Ablation System User Manual:

HexaGEN™ RF Generator

HexaPULSE™ PF Generator Module

HexaFLOW™ Irrigation Pump

Contents

1 Definitions

Term	Definition
CIU	Catheter Interface Unit
EMC	Electromagnetic Compatibility
PF	Pulsed Field
PFG	HexaPULSE™ PF Generator Module
Pump	HexaFLOW™ Irrigation Pump
RF	Radiofrequency
RFG	HexaGEN™ RF Generator

2 About the Affera Ablation System

The Affera Ablation System is comprised of the HexaGEN™ Radiofrequency (RF) Generator, the HexaPULSE™ Pulsed Field (PF) Generator Module, and the HexaFLOW™ Irrigation Pump, along with additional accessories that are designed for use with compatible ablation catheters to treat cardiac arrhythmias.

The Affera Ablation System is also designed for integrated operation with the Prism-1™ Mapping System, which is provided separately.

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

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

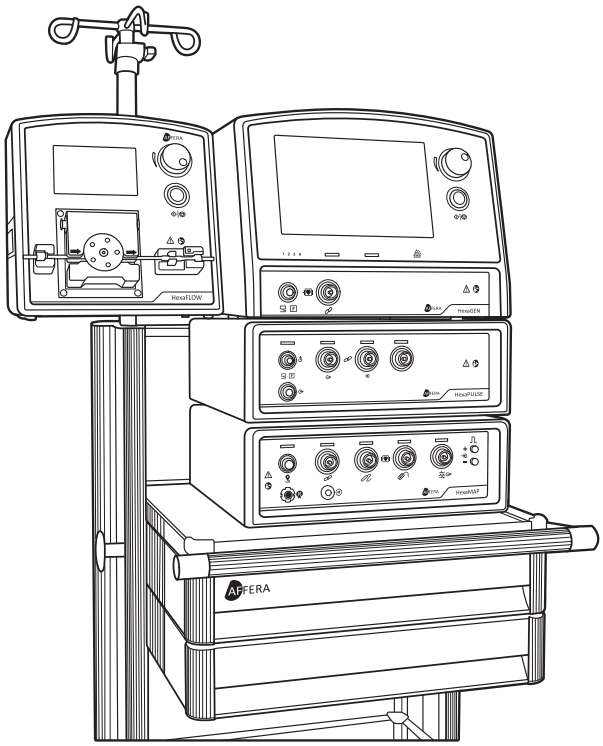
The HexaPULSE™ PF Generator Module is an optional accessory to the Ablation System. The PF Generator Module is specialized medical electrical equipment designed to supply PF energy for the ablation treatment of cardiac arrhythmias. It is connected in series with the HexaGEN™ RF Generator to provide PF energy using the same compatible ablation catheter, extension cable and return electrodes as the HexaGEN™ RF generator.

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

The HexaGEN™ RF Generator communicates with the Irrigation Pump to monitor and control irrigation flow rate as appropriate during ablation.

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

Figure 1. The Affera Ablation System: HexaGEN™ RF Generator (top right), HexaPULSE™ PF Generator Module (middle right), and HexaFLOW™ Irrigation Pump (left) (shown with the Prism-1™ Mapping System HexaMAP™ CIU and the Affera System Cart)



3 Functional Principles

3.1 RF Application

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

3.2 PF Application

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

3.3 Temperature Feedback

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

3.4 Ablation Circuit Impedance

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

3.5 Return Electrodes

The Affera Ablation System operates with four (4) return electrodes. The Return Electrode Adapter is connected to the front of the HexaPULSE™ PF Generator Module and connects to the HexaGEN™ RF Generator via the Ablation Return Link cable.

The Affera Ablation System is designed for use with “split plate” return electrodes. When used with “split plate” return electrodes, the Affera Ablation System employs a Contact Quality Monitoring system to monitor the impedance between the two halves of each return electrode and warns the user of any change in impedance consistent with poor contact quality. Colored indicators on the HexaGEN™ RF Generator front panel above the Ablation Return Link connection indicate which return electrodes are connected and their status (*Table 3*).

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

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

3.6 Peristaltic Irrigation

The HexaFLOW™ Irrigation Pump is used with the HexaFLOW™ Tubing Set to deliver irrigation solution to the compatible ablation catheter. The HexaFLOW™ Irrigation Pump has a bubble detector to stop flow in the event that air is detected in the line. The HexaFLOW™ Irrigation Pump can deliver irrigation solution at a low flow rate during mapping and at a high flow rate during ablation. The HexaFLOW™ Irrigation Pump is controlled remotely by the HexaGEN™ RF Generator to automatically synchronize the flow rate with energy delivery.

3.7 Mapping System Integration

The Affera Ablation System is designed for use with the Prism-1™ Mapping System, which is provided separately. The compatible ablation catheter is connected to the Affera Ablation System via the HexaMAP™ Catheter Interface Unit (CIU) and the front panel Generator Link Cable. A Communication Cable enables information sharing between the units. When properly connected, the Prism-1™ Mapping System will display the real-time and historical ablation parameters and can use this information to display 3D ablation tags. The ablation catheter signals are not modified by the HexaMAP™ CIU. The Prism-1™ Mapping System has no influence on the operation of the Affera Ablation System, including delivery of RF or PF energy. See the *Prism-1™ Mapping System User Manual* for further information.

4 Intended Use

Read and follow the instructions for use provided in this user manual before operating the system in a clinical application. Also refer to the Instructions for Use accompanying the compatible ablation catheter for further information regarding safe use.

4.1 Intended Purpose

The Affera Ablation System (HexaGEN™ RF Generator, HexaPULSE™ PF Generator Module, and HexaFLOW™ Irrigation Pump) is intended for the ablation of cardiac tissue when used with a compatible ablation catheter in patients with atrial tachyarrhythmias. The Affera Ablation System allows delivery of radiofrequency (RF) energy, pulsed field (PF) energy, and saline irrigation through a compatible ablation catheter.

4.2 Indications for Use

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

4.3 Intended Patient Population

Refer to the Instructions for Use accompanying the compatible ablation catheter for the intended patient population.

4.4 Intended User Population

The intended user population is physicians and nurses/EP technicians trained in interventional cardiac electrophysiology (EP).

4.5 Clinical Benefit

Refer to the Instructions for Use accompanying the compatible ablation catheter for the clinical benefit.

4.6 Contraindications

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

4.7 Potential Adverse Events

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

Note: Any serious incident that has occurred in relation to the Affera Ablation System should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

5 Safety Information

5.1 Warnings: General Use

- Carefully read all system instructions before use. Observe all contraindications, warnings, and precautions noted in the directions. Failure to do so may result in patient complications. Review any applicable product information with the patient, including known risks and contraindications.
- Inspect all items for possible damage during shipment. Do not operate the Affera Ablation System if any components appear damaged. If any items are damaged, do not use them and contact an Affera representative.
- Cardiac ablation procedures should only be performed by personnel trained in RF catheter ablation techniques.
- Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias. Defibrillation equipment must be available for immediate use in the case of a life-threatening arrhythmia.
- Use only the accessories provided with the system or supplied by the manufacturer. Use of unauthorized or unapproved accessories, or modification of accessories, can alter system performance and lead to damage or patient harm.
- Ensure that the HexaGEN™ RF Generator, HexaPULSE™ PF Generator Module, and HexaMAP™ CIU components are placed on a firm and stable surface, and ensure that airflow is not restricted to the air vents prior to initiating the case.
- Do not operate the Affera Ablation System stacked on or in close proximity with other electrical equipment other than the Prism-1™ Mapping System. If adjacent or stacked use is necessary, the system should be observed prior to use to verify normal operation in the configuration in which it will be used.
- Ensure the patient cannot directly contact grounded metal components or metal components that have a large, grounded surface area, such as the operating table.
- Skin contact between the patient's appendages and body should be avoided by insertion of dry gauze or other means.
- Physiological monitoring electrodes without protective resistance or RF filters should be applied to the patient's body as far as possible from the ablation site and the return electrodes. The use of monitoring systems incorporating high frequency current limiting devices is recommended.
- Avoid using flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen (O_2). Due to the risk associated with flammable liquids under the patient or in the patient's body cavities, wipe the liquid away in these places before starting a procedure, and allow time for flammable substances such as disinfectants, cleaning agents, or solvents to evaporate. The use of non-flammable cleaning and disinfectant agents is recommended.

