| INTELLAGEN™ RF Generator | |
|---|---|
| Dimensions | 399mm wide x 178mm high x 344mm deep (15.7" wide x 7.0" high x 13.5" deep) |
| Weight | 18.5kg (40.8 lbs) |
| Power | 115–120V/230V (50/60Hz) |
| Catheter detection | Yes |
| Contact quality monitor | Yes – 2 indifferent electrodes (independently) |
| Maximum RF output | 100W (preset dependent) |
| Overheat warning | >700mA for >10sec |
| RF frequency | 480kHz ± 1kHz |
| RF maximum output voltage | 290Vp |
| RF maximum output current | 1.7A |
| Modes | Power control (all presets) Temperature control (small-tip & high-power) |
| Impedance measurement range | 0Ω–500Ω |
| Impedance measurement accuracy (without catheters, cables, or OPAL HDx™) | ±5% or ±3Ω (whichever is higher) |
| Impedance measurement current | 6.5µA, 45kHz sinusoidal |
| IP rating | IP21 |

| INTELLAGEN™ Cardiac Ablation System and Components | |
|---|---|
| Max. operating noise | Standby max. 45db(A) (Device switched on, but no energy output); Error condition min. 75db(A) |
| Operating Conditions | |
| Ambient temperature | +10°C to +40°C (50°F to 104°F) |
| Relative humidity | 10% to 85% (non-condensing) |
| Atmospheric pressure | 700mbar to 1060mbar (10.2 psi to 15.4 psi) |

| INTELLAGEN™ Irrigation Pump | |
|---|---|
| Dimensions | 195mm wide x 180mm high x 235mm deep (7.7" wide x 7.1" high x 9.3" deep) |
| Weight | 5.5kg (12.1lbs) |
| Power | 100–120V/220–230V (50/60Hz) |
| Display | 2.8in TFT display, 18-bit color, 240x320 pixel |
| Bubble detection | ≥2µL using ultrasound |
| Flow rate | Low (Standby) 1mL/min–5mL/min High (Ablation) 6mL/min–30mL/min |
| Flush/purge flow rate | 60mL/min |
| Flow rate configuration | Automatic flow rate adaption to power output possible (in power steps of 10W) |
| Flow rate accuracy | ±15% or ±0.5mL/min (whichever is greater) up to a back pressure of 75psi |
| Maximum infusion pressure | 120psi with flow rate accuracy guaranteed to 75psi |
| INTELLAGEN Tubing Set | Tubing Set connected from saline solution bag to irrigated catheter and inserted in INTELLAGEN Irrigation Pump |
| IP rating | IP54 |

| INTELLAGEN™ Remote Control | |
|---|---|
| Dimensions | 395mm wide x 220mm high x 170mm deep (15.6" wide x 8.7" high x 6.7" deep) |
| Weight | 4.5kg (9.9 lbs) |
| IP rating | IP21 |

| INTELLAGEN™ Foot Pedal | |
|---|---|
| Dimensions | 144mm wide x 39mm high x 135mm deep (5.7" wide x 1.5" high x 5.3" deep) |
| Weight | 0.82kg (1.8 lbs) |
| IP rating | IPX8 |

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STOCKERT medical solutions



INTELLAGEN Cardiac Ablation System is manufactured by Stockert GmbH, Boetzinger Strasse 31, 79111 Freiburg, Germany.



RHYTHMIA HDx™ has evolved into the OPAL HDx™ Mapping System.

Boston Scientific
Advancing science for life™

# The Intelligent Way to Ablate


# INTELLAGEN™ Cardiac Ablation System

# With an updated interface and enhanced features, the INTELLAGEN™ Cardiac Ablation System modernizes the EP lab.


## The INTELLAGEN Cardiac Ablation System includes:

- INTELLAGEN™ RF Generator Kit (UPN M004GEN100204010), which includes the INTELLAGEN™ Foot Pedal
- INTELLAGEN™ Irrigation Pump Kit (UPN M004GEN100204020)
- INTELLAGEN™ Remote Control Kit (UPN M004GEN100204030)
- INTELLAGEN™ Tubing Set (UPN M004GEN100206251, pack of 10), required with use of Irrigation Pump

## Efficient setup with automatic catheter identification and presets

Designed for ease of use, the INTELLAGEN Cardiac Ablation System streamlines workflow in the EP lab, with:

- Boston Scientific catheter detection
- Up to three catheter preset groups to generate 80 presets
- Five configurable steps for ablation flow rate based on power setting

