expose the irrigation pump to excessive moisture, especially when power is connected.
- To avoid the risk of exceeding the allowable touch current to the patient, do not simultaneously touch the patient and the accessible contacts of the pump-RFG communications connector. The connector is located on the irrigation pump's rear panel.
- Moving parts such as the transparent pump head door, pump head clamps, and rotating pump head should be operated with care.
- Before use, inspect the irrigation pump and packaging to verify that no damage has occurred. Do not use damaged products.
- Do not immerse the irrigation pump in any liquid or expose the pump to steam autoclave or ethylene oxide (EtO) sterilization.
- Electromagnetic interference produced by the irrigation pump may adversely affect the performance of other equipment. Excessive EMI may cause the irrigation pump to enter a Safe State with a low flow rate. The pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

**Note:** The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals. It is not intended for use in a residential environment where this equipment might not offer adequate protection to radiofrequency communication services. Use in such environments might require mitigation measures, such as relocating or reorienting the equipment.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the DiamondTemp system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- If for any reason the irrigation pump loses communication with the generator, or if the saline flow stops (0 mL/min), the generator displays an information message indicating that the condition should be corrected before any other steps are taken.
- During use of the irrigation pump, pay attention to all messages, error codes, warnings, and tones, and exercise caution as needed.

## 6 Potential adverse events

The potential adverse events that may be associated with ablation procedures can vary greatly in frequency and severity and may necessitate additional medical intervention, including surgery. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each DiamondTemp catheter before using the DiamondTemp irrigation pump.

## 7 How supplied

The DiamondTemp irrigation pump is supplied with the following accessories and documentation:

- Power cord
- User manual
- Ethernet cable to connect the irrigation pump to the generator

## 8 Unpacking the irrigation pump

Remove the power cord, Ethernet cable, and irrigation pump from the shipping container and inspect the irrigation pump. If the irrigation pump has been damaged during shipping, do not use and contact a Medtronic representative.

## 9 Setting up the irrigation pump

### 9.1 Electrical connections

The DiamondTemp irrigation pump is intended for use only with the DiamondTemp ablation system. The irrigation pump should be connected to the generator using the supplied Ethernet cable. Consult the generator user manual for additional details.

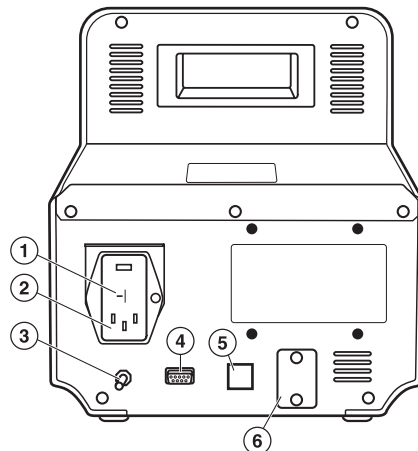
The irrigation pump operates using line power of 100 to 240 V, 50 to 60 Hz. The irrigation pump is not battery-powered and cannot be moved during use.

**Caution:** To avoid the risk of electric shock, the irrigation pump must be connected to a supply mains with protective earth ground.

### 9.2 Turning on the irrigation pump

Before operation, the irrigation pump must be placed on a stable surface. Ensure that the power cord is plugged into a power line of 100 to 240 V, 50 to 60 Hz. Connect the irrigation pump to a hospital-grade grounded power outlet only. The power switch (1, *Figure 2*) is located on the back panel of the irrigation pump near the power cord inlet. Turn on the switch at the rear of the irrigation pump. The Epix Therapeutics logo will appear on the front screen and the irrigation pump will perform a self-test. Once the self-test has passed, a tone will sound, and the touch-screen display will indicate a flow rate of 0 mL/min. The irrigation pump and generator must be used in communication mode. To establish this, plug the Ethernet cable into the inlet on the rear panel of the irrigation pump and connect the other end to the inlet on the rear panel of the generator. Once communication is established between the two devices, a communication icon will be displayed on the upper portion of the irrigation pump touch-screen.

**Figure 2.** Rear Panel View of the Irrigation Pump



- |                       |   |
|-----------------------|---|
| 1 Power Switch        | 4 Serial Port                             |
| 2 AC Power Cord Inlet | 5 Pump-Generator Communications Connector |
| 3 Equipotential Stud  | 6 USB Connection (maintenance)            |
- 

### 9.3 Loading the tubing set in the irrigation pump

To load the tubing set in the irrigation pump, complete the following steps:

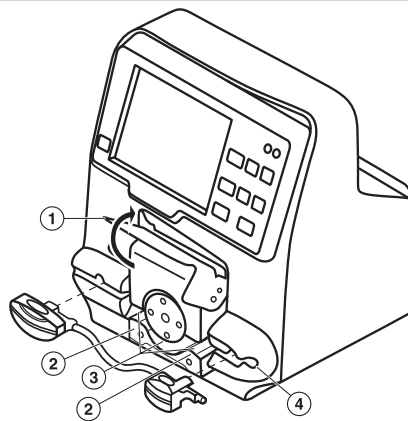
**Caution:** The DiamondTemp irrigation pump is intended for use only with the DiamondTemp tubing set.

1. Connect the 3-way stopcock (provided with the tubing set) to the patient end of the tubing set.

**Cautions:**

- A new tubing set must be used for every procedure.
  - Do not reuse the tubing set.
2. Insert the drip chamber end of the tubing set into the heparinized normal saline solution bag. Hang the normal saline bag near the irrigation pump and fill the drip chamber to approximately 2/3 full. Pass the patient end of the tubing set to the sterile field. While in the sterile field, open the stopcock and fill the tubing set with irrigation fluid at the patient end of the tubing set. Remove any trapped air and then close the 3-way stopcock. To ensure proper operation of the pump air bubble detectors, the outer surface of the tubing set must be dry.
  3. Open the transparent pump head door of the irrigation pump by lifting up from the bottom (*Figure 3*) to release the tubing set guides and expose the tubing set path from the lower portion of the pump head.

**Figure 3.** Irrigation Pump with Pump Head Door Open



- 1 Transparent pump head door
- 2 Tubing guides

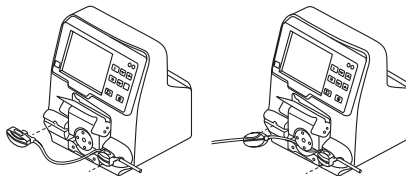
- 3 Tubing path around pump head
- 4 Tubing Set retainer

4. Note that the pump head rotates in a clockwise direction. Irrigation flow will enter the right-hand side of the pump and exit on the left hand side of the pump head. The indicator arrows that are molded onto the proximal and distal tubing set retention clips align with the direction of irrigation flow. Install the proximal tubing set retention clip (smaller of the two clips) into the tubing set retainer on the right-hand side of the pump head by inserting it into the tubing set retainer with the molded indicator arrow facing outward and in the direction of the pump flow path (*Figure 4*). Tactile feedback indicates when the tubing set retention clip is engaged correctly into the retainer. Press the retention clip firmly into its respective slot. Confirm that the red warning light, visible through the clip, turns off after proper positioning.
5. Slide the pump head tubing set section under the pump head rollers into the tubing path, ensuring that the tubing set is grasped by each of the tubing set guides (*Figure 4*). The tubing set has special features to reduce triboelectric-charge artifacts. An ESD pink sleeve is placed over the tubing set, in between the retention clips.

**Caution:** Do not attempt to remove the pink ESD sleeve from the tubing set. Removing the sleeve may damage the tubing set or render it non-functional.

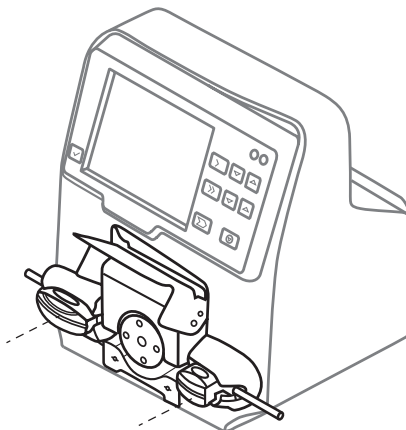
This section of the tubing set must be seated smoothly under the pump head rollers, with no bends, twists, or kinks. Place the tubing set snugly and smoothly over the two small metallic tubing set guides located to the right of the pump head rollers and over the one small metallic tubing set guide to the left of the pump head rollers.

**Figure 4.** Insertion of Proximal Pump Retention Clip and Pump Head Tubing Set Section



6. Gently stretch the tubing set and install the larger distal tubing set retention clip into the tubing set retainer on the left-hand side of the pump head in the same manner as described in step 4 (*Figure 5*). Press the retention clip firmly into its respective slot. Confirm that the red warning light, visible through the clip, turns off after proper positioning. Do not twist, bend, or kink the tubing set.

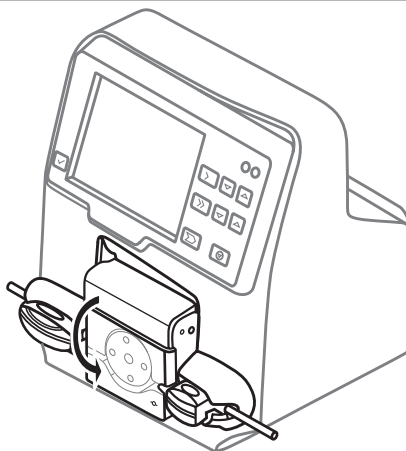
**Figure 5.** Insertion of Tubing Set Distal Pump Retention Clip



7. Ensure that all tubing set elements are correctly placed in the tubing set path and both tubing set retention clips are securely placed in the tubing set retainers. A red light will appear until clips are properly inserted.
8. Fully close the transparent pump head door of the irrigation pump (*Figure 6*). A message will appear at the bottom of the screen if the clips are not properly inserted. The message will disappear when the clips are properly inserted. Ensure that the irrigation pump touch-screen display does not show any messages. If the transparent pump head door of the irrigation pump is not closed properly, a “pump cover open” message will appear on the information bar at the bottom of the touch-screen display.

**Note:** A message will not appear if the transparent pump head door is in the raised position when the irrigation pump is turned on.

**Figure 6.** Pump with Tubing Set Inserted and Transparent Pump Head Door Closed



## 9.4 Preparing for irrigation

1. To prepare for irrigation, open the stopcock on the end of the tubing set, while continuing to maintain sterility on the patient end of the tubing set.
2. Press and hold the purge button (*Figure 7*) on the irrigation pump to verify tubing set integrity. If air is visible in the tubing set or if the pump displays an air bubble warning on the touch-screen display, press the purge button until the air is expelled through the open end of the tubing set. The air bubble warning should clear after successfully purging the tubing set.

- Securely connect the tubing set through the 3-way stopcock to the female luer on the DiamondTemp catheter. Press the purge flow button to fill the catheter with saline. Prepare the catheter as described in the DiamondTemp catheter instructions before introducing it into the patient.

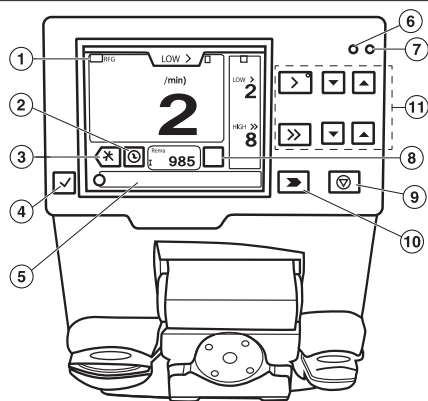
## 10 Working with the system controls

**Note:** The screen images shown are representative of what is seen on-screen with the software; actual images may differ slightly.

### 10.1 Touch-screen display and irrigation flow control panel

The irrigation flow control panel (*Figure 7*) and touch-screen display are located on the front of the irrigation pump and are used to set and display the flow rate, to control the pump operation, to estimate the remaining available saline, and to display status messages. The irrigation pump control panel consists of a touch-screen display, a message clearing button located to the left of the screen, and a set of irrigation control buttons located to the right of the screen. The main screen displays real-time information on the rate of flow, infused volume, and remaining volume. It also displays flow rate set-points for the low and high flow rate ranges and allows access to the irrigation pump set-up menu. The control panel, touch screen, and use of the controls are detailed in *Figure 7*.

**Figure 7.** Irrigation Pump Front Panel



- |                                |                              |
|--------------------------------|------------------------------|
| 1 Communications Link Icon     | 7 Fault Indicator            |
| 2 Reset Remaining Fluid Button | 8 Total Infused Fluid Button |
| 3 Set Up/Screen Display        | 9 Stop Flow Button           |
| 4 Message Clear Button         | 10 Purge Button              |
| 5 Message Field                | 11 Set Point Adjust Buttons  |
| 6 Power Indicator              |                              |

**Set Point Adjust Buttons** – Press the up or down arrow to increase or decrease the respective flow rate set point by 1 mL/min. Set-points for non-active flows may be adjusted without changing the current flow rate.

**Flow Rate Set Points** – The current set-points for each flow rate are indicated to the right of the actual flow indicator.

**Current Flow Rate** – The current flow rate is indicated in large type in the center of the screen. It may be adjusted by using the set-point adjust buttons for the currently selected set point.

**Note:** All of the previously listed controls may also be adjusted from the generator. Consult the generator user manual for more details.

**Stop Flow Button** – Press to stop rotation of the pump head. This will stop the flow of saline.

**Purge Button** – Press to purge the tubing set. When the button is held down, a flow of 60 mL/min is delivered and continues until the button is released. Detection of air bubbles in the tubing set is disabled during this process. The purge button will not function unless the irrigation pump has been stopped first.

**Total Infused Volume** – Press and hold down to view the estimated amount of fluid infused during the procedure.

**Reset Remaining Fluid** – Press and hold for 2 s when a new saline bag is started. This action resets the flow counter for each individual bag.

**Setup Screen/Display** – Press to navigate to the setup screen.

**Message Clear Button** – Press to acknowledge and clear resolved messages.

**Message Field** – When a condition is detected, a message is displayed in this field until the condition is corrected and acknowledged with the accept button. Once the condition is resolved and cleared, the irrigation pump will return to normal operation. This field also displays status updates during the irrigation pump operation.

**Communications Link Icon** – The RFG icon will display when the link to the generator has been established.

**Flow Status** – Indicates the current state of the irrigation pump (Off, Low, etc.).

**Power Indicator** – Light is displayed when power is applied.

**Fault Indicator** – Light is displayed when a hardware fault is encountered.

## 10.2 Set-up screen

The set-up screen (*Figure 8*) is used to select different operating parameters for the irrigation pump.

**Figure 8.** Irrigation Pump Touch-Screen Display



1 Saline Bag Size

2 High Flow ON Time Warning

3 Low Fluid Warning Level

4 Volume Control

5 Language Button

6 Remaining Fluid Display Units

7 Back Button

**Saline Bag Size** – Choose the correct size of saline bag being used.

**Low Fluid Warning Level** – Press the up and down arrows to increase or decrease the fluid volume level at which the irrigation pump will issue a warning indicating low saline volume remains. For this feature to work accurately, it is important to select the correct size of the saline bag.

**High Flow ON Time Warning** – Press the up and down arrows to select when the irrigation pump will issue a warning that the pump has been delivering fluid continuously at the high flow rate after the indicated time has passed.

**Language** – Press the up and down arrows to select a language for the device display.

**Note:** After a language is selected and the Back button is pressed to save the selection, restart the pump to display information in the new language.

**Remaining Fluid Display Units** – Choose whether the remaining saline amount will be displayed in volume (mL) or time (min:s).

**Volume Control** – Press the up and down arrows to select the desired irrigation pump sound volume.

**Back button** – Press the back button to return to the main screen.

## 11 Irrigation pump operation

After the irrigation pump has been turned on and appropriately set up (the tubing set is connected to the saline bag, loaded into the pump and primed, and the patient end of the tubing set is connected to the DiamondTemp catheter), the system is ready for operation. Refer to the instruction manuals for the DiamondTemp tubing set, DiamondTemp catheter, and the DiamondTemp generator. All connections should be checked before introducing the catheter into the patient.