- Use care in patients with a cardiac pacemaker, as there is a risk of interference with pacemaker function or damage to the pacemaker. In case of doubt, consult the pacemaker manufacturer.
- Electromagnetic radiation emitted by the system can interfere with the function of other electrical devices. Radiation from other electrical devices can affect the function of the system if operated near the generator.
- This equipment generates and can radiate radiofrequency energy and may interfere with radio communications. Portable and mobile communication devices may interfere with the functioning of the system.
- If error messages repeatedly appear and cannot be resolved, stop using the system and contact Affera.
- To avoid damage to the system and its accessories, use only appropriate cleaning agents (see *Section 9.1*).
- The Affera Ablation System contains no user-serviceable parts and must not be disassembled by anyone other than persons authorized by Affera. No modifications to this equipment are allowed.
- Electrodes and probes for monitoring and stimulation devices can be electrical conductors of RF current. Reduce the risk of burns by placing the electrodes and probes as far as possible from the site of ablation and from the return electrodes.
- The Ablation Catheter and the Tubing Set are intended for single patient use only. To avoid the risks of cross contamination or use of degraded products, do not reuse disposable accessories that are marked for single use.
- The Ablation System has been designed for use in the anticipated operating, storage and transportation environments, described in *Table 6*. There are no special operating, storage or transportation conditions required. Standard storage conditions are sufficient to safeguard the device.

5.2 Warnings: System Connections and Safety

- The Affera Ablation System is intended for use with compatible ablation catheters and cables only. Do not use with devices having a rated accessory voltage less than the maximum output voltage specified in this user manual. See *Section 6.2*.
- Use caution when connecting the Ablation System to other medical electrical equipment. The operator is responsible for installation and operation that complies with IEC/EN 60601-1-1. All system components must comply with applicable requirements and standards.
- The Affera Ablation System may be interfered with/by other equipment, even if the other equipment complies with CISPR emission requirements.
- Portable and Mobile RF Communications Equipment can affect the operation of the Affera Ablation System. Refer to the information provided in *Table 9* to ensure minimum safe operating distance is observed.

- Do not use the system near a strong magnetic field such as MRI. The system has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The safety of the system in the MR environment is unknown (such as any heating, migration, or image artifacts). Scanning a patient during the use of these devices may result in patient injury.
- To avoid risk of electric shock, this equipment must be connected to a mains power supply with protective earth using the power cord supplied. Do not use an additional multiple socket outlet or extension cord unless provided by Affera. Ensure the system is not positioned in such a way as to make it difficult to readily disconnect the device from the mains power supply if required.
- Connecting electrical equipment to an incompatible multiple socket outlet effectively leads to creating a Medical Electrical System, and the result can be a reduced level of safety. For the requirements that are applicable to a Medical Electrical System, please refer to IEC 60601-1.
- Do not connect the Ablation System ethernet ports to a hospital IT network or computing device.
- Do not upload unauthorized software onto the device.
- Inspect cables for damage to insulation or other signs of damage. Inspect cable connectors for bent pins. Do not use cables that appear damaged.
- To avoid differences in potential between the Ablation System components and other medical electrical equipment, potential equalization (equipotential) cables are provided for connection to a central ground in the operating room as specified in IEC/EN 60601-1.
- Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Any person connecting additional equipment to a medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above-mentioned requirements. If in doubt, contact Affera.

5.3 Warnings: Irrigation Pump and Tubing Set Operation

- Use the HexaFLOW™ Irrigation Pump only with the HexaFLOW™ Tubing Set. Use of unauthorized tubing in the pump may cause flow inaccuracy and other dangerous conditions. The HexaFLOW™ Irrigation Pump is intended for use only with the Affera Ablation System and compatible devices.
- Ensure the HexaFLOW™ Tubing Set is placed properly in the bubble detector of the HexaFLOW™ Irrigation Pump prior to connection to the patient.
- Verify flow from the catheter prior to insertion into the patient.
- Verify the tubing is free of air bubble prior to insertion of the catheter into the patient.

- When mounting the pump to an IV pole, ensure stability prior to starting that case. It is recommended that the pump be mounted on the IV pole provided with the Affera System Cart, or a 5-legged hospital grade IV pole may be used. To ensure stability, the pump should not be mounted higher than 135 cm above the base of the pole.
- The Tubing Set is intended to be connected directly to a compatible catheter. Do not use stopcocks or extend the length of tubing between the pump and the catheter using unauthorized tubing extension devices.
- When the PURGE button is pressed, the air bubble detector is disabled. Do not press the PURGE button or the Catheter Preparation Sequence button while the catheter is in the patient.
- Follow the catheter preparation instructions in the catheter Instructions for Use in order to reduce the likelihood of accidental infusion of air.
- The pump and tubing set are intended for use with normal saline irrigation solution. Patient injury may result from excessive delivery of inappropriate fluids.
- The HexaFLOW™ Irrigation Pump stops flow automatically when air is detected in the line or in case of other operational errors. When the pump alarm indicates flow has stopped, ensure that energy delivery has been terminated. If irrigation flow cannot be restored immediately, remove the ablation catheter from the patient until irrigation flow is resumed.

5.4 Warnings: Return Electrode Management

- Care should be taken in the placement of the return electrodes. Each return electrode should be placed at a similar distance and with a similar mass of tissue from the ablation site.
- The entire surface of the return electrodes must be as close as possible to the operating field and must have reliable contact with the patient's body. The skin surface must be free of excessive oil and body hair.
- Use only return electrodes with a surface area of ≥ 124 cm^2 that conform with IEC/EN 60601-2-2.
- The Affera Ablation System employs a Contact Quality Monitoring feature to ensure return electrode contact. Use of compatible split type indifferent return electrodes is recommended to ensure poor return electrode contact is detected, resulting in an audible alarm. Use of non-split plate return electrodes will prevent the Contact Quality Monitoring circuitry from operating, and may increase the risk of patient skin burn.
- Read the instructions for use for the return electrodes carefully, and take special note of warnings and precautions. An unsuitable or incorrectly applied return electrode can lead to skin burns. Check the return electrode and the connection cable before use. Do not use a return electrode that is damaged or modified.
- Ensure that the return electrode contact surface is moist and not dry. Replace dry electrodes with a new electrode. Do not use contact gel with single-use return electrodes.
- A single-use return electrode cannot be reused. If the return electrode becomes loose or must be moved, use a new return electrode.

- All patient leads and cables should be positioned in such a way that contact with the patient or other leads is avoided.
- Do not position a return electrode in contact with or covering any other body surface electrode or Location Reference Patch.

5.5 Warnings: During Ablation

- To avoid possible injury to the patient or to the operator, do not start energy delivery until the catheter is positioned in the intended ablation site. Always select the lowest appropriate output ablation setting for the intended site.
- Avoid high catheter electrode temperatures. High electrode temperatures during ablation are associated with char and thrombus, the formation of which could lead to embolism.
- High temperatures observed with low applied RF energy may indicate an obstruction of irrigation.
- Prevent contact between the ablation electrode and other electrically conductive devices or implants in the heart (e.g. diagnostic catheters or pacemakers) to avoid the possibility of shunting energy away from the target location.
- Monitor the ablation circuit impedance measurement during RF energy delivery, and immediately terminate RF delivery if an abrupt change is observed.
- In case of apparent low power output or failure to function as expected at the selected output setting, verify contact of the return electrodes and connections before increasing the power setting.
- A failure of the HexaGEN™ RF Generator or HexaPULSE™ PF Generator Module could result in an unintended increase of output energy.
- The system monitors the energy delivered through each return electrode during the procedure to prevent heating. If the energy delivered to any return electrode exceeds the safe threshold, delivery will be stopped automatically. If the operator attempts to deliver energy that will cause the safe energy delivery limit to be exceeded, the system will not start the ablation and will present a message to wait until the selected energy can be safely delivered.
- Neuromuscular stimulation may occur during PF energy delivery. If patient movement occurs, verify the catheter position.
- Continuously monitor the patient and patient vital signs during ablation.
- Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias. Defibrillation equipment must be available for immediate use in the case of a life-threatening arrhythmia.
- Ensure a minimum flow of 4 mL/min throughout the entire procedure to prevent coagulation formation or occlusion of the catheter irrigation holes.
- Once the Start/Stop Button is pressed, energy delivery will continue until the energy delivery sequence is completed or until the Start/Stop Button is pressed a second time. Use caution manipulating the ablation catheter when delivering energy.