## Protect patients with enhanced safety notifications

The system features a range of notifications and settings to help protect patients throughout the ablation procedure:

- Overheating warning: alarm at >700mA on one indifferent electrode for more than 10 seconds without stopping ablation
- Contact quality monitoring for indifferent electrodes
- User-selectable cutoff temp
- User-selectable minimum and maximum impedance
- Impedance spike cutoff
- User-selectable power ramp duration
- Compliant with IEC/EN 60601-2-2

## Elevate your lab with an intuitive, modern interface

Modern interface supports the lab staff learning process with these features:

- Touch screen
- Ability to save up to 10 physician names and make 80 presets
- Real-time parameter visualization
- Instant feedback on system device connections
- Clear warning messages

***CAUTION:*** *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.*

**INTENDED USE/INDICATIONS FOR USE**
The INTELLAGEN™ RF Generator is a specialized device intended for use during RF ablation therapy of the human heart. This device is used in conjunction with specialized therapeutic catheters and a dispersive pad (indifferent electrode) to create a closed electrical circuit capable of delivering specified doses of RF energy. The RF energy is delivered to cardiac tissue that forms unwanted electrical pathways that either drive or maintain arrhythmias. The RF energy heats the tissue such that it becomes denatured and no longer functional. This interrupts and/or destroys the unwanted electrical pathways, thereby restoring normal heart function.

Indications are defined for the respective applied part (ablation catheters).

**CONTRAINDICATIONS**
Contraindications are defined for the respective applied part (ablation catheters). No contraindication known for the RF Ablation System.