The irrigation pump must be operated in communication mode with the generator.

When communication mode is established between the irrigation pump and the generator via the Ethernet cable:



- An icon with a checkmark and “RFG” appears in the upper-left corner of the pump display screen.
- The controls on the generator operate both devices.
- The controls on the irrigation pump do not change the output of the generator. However, the generator controls may adjust the flow rate of the irrigation pump. The generator receives flow rate information from the irrigation pump and displays it accordingly.
- When the devices are connected, it is strongly recommended that the controls of the generator be used to operate both devices for the duration of the procedure.
- The controls of the irrigation pump should be used only in the following cases:
  - During setup
  - During the initial purge of the tubing set
  - During preparation of the catheter
  - When an informational message needs to be addressed, acknowledged, or cleared
  - When air is discovered in the tubing set
  - In case of emergency

Operating the irrigation pump from the generator:

- The flow rate may be adjusted from the generator on the ablation screen on the main touch-screen display of the generator.
- Flow rate set-point for the low and high flow rate ranges can be adjusted on the main touch-screen display of the generator when the generator is not delivering RF energy. Only the high flow rate can be adjusted on the generator during ablation.
- Flow rate set-point, pre-ablation ramps, and post-ablation ramps can be set in the Advanced Settings screen of the generator.
- To adjust the rate of flow from the Ablation screen, touch one of the flow adjustment buttons on the right side of the screen.
- For more details on the operation of the generator, reference the generator user manual.

When an ablation is initiated on the generator, irrigation flow from the irrigation pump will automatically be initiated at the “High” flow rate set-point for the specified ramp time before delivery of RF energy. During the ablation, the irrigation pump will automatically deliver irrigation flow at the “High” flow rate set-point. After termination of the ablation, the irrigation flow from the irrigation pump will automatically continue at the “High” flow set-point for the specified post-cool period. After this time period, the irrigation pump will automatically adjust the flow rate range to the range that was used before starting the ablation.

To adjust the preset rates of flow for the flow adjustment buttons, navigate to the Advanced Settings panel of the generator. Refer to the generator user manual for additional details.

During ablation, the set rates of the low levels can only be changed using the irrigation pump controls.

**Caution:** Ensure the integrity of the irrigation pump and generator communication link throughout the duration of the procedure. If the link becomes disconnected, check the connections between the devices and the link cable. The communications link will automatically reestablish itself when the physical connections are corrected.

## 12 Indicators and informational codes

When certain conditions occur, the irrigation pump activates audible or visual indicators or displays informational messages. An associated message will be displayed in the message field. For conditions such as an air bubble being detected, the pump flow will be stopped, an audible indicator will be activated, and an informational message will be displayed.

To clear the message, press and hold the “Message Clear” (*Figure 7*) button to the left of the message field. Once the message has been addressed and accepted, the pump will return to the normal operating mode. A list of indicators and messages, with appropriate course of action, is provided in *Table 1*. Although codes P05 – P19 display an identical message on the pump screen, they provide different troubleshooting information should the pump need repair work.

**Table 1.** Indicators/Informational Codes and Appropriate Action

Code	Message & Actions
F-01	Low saline level. (F-01) Please attach a new bag and reset the saline counter. The warning will automatically clear.
F-02	Extended high flow use. (F-02) Please avoid the use of high flow rates outside of ablation. The warning will automatically clear.
T-03	Air bubble detected! (T-03) Please purge the tubing set of any bubbles. Press the Message Clear button.
P-01	Pump cover open. (P-01) Pump cover was open when flow was off. Please close the transparent pump head cover. The warning will automatically clear.

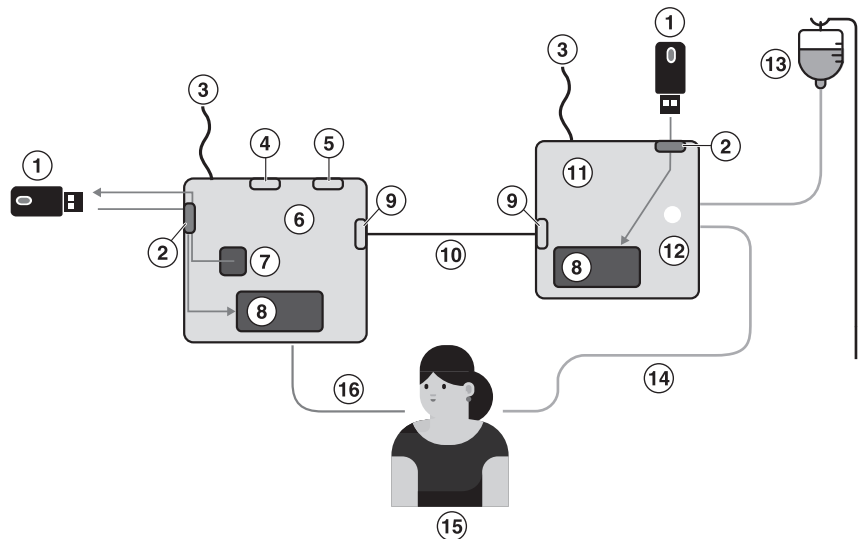
**Table 1.** Indicators/Informational Codes and Appropriate Action (continued)

<b>Code</b>	<b>Message &amp; Actions</b>
P-02	Close pump cover. (P-02) Pump cover was open when flow was on. This represents a potential risk and needs acknowledgment from user in order to clear the message. Please close the transparent pump head cover when flow is on. Press the Message Clear button.
P-03	Internal pump failure. (P-03) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-04	Duplicate Variables. (P-04) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-05	Internal pump failure. (P-05) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-06	Internal pump failure. (P-06) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-07	Internal pump failure. (P-07) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-08	Internal pump failure. (P-08) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-09	Internal pump failure. (P-09) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-10	Internal pump failure. (P-10) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-11	Internal pump failure. (P-11) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-12	Internal pump failure. (P-12) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-13	Internal pump failure. (P-13) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-14	Internal pump failure. (P-14) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-15	Internal pump failure. (P-15) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-16	Internal pump failure. (P-16) Make sure no buttons are being depressed, and cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-17	Internal pump failure. (P-17) Make sure the touchscreen is not being touched, and cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-18	Internal pump failure. (P-18) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.
P-19	Internal pump failure. (P-19) Cycle the power on the irrigation pump. If problem persists, contact Medtronic.



13 DiamondTemp ablation system architecture and cybersecurity

Figure 9. DiamondTemp Ablation System Architecture Diagram



- |  |   |
|--|---|
| 1 Specially Configured Maintenance USB Thumb Drive | 10 CAT 5 Cable (Pump Flow Rate Commands & Acknowledgements) |
| 2 USB Port   | 11 Irrigation Pump  |
| 3 Power Cable                                      | 12 Motor  |
| 4 RS-232 Output to EP Recording System             | 13 Saline Bag   |
| 5 Static IP Output only Ethernet Port              | 14 Irrigation Tubing  |
| 6 RF Generator                                     | 15 Patient  |
| 7 Logged Measurements                              | 16 Catheter   |
| 8 Program & Settings                               |   |
| 9 Pump Control port                                |   |

The DiamondTemp generator and irrigation pump devices are not intended for use on or to be connected to a computer network and do not accept wireless or unknown physical connections. A system architecture diagram for the DiamondTemp ablation system is presented in *Figure 9*. The Pump Control port is dedicated only for communications between the DiamondTemp generator and DiamondTemp irrigation pump. The USB ports are provided for maintenance only and are only for use by authorized personnel.

Any suspected compromise of the DiamondTemp ablation system’s cybersecurity, from such events as unauthorized access, computer virus infection, or inadvertent connection to a network, should be reported to Medtronic. A proper course of action, determined by Medtronic and the end user, should be determined before the system can be further used.

Software upgrades are to be performed only by Medtronic or authorized personnel.

The DiamondTemp ablation system contains the following commercial, open source, or off-the-shelf software:

- QT Third party graphics library
- ALSA Linux Sounds generation library
- SQLite Database Interface library
- Customized Linux Operating System including TCP/IP stack

14 Maintenance and service

14.1 Cleaning

The irrigation pump exterior surface may be cleaned with nonflammable and nonexplosive agents according to the following steps. Follow recommended hospital procedures for cleaning and universal precautions for protective apparel when handling and cleaning contaminated instruments. Make sure no fluids or moisture enter the interior of the irrigation pump during cleaning.

1. Before cleaning, turn off the irrigation pump and all its connections. Disconnect the power cord from the electrical power source and from the rear of the generator.
2. Disconnect all other cables and peripherals.
3. Wipe the irrigation pump enclosure with a clean, soft nonlinting cloth dampened with a pH neutral detergent.
4. Wipe again with distilled or sterilized water.

5. Wipe dry with a clean, soft, nonlinting cloth.
6. To disinfect, use broad spectrum disinfectants like phenolics, aldehydes, or alcohols. Recommended disinfectants are Glutaraldehyde 2.4%, 70% IPA, sodium hypochlorite (0.1%), or equivalent. Follow the manufacturer's instructions for using the disinfectant.
7. Do not immerse the irrigation pump in any liquid or expose the irrigation pump to steam autoclave or ethylene oxide (EtO) sterilization.
8. Do not expose the irrigation pump to excessive moisture, especially when the power is connected.

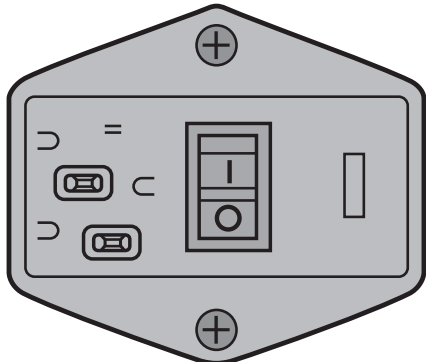
## 14.2 Maintenance

All servicing activities for the irrigation pump, except flow rate verification and fuse replacement, are performed only by the manufacturer. It is recommended that pump flow verification be performed every 12 months. Contact a Medtronic representative for details.

Improper operation may cause damage to the irrigation pump. The irrigation pump may be damaged if altered by unauthorized personnel. Contact a Medtronic representative for service or if you suspect an issue with the irrigation pump.

## 14.3 Replacing fuses

To replace a fuse in the pump:

	<ol style="list-style-type: none"> <li>1. Remove the power cord.</li> <li>2. Use a small blade screwdriver or similar tool to unlatch the fuse holder door at the top of the fuse holder.</li> <li>3. Use a small blade screwdriver or similar tool to remove the red fuse block from the fuse holder.</li> <li>4. Remove the defective fuse(s) and replace with the correct size, rating, and type (replace with Littelfuse 218001.P or equivalent). To avoid the risk of fire, use only the specified fuse.</li> <li>5. Reinstall the fuse block, close the fuse holder door, and reinstall the power cord.</li> <li>6. Switch on the pump and confirm it powers up.</li> </ol>
---	---

## 15 Storage

Ensure that the irrigation pump transparent pump head door is closed when not in use.

Disconnect power prior to long-term storage. For additional storage information, see *Chapter 19, Environmental conditions*, page 17.

## 16 Disposal

Refer to local requirements regarding the disposal of the irrigation pump and accessories.

## 17 Guidance and manufacturer's declarations

**Table 2.** Guidance and manufacturer's declaration – electromagnetic emissions

The irrigation pump is intended for use in the electromagnetic environment specified below. The customer or the user of the irrigation pump should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR11	Group 1	The irrigation pump may emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR11	Class A	The irrigation pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

**Table 3.** Guidance and manufacturer's declaration – electromagnetic immunity

The irrigation pump is intended for use in the electromagnetic environment specified below. The customer or the user of the irrigation pump should ensure that it is used in such an environment.				
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment—guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact  ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact  ±2 kV, ±4 kV, ±8 kV, ±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 @ 100 kHz repetition frequency for power supply lines ±2 kV @ 100 kHz repetition frequency for input/output lines	±2 kV @ 100 kHz repetition frequency for power supply lines ±2 kV @ 100 kHz repetition frequency for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.	
Surge  IEC 61000-4-5	Power inputs: ±0.5 kV, ±1 kV Line-to-Line ±0.5 kV, ±1 kV, ±2 kV Line-to-Ground Signal input/outputs: ±2 kV Line-to-Ground	Power inputs: ±0.5 kV, ±1 kV Line-to-Line ±0.5 kV, ±1 kV, ±2 kV Line-to-Ground Signal input/outputs: ±2 kV Line-to-Ground	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	Voltage dips: 0% µT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% µT; 1 cycle and 70% µT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% µT; 250/300 cycle	Voltage dips: 0% µT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% µT; 1 cycle and 70% µT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% µT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.  If the user of the irrigation pump requires continued operation during power mains interruptions, it is recommended that the irrigation pump be powered from an uninterruptible power supply or battery.	
<b>Note:</b> µT is the a.c. mains voltage before application of the test level.				
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m  50 Hz or 60 Hz	30 A/m  50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	
Conducted RF  IEC 61000-4-6	0.15 MHz – 80 MHz 3 V, 80 % AM at 1 kHz ISM bands between 0.15 MHz and 80 MHz 6 V, 80 % AM at 1 kHz	0.15 MHz – 80 MHz 3 V, 80 % AM at 1 kHz ISM bands between 0.15 MHz and 80 MHz 6 V, 80 % AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.	
Radiated RF EM fields including proximity fields	<b>Band (MHz)</b>	<b>Wireless Service</b>	<b>Immunity Test Level (V/m)</b>	<b>Compliance Test Level (V/m)</b>

**Table 3.** Guidance and manufacturer's declaration – electromagnetic immunity (continued)

from RF wireless communications equipment IEC 61000-4-3				
	150 kHz – 80 MHz	General	< 3	< 3
	80 MHz – 2.7 GHz	General	3	3
	380 – 390	TETRA 400	27	27
	430 – 470	GMRS 460, FRS 460	28	28
	704 – 787	LTE Band 13, 1	9	9
	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28	28
	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28	28
	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28	28
	5,100 – 5,800	WLAN 802.11 a/n	9	9

Portable and mobile RF communications equipment should be used no closer to any part of the irrigation pump, including cables, than the recommended separation distance calculated from the equation:


$$d = 6 / E \times \sqrt{P}$$

Where:

d is the separation in meters

P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer

E is the Compliance Test Level indicated above.

Interference may occur in the vicinity of equipment marked with the following symbol: 

<sup>a</sup> 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 irrigation pump or any of its components are used exceeds the applicable RF compliance level above, the irrigation pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating components or the irrigation pump.

<sup>b</sup> Within the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Table 4.** Recommended separation distances between portable and mobile RF communications equipment and the Irrigation Pump

The irrigation pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the irrigation pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the irrigation pump as recommended below, 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 determined 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 1 – At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## 18 Technical specifications

- According to IEC 60601-1, the irrigation pump is classified as a Class 1, Type CF ordinary equipment for continuous use.
- Applied Part Classification, Catheter – Type CF defibrillation proof.
- The irrigation pump complies with IEC 60601-1 and IEC 60601-1-2.
- AC Power: 100-240 VAC, 0.40-0.26 A, 50-60 Hz.
- To avoid the risk of electric shock, connect only to a grounded hospital outlet.
- To avoid the risk of fire, use two Littelfuse 218001.P fuses, or equivalent.

## 19 Environmental conditions

**Note:** Allow the system to equilibrate to room temperature for a minimum of 4 hours if the system has been stored at temperatures outside of the operational temperature range.

Operational temperature:	15°C to 30°C (59°F to 86°F)
Operational humidity:	30% to 75% relative humidity (noncondensing)
Operational pressure:	70 to 160 kPa.
Storage temperature:	15°C to 30°C (59°F to 86°F)
Stacking height:	Maximum of two shipping boxes on top of each other
Low flow rate range:	1 – 5 mL/min, 1 mL/min increment
High flow rate range:	6 – 30 mL/min, 1 mL/min increment
Purge flow rate:	60 mL/min. Note that air bubble detection is disabled during purging flow.
Maximum back pressure:	45 psi (310 kPa), max
Flow rate accuracy:	6 – 30 mL/min (±10%), 3 – 5 mL/min, ±15%, 1 to 2 mL/min, ±20%
Weight:	6 kg
Moisture protection rating:	IPX0, This product complies with international electrical safety rating of IPX0 with regard to water, as required by IEC 60601-1.