6 System Overview and Connections

6.1 Components and Accessories

Each component of the Affera Ablation System is supplied with the cables and accessories listed in *Table 1*, along with this user manual.

Table 1. Affera Ablation System Components and Accessories

AFR-00004 HexaGEN™ RF Generator (RFG)	
ASM-00083	RF Generator unit
CBA-00018	Generator Link Cable
ASM-00072	Return Electrode Adapter
SWH-00014	Foot Pedal
ASM-00102	Remote Control
CBL-00104	Fiber Optic Communication Cable, 30 m
PWR-00018	Remote Control Power Supply
AFR-00008 HexaPULSE™ PF Generator Module (PFG)	
ASM-00094	PF Generator unit
CBA-00018	Generator Link Cable
CBA-00119	Ablation Return Link Cable
CBA-00117	Generator Communication Cable (qty. 2)
AFR-00005 HexaFLOW™ Irrigation Pump	
ASM-00077	Irrigation Pump unit
CBA-00139	RFG to Pump Communication Cable
PRT-00331	Pump Pole Clamp
Power Cords	
Various	Power Cord
CBL-00100	Equipotential Cable

6.2 Device Compatibility

Table 2. Compatible devices

AFR-00002	HexaFLOW™ Tubing Set
AFR-00006	Catheter Extension Cable
AFR-00001	Sphere-9™ Mapping and Ablation Catheter

Table 2. Compatible devices (continued)

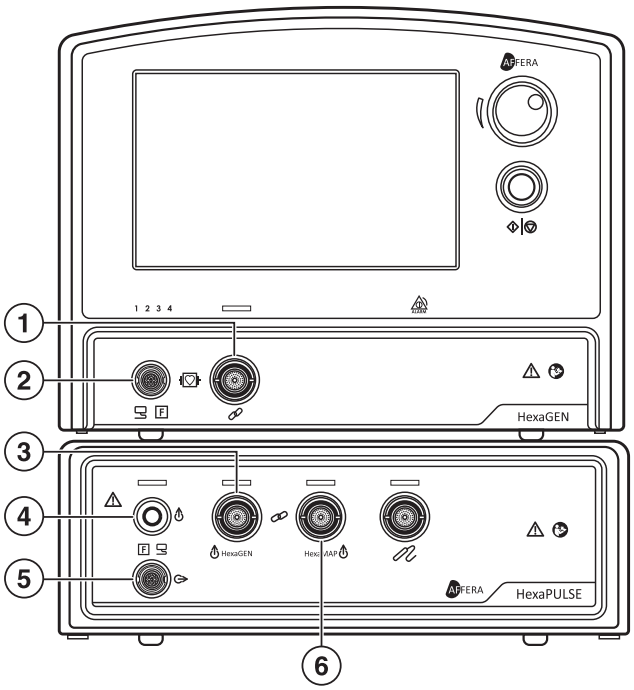
AFR-00003	Prism-1™ Mapping System
AFR-00013	Affera System Cart

6.3 System Connections

The Affera Ablation System is designed for use in cardiac ablation procedures conducted in an appropriately equipped and qualified surgical suite. The system is intended to be used with a compatible mapping system and a compatible ablation catheter. Additional system connection information can be found in the *Prism-1™ Mapping System User Manual*.

6.3.1 Front Panel Connections

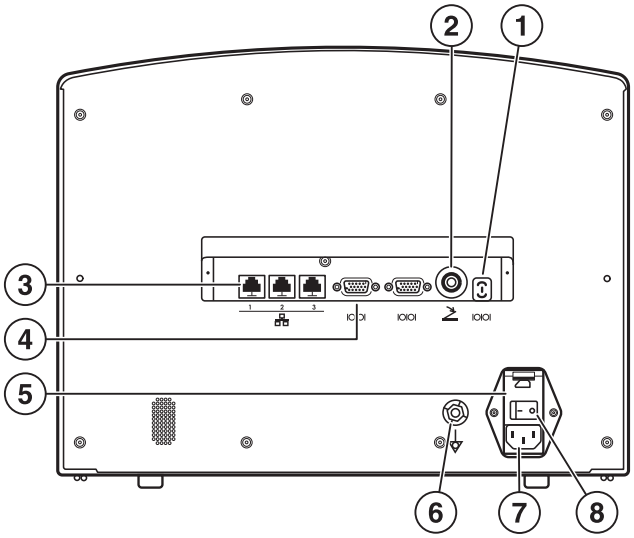
Figure 2. Front panel connections for HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module



1 Generator Link Cable (to PFG)
2 Ablation Return Link Cable
3 Generator Link Cable (to RFG)
4 Ablation Return Link Cable
5 Return Electrode Adapter
6 Generator Link Cable (to CIU)

6.3.2 HexaGEN™ RF Generator back panel

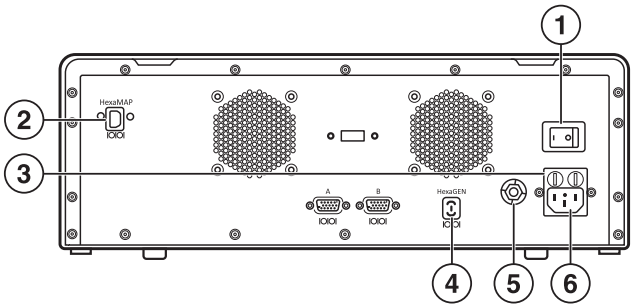
Figure 3. HexaGEN™ RF Generator back panel



1 Generator Communication Cable (to PFG)
2 Foot Pedal
3 System Network Communication
4 RFG to Pump Communication Cable
5 Fuse Access
6 Equipotential Cable
7 Mains Power Cord
8 Power Switch

6.3.3 HexaPULSE™ PF Generator Module back panel

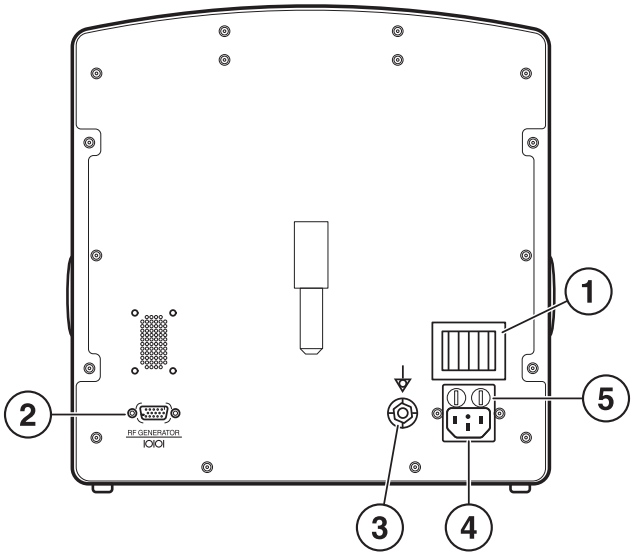
Figure 4. HexaPULSE™ PF Generator Module back panel



1 Power Switch
2 Generator Communication Cable (to CIU)
3 Fuse Access
4 Generator Communication Cable (to RFG)
5 Equipotential Cable
6 Mains Power Cord

6.3.4 HexaFLOW™ Irrigation Pump back panel

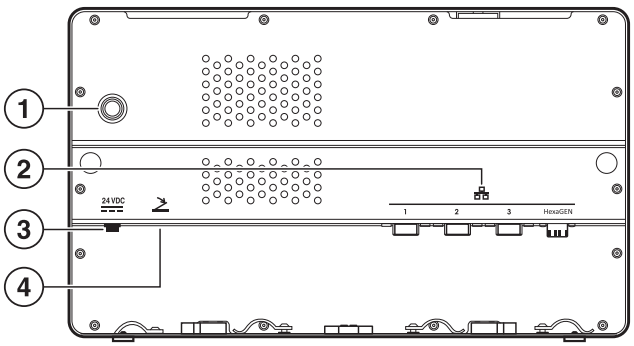
Figure 5. HexaFLOW™ Irrigation Pump back panel