**WARNINGS**

**Warnings: Generator Usage**
- Read this user manual carefully before using the INTELLAGEN™ RF Generator for the first time. Note especially the instructions in Section 4.5, Setup.
- Cardiac ablation procedures should be performed only by physicians who have been thoroughly trained in RF catheter ablation techniques. Catheter ablations should be performed only in medical rooms in compliance with IEC/EN 60601-1.
- In catheter ablation procedures, fluoroscopy is commonly used. When using fluoroscopy, there is the risk of exposure to considerable radiation. The intensity of the X-rays and the duration of the radiation can lead to acute radiation damage or to an increased risk of a physical or genetic defects for both patients and medical personnel. Therefore, perform catheter ablations only after carefully considering the potential radiation dose. The advantages and disadvantages of X-ray exposure should be considered carefully before catheter ablation is performed in pregnant women. Also, the long-term risk of prolonged X-ray imaging has not been researched. Therefore, the advantages and disadvantages should be considered carefully before this procedure is performed in prepubertal children. Consider using a navigation system without fluoroscopy to reduce exposure to X-rays.
- Do not apply RF energy while a stimulator is connected to the generator unless specifically indicated by the stimulator's instructions for use. Doing so might induce ventricular fibrillation.
- Always verify that the generator's visual and acoustic alarms are working before using the generator (see Section 6.1.1, System Startup).
- When the generator has been turned off, power continues to be supplied to the generator through the mains cable. To completely cut off power to the generator, disconnect the mains cable from the generator. To allow easy disconnection in the event of severe power failure, make sure that the generator is located where there is easy access to the mains cable on the back of the generator.
- After turning on the generator, always wait until the automatic self-test has been successfully completed before starting the first steps of the procedure on the patient (for example, before anesthesia or before creating percutaneous access). Also, if using a remote control, a pump, a mapping system, or an electrophysiology recording system, verify that the connections to those systems are functional prior to starting the first steps of the procedure. Doing this helps to detect problems with the device before the patient is in a phase of the intervention in which interruption could lead to an increased risk to the patient's health. Also perform a visual inspection of the accessories (see Section 5.3, Caring for Accessories).
- Use only catheters that have been approved for use with the maximum voltage specified in this user manual (see Section 8.1, Specifications).
- Use only accessories that have been provided by or recommended by the generator's manufacturer (see Chapter 5, Accessories). The use of other accessories can have a negative effect on the technical specifications. Do not modify accessories. Visually inspect all accessories on a regular basis. Make sure that the connected cables are not damaged. When using sterile accessories, be sure to maintain the sterility of those accessories.
- Place the generator on a secure, non-slip surface. If the generator is placed on a mounting plate, make sure it is securely fastened. Do not place the generator directly above another device and do not place any other device directly on the generator. Make sure that there is enough free space on all sides of the generator to allow the heat created by the generator to escape.
- The entire surface of the indifferent electrode must be as close as possible to the operating field and must have fully reliable contact with the patient's body. The skin surface must be free of excessive oil and body hair (see Section 3.3, Warnings and Precautions: During an Ablation Procedure.).
- The generator is equipped with a contact quality monitoring feature for split indifferent electrodes. If the contact quality falls below a defined value, the generator displays an alert message.
- The patient must not be in contact with grounded metal components or with metal components that have a large grounded area (for example, the operating table supports). For this purpose, the use of sufficiently insulating antistatic covers on the operating table is recommended. Electrostatic discharge (ESD) can give rise to extremely high current densities at the catheter tip, which can injure the patient. Therefore, do not touch the pins in the plug at the end of the catheter or the pins in the plug at the end of the cable after the catheter has been placed in the patient's body.
- Skin contact between parts of the patient's body (for example, between the arms and the body) should not occur. Such contact can be avoided by using dry gauze, for example.
- If the generator and physiological monitoring devices are used on a patient at the same time, all monitoring electrodes without protective resistances or RF filters should be applied to the patient's body as far away as possible from the ablation electrodes. Needle electrodes are not recommended for monitoring purposes. In all cases, it is appropriate to use monitoring electrodes and other monitoring devices that limit the RF current.
- Position the connection cables of the ablation electrodes in such a way that they do not touch either the patient or other cables. Keep active electrodes that are temporarily not in use at a safe distance from the patient.
- Set the RF power at only moderate output to avoid charring and clotting at the catheter ablation electrode. Refer to the instructions for use of the connected catheter for recommended power settings.
- When the INTELLAGEN™ RF Generator is used with irrigated catheters, monitor the irrigation flow rate to avoid hazards caused by insufficient irrigation flow. The approximate flow rate can be estimated by observing the drip speed in the drip chamber. The hospital staff is responsible for determining and monitoring the flow rate to avoid insufficient flow of the irrigation solution. The hospital staff is responsible for monitoring the total amount of solution delivered to the patient to avoid an excessive loading of the irrigation solution in the patient. For recommended flow rates, refer to the catheter's instructions for use.
- Avoid using flammable anesthetics or oxidizing gases such as nitrous oxide ($N^2O$) and oxygen ($O^2$) if the procedure is being performed in the region of the thorax or head, unless the gases are being aspirated off or an anesthesia-safe device is being used. Before starting RF ablation, allow time for flammable substances that are used as cleaning agents, disinfectants, or solvents to evaporate. There is a risk associated with flammable liquids under the patient or in the patient's body cavities. Wipe away the liquid in these places before the generator is turned on. Beware of flammable endogenous gases. Materials such as cotton and gauze, when saturated with oxygen, can be ignited by sparks that arise even during normal use of the generator. (The foot pedal is suitable for use in operating rooms.)
- Be aware during ablation procedures that in patients with intracardiac pacemaker, intracardiac defibrillator, or relating leads, there is a risk of interference with the pacemaker or defibrillator that could lead to malfunction or damage of the same resulting in no therapy or inappropriate therapy. In case of doubt, consult the manufacturer of the implanted device.
- The electromagnetic radiation emitted by the generator can interfere with the function of other electrical devices. Conversely, other electrical devices can influence the function of the generator if they are operated at the same time in the immediate vicinity of the generator.
- The plugs on the catheter and the catheter connection cable must not be brought into contact with parts that have high voltage (such as mains outlets) or metallic objects. This can lead to the patient's death by electrocution.
- To avoid damage to the connection cables, do not wrap the cables around the generator or other apparatus. Coiling the connection cables during normal operation of the generator creates inductive components, which can lead to measurement errors. The values indicated in error can lead to misinterpretations.
- Special safety measures with regard to electromagnetic compatibility (EMC) must be taken with electrical medical devices. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with this user manual, may cause harmful interference to radio communications. Similarly, portable and mobile communication devices may cause harmful interference to the functioning of the generator.
- If error messages repeatedly appear, stop using the generator and contact Customer Support.
- To avoid damage to the generator and its accessories, use only appropriate cleaning agents (see Sections 4.6, Preparing the Generator for Use/Reuse, and 5.4, Cleaning, Disinfecting, and Sterilizing Accessories).
- To avoid the risk of electric shock, connect the mains cable from the generator mains socket (see Item 6 in Section 4.3, Controls on the Back of the Generator) to a mains wall socket that meets the specifications in Section 8.1, Specifications. Do not connect electrical components of the generator to a multiple socket power strip. Using a multiple socket power strip may affect safety or performance.
- The generator may be opened only by persons authorized by the manufacturer. When the generator is open, parts that have high voltage or are very hot are accessible and can cause injury. If the generator is opened by an unauthorized person, any claims on the warranty are void. No modification of the generator is permitted.