Flow rate, back pressure, and flow rate accuracy depend upon the use of compatible substances. The irrigation pump is only compatible with 0.9% saline solution (pure or heparinized).

Minimum detectable air bubble size:	2 microliters
Dimensions:	31 cm x 27 cm x 26 cm (H x W x D)

## 20 Limited warranty

The following limited warranty applies to customers within the United States only:

A. This limited warranty provides the following assurance to the customer of the Medtronic DiamondTemp RF generator, irrigation pump, and GenConnect cable, with reusable parts (foot switch, ethernet cable, and power cord), hereafter collectively referred to as the DiamondTemp ablation system. Subject to the limitations herein, Medtronic warrants the DiamondTemp ablation system sold to the customer will be free from defects in materials and workmanship under normal usage for a period of 12 months from the delivery date at the customer's facility.

B. Should the DiamondTemp ablation system fail to meet the above warranty, Medtronic will at its option, repair or replace such DiamondTemp ablation system, or any portion thereof. For the limited warranty to apply, the following conditions must be met: (1) Medtronic must be notified of and confirm the failure of the alleged defect within 60 days after discovery of the defect.

(2) The DiamondTemp ablation system must not have been repaired or altered outside of authorized personnel at Medtronic.

(3) THE DIAMONDTEMP ABLATION SYSTEM MUST BE USED IN ACCORDANCE WITH LABELING AND NOT ALTERED OR SUBJECTED TO MISUSE, ABUSE, IMPROPER HANDLING, OR ACCIDENT, INCLUDING, BUT NOT LIMITED TO, FIRE, FLOOD OR NATURAL DISASTERS.

C. At the discretion of Medtronic, parts or assemblies used or installed as part of the DiamondTemp ablation system may be either new or rebuilt of equal or improved quality. All parts removed or replaced during maintenance become the property of Medtronic.

D. This limited warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this limited warranty, MEDTRONIC EXPRESSLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WHETHER AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER MATTER. THE REMEDIES SET FORTH IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE TO THE CUSTOMER OR ANY THIRD PARTY FOR BREACH OF WARRANTY. MEDTRONIC SHALL HAVE NO LIABILITY TO ANY PERSON FOR INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES OF ANY DESCRIPTION, WHETHER ARISING OUT OF WARRANTY, OTHER CONTRACT, TORT, OR OTHERWISE.

(2) Except as expressly provided by this limited warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, MALFUNCTION, OR FAILURE OF THE DEVICE TO FUNCTION WITHIN NORMAL TOLERANCE, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.













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

F. No person has any authority to bind Medtronic to any representation, condition, or warranty except this limited warranty.




G. This limited warranty is not applicable to accessories or products used with the DiamondTemp ablation system unless specifically noted.

## 21 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
<b>Rx only</b>	21 CFR 801.109 <sup>a</sup>	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1 <sup>d</sup>	Consult instructions for use (clause 5.4.3)	Consult instructions for use at this website: <a href="http://www.medtronic.com/manuals">www.medtronic.com/manuals</a>
	EN 50419 <sup>b</sup>	Recycle: Electronic Equipment	Do NOT throw in trash.
	IEC 60601-1 <sup>c</sup>	Follow instructions for use (Table D2, Symbol 10)	Refer to instruction manual/booklet (blue symbol).
	ISO 15223-1 <sup>d</sup>	Catalog number (clause 5.1.6)	Indicates the manufacturer's catalog number so the device can be identified
	ISO 15223-1 <sup>d</sup>	Serial number (clause 5.1.7)	Indicates the manufacturer's serial number so that the device can be identified
	ISO 15223-1 <sup>d</sup>	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer
	N/A	Manufactured in/ manufacturing site	Indicates where the device was manufactured
	ISO 15223-1 <sup>d</sup>	Date of manufacture (clause 5.1.3)	Indicates the date when the medical device was manufactured
	ISO 15223-1 <sup>d</sup>	Keep dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1 <sup>d</sup>	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 <sup>d</sup>	Temperature limit (clause 5.3.7)	Indicates the temperature limits to which the medical device can be safely exposed
	N/A	Storage temperature limit	Indicates the required temperature range for storing the device

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	N/A	Transit temperature limit	Indicates the required temperature range for transporting the device
	ISO 15223-1 <sup>d</sup>	Humidity limitation (clause 5.3.8)	Indicates the range of humidity to which the medical device can be safely exposed
	ISO 15223-1 <sup>d</sup>	Atmospheric pressure limitation (clause 5.3.9)	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	ISO 7000 <sup>e</sup>	Stacking limit by number (symbol 2403)	To indicate that items shall not be vertically stacked beyond the specified number
<b>IPX0</b>	IEC 60529 <sup>f</sup>	International Protection (IP) Code	Indicates the product is not water resistant
	N/A	Package contents	Indicates the components included in the device package
	N/A	Irrigation pump	Indicates that the type of device is an irrigation pump
	N/A	Accessories	Indicates that accessories are included in the device package
	ISO 7000 <sup>e</sup>	Product documentation	Indicates that product documentation is included in the device package
	N/A	RFG connection	Indicates a generator connection
	ISO 7000 <sup>e</sup>	Equipotentiality (symbol 5021)	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
	ISO 7000 <sup>e</sup>	Alternating current (symbol 5032)	Alternating current
	ISO 7000 <sup>e</sup>	Defibrillation Proof Type CF Applied Part (symbol 5336)	To identify a defibrillation-proof type CF applied part complying with IEC 60601-1.
	ISO 7000 <sup>e</sup>	Stand by (symbol 5009)	Power in Standby (lit amber) or ON (lit green)
	ISO 7000 <sup>e</sup>	OFF (symbol 5008)	Power OFF
	ISO 7000 <sup>e</sup>	ON (symbol 5007)	Power ON
	N/A	N/A	Fuses
	N/A	N/A	EGM Output – Filtered ECG Pace
	N/A	N/A	Video Output
	N/A	N/A	Serial Output
	N/A	N/A	USB port
	N/A	N/A	Catheter connection

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	N/A	N/A	Indicates the device Stop button (red symbol)
	N/A	N/A	Indicates the device Start button (green symbol)
	N/A	Compliance mark	Indicates conformance to applicable standards

<sup>a</sup> 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

<sup>b</sup> EN 50419: Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

<sup>c</sup> IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

<sup>d</sup> ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

<sup>e</sup> ISO 7000: Graphical symbols for use on equipment

<sup>f</sup> IEC 60529: Degrees of protection provided by enclosures (IP Code)





# Medtronic

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\*M005670C001\*

# Medtronic

DiamondTemp™  
Irrigation Tubing Set

Instructions for Use

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DiamondTemp™

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## 1 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
<b>Rx only</b>	21 CFR 801.109 <sup>a</sup>	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	IEC 60601-1 <sup>b</sup>	Follow instructions for use (Table D2, Symbol 10)	Refer to instruction manual/booklet (blue symbol).
	EN 50419 <sup>c</sup>	Recycle: Electronic Equipment	Do NOT throw in trash.
	ISO 7000 <sup>d</sup>	Defibrillation Proof Type CF Applied Part (symbol 5336)	To identify a defibrillation-proof type CF applied part complying with IEC 60601-1.
	ISO 15223-1 <sup>e</sup>	Sterilized by ethylene oxide treatment (clause 5.2.3)	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1 <sup>e</sup>	Catalog number (clause 5.1.6)	Indicates the manufacturer's catalog number so the device can be identified.
	ISO 15223-1 <sup>e</sup>	Batch code (clause 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 <sup>e</sup>	Date of manufacture (clause 5.1.1)	Indicates the date when the medical device was manufactured.
	ISO 15223-1 <sup>e</sup>	Use by (clause 5.1.4)	Indicates the date after which the device is not to be used.
	ISO 15223-1 <sup>e</sup>	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer.
	ISO 15223-1 <sup>e</sup>	Keep Dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1 <sup>e</sup>	Do not reuse (clause 5.4.2)	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	ISO 15223-1 <sup>e</sup>	Do not re-sterilize (clause 5.2.6)	Indicates a medical device that is not to be resterilized.
	ISO 15223-1 <sup>e</sup>	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 <sup>e</sup>	Temperature limit (clause 5.3.7)	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 <sup>e</sup>	Consult instructions for use (clause 5.4.3)	Indicates the need for the user to consult the instructions for use at this website: <a href="http://www.medtronic.com/manuals">www.medtronic.com/manuals</a>
	N/A	Manufactured in/ manufacturing site	Indicates where the device was manufactured.
	N/A	Storage temperature limit	Indicates the required temperature range for storing the device.
	N/A	Transit temperature limit	Indicates the required temperature range for transporting the device.
	ISO 15223-1 <sup>e</sup>	Humidity limitation (clause 5.3.8)	Indicates the range of humidity to which the medical device can be safely exposed.
	N/A	Package contents	Indicates the components included in the device package.
	ISO 15223-1 <sup>e</sup>	Atmospheric pressure limitation (clause 5.3.9)	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	N/A	Irrigation tubing	Indicates that tubing is included in the device package.
	ISO 7000 <sup>d</sup>	Product documentation	Indicates that product documentation is included in the device package.
	ISO 15223-1 <sup>e</sup>	Sterile barrier	Single sterile barrier system.

<sup>a</sup> 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

<sup>b</sup> IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

<sup>c</sup> EN 50419: Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

<sup>d</sup> ISO 7000: Graphical symbols for use on equipment

<sup>e</sup> ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

## 2 Device description

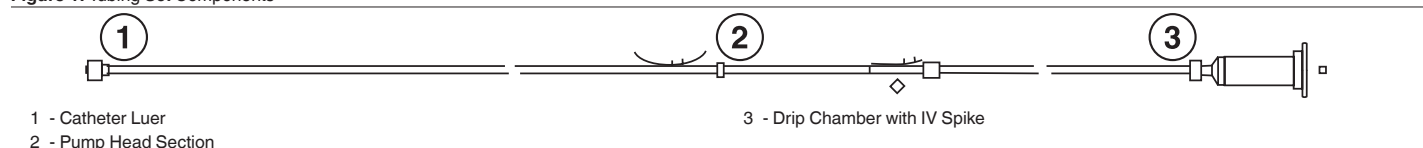
The Medtronic DiamondTemp irrigation tubing set is part of the DiamondTemp ablation system, which also includes the DiamondTemp ablation catheter, DiamondTemp RF generator (RFG), DiamondTemp catheter-to-RF generator cable, DiamondTemp GenConnect cable, DiamondTemp EGM cable, and DiamondTemp irrigation pump.

The DiamondTemp Model CEDTTS100 irrigation tubing set is designed to deliver radiofrequency (RF) energy to the cardiac anatomy via the DiamondTemp catheter.

The DiamondTemp Model CEDTTS100 irrigation tubing set consists of the following components (*Figure 7*). The length of the tubing set assembly is 3.66 m ± 5.08 cm (144 in ± 2 in).

- A drip chamber with an intravenous (IV) spike for connection to an IV bag
- A pump head section with plastic retention clips that fit the slots for the air-bubble detectors (located inside the irrigation pump)
- An electrostatic discharge (ESD) pink sleeve that reduces electrogram artifacts caused by the peristaltic motion tribo-charge
- A catheter end that terminates in a standard luer lock connector and connects to the DiamondTemp catheter
- A 3-way stopcock (not shown)

**Figure 1. Tubing Set Components**



### 3 Indications for use

The DiamondTemp irrigation tubing set is designed for use with the DiamondTemp ablation system. Refer to the DiamondTemp catheter instructions for the indications for use. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the tubing set.

### 4 Principle of operation

The tubing set delivers saline (0.9%) with Heparin at 1 IU/mL to the catheter when used with the irrigation pump. The delivery action is based on a peristaltic mechanism employing rollers and mechanical fingers that push fluid through the tubing.

The tubing set is supplied sterile and is for single-use only.

### 5 Contraindications

The contraindications listed in the DiamondTemp catheter instructions apply to the use of the DiamondTemp irrigation tubing set. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the tubing set.

### 6 Warnings and precautions

- Refer to the DiamondTemp catheter instructions for warnings and precautions related to the use of the DiamondTemp ablation system.
- The tubing set is designed for use with the DiamondTemp irrigation pump only.
- The tubing set is designed for use with the DiamondTemp catheter only.
- The tubing set includes an ESD pink sleeve, which is specially designed to minimize the noise that may be induced on electrograms by the tribo-charge caused by the pump head peristaltic motion. The irrigation pump should not be used with tubing other than that provided by Medtronic.
- The tubing set is designed for use with only heparinized normal saline solution. Specified flow rate accuracy may not be maintained when used with incompatible fluids or delivery devices.
- Use of fluid extension lines with the DiamondTemp irrigation tubing set may cause errors in the operation of the irrigation pump and can result in improper irrigation or air induction into the patient.
- It is the responsibility of hospital personnel to monitor and track the total saline load delivered to the patient to prevent overinfusion of saline to the patient.
- The tubing set must not be primed or purged while in-line with a catheter that is inside the patient because the air bubble detector is disabled during priming or purging.
- The tubing set should not be removed from the irrigation pump while in-line with a catheter that is inside the patient.
- Do not expose the tubing set to organic solvents.
- The contents are supplied sterile, using ethylene oxide (EtO). Do not use if the sterile barrier is damaged, as use of nonsterile devices may result in patient injury.
- Use the device before the "Use By" date on the device package.
- The tubing set is for single-use only. Do not reuse or re-sterilize. Adverse patient reactions, such as patient infection, may result from reuse of this device. Reuse may lead to device malfunction resulting in failure to complete the procedure or possibly patient injury.
- Store the tubing set in a cool, dry place.
- Before use, inspect the tubing set and packaging to verify that no damage has occurred. Do not use if damaged.
- To ensure proper performance, do not use the irrigation tubing set for more than 4 hours.
- Carefully load the irrigation tubing set into the irrigation pump head. Do **not** attempt to remove the ESD pink sleeve that is positioned over the tubing set.
- The tubing set uses an ESD pink sleeve to reduce triboelectric-charge artifacts. The ESD pink sleeve is located on the outer surface, between the retention clips. This section of the tubing must be seated smoothly under the pump head rollers, with no bends, twists, or kinks. Place the tubing snugly and smoothly over the two small metallic guides located to the right and over the one small metallic guide to the left of the pump head rollers. Press the retention clips firmly into their respective slots. Confirm that the red warning lights, visible through the clips, turn off after proper positioning.
- The tubing set and irrigation pump should not be connected to any other infusion systems.

### 7 Potential adverse events

The potential adverse events that may be associated with ablation procedures can vary greatly in frequency and severity and may necessitate additional medical intervention, including surgery. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each DiamondTemp catheter, before using the DiamondTemp ablation system.

### 8 Directions for use

1. Carefully remove the sterile tubing set from its packaging using standard hospital sterile technique practices and inspect for damage, rough surfaces, sharp edges, or protrusions before use. Discard if any defects are noted and contact a Medtronic representative.
2. Securely connect the 3-way stopcock to the catheter end of the tubing set and ensure that it is in the closed position before use.
3. Connect the tubing set to the IV solution container using standard hospital practices. Hang the IV container near the pump and fill the drip chamber to approximately 2/3 full.
4. Open the stopcock and fill the tubing set with the saline, maintaining aseptic technique for the patient end of the tubing set. Remove any trapped air by purging saline through the tubing until it flows freely and no bubbles are visible. Close the stopcock. To ensure proper operation of the air bubble detectors, the outer surface of the tubing set must be dry.
5. Refer to the DiamondTemp irrigation pump user manual for instructions on inserting the tubing set into the pump.