1 Power Switch
2 RFG to Pump Communication Cable
3 Equipotential Cable
4 Mains Power Cord
5 Fuse Access

6.4 Remote Control back panel

Figure 6. Remote Control back panel

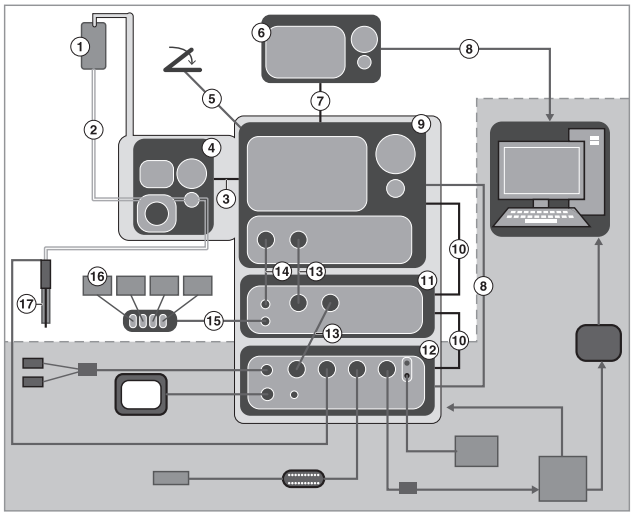


1 Power Button
2 System Network Communication
3 Remote Control Power Supply
4 Foot Pedal

6.5 System Connection Diagram

The Prism-1™ Mapping System and the Affera Ablation System are collectively referred to as the Affera Mapping and Ablation System, which is shown in *Figure 7*. The Ablation System components are shown above the dotted line. (See the *Prism-1™ Mapping System User Manual* for a system diagram of the Mapping System components, shown below the dotted line.)

Figure 7. Affera Mapping and Ablation System connection diagram

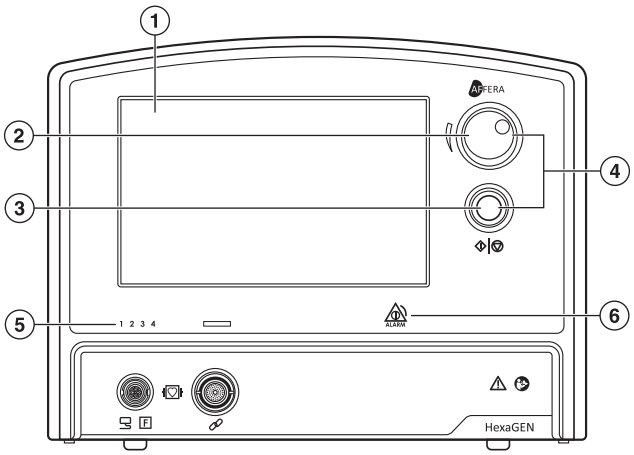


1 Saline bag
2 Tubing Set (AFR-00002)
3 RFG to Pump Comm Cable (CBA-00139)
4 Irrigation Pump Unit (ASM-00077)
5 Foot Pedal (SWH-00014)
6 Remote Control (ASM-00102)
7 Fiber Optic Comm Cable, 30 m (CBL-00104)
8 Ethernet Cable (CBL-00101)
9 RFG Unit (ASM-00083)
10 Generator Comm Cable (CBA-00117)
11 PFG Unit (ASM-00094)
12 Prism-1™ Mapping System CIU (ASM-00084)
13 Generator Link Cable (CBA-00018)
14 Ablation Return Link (CBA-00119)
15 Return Electrode Adapter (ASM-00072)
16 Return Electrodes
17 Sphere-9™ Ablation Catheter (AFR-00001)

6.6 System Controls and Indicators

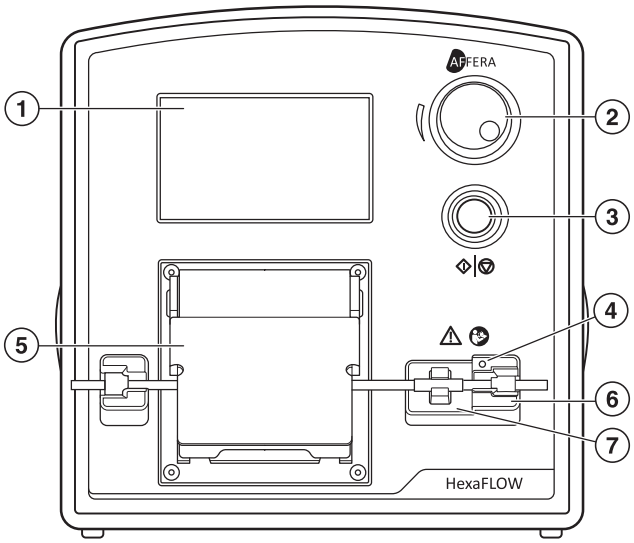
The Affera Ablation System provides an intuitive user interface via touchscreen and rotary dial controls. Warning indicators are provided on the touchscreen and in some cases by dedicated indicators on the front panel. An optional Remote Control user interface is available with the same touchscreen, Rotary Dial, and Start/Stop Button.

Figure 8. HexaGEN™ RF Generator front panel controls and indicators



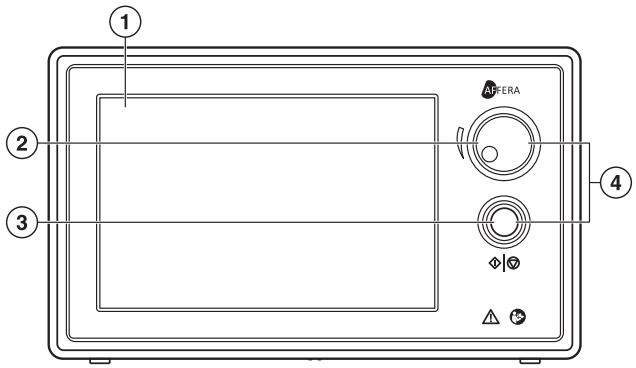
1 Touchscreen Interface
2 Rotary Dial
3 Start/Stop Button
4 Ablation Indicator Lights
5 Return Electrode Status Indicators
6 Error Warning Indicator

Figure 9. HexaFLOW™ Irrigation Pump front panel controls and indicators



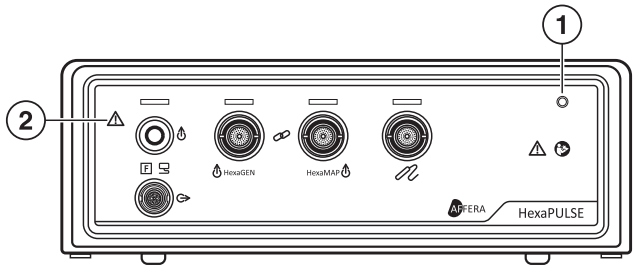
1 Touchscreen Interface
2 Rotary Dial
3 Start/Stop Button
4 Bubble Detected Indicator
5 Door
6 Tubing Mount
7 Bubble Detector

Figure 10. Remote Control front panel controls and indicators



1 Touchscreen Interface
2 Rotary Dial
3 Start/Stop Button
4 Ablation Indicator Lights

Figure 11. PF Generator front panel indicators



1 Power Indicator
2 High Voltage Indicator

7 System Setup and Operation

7.1 System Setup

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

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

For assistance with initial installation, setup, and operation, contact Affera.

1. Connect all mains power connections.

   Note: The HexaFLOW™ Irrigation Pump is intended to be connected directly to mains power and is not to be connected to the multiple socket outlet on the Affera Cart.

2. Mount the HexaFLOW™ Irrigation Pump on the IV pole of the Affera System Cart (AFR-00013) or a suitable 5-leg IV pole and place the system components near the patient.
3. Connect the communication cables between the following components according to the system connection diagram in *Figure 7*:

- HexaGEN™ RF Generator
- HexaPULSE™ PF Generator Module
- HexaFLOW™ Irrigation Pump

4. If used, connect the communication cables with the following additional components according to the system connection diagram in *Figure 7*:

- Remote Control
- HexaMAP™ CIU
- Prism-1™ Mapping System Workstation

5. Power on each unit of the Affera Ablation System using the power switch on the back panel, and ensure the self-test shown on the HexaGEN™ RF Generator passes before continuing.