- If fluid penetrates the generator, stop using the generator and contact Customer Support.
- In the unlikely event that there is a fatal system error (the system will stop and the **Alarm** indicator will flash red), immediately disconnect the mains cable from the generator.
- Electrodes and probes for monitoring and stimulation devices can be electrical conductors of RF current. Reduce the risk of burns by placing the electrodes and probes as far away as possible from the site of ablation and from the indifferent electrode.
- To avoid possible injury to patients and medical personnel, do not start RF power application until the catheter is positioned in the intended ablation area and the ablation parameters (temperature and impedance) are within the expected range.
- To minimize electrical noise on the ECG recordings, position catheter connection cables so that they do not touch either the patient or other cables. For an optimal ECG trace, keep unused active surface electrodes at a distance from the patient.
- To prevent fluid from impairing system performance, ensure that sterile catheters and cable plugs are completely dry.
- To prevent a system malfunction, inspect all reusable accessories regularly. Do not use damaged cables.
- Ablation data stored electronically must not be used for diagnosis or therapy. The intended use is for archiving or research only.

**Warnings: System Safety and Connections**
The INTELLAGEN™ RF Generator can be connected directly or indirectly to certain other devices and accessories. The generator and the connected group of devices and accessories are referred to in the following warnings as the "system."

- The generator connections for the ECG signals and for the stimulator are galvanically connected with the ablation catheter. Only cables and plugs approved for a CF type of device (CF safety classification) may be used (see Section 5.2, Accessory Lists).
- All devices with these cables and plugs must fulfill the requirements stated in IEC/EN 60601-1-1. Fulfillment of the requirements must be monitored and documented in a suitable way.
- The person who connects the generator and accessories to each other or who uses the generator and accessories is responsible and liable for installation and operation that complies with IEC/EN 60601-1-1.
- All system components must comply with all applicable requirements and standards and be labeled pursuant to these standards.
- If there are any concerns regarding the use of a component, contact the distributor of the component to obtain further information.
- If several devices are connected to the generator and to each other, they should be as safe, both individually and together, as specified in IEC/EN 60601-1 and its sub-standards and IEC/EN 60601-1-2. All devices and accessories, when located within the patient area, must comply with IEC/EN 60601-1 and its sub-standards.
  Keep in mind that the ECG connection cable for the generator creates a direct electrical connection to the patient's heart. Incorrect use of this connection can endanger the patient's life. Make sure that the leakage current of the connected system (in any combination) never exceeds the maximum permissible value (patient leakage current ≤ 0.05 mA).
  Take into account that the system's RF leakage current can be negatively influenced by other system components. The maximum allowable values are specified in IEC/EN 60601-2-2. Displacements of the ECG baseline surface signals is a sign of uncontrolled RF current leakage through the body surface ECG electrodes. Heating of these electrodes gives rise to a shift in direct current voltage, which, in turn, leads to a displacement of the baseline. In this case, check the whole system combination to avoid uncontrolled current leakage. It may also be the case, however, that the electrocardiograph is unsuitable for this use or that the body surface ECG electrodes have a too-high contact impedance. Make sure that the ECG device is appropriate for this application. Skin burns at the body surface ECG electrodes can be a sign of uncontrolled current leakage.
- There are many electrocardiographs to which a stimulator can be directly connected. The stimulator must be galvanically isolated (or physically disconnected) before the RF current is turned on. The reason for this is the parallel connection between the output of the generator and the stimulator. If the connection is not isolated, the stimulator's patient interface and safety insulation may be damaged. The transfer of RF energy into the electrodes connected to the stimulator can also cause injury to the patient.
- Only classified electrical medical devices may be connected to the generator. If a PC system does not fulfill the requirements of IEC/EN 60601-1 / UL 60601-1 and their sub-standards, the distance between the PC system and the patient must be at least 1.83 m (6 ft) and the PC system must fulfill the requirements of IEC 950 / UL 60950-1. All medical devices that are connected electrically to the generator must fulfill the requirements of IEC/EN 60601-1-1, the standard for medical systems.
- When the RHYTHMIA HDx™ Mapping System is connected to the INTELLAGEN™ RF Generator, the impedance reading on the generator may be higher than expected. Consult the instructions for use provided with the RHYTHMIA HDx™ Mapping System for further information and restrictions.
- Do not use the INTELLAGEN™ Cardiac Ablation System with its accessories and catheters closer than 30 cm (12 inches) to any wireless power transfer (WPT) and 5G cellular devices; otherwise, electromagnetic interference from those devices could result in degradation of the performance of this equipment.