### 9 Device disposal

The tubing set does not contain any hazardous materials or residues that require special disposal of the device. Follow hospital and local regulations for proper disposal.

### 10 How supplied

The DiamondTemp tubing set is an accessory to the DiamondTemp irrigation pump and is supplied separately, along with the required documentation. The tubing set is provided sterile, provided that the packaging is unopened and undamaged at the time of use. If there is damage to the packaging, do not use the product and contact a Medtronic representative.

### 11 Storage

The tubing set should be stored in its original packaging. Take care to ensure that the device will not be damaged. Store in a cool and dry place, in a 15°C to 30°C (59°F to 86°F) noncondensing environment.

### 12 Limited warranty

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

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

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

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

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

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

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

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

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

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

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUNCTION OF THE Product, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

(2) This Limited Warranty is made only to the purchaser of the Product. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

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

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





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# Medtronic

## DiamondTemp™

RF Generator

User Manual

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DiamondTemp™, Valleylab™

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## 1 Device description

The Medtronic DiamondTemp FASTR RF generator is part of the DiamondTemp ablation system, which also includes the DiamondTemp ablation catheter, DiamondTemp irrigation pump, DiamondTemp catheter-to-RF generator (RFG) cable, DiamondTemp GenConnect cable, DiamondTemp EGM cable, and DiamondTemp irrigation tubing set.

The DiamondTemp ablation system is designed to deliver radiofrequency (RF) energy to the cardiac anatomy via the DiamondTemp catheter. The DiamondTemp RF generator provides RF energy and temperature monitoring functions, as well as control and communication to the DiamondTemp irrigation pump and commercially available external devices, such as cardiac stimulators, electrophysiology (EP) recording systems, and EP navigational and mapping systems like the EnSite™ Precision™ or Velocity™ Cardiac Mapping System (Abbott, MN).

The generator operates in temperature control mode. The desired catheter tip-to-tissue temperature is selected by the user. Thermocouples in the catheter tip provide temperature feedback and the generator automatically adjusts the power output to maintain the desired tip-to-tissue temperature.

The generator (*Figure 1*) has a touch-screen display, control buttons, and a control knob for modifying and controlling ablation parameters during the procedure. Ablation parameters such as temperature, power, impedance, duration, and irrigation flow rate are displayed on the front panel and can be recorded and saved by the generator in a format that can be downloaded to a computer or a USB flash drive.

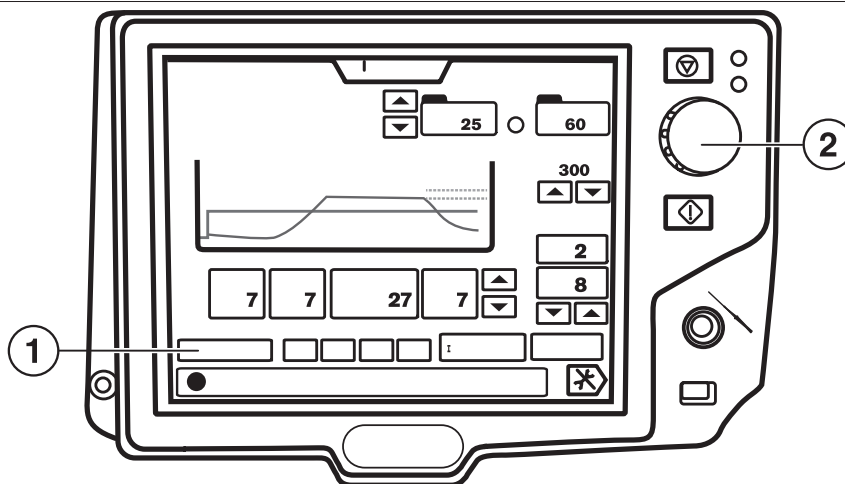
Audible indicators, visual indicators, and informational messages (with codes) are sounded out or displayed on the touch-screen panel of the generator. A foot switch is also included with the generator and may be used as an option to start or stop RF energy delivery.

The generator can be placed on a cart or a table top.

The DiamondTemp FASTR RF generator (model CEDTG200) has a power ramp time programmed to reach temperature set-point in approximately 1 second.

**Note:** There are many factors that influence the time to reach the temperature set-point: tissue contact, tissue morphology and thickness, etc. The actual ramp time to reach maximum power may be greater than the programmed ramp time.

**Figure 1.** DiamondTemp RF Generator



- 1 Touch-screen display
- 2 Control knob

## 2 Indications for use

The DiamondTemp RF generator is designed for use with the DiamondTemp ablation system. Refer to the DiamondTemp catheter instructions for the indications for use. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the generator.

## 3 Principle of operation

The generator operates by delivering RF energy, via the catheter, to discrete regions of the cardiac anatomy. The application of RF energy causes localized thermal injury, which results in a conduction block at the targeted location.

## 4 Contraindications

The contraindications listed in the DiamondTemp catheter instructions apply to the use of the DiamondTemp generator. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with the DiamondTemp catheter before using the generator.

## 5 Warnings and precautions

- Refer to the DiamondTemp catheter instructions for warnings and precautions related to the use of the DiamondTemp ablation system.
- The generator materials are not compatible with magnetic resonance imaging (MRI).
- The generator is designed for use only with the DiamondTemp catheter, catheter-to-RFG cable, irrigation pump, tubing set, and GenConnect cable. Use of other devices or improper cables may cause conditions in the operation of the generator that may result in hazards to the patient.
- There is a direct electrical connection to the catheter electrodes through the EGM connection cables or the generator. Improper use may be dangerous for the patient.
- Do not touch the accessible contacts of the connectors while touching the patient.
- To avoid unintentional skin burns to the patient at the return pad site during RF energy delivery, do the following:
  - Minimize the distance between the return pad and the operating field.
  - Minimize skin-to-skin contact between parts of the patient's body by covering these areas with dry gauze.
  - When using multiple ablation devices, remove those devices not actively in use from patient contact. In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.
  - Ensure the entire area of the return pad makes reliable contact with the patient's body during ablation. Using the RF START button to initiate an ablation results in continuous activation of RF energy output for the programmed duration. Do not remove the return pad while the system is ablating.
- Radiofrequency temperature and power should not exceed the maximum limits specified in the catheter instructions.
- The Serial Communication port and Remote Control port on the rear panel are for Service Only and no connections should be made during normal use.
- The USB port on the rear panel is used to export generator data stored in internal memory. This data contains ablation data from previous cases. Exporting of the data should only be performed when the system is not in use.
- Failure of the generator could result in an unintended increase of output power. Monitor informational messages displayed by the generator and the irrigation pump.
- It is the responsibility of hospital personnel to use compatible return pads as specified in *Chapter 9* and *Chapter 10* of this user manual. Improper return pad use may result in skin burns to the patient. When applying the return pad, position the lead such that contact with the patient or other leads is avoided.
- The generator should be placed on a hard, level surface and not stacked on other equipment.
- Do not modify the generator or accessory components. Modifications may reduce system effectiveness and impact patient health.
- The generator should not be used with a Booker box or equivalent devices.
- All devices connected to the generator must be safe for the patient per specifications in IEC 60601-1 and IEC 60601-2-2. Improper use may be dangerous for the patient.
- When using the generator with the DiamondTemp catheter, the generator can be operated only in temperature control mode.
- The patient should not come into contact with grounded metal parts or metal parts that have considerable ground capacity (for example, operating table).
- To avoid the risk of explosion, do not use the generator in the presence of flammable anesthetics or gases.
- To avoid the risk of electrical shock or fire, do not expose the generator to excessive moisture, especially when power is connected. Make sure that the connectors to the catheter and cables are completely dry before connecting.
- The rear panel of the generator should remain readily accessible, so the power cord may be easily detached from the mains power module, should that become necessary as part of providing mains isolation.
- Ensure that the return pad is positioned and connected properly. RF application will not start if the return pad is missing or incorrectly connected to the generator.
- Verify effective contact between the patient and the return pad whenever the patient is repositioned. Patient movement may disrupt return pad contact, resulting in patient injury or extended procedure times.
- Prior to increasing any ablation settings, such as temperature set-point, ablation duration, or consecutive ablations with short off-periods, check the adherence of the return pad and its connections.
- Loss of contact between the return pad and the patient results in an error message, as controlled by the impedance cut-off set-point (11, *Figure 7*).

- Read and follow the manufacturer's instructions for use with the return pad. Use only return pads that meet appropriate regulatory requirements.
- All reusable accessories should be visually inspected on a regular basis to avoid system malfunction and maintain patient safety. No broken insulation of wires is allowed.
- Once the generator output START button is pressed, it will remain energized until either the front panel RF STOP button is pressed or until the foot switch is released.
- Before use, inspect the generator and the packaging to verify that no damage has occurred. Do not use damaged products.
- Do not immerse the generator in any liquid or expose the generator to steam autoclave or ethylene oxide (EtO) sterilization.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth ground.
- Electromagnetic interference (EMI) from the environment or produced by the generator may adversely affect the performance of other equipment, including that of EP recording, mapping, or navigation systems. Excessive EMI may cause the generator to enter a Safe State, which requires a reboot. The generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

**Note:** The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals. It is not intended for use in a residential environment where this equipment might not offer adequate protection to radiofrequency communication services. Use in such environments might require mitigation measures, such as relocating or reorienting the equipment.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the DiamondTemp system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Position connecting cables to avoid contact with the patient and other electrical leads.
- If for any reason (including EM interference) the generator loses communication with the irrigation pump, or if the irrigation pump flow becomes 0 mL/min, the generator displays a message indicating that the condition should be corrected before any other steps are taken.
- During use of the RF generator, pay attention to all messages, error codes, warnings, indicators, and tones, and exercise caution as needed.
- Do not attempt ablation without the use of the irrigation pump. Before attempting ablation, make sure the pump flow rate is at the minimum continuous flow and the pump is actively communicating with the generator.
- If the DiamondTemp system is used in conjunction with a compatible mapping system and GenConnect box (or similar connection box), consult their respective instruction manuals to ensure correct connectivity and use. Construct the 3D anatomic map of the region of interest only after all mapping catheters, the DiamondTemp catheter, and all respective cables and neutral electrodes (including the ablation return pad) are completely and properly connected and positioned at the cardiac location of interest. The subsequent addition of catheters or electrodes may lead to inaccurate anatomic mapping and may require remapping.
- Do not stack more than two generator shipping boxes on top of each other.
- If a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.
- Carefully inspect the package before opening. If the package has been damaged or opened, do not use and contact your Medtronic representative.
- If you find information in this manual that is incorrect or illegible, contact your Medtronic representative.

## 6 Potential adverse events

The potential adverse events that may be associated with ablation procedures can vary greatly in frequency and severity and may necessitate additional medical intervention, including surgery. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each DiamondTemp catheter before using the DiamondTemp generator.

## 7 How supplied

The DiamondTemp generator is supplied with the following accessories and documentation. The generator and accessories are packaged nonsterile and are not intended for sterilization.

- Foot switch
- Power cord
- User manual



The following additional accessories may be used with the DiamondTemp ablation system. Read all applicable instructions before use.

- DiamondTemp catheter-to-RFG cable (supplied separately)
- DiamondTemp GenConnect cable (supplied separately)
- DiamondTemp EGM connecting cable, 4 male 2.0 mm shrouded connectors (supplied separately)
- Return pad - single-use, nonsterile, adult patient return pads that utilize high-moisture, conductive adhesive with 2.7 m (9 ft) cord, for example the Valleylab E7507, E7507DB, or equivalent (not supplied)

**Note:** The term "return pad" is used throughout this manual and on the RF generator user interface. A return pad is also commonly called dispersive electrode, dispersive indifferent patch (DIP), grounding pad, patient return electrode, or passive/plate electrode.

**Note:** Ensure that the connector on the return pad cable is compatible with the DiamondTemp RF generator port.

- Grounding cable, equipotential connector, DIN 42801, or equivalent (not supplied)
- Serial communication cable, shielded, DB-9 connector, EIA RS-232, or equivalent (not supplied)
- Video output cable, shielded, DB15 connector, VGA, or equivalent (not supplied)

## 8 Unpacking the generator

Carefully remove the generator from the shipping container. Unpack the user manual and all accessories to be used with the generator. Inspect all items for possible damage during shipment. If any items are damaged, do not use them and contact a Medtronic representative.

## 9 Setting up the generator

The generator is intended for use with the DiamondTemp catheter-to-RFG cable only (supplied separately). The catheter-to-RFG cable connects the generator to the catheter. The catheter-to-RFG cable plugs into the front of the generator. When using the DiamondTemp ablation system with a compatible mapping system, the GenConnect cable (supplied separately) can be connected between the catheter-to-RFG cable and the generator to the GenConnect box (or similar connection box) (*Section 10.3*). Consult the respective instructions for the catheter-to-RFG and GenConnect cables. Do not use cables with devices not indicated in the respective instruction manuals.

The generator is designed for use with a one return pad, which connects to the front of the generator. Apply the return pad per its instructions and according to the guidance in *Section 9.2* of this user manual.

The generator is intended for use with the DiamondTemp irrigation pump and DiamondTemp irrigation tubing set only (supplied separately). Included with the irrigation pump is a standard Ethernet cable to connect the irrigation pump to the generator. (See the irrigation pump user manual for more information.)

### 9.1 Technical safety inspections

The following inspections for safety must be performed at first use and after each repair.

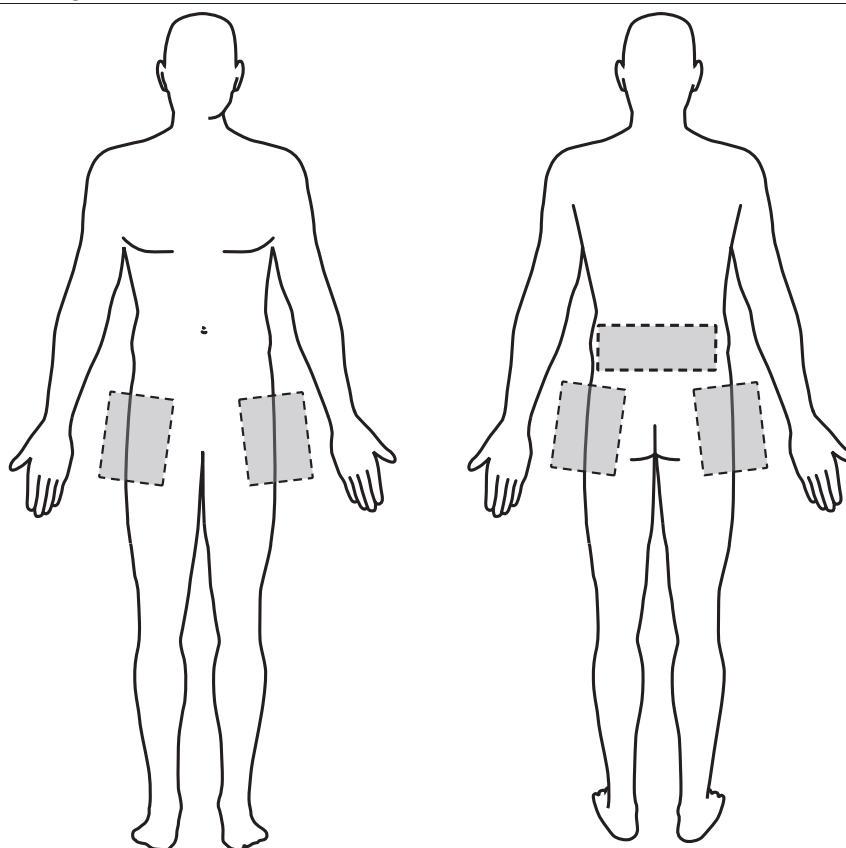
- Perform a general inspection of the generator:
  - Assure the front and rear panels are not loose.
  - The touch-screen display must not show signs of damage.
- Check that the selector knob is securely connected and able to easily rotate.
- Perform a visual and functional inspection of the accessories:
  - Check the power cord and connector for any damage.
  - Check the connecting cable input for the return pad electrode.
  - Check the foot switch and its connector to ensure that it is not damaged and that it functions correctly.
- Check that the catheter (supplied separately) is connected appropriately.
- Check the return pad connector on the front panel of the generator for proper connection.
- Check the power cord connector for damage.
- Before operation, ensure that all connections are established and checked.
- The rear panel of the generator should remain readily accessible so that the power cord may be easily detached from the mains power module. The means of isolating equipment from mains are provided by a power entry module with detachable power cord.