7.2 Return Electrode Placement and Connections

1. Place return electrodes on the patient's skin as described below and connect them to the Return Electrode Adapter. The system requires four (4) return electrodes.

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

Table 3. Contact Quality Monitoring status color codes

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

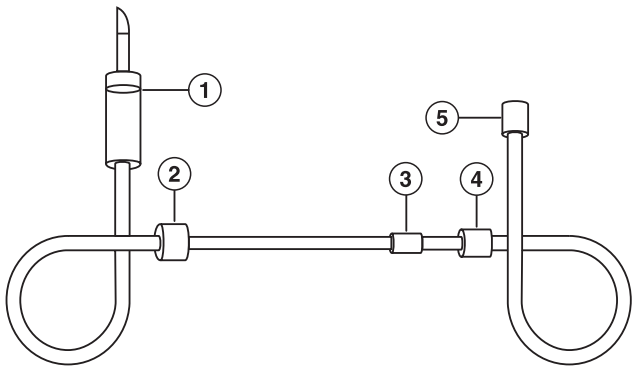
Warning: An unsuitable or incorrectly applied return electrode can lead to skin burns. Check the return electrode and the connection cable before use. Do not use a return electrode that is damaged or modified. Refer to the warnings in *Section 5.4*.

7.3 HexaFLOW™ Tubing Set Installation

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

9. Fill the HexaFLOW™ Tubing Set with irrigation solution by pushing the **PURGE** button on the HexaFLOW™ Irrigation Pump (*Figure 20*). The **PURGE** button can also be found on either the HexaGEN™ RF Generator or the Remote Control (*Figure 13*). Hold the **PURGE** button until the bubble alarm is cleared.

Figure 12. HexaFLOW™ Tubing Set



1 Drip Chamber
2 Large Pump Mounting Block
3 Bubble Detector Feature
4 Small Pump Mounting Block
5 Catheter Luer Connector

10. Visually inspect the HexaFLOW™ Tubing Set to verify there are no air bubbles between the drip chamber and the Luer connector prior to connection to the catheter.
11. Connect the HexaFLOW™ Tubing Set to the Luer fitting of the compatible ablation catheter, and follow the instructions provided in the catheter instructions for use.
12. As directed in the ablation catheter instructions for use, submerge the tip of the ablation catheter in a bowl of sterile saline, and press the **CATHETER PREPARATION SEQUENCE** button (*Figure 20* and *Figure 13*). Keep the ablation catheter tip submerged until the sequence is complete.
13. Follow the ablation catheter instructions for use regarding use of an Insertion Tool.
14. Ensure irrigation fluid is flowing from the tip of the ablation catheter prior to insertion into the patient.
15. Verify there are no leaks from the tubing connections or catheter handle.

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

7.4 Bubble Detection

If a bubble is detected in the HexaFLOW™ Tubing Set, the HexaFLOW™ Irrigation Pump will sound an audible warning and stop irrigation flow before the bubble is delivered to the ablation catheter. The air must be purged from the HexaFLOW™ Tubing Set as described below prior to continuing irrigation.

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

   Caution: The Affera Tubing Set should not be used with extension tubing or stopcocks.

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

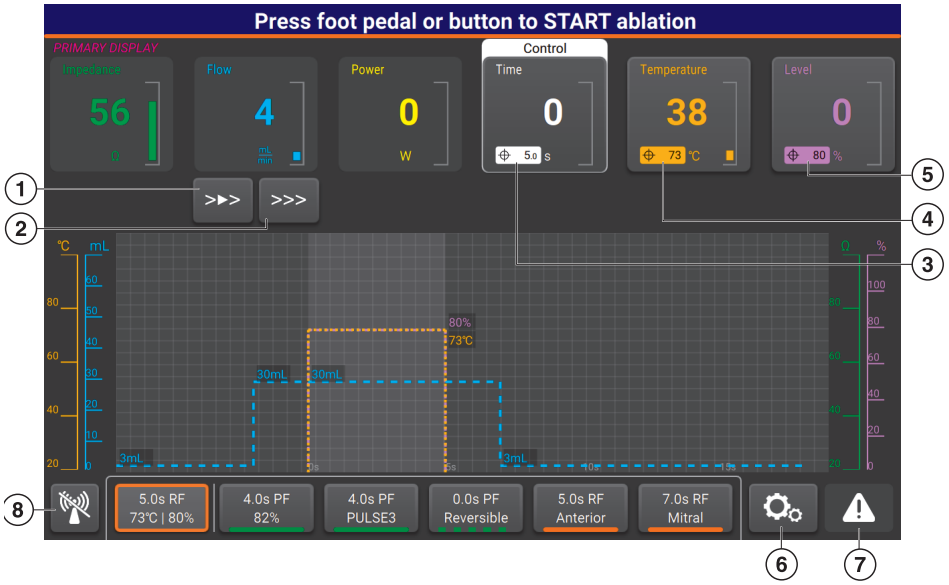
   Warning: The HexaFLOW™ Irrigation Pump stops flow automatically when air is detected in the line or in case of other operational errors. When the pump alarm indicates flow has stopped, ensure that energy delivery has been terminated. If irrigation flow cannot be restored immediately, remove the ablation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

7.5 Energy Delivery

- Energy delivery parameters can be viewed and modified via the touchscreen on the HexaGEN™ RF Generator (*Figure 8*). The HexaGEN™ RF Generator Home Screen is shown below in *Figure 13*.
- When the Remote Control is used, the touchscreen on the Remote Control presents the same user interface as the HexaGEN™ RF Generator (see *Figure 10*). Only one interface, called the Primary Interface, can be used to select and configure ablation parameters. The other interface, called the Secondary Interface, acts as a passive display.
- A set of ablation parameters can be selected from the list of saved presets. To select an ablation preset, touch one of the preset buttons at the bottom of the touchscreen. The selected preset will be highlighted with a colored border (see *Figure 13*). A green border indicates PF energy. An orange border indicates RF energy.
- To adjust a parameter, touch that parameter. The Rotary Dial to the right of the touchscreen will illuminate in the color of the selected parameter. Rotate the dial and press to apply the adjusted parameter.
- Use the touchscreen and Rotary Dial to:

– Set the **Level Limit** for either PF or RF ablation. PF **Level Limit** is expressed as a percentage of maximum current (A). RF **Level Limit** is expressed as a percentage of maximum squared current (A^2).
– Set the **Target Temperature** (°C) for temperature-controlled RF ablation
– Set the **Duration** (s) for RF ablation

Figure 13. HexaGEN™ RF Generator Home Screen with an RF ablation preset selected



1 CATHETER PREPARATION SEQUENCE button
2 PURGE button
3 Target duration of selected preset
4 Target temperature of selected preset
5 Level limit of selected preset
6 Settings icon
7 Notifications icon
8 Deselect all presets

- The Foot Pedal can be used to toggle between two predefined presets. Press and release the Foot Pedal twice in rapid succession (Double-Tap) to toggle. Visually verify the settings on the screen prior to energy delivery.

  Note: When the Affera Ablation System is ready for ablation, the Rotary Dial and the Start/Stop Button are illuminated in green.

- Energy delivery can be started and stopped in one of two ways:

– Press the Start/Stop Button on the HexaGEN™ RF Generator (*Figure 8*) or the Remote Control (if connected and in use; *Figure 10*) once to initiate the delivery sequence. Energy delivery will continue up to the target Duration. Press the Start/Stop Button again to stop delivery of energy before the target Duration has elapsed.
– Depress and hold the Foot Pedal to initiate the delivery sequence, and release the Foot Pedal at any time to stop delivery of energy. With the Foot Pedal depressed, energy delivery will end automatically when the target Duration is reached.

Note: Once the delivery sequence has been initiated, the HexaFLOW™ Irrigation Pump will play a sound indicating the sequence has started. The sound from the HexaFLOW™ Irrigation Pump is unique for RF or PF ablation. When energy delivery begins, the HexaGEN™ RF Generator will play a sound that is unique for RF or PF ablation.

Note: During energy delivery, the Rotary Dial and Start/Stop Button are illuminated in blue. If energy delivery is terminated by the Affera Ablation System for any reason, the Rotary Dial and Start/Stop Button are illuminated in red.