**Warnings and Precautions: During an Ablation Procedure**
- Blood vessel perforation is a risk inherent in the placement of an electrophysiology catheter. The catheter needs to be moved carefully to avoid damage or perforation of blood vessels.
- When performing ablation of the posterior wall of the left atrium, beware of the risk of forming a lesion in the esophagus.
- Avoid high ablation temperatures. High ablation temperatures can lead to clot formation, charring of the heart tissue or blood, and/or evaporation of interstitial intracellular fluid.
  **Note:** The temperature indicated on the generator is not the tissue temperature. The indicated temperature is the temperature of the catheter's ablation electrode, which does not necessarily represent the tissue temperature. This applies especially when catheters with saline-cooled ablation electrodes are used. When catheters with cooled ablation electrodes are used, the temperature measurement reflects the temperature of the cooled electrode, not the temperature of the tissue. The temperature of the tissue may be distinctly higher and the risk of steam pops (explosion of steam bubbles) may increase. Therefore, use only moderate RF power output. Follow the recommendations in the instructions for use provided with the therapeutic catheters that are used with the system.
- Keep in mind when setting the temperature that only the temperature of the electrode and not the temperature of the heart tissue is measured. Because of the cooling effect of blood flow, the temperature of the heart tissue may be higher than the temperature measured at the ablation electrode.
- Avoid sudden increases in impedance to minimize charring at the ablation electrode. Charring at the ablation electrode can result in reduced RF energy delivery and/or an embolism.
- Make sure that the active RF electrode of the ablation catheter is not in contact with another catheter or with another metallic conductor, such as an implanted pacemaker lead. This could lead to uncontrolled conduction of the RF energy to other parts of the body, or to an uncontrolled increase in the effective size of the active RF electrode.
- Do not set any extreme, unrealistic limit values. The limit values serve to trigger an alarm when a limit value is exceeded. If unrealistic values are set, important alarm functions will be triggered too late or not at all.
- To minimize the risk to the patient, do not exceed the ablation duration specified in the instructions for use for the catheter.
- When using the usual operating settings, a low output RF power or a problem with the ablation device can be a sign that the indifferent electrode is not correctly positioned or has poor contact with its connection cable.
- Continuously monitor the generator's impedance measurement during RF energy application. If a sudden increase in impedance is observed, stop the RF energy delivery. Remove the catheter from the patient's body and clean the ablation electrode of the catheter with a sterile cloth to remove any adherent materials.
- If there is any doubt about an unintended increase in RF energy or the proper functioning of the touch screen, **Data Entry knob**, foot pedal, or remote control during RF delivery, immediately stop the RF energy delivery by pressing the **Stop** button on the generator, releasing the foot pedal, or pressing the **Stand-by** button. If none of these measures stops the RF energy delivery, disconnect the mains cable from the generator.
- For patients with electrically conductive implants, a possible hazard exists due to concentration or re-direction of high-frequency (HF) currents. In case of doubt, qualified advice should be obtained.
- This device is not intended for use as an electrosurgical cutting device. The use of RF ablation devices at high temperature may lead generation of smoke plume. Care should be taken by the operator to reduce exposure to smoke plume by using smoke plume extraction.

**Handling Indifferent Electrodes**
An indifferent electrode is used for unipolar ablations (see Section 2.4, Unipolar Application Method).

When connected to the system, the generator monitors the impedance at the indifferent electrode, which is an indicator of the quality of adhesion of the electrode to the patient skin.

- To ensure patient protection, the generator prevents unipolar ablation in the absence of an indifferent electrode.
- If the indifferent electrode is not correctly connected to the generator, the generator immediately stops RF energy delivery and displays a message.
- The generator is equipped with a contact quality monitoring feature for split indifferent electrodes. When a split indifferent electrode is used, the generator displays an alert message as soon as skin contact with the electrode surface decreases by 40% from the best achieved contact quality. This value is reset every time the indifferent electrode is disconnected from the patient.

Place the indifferent electrode within the operating field on the patient's back.