### 9.2 Handling the return pad

One (1) return pad is required in order to operate the generator. The generator does not deliver RF energy without a return pad properly connected. If the return pad is or becomes disconnected, the generator will either not allow entry into RF energy delivery mode or will terminate the delivery of RF energy with a 'High Impedance' informational code. The RF generator does not implement a continuity monitor or a contact quality monitor for the return pad. For optimal performance, the self-adhesive return pad should be applied close

to the operating field. *Figure 2* shows the recommended locations for the return pad. Ensure that the entire area of return pad is reliably attached to a suitably prepared and appropriate area of the patient's body, as defined by the return pad manufacturer. Use only a compatible return pad (see *Chapter 7*).

**Figure 2.** Return Pad Positioning



## 10 Directions for use

**Note:** The screen images shown in this user manual are representative of what is seen on-screen with the software; actual images may differ slightly.

### 10.1 Electrical connections

The generator operates using line power of 100 to 240 V~ 50/60 Hz. To avoid the risk of electric shock, connect only to a hospital-grade grounded power outlet. The means of isolating equipment from mains are provided by a power entry module with detachable power cord. The generator is not battery powered and cannot be moved during use.

### 10.2 Turning the generator on and off

Before operation, the generator must be placed on a stable surface with adequate circulation of air around the device to avoid overheating. Additionally, the generator must be protected from moisture, contamination, and contact with flammable or explosive substances.

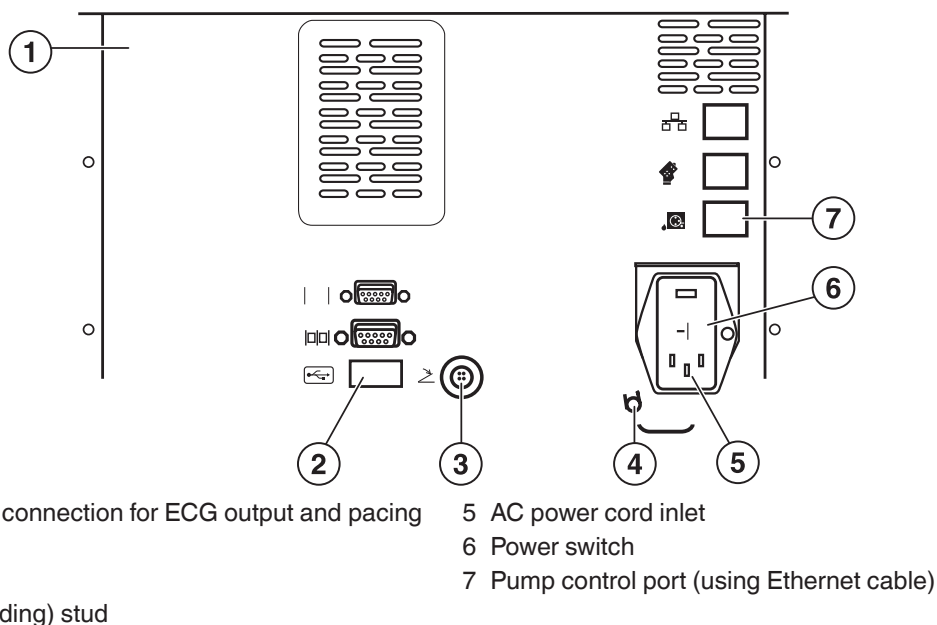
Ensure that the power cord is plugged in to a power line of 100 to 240 V~ 50/60 Hz. Connect the power cord only to a hospital-grade grounded power outlet and to the rear AC power cord inlet (5), as depicted in *Figure 3*. The grounding cable serves the purpose of equipment potential equalization and should be connected to the equipotential (grounding) stud (4) located on the rear panel of the generator. The other end of the grounding cable should be connected to the grounding stud of another medical electrical equipment. The daisy-chaining of grounding cables ensures that relevant medical electrical equipment operates at the same potential, thereby reducing the chances of electrostatic or AC potential build-up. The power switch (6) is located on the back panel of the generator near the power cord inlet. Turn on the switch at the rear of the generator. Next, to start the generator, depress the soft power button on the lower-left front panel of the generator (1), as shown in *Figure 4*. This button appears green when the generator is on, and amber when the generator is in standby mode. An image with the Epix Therapeutics logo will appear on the touch-screen display (2) on the front of the generator after this button is depressed. Once turned on, the generator will perform a self-test. Once the self-test has passed, an audible tone is heard, and the touch-screen display will show the Advanced Settings screen in standby mode with the word “STANDBY” displayed in the top center of the screen.

The generator has four screen options that will be used during the procedure:

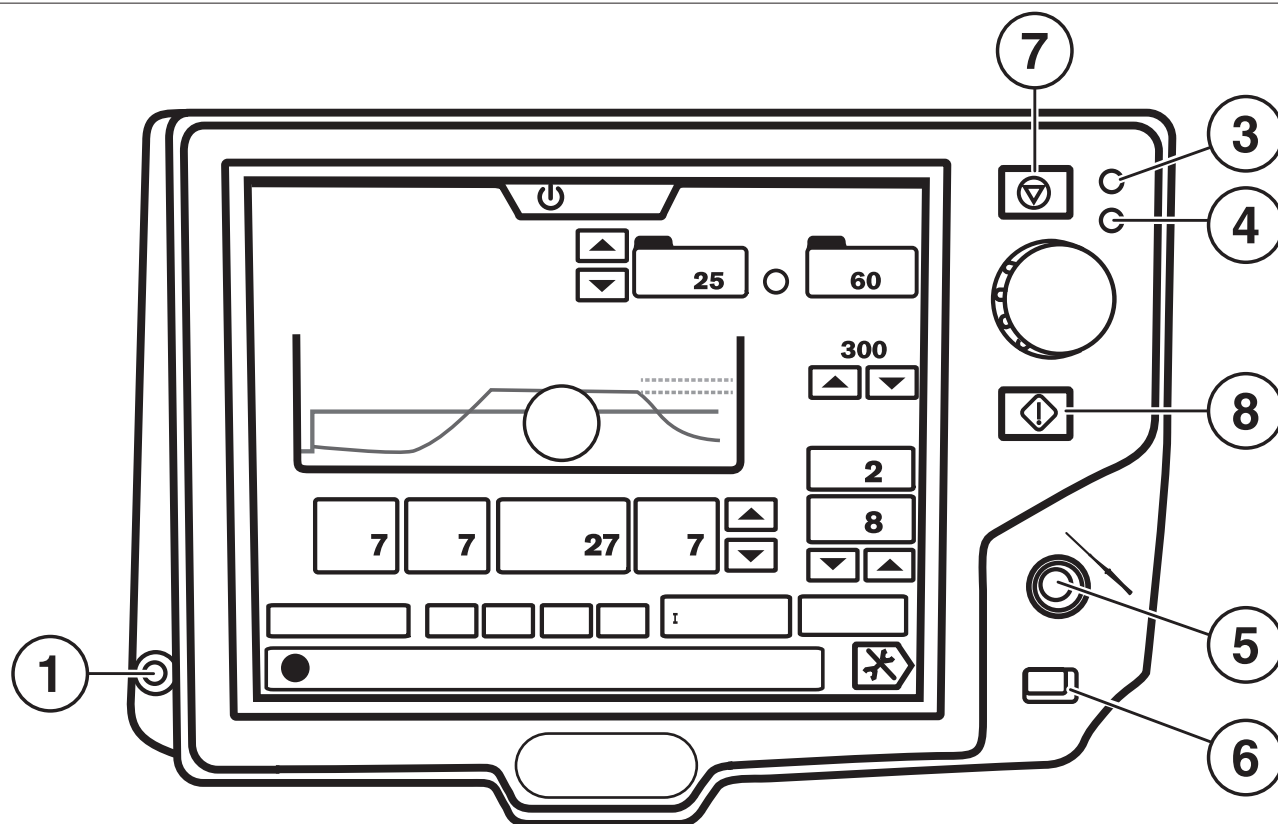
- Advanced Settings screen
- Tissue Contact Impedance Monitoring screen
- RF Ablation Treatment screen
- Configuration screen

Unless otherwise instructed by an on-screen message, the device should be powered down by first pressing the soft power on/off button on the front panel, not the rear power switch. Once the device returns to standby mode (front panel button illuminated amber in color), the device may be completely powered off by switching the rear panel power switch to the 0 position.

**Figure 3.** RF Generator Rear Panel



**Figure 4. RF Generator Front Panel**



- |   |                                     |
|---|-------------------------------------|
| 1 Soft power on/standby button                                | 5 Catheter-to-RFG cable port        |
| 2 Touch-screen display  | 6 Return pad connection port        |
| 3 Power indicator – green when power is on                    | 7 RF STOP - generator stop button   |
| 4 Fault indicator – red when a fault condition is encountered | 8 RF START - generator start button |

### 10.3 Connecting the cables and accessory components

Use only the cables, accessories, and catheters provided or recommended. Refer to *Chapter 7* for a list of supplied components and compatible devices.

The irrigation pump and the generator must be used in communication mode. To establish this mode, plug the Ethernet cable provided with the irrigation pump into the port on the rear panel of the pump, and connect the other end to the port on the rear panel of the generator (7, *Figure 3*). Once communication is established between the two devices, a communication icon (5, *Figure 7*) will be displayed on the upper portion of the generator touch-screen.

**Note:** When communication is established between the two devices, modifications to the flow rate or flow rate set-points on the generator or pump will be enacted. However, the generator should be used to control the irrigation pump during the procedure.

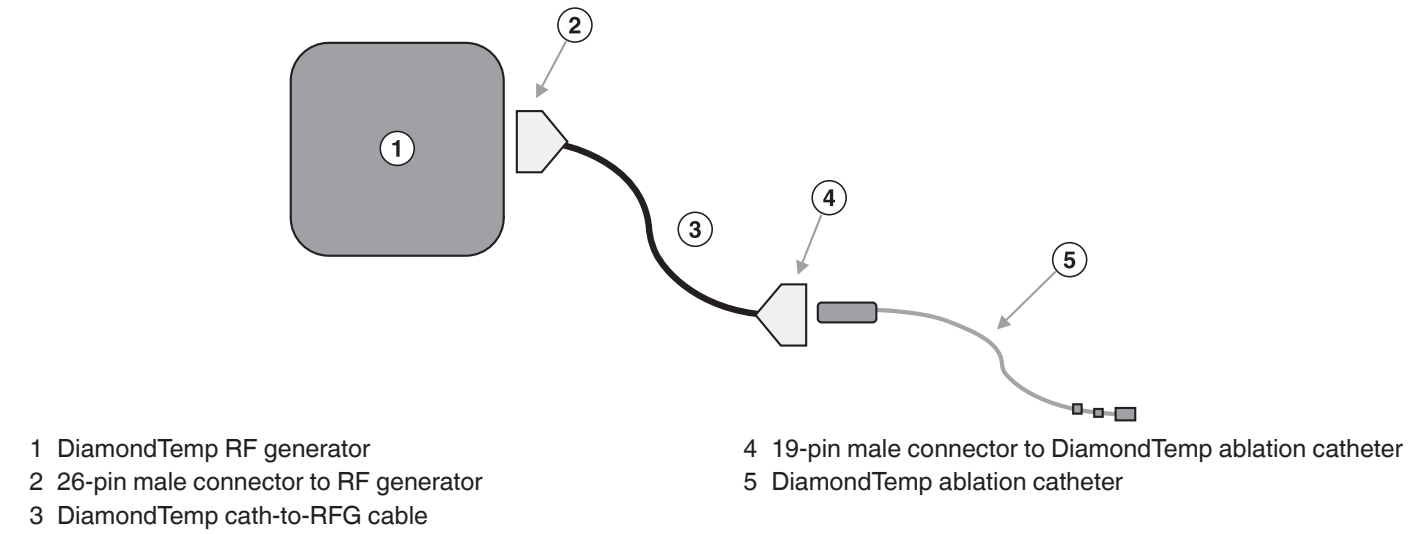
Once the return pad has been adhered to the patient (*Section 9.2*), the return pad connector may be plugged into the front panel of the generator (6, *Figure 4*).

Plug the sterile catheter-to-RFG cable into the catheter interface cable port on the front panel of the generator, marked by the catheter icon (5, *Figure 4*). The multi-pin connector of the catheter-to-RFG cable, which has a green band on the connector to match the green connector on the generator, will lock into place once plugged into the generator. In order to disconnect the catheter-to-RFG cable plug, its corrugated sleeve must be slid back. When ready to connect the catheter, plug the distal end of the sterile catheter-to-RFG cable into the back connector of the catheter. Refer to the catheter-to-RFG cable instructions for more detailed information.

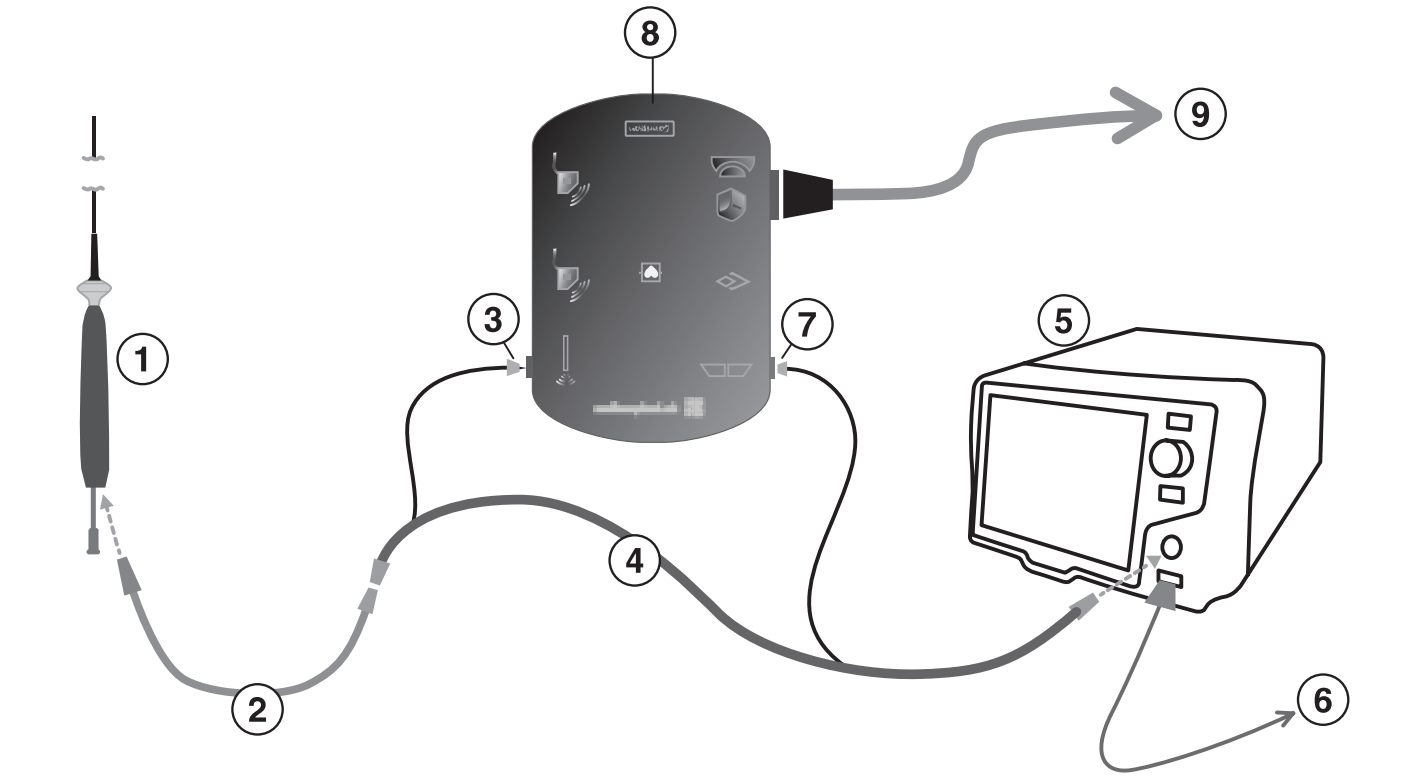
Signals from the electrodes located on the tip of the catheter are passed through the generator and can be accessed for intracardiac electrogram recording, stimulation, and navigation purposes from the output port labeled “ECG/Pace” on the rear panel of the generator (1, *Figure 3*). An EGM cable can be plugged into the output port to route these signals to the appropriate recording, mapping, and navigation systems. The signals on the output port are filtered; however, electromagnetic interference from the environment or from the generator may affect recording, mapping, or navigation systems. Connectivity to such systems should be made with caution, avoiding unnecessary cable loops. Also, it is recommended to use monitoring systems that incorporate high frequency current-limiting devices.