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

- Ablation parameters are displayed on a graph on the HexaGEN™ RF Generator touchscreen interface during the energy delivery sequence and remain on the screen until either (a) the next delivery sequence is initiated or (b) the touchscreen or Rotary Dial are used to change parameters. If in use, the Remote Control displays the same information.
- RF and PF energy delivery are differentiated by unique audible tones.

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

7.6 System Shutdown

- Ablation energy can be terminated during delivery by pressing the Start/Stop Button on the HexaGEN™ RF Generator (*Figure 8*) or the Remote Control (if connected and in use; *Figure 10*) or by pressing and releasing the Foot Pedal.
- Irrigation delivery can be stopped by pressing the Start/Stop Button on the HexaFLOW™ Irrigation Pump (*Figure 9*).
- Power off each unit using the power switch on the back panel (*Section 6.3*). Power off the Remote control by pressing the power button on the back panel (*Figure 6*).

8 Graphical User Interface

8.1 HexaGEN™ RF Generator and Remote Control

The HexaGEN™ RF Generator provides a single user interface for controlling RF delivery, PF delivery, and irrigation.

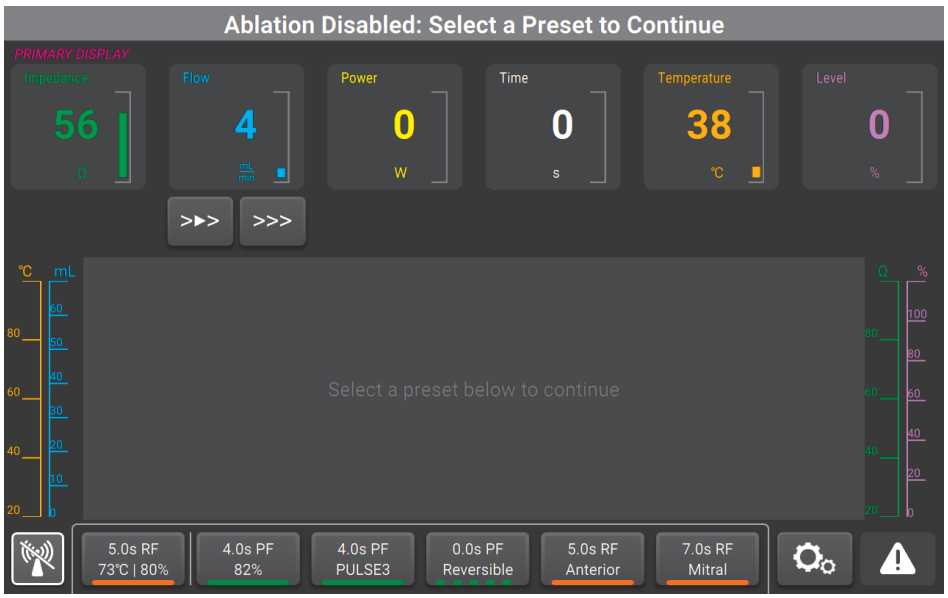
Note: The screen images shown in this user manual are representative of what is seen on-screen with the software; actual images may differ slightly.

If the Remote Control is in use and connected, the Remote Control touchscreen presents the same user interface as the HexaGEN™ RF Generator. The HexaGEN™ RF Generator and the Remote Control both display ablation settings and ablation-related measurements, but only one user interface may be defined as the Primary Interface, which can be used to modify ablation settings. The other user interface acts as a Secondary Interface for passive display. The user interface selected as the Primary Interface can be changed through the Settings Screen as further described below (*Section 8.1.2*).

8.1.1 Home Screen

The HexaGEN™ RF Generator touchscreen interface Home Screen is shown below in *Figure 14*. From the Home Screen, the user can select ablation presets, manually adjust ablation parameters, view and clear notifications, and access the Settings Screen.

Figure 14. HexaGEN™ RF Generator Home Screen



Status Bar

The Status Bar at the top of the Home Screen displays the energy delivery state of the Affera Ablation System (*Figure 13*, *Figure 14*). A colored border at the bottom of the Status Bar indicates the selected energy type (*Figure 13*), with orange indicating RF energy and green indicating PF energy. When energy is delivered, the Status Bar shows the progress through the energy delivery sequence.

Parameter Displays and Controls

Several ablation-related measurements, ablation settings, and controls are presented at the top of the Home Screen, below the Status Bar:

- **Impedance**: This element shows the real-time ablation circuit impedance (Ω) measured between the ablation electrode and the return electrodes. Impedance is displayed in green.
- **Flow**: This element shows the real-time flow rate (mL/min) being delivered by the HexaFLOW™ Irrigation Pump. Flow is displayed in cyan (light blue).

– Just below this element are buttons that can be used to initiate the **CATHETER PREPARATION SEQUENCE** and to **PURGE**.

- **Power**: During RF delivery, this element shows the real-time power (W) being delivered by the HexaGEN™ RF Generator. Power is displayed in yellow. This element does not display a value during PF ablation.
- **Time**: This element shows the elapsed energy delivery duration (s). Time is displayed in white.

– When a preset is selected, the Target duration of the selected preset is shown at the lower left (see *Figure 13*).
– When an RF ablation preset is selected, this element can be highlighted via the touchscreen interface, and the Target duration can be adjusted using the Rotary Dial.

- **Energy**: At the conclusion of RF delivery, this element shows the energy delivered (J). Energy is displayed in yellow. This element does not display a value during PF ablation.
- **Temperature**: This element shows the real-time temperature (°C) measured with the ablation catheter. For catheters with multiple temperature sensors such as the Sphere-9™ Catheter, the displayed temperature is the maximum across the multiple temperature sensors. Temperature is displayed in orange.

– When an RF ablation preset is selected, the Target temperature for the selected preset is shown in the lower left (see *Figure 13*). For more information on ablation presets, see *Section 8.1.2*.
– When an RF ablation preset is selected, this element can be highlighted via the touchscreen interface, and the Target temperature can be adjusted using the Rotary Dial.

- **Level**: This element shows the real-time current level (%) being delivered by the HexaGEN™ RF Generator or the HexaPULSE™ PF Generator Module. During RF ablation, level is reported as a percentage of the maximum current squared (A^2). During PF ablation, level is reported as a percentage of the maximum current (A). Level is displayed in purple.

– When a preset is selected, the Level limit is shown in the lower left (see *Figure 13*). For more information on ablation presets, see *Section 8.1.2*.

– When a preset is selected, this element can be highlighted via the touchscreen interface, and the Level limit can be adjusted using the Rotary Dial.

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

Note that modifying an ablation parameter on the Home Screen automatically updates the Manual preset to match the modified ablation parameters and activates the Manual preset. See below for more information regarding presets.

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

Ablation Graph

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

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

Information in the Ablation Graph is also provided to the connected compatible mapping system for secondary display.

Presets

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

Presets can be selected in two ways:

- Press the corresponding button at the bottom of the Home Screen on the touchscreen interface, activating the selected preset. This can only be done using the Primary Interface.
- Press and release the Foot Pedal twice in rapid succession (Double-Tap) to toggle between two predefined presets labeled with the Foot Pedal symbol (see *Figure 16*). Presets available for toggling with the Foot Pedal are defined in the preset settings (see *Section 8.1.2*).

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

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

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

Notifications

Affera Ablation System notifications are displayed at the bottom right of the Home Screen. The HexaGEN™ RF Generator touchscreen interface displays notifications from the HexaGEN™ RF Generator, the HexaPULSE™ PF Generator Module, and the HexaFLOW™ Irrigation Pump. Affera Ablation System notifications are also provided to the connected compatible mapping system for secondary display.

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

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

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

8.1.2 Settings Screen

The Settings Screen can be accessed by pressing the Settings icon at the bottom of the Home Screen, to the right of the presets. The Settings Screen displays system information and allows adjustment of system settings including limits, ablation control parameters, display brightness, audio volume, and the Primary Interface. The Settings Screen is comprised of several tabs, each of which is described in more detail below.

Note: Ablation is disabled when the Settings Screen is open.

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

General Tab

The **General** Tab of the Settings Screen is shown below in *Figure 15*. The **General** tab includes two sections:

- **Limits** define the impedance and temperature ranges within which ablation delivery is allowed. Parameters and limits are listed in *Table 4*.
- **Axis Settings** define the vertical axis ranges for the Ablation Graph. Parameters and limits are listed in *Table 5*.