Split indifferent electrode

The generator provides the option of connecting two separate split indifferent electrodes. Contact quality monitoring described herein works independently for each connected split indifferent electrode.
It is strongly recommended to use two separate split indifferent electrodes in ablations with high output (> 50 watts) for heavy patients with a low muscle mass and in the case of prolonged RF energy delivery (> 60 seconds). If two split indifferent electrodes are used, apply one electrode to the left side of the ablation site and the other electrode to the right side of the ablation site, both at approximately the same distance from the ablation site. The two indifferent electrodes must not overlap.

**Guide to the Use of Indifferent Electrodes with the INTELLAGEN™ RF Generator**

- Use only compatible indifferent electrodes. For a list of compatible indifferent electrodes for the INTELLAGEN™ RF Generator, please contact Customer Support.
- Solid and non-split indifferent electrodes shall not be used due to IEC 60601-2-2.
- Read the instructions for use for the indifferent electrodes carefully and take special note of the Warnings and Precautions sections.
- **For a single-use electrode:** Make sure that the electrode contact surface is not dry. If it is dry, replace it with a new, unused electrode before continuing with the ablation procedure. Do not use any contact gel with single-use electrodes. Use the single-use electrode for only one procedure. If the indifferent electrode becomes loose or needs to be moved, use a new indifferent electrode. Repeated use of an already applied electrode can mean a loss of adhesiveness and thus reducing contact quality.
- **For a reusable electrode:** Make sure that the electrode contact surface is not dry. If it is dry, use a small, evenly distributed quantity of conductive gel.
- **Carefully select the contact area:** Choose a muscular area on the back of the patient that is as near the heart as possible and that has sufficient blood flow. Do not place the indifferent electrode near wounds.
- **Carefully prepare the contact area:** Prepare the contact area on the patient and on the indifferent electrode according to the instructions for use provided with the indifferent electrode. Place the indifferent electrode closer to the ablation site than any ECG electrode or other products that could represent an alternative lead. Shave and degrease the skin.
- **Carefully apply the indifferent electrode to the contact area:** Make sure that the whole surface of the indifferent electrode forms a closed contact with the patient's back. There should be no pockets of air between the skin and the indifferent electrode. Oil, hair, dirt, repeatedly used adhesive electrodes, and electrodes of low quality can impair contact quality and increase the risk of a skin burn.
- Heat produced by thermal blankets or other sources of heat adds to the heat arising under the indifferent electrode. This increases the risk of skin burns. Do not use such sources of heat in immediate proximity to the indifferent electrode.

**WARNING**
An unsuitable indifferent electrode or an incorrectly applied indifferent electrode can lead to burns on the skin surface. Check the indifferent electrode and the connection cable before use. Do not use these if they are damaged or modified.

**Icons regarding Indifferent Electrodes in the Navigation Bar (see 6.1.4 Screen Features)**

| | Icons Displayed | Description |
|---|---|---|
| **Split indifferent electrodes** |  | Split indifferent electrode is connected and has proper skin contact. |
| |  | The split indifferent electrode is not connected or contact quality monitoring indicates bad skin contact. |
| |  | Warning for potential overheating of split indifferent electrode: Occurs when RF current is over 700 mA per indifferent electrode (equals 50 watts at 100 Ω) for more than 10 seconds. (The usage of two indifferent electrodes is strongly recommended to reduce the possibility for overheating). |
| **Solid/non-split indifferent electrodes** |  | Solid/non-split indifferent electrode is connected. Contact quality monitoring is not supported with this electrode type. |
| |  | Warning for potential overheating of solid/non-split indifferent electrode: Occurs when RF current is over 700 mA per indifferent electrode (equals 50 watts at 100 Ω) for more than 10 seconds. (The usage of two indifferent electrodes is strongly recommended to reduce the possibility for overheating.) |

**PRECAUTIONS**
Precautions are included within the warnings documented in the previous section.

**POTENTIAL ADVERSE EVENTS**
Reported adverse events or complications for cardiac RF ablation procedures include, but are not limited to, the following:

- Skin burns
- Cardiac tamponade
- Peripheral vascular complications (hematomas, pseudoaneurysms, arteriovenous fistulas)
- Cerebrovascular events (stroke, transient ischemic attack)
- Pulmonary vein stenosis
- Phrenic nerve injury
- Atrio-esophageal fistula
- Death

For a full list of potential adverse events, please refer to the instructions for use of the respective applied part (ablation catheter). 97246162 Rev. A