The DiamondTemp system can also be used with a compatible cardiac mapping system (such as the Abbott EnSite™ system). When connecting the DiamondTemp system to the mapping system, use a GenConnect box (or similar connection box). For this purpose, use the GenConnect cable. Connect one end of the GenConnect cable to the catheter-to-RFG cable. Connect the distal end of the GenConnect cable to the generator. Connect the grey 9-pin connector to the catheter input of the GenConnect box. Connect the black 14-pin connector to the RF generator output of the GenConnect box. *Figure 5* and *Figure 6* provide connectivity diagrams for using the DiamondTemp catheter and DiamondTemp RF generator, without the mapping system and with the mapping system. Confirm the correct connectivity by using the 3-D navigation function of the mapping system. Use the mapping system and the GenConnect box according to their respective instructions. Connect the return pad directly to the generator.

**Figure 5.** Connectivity Diagram between Catheter and RF Generator



**Figure 6.** Connectivity Diagram between Catheter and RF Generator When Using a Mapping and Navigation System



- |                                 |  |
|---------------------------------|--|
| 1 DiamondTemp ablation catheter | 6 Ablation return pad  |
| 2 DiamondTemp cath-to-RFG cable | 7 14-pin twist connector   |
| 3 9-pin quick connector         | 8 GenConnect box (oriented up-side down, for purposes of illustration) |
| 4 DiamondTemp GenConnect cable  | 9 Amplifier  |
| 5 DiamondTemp RF generator      |  |

## 10.4 Advanced Settings screen

The generator will first display the Advanced Settings screen (*Figure 7*) upon powering-up on the touch-screen display panel. This screen can also be accessed at any time during the procedure from the RF Ablation Treatment screen. The Advanced Settings screen allows for generator and pump settings to be established, for presets to be saved, and for a new case to be started for each patient. The default pump settings are 2 mL/min for low flow and 8 mL/min for high flow. A catheter does not need to be connected to the generator to use the Advanced Settings screen.

**Figure 7.** DiamondTemp Generator Advanced Settings Screen



- |   |   |
|---|---|
| 1 Low irrigation flow rate preset adjustment  | 7 Settings for Pre-Cool, Ramp Time, Duration and Post-Cool              |
| 2 High irrigation flow rate preset adjustment | 8 "Treatment" button: touch to proceed to the Ablation Treatment screen |
| 3 Impedance cut-off set-point                 | 9 "Set-up" button: touch to proceed to the Set-Up screen                |
| 4 Temperature set-point                       | 10 Export data button   |
| 5 Pump connection icon                        | 11 Start GenConnect auto calibration                                    |
| 6 Preset memory keys                          |   |

The following ablation and flow rate parameters can be set up for the start of each case or established as a preset configuration. Recommended settings are defined in *Table 1*.

- **GenConnect auto-calibration process** (11, *Figure 7*): Press this button to initiate the auto-calibration feature. The system will detect absence or improper connection of a GenConnect unit or respective cable. When everything is properly connected, the system will complete the calibration process and activate the Treatment button (8). If the auto-calibration fails, or if it is not attempted, the Treatment button (8) is grayed out and further steps cannot be taken.
- **Low and high irrigation pump flow rates, in mL/min** (1, 2 in *Figure 7*): The value of the low irrigation flow rates can be set on the side of the Advanced Settings screen by using the up or down arrows to change the value of the flow rate for each box. The value of the high irrigation flow rate, which is only used during RF ablation, can also be set on the same screen.  
**Note:** These functions will only be active (indicated by blue text) when communication is established between the generator and irrigation pump.
- **Power set-point, in Watts** (4, *Figure 7*): With DiamondTemp catheters, the generator operates only in temperature control mode. This means the generator controls the power level automatically, so that the temperature set-point is reached.  
**Note:** The user cannot define or control the actual level of RF power delivered by the generator.

A maximum power set-point is available and may be adjusted up or down using the arrows next to the Power display. During temperature-controlled RF energy delivery, the generator automatically adjusts the power only up to levels equal to or less than

this maximum power set-point. The recommended setting, which is also the default setting, is 50 W. By design, the generator cannot deliver more than 50 W.

- **Temperature set-point, in Celsius** (4, *Figure 7*): The value of the temperature control set-point can be established by turning the knob to the desired level.
- **Timing for each stage of the ablation, in seconds** (7, *Figure 7*): To adjust the timing for each stage of treatment, touch the button for the desired stage located below the graph in the center of the screen. Once selected, the active stage will be highlighted blue and the up and down arrows to the right can be used to increase or decrease the time increments in seconds.
  - The pre- and post-cooling stages set the amount of time that the irrigation pump delivers irrigation before and after the ablation to cool the tissue interface. No RF energy is delivered during the pre-cooling or post-cooling stage. At this stage, the generator will set the irrigation pump flow rate to “High”.
  - The set-point for the duration of the ablation can also be established on this screen. This number can be set at 1 second increments between 0 and 999 seconds.

**Table 1.** Recommended Generator and Irrigation Pump Settings

RECOMMENDED/DEFAULT GENERATOR SETTING	
Operational Mode	Temperature Control
Maximum Temperature Set-Point	60°C
Maximum Power Setting	50 W
Maximum Ablation Duration	45 seconds
DEFAULT PUMP SETTING	
Irrigation Flow Rate during ablation	8 mL/min
Minimum continuous flow rate	2 mL/min

### Preset memory keys

The generator has four (4) programmable preset memory keys (6, *Figure 7*), which can save and retrieve any desired combination of preset parameters. To program a preset memory key, first set up the desired preset values as previously described, then push and hold the preset key for 3 seconds. After holding the preset key for the required time, there will be an audible tone and the key will turn blue to indicate successful programming of the preset values. The saved preset parameters can be retrieved from the Advanced Settings screen or the Ablation Treatment screen by selecting the desired key. All presets are saved in the generator internal memory, even when the generator is powered down between cases.

### Case ID and starting a new case

A case is defined as a set of ablations performed in a patient or in a particular chamber of the heart. A new case is started each time the generator is powered up, each time the new case button is selected. The generator saves relevant ablation parameters for each patient into a case file with this unique identifier (see “Exporting Data” for additional details on saving ablation data).

To proceed to the Ablation Treatment screen, touch the “Treatment” button (8, *Figure 7*) in the lower right corner of the screen. The Set-Up screen can also be navigated to by pressing the Set-Up icon (tools image, 9, *Figure 7*) at the bottom right-hand side of the Advanced Setting screen.

### Exporting Data

Data from each ablation procedure is saved to the internal memory of the generator. Each unique case ID created will have a unique folder that stores the ablation data during the procedure. An external hard drive or memory stick with a USB connector can be connected to the USB Data Export port on the rear panel of the generator (2, *Figure 3*). Once connected, the “Export Data” (10, *Figure 7*) will become active on the touch-screen display panel. Selecting this button will allow all data stored on the generator to be exported to the connected USB device. Exporting data should only be performed when the system is not in use. The generator has storage capacity for at least 1000 case files. Exporting the data does not clear the internal memory. If the internal memory reaches >80% capacity (on the Configuration screen), contact a Medtronic representative.

## 10.5 Configuration screen

The Configuration screen (*Figure 8*) can be accessed from either the Advanced Settings screen or the Ablation Treatment screen by pressing the Configuration icon at the bottom right-hand side of either screen (with the tools icon).



**Figure 8.** Configuration Screen



The Configuration screen allows the generator system and display preferences to be adjusted using the following buttons:

- **Date and Time:** Touch the part of the time or date to be changed. The active box will have a purple border. Press the up and down arrows to set the date and time. Time can be selected in 12-hour or 24-hour format.  
**Note:** If the date and time setting reverts to a time in the past (e.g. Jan 01, 2003) when the generator is powered off, contact your Medtronic representative.
- **Volume:** Touch the green volume bar to set the desired volume.
- **Brightness:** Touch the yellow brightness bar to set the desired brightness.
- **Language:** Press the up and down arrows to choose a language.  
**Note:** Once a new language is selected, the generator will restart and display information in the new language.
- **Save & Exit:** Press to save and exit back to the prior screen.
- **Cancel:** Press the Cancel button to exit without saving changes.

The Configuration screen also displays the Generator Serial Number, Software Version, Date of Manufacture (DOM), and the percentage of memory available.

## 10.6 Contact Impedance screen

The Contact Impedance screen (*Figure 9*) can be accessed from the Advanced Settings screen. When a catheter is correctly connected to the generator, the text at the top center of this screen will change from “STANDBY” to “READY”, indicating that ablation may be performed. In READY mode, before initiating RF energy delivery, the Contact Impedance screen displays the tissue-contact impedance vs. time. This impedance may be utilized to monitor the level of contact between tissue and the RF electrode. A higher impedance value may indicate better tissue contact. However, caution should be exercised as other parameters, such as electrograms, fluoroscopic or intracardiac echo images, should also be monitored.

*Figure 9* shows an example of the Contact Impedance when the electrode is in good contact with tissue. The real-time trace shows the history of tissue contact impedance over the previous 30 seconds.

Tissue contact impedance is not available during pre-cool, ablation, and post-cool phases. Once the RF START button is pressed, the front panel screen toggles to the Ablation Treatment screen (*Section 10.7*).



**Figure 9.** Contact Impedance Screen Displaying Impedance Trace



**10.7 Ablation Treatment screen**

The Ablation Treatment screen (Figure 10) can only be accessed from the Contact Impedance Monitoring screen (Section 10.6), after the RF START button is pressed, or during READY mode by selecting the ‘Graph’ tab.

**Figure 10.** Ablation Treatment Screen



- 1 Real-time ablation parameter display
- 2 Ablation Temperature set-point (Celsius)
- 3 Ablation Duration set-point (seconds)
- 4 Graphical display area
- 5 Message field

The Ablation Treatment screen displays the real-time parameters (irrigation flow rate, RF impedance, RF impedance relative change with respect to RF impedance start value, catheter highest temperature from all thermocouples, and ablation power and ablation duration) across the top of the screen in four boxes (1, Figure 10). On this screen, purple color indicates duration, green color indicates RF impedance, yellow color indicates power and orange color indicates temperature. The green Impedance field also includes the relative change in RF impedance during the course of RF delivery. The relative change is displayed as a signed percent variable (%) and it is computed relative to the initial value of RF impedance at the start of RF delivery. A change with a negative sign indicates a relative drop in RF impedance with respect to its initial value.

On the right-hand side of the Ablation Treatment screen, the top display section in the “Settings” segment is outlined in orange and labeled “Temperature,” if the generator is in temperature control mode. The temperature value represents the temperature set-point

to be used during temperature control ablation. Rotating the knob adjusts the temperature set-point up or down. These settings can be adjusted at any point during the procedure.

The Duration set-point displays the ablation duration set-point value in seconds. This value can be increased or decreased at any time during the procedure by using the up and down arrows located just below it. The maximum duration setting in the generator is 999 seconds. This time does not include the pre-cooling or post-cooling duration. An ablation will automatically terminate if this ablation duration set-point is reached.

Once correct communication has been established between the generator and the irrigation pump, irrigation flow rate levels can be selected by touching the desired level. The irrigation flow set-points for the low and high levels can be modified remotely with the generator by selecting the desired level and using the up and down arrows to modify the level to the desired value. With the communication link established, the generator will automatically switch the irrigation pump between the low and high flow rate before ablation, and then back down to the prior flow rate after the ablation has terminated. The irrigation flow from the pump can also be stopped by touching the “STOP PUMP” button on the touch-screen panel.

**Note:** When the communication link is established between the generator and irrigation pump, modifications to the flow rate or flow rate set-points on either the generator or pump will be enacted. Use the generator to control the irrigation pump during the procedure.

A preset memory value can also be selected by touching the desired preset button (6, *Figure 7*) to recall the stored preset value to one of the predetermined ablation settings. Selecting a preset will change the current ablation and flow rate preset values on the generator to those stored in the preset. If any of the values stored in the preset are changed on the generator after it is selected, the preset will become inactive and the generator functionality will default to the adjusted parameters.

To start an ablation at the selected values on the generator, press the green “Start” button located below the control knob on the front panel of the generator (*Figure 1*). Alternatively, the foot switch can be activated, if one is connected. Once the ablation duration set-point has been reached, the ablation will be stopped. To terminate an ablation sequence before reaching the duration set-point, press the red “Stop” button located above the control knob on the front panel of the generator (*Figure 1*) or alternatively, release the foot switch pedal. The ablation duration set-point will still remain at the current value. The ablation process can be restarted by pressing the “Start” button again. The top of the screen will display “RF ON”, and a constant audible tone will sound at all times while RF energy is being delivered.

Once an ablation is initiated, a real-time graph of the temperature, power, and impedance (in Celsius, Watt and Ohm, respectively, on the vertical axis) versus time (in seconds, on the horizontal axis) will be created in the “GRAPH” display area on the display screen (4, *Figure 10*). The real-time graph displays temperature in orange, power in yellow, and impedance in green.

The “ABLATION DATA” and “CASE DATA” tabs located just above the graph contain summary information on the following parameters (*Table 2*) for the current case:

**Table 2.** Ablation and Case Data Information

PARAMETER	UNITS
Date	NA
Total number of ablations in procedure	NA
Total ablation time	min
Average ablation duration	s
RF power maximum	W
RF power average	W
Composite temperature range	°C
Composite temperature average	°C
RF Impedance start/end values	Ω
Maximum/Average RF impedance	Ω
Relative RF impedance change	%
Total infused fluid volume	mL
Tissue contact impedance maximum	Ω
Tissue contact impedance average	Ω

To access this information, touch the “ABLATION DATA” tab (*Figure 11*) or “CASE DATA” tab (*Figure 12*) to make it active (indicated by a blue highlighting of the tab). This will display a summary of the case and ablation information in the area where the ablation graph was located. Additionally, a summary of parameter values reached during the last ablation is also provided. The Last Ablation summary provides data about: Mode (such as Temperature control), last ablation duration, power, impedance, temperature and contact impedance values. To return to the graph, touch the tab labeled “GRAPH”. If any ablation is started while the tab is active, the display window will automatically switch back to the graph display.

Figure 11. Ablation Data Tab



Figure 12. Case Data Tab



From the Ablation Treatment screen, it is possible to access the Advanced Settings screen by selecting the “Advanced Settings” button at the lower-left corner of the screen. It is also possible to access the Configuration screen from the Ablation Treatment screen by selecting the Configuration screen icon at the lower-right corner of the screen.

### 10.8 Indicators and informational messages

During the procedure, informational messages are displayed in a separate pop-up window or in the message field (5, **\*\*\*Unresolved cross-reference: idref=whitim215760020300\*\*\***) at the bottom of the touch-screen display on the generator. The displayed message contains an error code, an error message, and (for some errors) recommended actions. Table 3 shows a sample of the informational messages that may occur during use.