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

Figure 15. HexaGEN™ RF Generator Settings Screen - **General** Tab

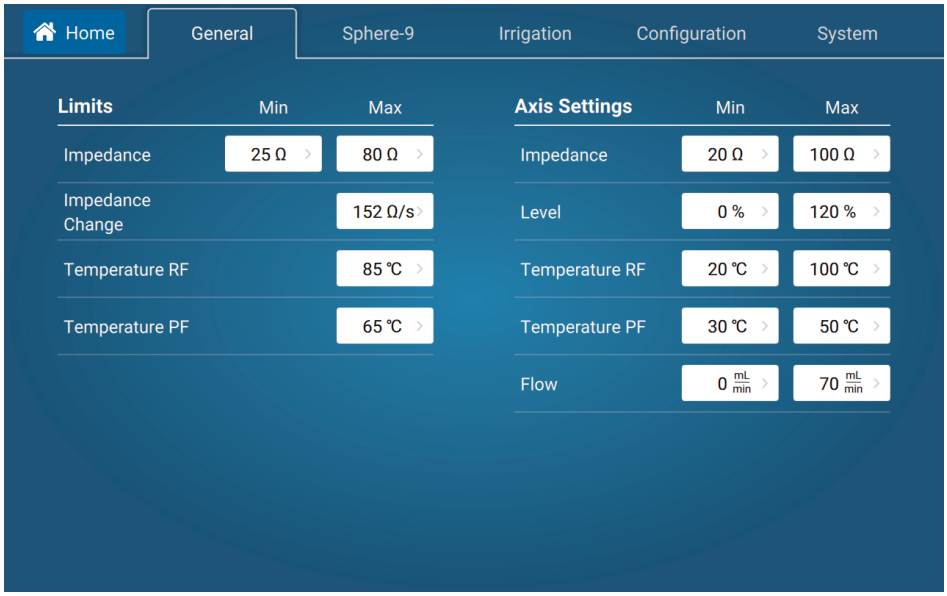


Table 4. HexaGEN™ RF Generator Settings Screen - **General** Tab - **Limits**

Parameter	Description	Lower Limit	Upper Limit
Impedance (Ω)	Energy delivery is stopped or prevented when the ablation circuit impedance is outside this range.	25 Ω	80 Ω
Impedance Change (Ω/s)	Energy delivery is stopped if the ablation circuit impedance changes faster than this rate.	0 Ω/s	300 Ω/s

Table 4. HexaGEN™ RF Generator Settings Screen - **General** Tab - **Limits** (continued)

Temperature RF (°C)	RF delivery is stopped if the maximum catheter temperature measurement exceeds this value.	40 °C	85 °C
Temperature PF (°C)	PF delivery is stopped if the maximum catheter temperature measurement exceeds this value.	40 °C	65 °C

Table 5. HexaGEN™ RF Generator Settings Screen - **General** Tab - **Axis Settings**

Parameter	Description	Lower Limit	Upper Limit
Impedance (Ω)	Ablation Graph axis range for **Impedance**	0 Ω	150 Ω
Level (%)	Ablation Graph axis range for **Level**	0%	150%
Temperature RF (°C)	Ablation Graph axis range for **Temperature** during RF ablation	0 °C	100 °C
Temperature PF (°C)	Ablation Graph axis range for **Temperature** during PF ablation	0 °C	100 °C
Flow (mL/min)	Ablation Graph axis range for **Flow**	0 mL/min	80 mL/min

Preset Tab

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

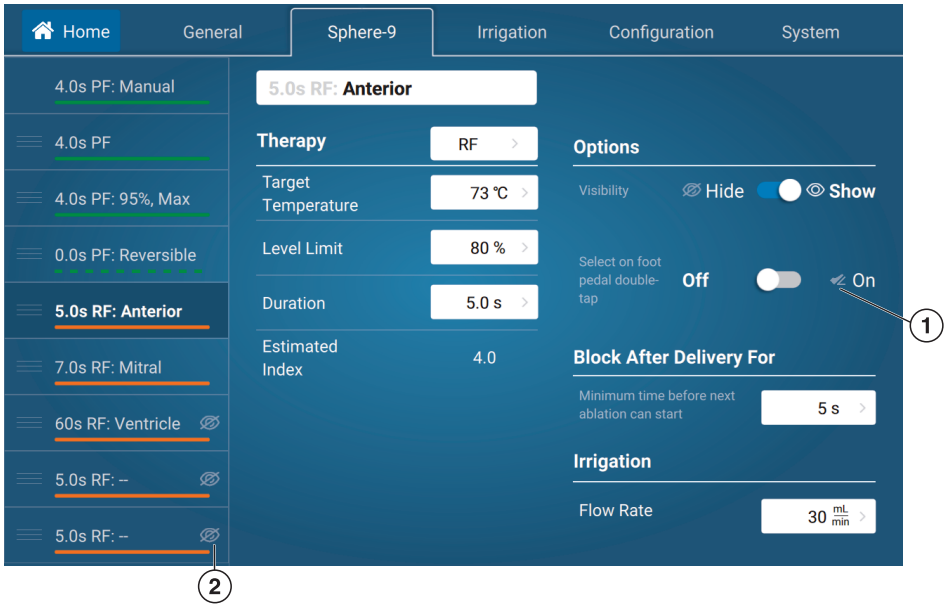
The preset labels on the left side of the Preset Tab provide basic information about each corresponding preset including delivery duration and energy type (RF or PF). Following the duration and energy type, the user-defined preset label is shown. To the right of the user-defined label, icons indicate if the preset is hidden from the Home Screen or can be selected using Foot Pedal Double-Tap (see *Figure 16*). (Presets without one of these icons are shown on the Home Screen and cannot be selected using Foot Pedal Double-Tap.) PF presets are underlined in green, while RF presets are underlined in orange.

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

Preset parameters include the following:

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

Figure 16. HexaGEN™ RF Generator Settings Screen - Preset Tab



1 Foot Pedal symbol
2 Icon indicating preset is hidden from Home Screen

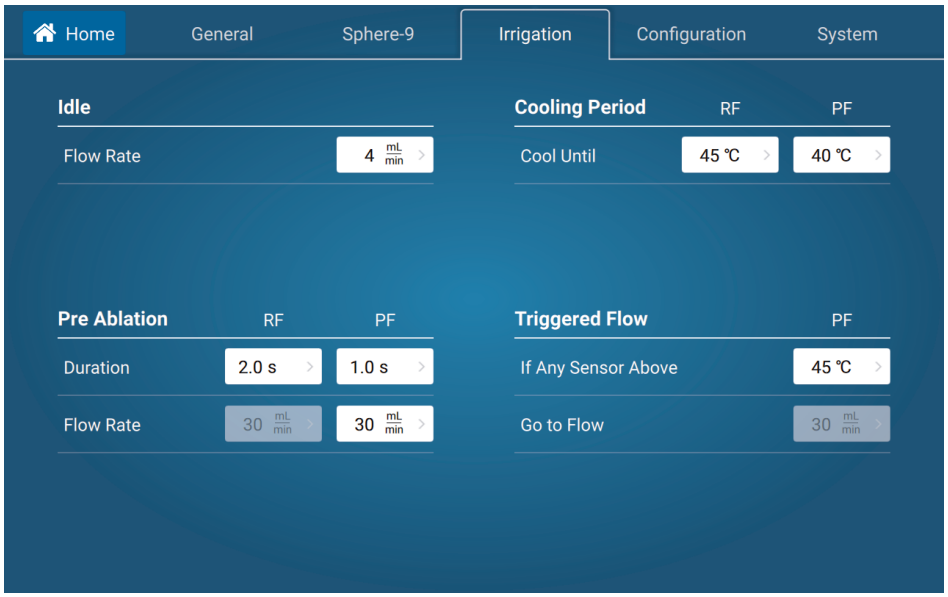
Irrigation Tab

The **Irrigation** Tab (*Figure 17*) is used to view and configure HexaFLOW™ Irrigation Pump parameters that apply to all ablation presets. The **Irrigation** Tab includes the following parameters:

- **Idle** Flow Rate is the flow rate of the HexaFLOW™ Irrigation Pump when not ablating (mL/min).