Some messages may indicate that there has been a hardware or software undesired operating condition of the generator. In addition, the red indicator light on the upper-right front panel of the generator will turn on. If such an informational message occurs during operation, attempt to restart the generator using the soft power on/standby switch on the front panel of the generator.

The informational messages are displayed with an error code (such as, E1003, P3032, or W110). The codes are useful for advanced engineering troubleshooting. If it is necessary to call an Medtronic representative for support, it can be helpful to provide the error code to the engineering team.

**Table 3.** Generator Codes, Message Descriptions, and Recommended Actions

Error Code	Error Message	Recommended Action
E1003	EXPIRED CATHETER	Replace catheter.
E1007-E1010	PUMP CONNECTION FAILURE	Check RFG-Pump connection.
E1025	UNSUPPORTED ADAPTER CABLE	Disconnect and reconnect catheter cable. If failure recurs, replace catheter cable.
E1033	PUMP COVER OPEN	Close pump cover.
E1034	EEPROM DATA INVALID	Disconnect and reconnect catheter. If failure recurs, replace catheter.
E1046-E1051	TEMPERATURE SENSOR FAILURE	Replace catheter.
E1052	TEMPERATURE ABOVE SET POINT	Check irrigation flow. Replace catheter if condition persists.
E1057	LOW IMPEDANCE	Catheter may need replacement.
E1058	HIGH IMPEDANCE	Cables may be disconnected, check connections.
E1061	PUMP FLOW OFF	Turn on flow.
E1062	VOLTAGE LIMIT EXCEEDED	Report to Medtronic if condition occurs repeatedly.
E1067	High RF current limit exceeded at return pad	Confirm adequate return pad contact to patient. Ablation may start once Heating Factor falls below 30 A <sup>2</sup> s (message W05 is cleared). For more information on ablation duration and power settings, see <i>Section 16.4</i> .
E1068	High RF current limit exceeded - wait to start ablation	Confirm adequate return pad contact to patient. Ablation may start once Heating Factor falls below 30 A <sup>2</sup> s (message W05 is cleared). For more information on ablation duration and power settings, see <i>Section 16.4</i> .
P10-P18	INTERNAL PUMP FAILURE	N/A
P21	DUPLICATE VARIABLE	N/A
P3017	INTERNAL LOAD TEST FAILURE	N/A
P3032	SOFTWARE FAILURE	N/A
P3038	INTERNAL LOAD TEST FAILURE	N/A
P3039-P3044	SELF TEST FAILURE	N/A
P3045	POST CONTACT INDICATION LOAD	N/A
P3046	POST CONTACT INDICATION PHASE	N/A
P3047	STUCK RF ON BUTTON	N/A
W05	RF current high at return pad - RF output limited	Confirm adequate return pad contact to patient. For more information on ablation duration and power settings, see <i>Section 16.4</i> .
W102, W104-W109	LOSS OF TISSUE CONTACT	Reposition catheter for better contact.
W103	IMPEDANCE OUT OF RANGE	Catheter tip electrode may be inside introducer sheath. Reposition catheter or check catheter connectivity.
W110-W111	INEFFICIENT IRRIGATION	Check pump flow or catheter contact to tissue. Replace catheter and irrigation tube if necessary.

## 10.9 Operation sequence for the generator

1. Before operation, the generator must be placed on a stable surface with adequate circulation of air around the device to avoid overheating. Additionally, the generator must be protected from moisture, contamination, and contact with flammable or explosive substances.
2. Plug in and turn on the generator.
3. Create and check all connections.

**Note:** The generator will recognize the catheter when the correct connection is made with the appropriate catheter-to-RFG cable. Refer to the message bar for information on any missing connections. It is not required to notify the generator or select the type of catheter connected.

4. Verify that the generator and irrigation pump are communicating by noting that the communication icon on the top of the generator touch-screen is illuminated.
5. Verify that the irrigation pump is fully operational, according to the irrigation pump user manual.
6. On the Advanced Settings screen, configure any procedure parameters, as desired. High caution and sound medical reasoning should be used when deciding to change any of these parameters. Maximum continuous ablation duration at a single site should not exceed 60 s.

**Note:** To start a new procedure immediately after a prior one without turning the generator off, press the “NEW CASE” button on the generator touch-screen.

7. Check or modify any of the preset memory keys, if desired.
8. Enter patient information.
9. Touch the GenConnect auto-calibration button and wait until this process completes successfully.
10. Touch the configuration icon at the bottom right corner of the Advanced Settings screen to advance to the Configuration screen.
11. Ensure the generator configuration preferences are accurate. Modify configuration preferences, if desired.
12. Touch the “SAVE & EXIT” button at the bottom right corner of the generator touch screen to return to the Advanced Settings screen.
13. When the preceding steps are complete, touch the “TREATMENT” button on the Advanced Settings screen to begin the procedure.
14. Ensure that the generator displays “READY” in the top center field shaded green on the screen.
15. The generator enters the Contact Impedance screen. Monitor the electrode-tissue contact so that it is suitable for the goals of the procedure.
16. Use the controls of the generator to establish the desired irrigation flow rate through the catheter. See the DiamondTemp catheter and irrigation pump instructions for full information on setting up and operating the irrigation pump, as well as appropriate irrigation flow rates during the ablation procedure.

**Note:** When communication is established between the two devices, modifications to the flow rate or flow rate set-points on either the generator or pump will be enacted. Use the generator to control the irrigation pump during the procedure.

**Note:** It is recommended that the controls of the irrigation pump only be used in three cases: (1) during initial flush of the tubing set and preparation of the catheter, (2) if air bubbles are detected in the tubing set, and (3) in case of an urgent need to change the irrigation flow rate or stop the irrigation pump. Refer to the irrigation pump user manual for full information on set-up and operation of the pump.

17. Set the desired ablation parameters on the generator or select the desired preset memory key. High caution and sound medical reasoning should be exercised when deciding to change any of these parameters. Maximum continuous ablation duration at a single site should not exceed 60 s.

**Note:** Read the complete DiamondTemp catheter manual for full instructions for use of the catheter, including ablation settings.

18. To start an ablation at the selected values on the generator, press the green “Start” button located below the control knob on the front panel of the generator. If the ablation duration set-point has been reached, the current ablation will be stopped. To terminate an ablation sequence before reaching the duration set-point, press the red “Stop” button located above the control knob on the front panel of the generator. The ablation duration set-point will still remain at the current value.

**Note:** During an ablation, the programmed set-points for the ablation temperature level and duration can be adjusted, without interrupting the ablation process, by using the knob or duration up and down keys, respectively.

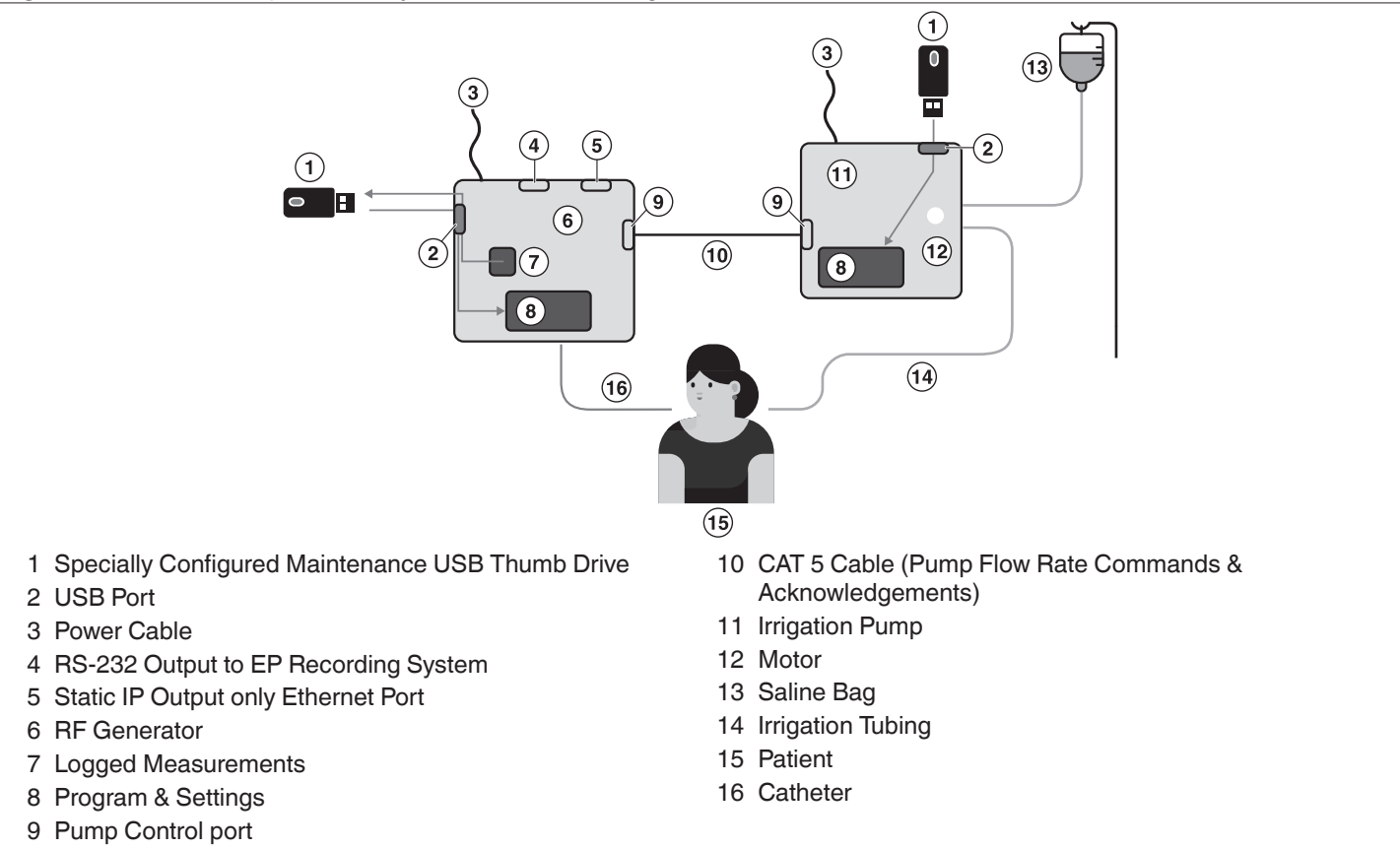
**Note:** With the communication link established between the irrigation pump and generator, the high irrigation flow rate used for ablation will be initiated automatically. After the ablation termination and the post-cooling phase, the irrigation pump will automatically return to the irrigation flow rate that was on before the start of that ablation.

19. To restart subsequent ablations, first ensure that the appropriate ablation settings are displayed on the generator touch screen. The ablation process can be initiated again by pressing the “Start” button on the generator front panel.
20. After the desired therapy has been delivered to the patient and the DiamondTemp catheter has been removed, the irrigation flow may be stopped by touching the “Stop Pump” button on the touch screen display.

21. Procedural ablation parameter data is automatically saved to the internal memory of the generator. To export this data after the case, return to the Advanced Settings screen and connect an external hard drive or memory stick with a USB connector to the USB port on the rear panel of the generator. Once connected, the “Export Data” button will become active on the touch-screen display panel. Selecting this button will allow all data stored on the generator to be exported to the connected USB device.
22. Unless otherwise instructed by an on-screen message, the device should be powered down by first pressing the soft power button on the front panel, not the rear power switch. Once the device returns to standby mode (front panel button illuminated amber in color), the device may be completely powered off by switching the rear panel power switch to the 0 position.

## 11 DiamondTemp ablation system architecture and cybersecurity

**Figure 13.** DiamondTemp Ablation System Architecture Diagram



The DiamondTemp generator and irrigation pump devices are not intended for use on or to be connected to a computer network and do not accept wireless or unknown physical connections. A system architecture diagram for the DiamondTemp ablation system is presented in *Figure 13*. The Pump Control port is dedicated only for communications between the DiamondTemp generator and DiamondTemp irrigation pump. The USB port is used to export data when the system is not in use.

Any suspected compromise of the DiamondTemp ablation system’s cybersecurity, from such events as unauthorized access, computer virus infection, or inadvertent connection to a network, should be reported to Medtronic. A proper course of action, determined by Medtronic and the end user, should be determined before the system can be further used.

Software upgrades are to be performed only by Medtronic or authorized personnel.

The DiamondTemp ablation system contains the following commercial, open source, or off-the-shelf software:

- QT Third party graphics library
- ALSA Linux Sounds generation library
- SQLite Database Interface library
- Customized Linux Operating System including TCP/IP stack



12 Maintenance and service

12.1 Cleaning

The generator must be protected from moisture, contamination, and contact with flammable or explosive substances. The generator and foot switch surface may be cleaned with non-flammable and non-explosive agents only, according to the following steps. Follow universal precautions for protective apparel when handling and cleaning contaminated instruments. Make sure no fluids or moisture enter the interior of the generator during cleaning.

- 1. Before cleaning, turn the DiamondTemp generator off. Disconnect the power cord from the electrical power source and from the rear of the generator. Disconnect all other cables and peripherals.
- 2. Wipe the generator enclosure with a clean, soft, nonlinting cloth dampened with a pH neutral detergent.
- 3. Wipe again with distilled or sterilized water.
- 4. Wipe dry with a clean, soft, nonlinting cloth.
- 5. To disinfect, use broad spectrum disinfectants like phenolics, aldehydes, or alcohols. Recommended disinfectants are Glutaraldehyde 1%, 70% IPA, sodium hypochlorite (0.1%) or equivalent. Follow the manufacturer's instruction for use to use the disinfectant.

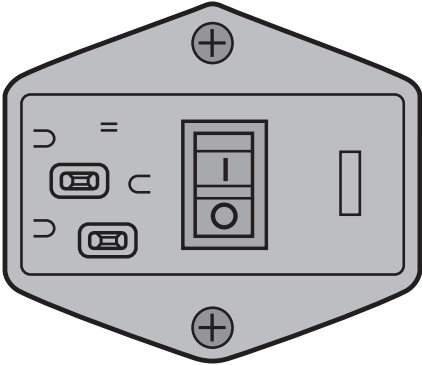
Do not immerse the generator in any liquid or expose the generator to steam autoclave or ethylene oxide (EtO) sterilization. For instructions on the use, cleaning, or sterilization of any accessory cables to the generator, refer to the cable instructions.

12.2 Maintenance

There are no user-serviceable parts in the generator, except as noted in the instructions below. The generator requires no adjustments, calibrations, or regularly-scheduled maintenance. While maintenance is not required, local standards and regulations should be followed with respect to periodic performance verification. If the generator requires repairs or is defective, the unit should be returned to the manufacturer for service or replacement. Contact a Medtronic representative for details.

12.3 Replacing fuses

To replace a fuse in the generator:

	<ul style="list-style-type: none"><li>1. Remove the power cord.</li><li>2. Use a small blade screwdriver or similar tool to unlatch the fuse holder door at the top of the fuse holder.</li><li>3. Use a small blade screwdriver or similar tool to remove the red fuse block from the fuse holder.</li><li>4. Remove the defective fuse(s) and replace with the correct size, rating, and type (replace with Littelfuse 2183.15P or equivalent). To avoid the risk of fire, use only the specified fuse.</li><li>5. Reinstall the fuse block, close the fuse holder door, and reinstall the power cord.</li><li>6. Switch on the RF generator on and confirm it powers up.</li></ul>
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13 Storage

Disconnect the generator from a power source for long-term storage. For additional storage information, see *Section 16.9*

14 Disposal

Refer to local requirements regarding the disposal of the generator and accessories.

## 15 Guidance and manufacturer's declarations

**Table 4.** Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The generator is intended for use in the electromagnetic environment specified below. The customer or the user of the generator should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment—Guidance
RF emissions CISPR11	Group 1	The generator must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR11	Class A	The generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

**Table 5.** Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The generator is intended for use in the electromagnetic environment specified below. The customer or the user of the generator should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact  ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact  ±2 kV, ±4 kV, ±8 kV, ±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 @ 100 kHz repetition frequency for power supply lines ±2 kV @ 100 kHz repetition frequency for input/output lines	±2 kV @ 100 kHz repetition frequency for power supply lines ±2 kV @ 100 kHz repetition frequency for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	Power inputs: ±0.5 kV, ±1 kV Line-to-Line ±0.5 kV, ±1 kV, ±2 kV Line-to-Ground Signal input/outputs: ±2 kV Line-to-Ground	Power inputs: ±0.5 kV, ±1 kV Line-to-Line ±0.5 kV, ±1 kV, ±2 kV Line-to-Ground Signal input/outputs: ±2 kV Line-to-Ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	Voltage Dips: 0% μT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% μT; 1 cycle and 70% μT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% μT; 250/300 cycle	Voltage Dips: 0% μT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% μT; 1 cycle and 70% μT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% μT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.  If the user of the generator requires continued operation during power mains interruptions, it is recommended that the generator be powered from an uninterruptible power supply or battery.
<b>Note:</b> μT is the a.c. mains voltage before application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m  50 Hz or 60 Hz	30 A/m  50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.



**Table 5.** Guidance and Manufacturer's Declaration – Electromagnetic Immunity (continued)

Conducted RF IEC 61000-4-6	0.15 MHz – 80 MHz 3 V, 80 % AM at 1 kHz ISM bands between 0.15 MHz and 80 MHz 6 V, 80 % AM at 1 kHz	0.15 MHz – 80 MHz 3 V, 80 % AM at 1 kHz ISM bands between 0.15 MHz and 80 MHz 6 V, 80 % AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.	
Radiated RF EM Fields including proximity fields from RF wireless communications equipment IEC 61000-4-3	<b>Band (MHz)</b>	<b>Wireless Service</b>	<b>Immunity Test Level (V/m)</b>	<b>Compliance Test Level (V/m)</b>
	150 kHz – 80 MHz	General	< 3	< 3
	80 MHz – 2.7 GHz	General	3	3
	380 – 390	TETRA 400	27	27
	430 – 470	GMRS 460, FRS 460	28	28
	704 – 787	LTE Band 13, 1	9	9
	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28	28
	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28	28
	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28	28
	5,100 – 5,800	WLAN 802.11 a/n	9	9

Portable and mobile RF communications equipment should be used no closer to any part of the generator including cables, than the recommended separation distance calculated from the equation:


$$d = 6/E \times \sqrt{P}$$

Where:

d is the separation in meters

P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer

E is the Compliance Test Level indicated above.

Interference may occur in the vicinity of equipment marked with the following symbol: 

<sup>a</sup> 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 generator or any of its components are 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 reorienting or relocating components or the generator.

<sup>b</sup> Within the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Table 6.** Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Generator

The generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the generator as recommended below, 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

**Table 6.** Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Generator (continued)

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined 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.
<b>NOTE 1</b> – At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
<b>NOTE 2</b> – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## 16 Technical specifications

### 16.1 Mains input

- Input voltage/current/frequency: 100 - 240 Vac / 2.5 A - 1.4 A / 50/60 Hz

### 16.2 Fuses

- Replace fuses with Littelfuse 2183.15P or equivalent

### 16.3 RF output

- RF frequency: 460 kHz  $\pm$  1%, quasi-sinusoidal
- Max rated power: 50 W into 50 – 288  $\Omega$  load
- Maximum current:
  - Heating Factor of 0-30 A<sup>2</sup> s: 1 ARMS
  - Heating Factor of >30 A<sup>2</sup> s: 0.8 ARMS
- Maximum voltage: 120 VRMS
- Maximum Heating Factor generated in any 60 second period: 40 A<sup>2</sup> s

### 16.4 Heating Factor

This generator model contains software that tracks RF current (A) applied to the return pad from the catheter tip over the duration of the ablation. This parameter is called ‘Heating Factor’ with units A<sup>2</sup>seconds (A<sup>2</sup> s).

Heating Factor calculations are tied to informational messages W05, E1067, and E1068 in *Table 3*. Full RF output current (1 ARMS) is allowed when Heating Factor is less than 30 A<sup>2</sup> s. Current output is reduced to 0.8 ARMS when Heating Factor goes above 30 A<sup>2</sup> s, in alignment with emission of W05 warning message. RF ablation is terminated when Heating Factor reaches 40 A<sup>2</sup> s (error E1067) and may not commence again until Heating Factor drops below 30 A<sup>2</sup> s (message W05 is cleared) to allow for heat dissipation at the return pad site.

Extended duration of high RF power output may result in excessive heating of the skin at the return pad site. To reach the maximum power set-point, current is modulated based on RF impedance. For an example of this relationship and its effect on Heating Factor see *Table 7*. At lower RF impedance values, higher current is required. At higher RF impedances, lower current is required, and the warning and error messages will not be seen (N/A in *Table 7*).

**Table 7.** Heating Factor and Current Limitations

Single Ablation Parameters		Duration to warning / error (seconds)	
Maximum RF Power (Watts)	Average RF Impedance ( $\Omega$ )	W05 (Heating Factor 30 A <sup>2</sup> s)	E1067 (Heating Factor 40 A <sup>2</sup> s)
50	60	36	51.6
50	80	48	N/A
50	100	60	N/A
50	101 and above	N/A	N/A
40	55	41.3	56.9
40	80	60	N/A
40	81 and above	N/A	N/A

### 16.5 Electrical safety

- IEC 60601 Class 1 equipment
- Rated for continuous operation
- Accessory rated voltage: 120 VRMS minimum

- Applied parts classification
  - Catheter - type CF defibrillation-proof
  - Neutral (Indifferent/Return) Electrode – type F high frequency isolated

### 16.6 Settings

- Temperature: 40°C to 80°C
- RF Power: 0 to 50 Watts
- RF On Time: 0 to 999 seconds
- RF Ramp Time: 0 to 30 seconds

### 16.7 Measurement accuracy

- Temperature: ± 1.5 °C
- Power: ± 7% or ± 2 W of setting
- Impedance: ± 10% or ± 5 Ω whichever is greater from 35 to 300 Ω
- Time: ± 1 sec of setting

### 16.8 Mechanical specifications

- Size: 38 cm x 45 cm x 22 cm
- Weight: less than 11 kg
- Foot switch cable length: 355 cm ± 15 cm

### Moisture protection rating

The generator and foot switch comply with the following international electrical safety ratings with regard to water as required by IEC 60601-1:

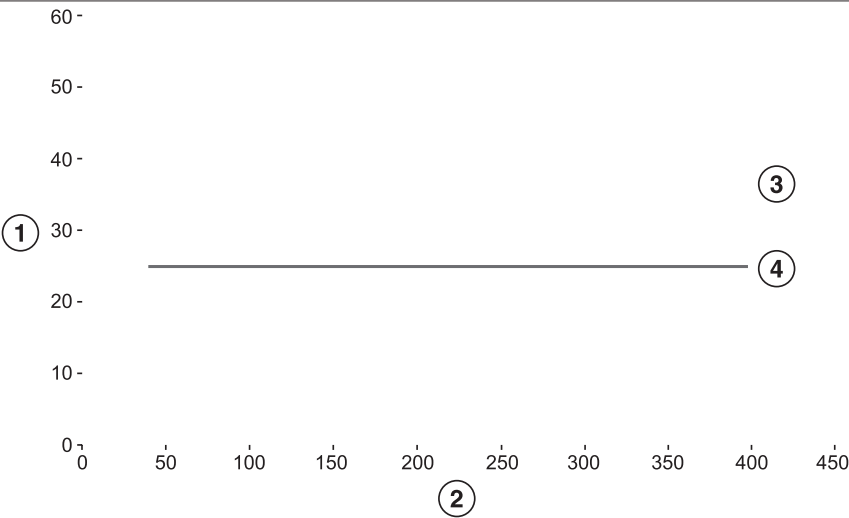
- Generator: IPX0, not water resistant
- Foot switch: IPX8, immersion resistant

### 16.9 Environmental specifications

- **Note:** Allow the system to equilibrate to room temperature for a minimum of 4 hours if the system has been stored at temperatures outside of the operational temperature range.
- Operational temperature: 15°C to 30°C (59°F to 86°F)
- Operational humidity: 30% to 75% relative humidity (noncondensing)
- Operational pressure: 70 to 106 kPa
- Storage temperature: 15°C to 30°C (59°F to 86°F)
- Stacking height: Maximum of two shipping boxes on top of each other

### 16.10 Output power curves

**Figure 14.** Power vs. Impedance RF Generator



## 17 Limited warranty

The following limited warranty applies to customers within the United States only:

A. This limited warranty provides the following assurance to the customer of the Medtronic DiamondTemp RF generator, irrigation pump, GenConnect cable, and EGM cable, with reusable parts (foot switch, ethernet cable, and power cord), hereafter collectively referred to as the DiamondTemp ablation system. Subject to the limitations herein, Medtronic warrants the DiamondTemp ablation system sold to the customer will be free from defects in materials and workmanship under normal usage for a period of 12 months from the delivery date at the customer's facility.

B. Should the DiamondTemp ablation system fail to meet the above warranty, Medtronic will at its option, repair or replace such DiamondTemp ablation system, or any portion thereof. For the limited warranty to apply, the following conditions must be met:

(1) Medtronic must be notified of and confirm the failure of the alleged defect within 60 days after discovery of the defect.(2) The DiamondTemp ablation system must not have been repaired or altered outside of authorized personnel at Medtronic.

(3) THE DIAMONDTEMP ABLATION SYSTEM MUST BE USED IN ACCORDANCE WITH LABELING AND NOT ALTERED OR SUBJECTED TO MISUSE, ABUSE, IMPROPER HANDLING, OR ACCIDENT, INCLUDING, BUT NOT LIMITED TO, FIRE, FLOOD OR NATURAL DISASTERS.C. At the discretion of Medtronic, parts or assemblies used or installed as part of the DiamondTemp ablation system may be either new or rebuilt of equal or improved quality. All parts removed or replaced during maintenance become the property of Medtronic.

D. This limited warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this limited warranty, MEDTRONIC EXPRESSLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WHETHER AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER MATTER. THE REMEDIES SET FORTH IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE TO THE CUSTOMER OR ANY THIRD PARTY FOR BREACH OF WARRANTY. MEDTRONIC SHALL HAVE NO LIABILITY TO ANY PERSON FOR INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES OF ANY DESCRIPTION, WHETHER ARISING OUT OF WARRANTY, OTHER CONTRACT, TORT, OR OTHERWISE.

(2) Except as expressly provided by this limited warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, MALFUNCTION, OR FAILURE OF THE DEVICE TO FUNCTION WITHIN NORMAL TOLERANCE, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.




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



















F. No person has any authority to bind Medtronic to any representation, condition, or warranty except this limited warranty.

G. This limited warranty is not applicable to accessories or products used with the DiamondTemp ablation system unless specifically noted.



## 18 Glossary of symbols

The following table defines symbols that are used on packaging and product labeling. Refer to the labels to determine which symbols apply to this product and for the product-specific information, such as the date of manufacture.

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
<b>Rx only</b>	21 CFR 801.109 <sup>a</sup>	Prescription only	USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1 <sup>d</sup>	Consult instructions for use (clause 5.4.3)	Consult instructions for use at this website: <a href="http://www.medtronic.com/manuals">www.medtronic.com/manuals</a>
	EN 50419 <sup>b</sup>	Recycle: Electronic Equipment	Do NOT throw in trash
	IEC 60601-1 <sup>c</sup>	Follow instructions for use (Table D2, Symbol 10)	Refer to instruction manual/booklet (blue symbol)

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	ISO 15223-1 <sup>d</sup>	Catalog number (clause 5.1.6)	Indicates the manufacturer's catalog number so the device can be identified
	ISO 15223-1 <sup>d</sup>	Serial number (clause 5.1.7)	Indicates the manufacturer's serial number so that the device can be identified
	ISO 15223-1 <sup>d</sup>	Manufacturer (clause 5.1.1)	Indicates the medical device manufacturer
	N/A	Manufactured in/ manufacturing site	Indicates where the device was manufactured
	ISO 15223-1 <sup>d</sup>	Date of manufacture (clause 5.1.3)	Indicates the date when the medical device was manufactured
	ISO 15223-1 <sup>d</sup>	Keep dry (clause 5.3.4)	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1 <sup>d</sup>	Do not use if package is damaged (clause 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened
	ISO 15223-1 <sup>d</sup>	Temperature limit (clause 5.3.7)	Indicates the temperature limits to which the medical device can be safely exposed
	N/A	Storage temperature limit	Indicates the required temperature range for storing the device
	N/A	Transit temperature limit	Indicates the required temperature range for transporting the device
	ISO 15223-1 <sup>d</sup>	Humidity limitation (clause 5.3.8)	Indicates the range of humidity to which the medical device can be safely exposed
	ISO 15223-1 <sup>d</sup>	Atmospheric pressure limitation (clause 5.3.9)	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	ISO 7000 <sup>e</sup>	Non-ionizing electromagnetic radiation (symbol 5014)	To indicate elevated, potentially dangerous, levels of non-ionizing radiation
	ISO 7000 <sup>e</sup>	Stacking limit by number (symbol 2403)	To indicate that items shall not be vertically stacked beyond the specified number
	ISO 7000 <sup>e</sup>	Equipotentiality (symbol 5021)	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding
	ISO 7000 <sup>e</sup>	Foot switch (symbol 5114)	To identify a foot switch or a connection for a foot switch
	ISO 7000 <sup>e</sup>	Alternating current (symbol 5032)	Alternating current
	ISO 7000 <sup>e</sup>	Defibrillation Proof Type CF Applied Part (symbol 5336)	To identify a defibrillation-proof type CF applied part complying with IEC 60601-1.

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	ISO 7000 <sup>e</sup>	Stand by (symbol 5009)	Power in Standby (lit amber) or ON (lit green)
	ISO 7000 <sup>e</sup>	OFF (symbol 5008)	Power OFF
	ISO 7000 <sup>e</sup>	ON (symbol 5007)	Power ON
	N/A	N/A	Fuses
	N/A	N/A	EGM Output – Filtered ECG / Pace
	N/A	N/A	Video Output
	N/A	N/A	Serial Output
	N/A	N/A	Service Communication port (not for clinical use)
	N/A	N/A	Remote Control port (for future generation use)
	N/A	N/A	Pump Control port
	N/A	N/A	USB port (when system is not in use)
	N/A	N/A	Catheter connection
	N/A	N/A	Neutral Electrode connection
	N/A	N/A	Floating Neutral Electrode con- nection
<b>IPX0</b>	IEC 60529 <sup>f</sup>	International Protection (IP) Code	Indicates the product is not water resistant (generator)
<b>IPX8</b>	IEC 60529 <sup>f</sup>	International Protection (IP) Code	Indicates the product is able to be submerged in water (foot switch)
	N/A	Package contents	Indicates the components included in the device package
	N/A	Generator	Indicates that the type of device is RF generator
	N/A	Accessories	Indicates that accessories are included in the device package
	ISO 7000 <sup>e</sup>	Product documentation	Indicates that product docu- mentation is included in the device package
	N/A	N/A	Indicates the device Stop but- ton (red symbol)
	N/A	N/A	Indicates the device Start but- ton (green symbol)
	N/A	N/A	Power cord
	ISO 15223-1 <sup>d</sup>	Lot number (clause 5.1.5)	Indicates the manufacturer's lot number so that the lot can be identified

Symbol	Standard/Standard title or reference	Symbol title/Reference number	Explanatory text
	ISO 15223-1 <sup>d</sup>	Fragile, handle with care (clause 5.3.1)	Indicates the device is fragile and should be handled with care
	N/A	Compliance mark	Indicates conformance to applicable standards

<sup>a</sup> 21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

<sup>b</sup> EN 50419: Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

<sup>c</sup> IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

<sup>d</sup> ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

<sup>e</sup> ISO 7000: Graphical symbols for use on equipment

<sup>f</sup> IEC 60529: Degrees of protection provided by enclosures (IP Code)







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