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

Figure 17. HexaGEN™ RF Generator Settings Screen — **Irrigation** Tab



Configuration Tab

The **Configuration** Tab (*Figure 18*) is used to view and configure settings related to the Remote Control and the Foot Pedal:

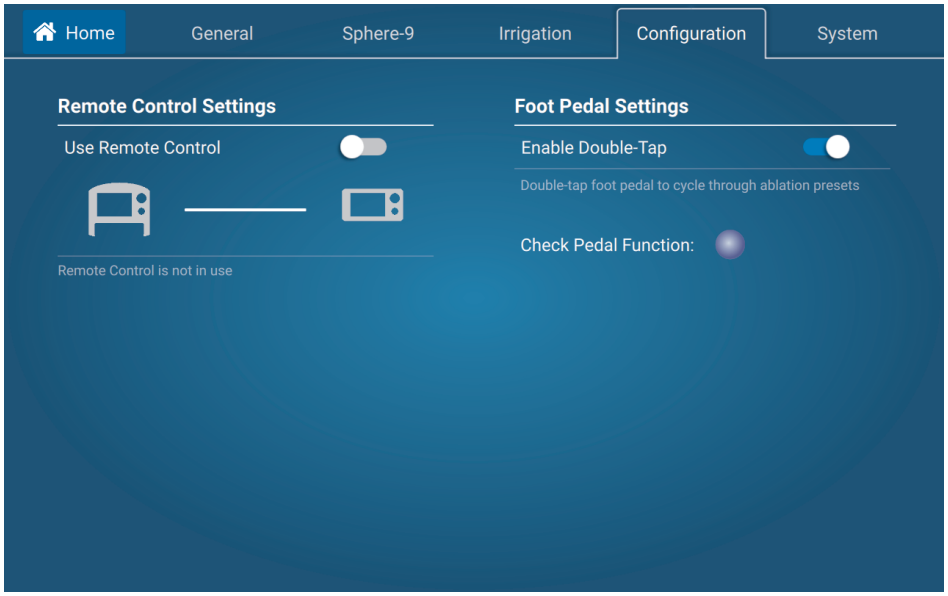
- **Remote Control Settings** includes controls for enabling use of the Remote Control (by toggling **Use Remote Control** on the HexaGEN™ RF Generator) and, once enabled, for becoming the Primary Interface. The control for becoming the Primary Interface is only available when (i) Use Remote Control is enabled on the HexaGEN™ RF Generator and (ii) the Remote Control is communicating with the HexaGEN™ RF Generator. The control for becoming the Primary Interface appears on the unit that is currently the Secondary Interface; the Primary Interface does not have a control for becoming the Secondary Interface.

  Note: If the Remote Control is being used (i.e., **Use Remote Control** is enabled on the HexaGEN™ RF Generator) and communication with the Remote Control is lost, a notification will appear on the HexaGEN™ RF Generator, and ablation will be disabled.

- **Foot Pedal Settings**:

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

Figure 18. HexaGEN™ RF Generator Settings Screen — **Configuration** Tab



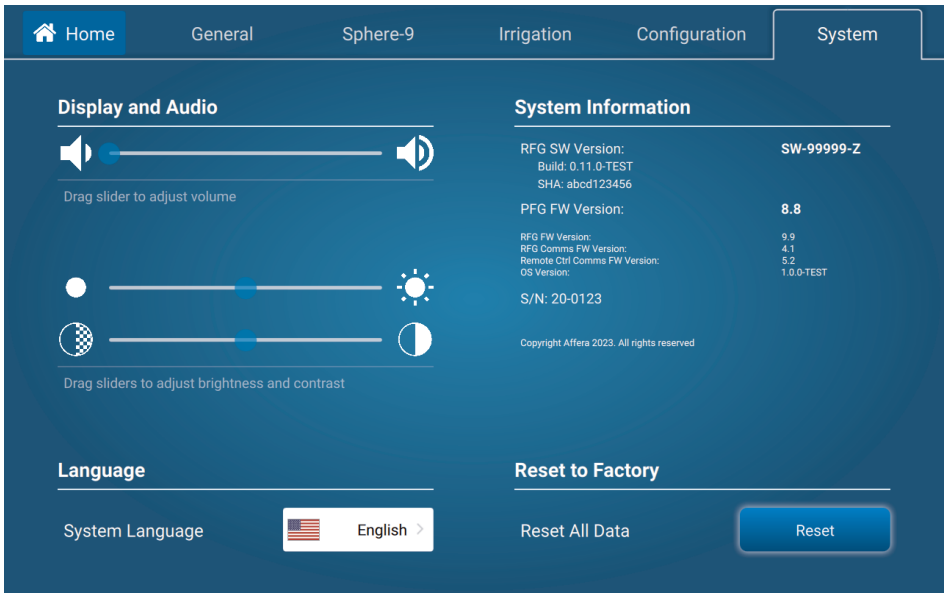
System Tab

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

- **Display and Audio** includes controls for audible notification volume as well as display brightness and contrast. These settings apply only to the unit on which they are shown; they do not apply to other components of the Affera Ablation System.

- **System Information** shows the software versions that are currently installed on the HexaGEN™ RF Generator, the Remote Control, and the HexaPULSE™ PF Generator Module.
- **Language** is used to choose the language for the HexaGEN™ RF Generator touchscreen interface.
- **Reset to Factory** can be used to reset all manually configured settings within the HexaGEN™ RF Generator. Settings are restored to the factory default state. This includes but is not limited to presets, Foot Pedal settings, volume, and brightness.

Figure 19. HexaGEN™ RF Generator Settings Screen — **System** Tab



8.2 HexaFLOW™ Irrigation Pump

The HexaFLOW™ Irrigation Pump provides a touchscreen user interface that can be used for setting up the HexaFLOW™ Irrigation Pump and Tubing Set at the beginning of the procedure.

8.2.1 Home Screen

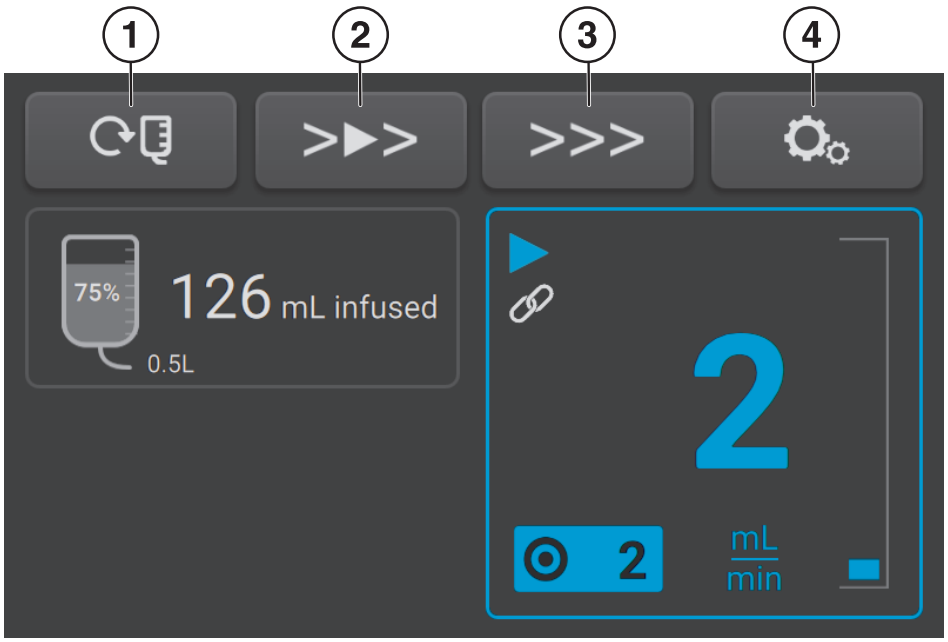
The HexaFLOW™ Irrigation Pump Home Screen is shown below in *Figure 20*. From the Home screen, the user can reset the bag volume counter, start the Catheter Preparation Sequence, run at Purge speed, view notifications, and access the Settings Screen.

8.2.2 Settings Screen

The HexaFLOW™ Irrigation Pump Settings Screen is shown below in *Figure 21*. The Settings Screen includes two tabs:

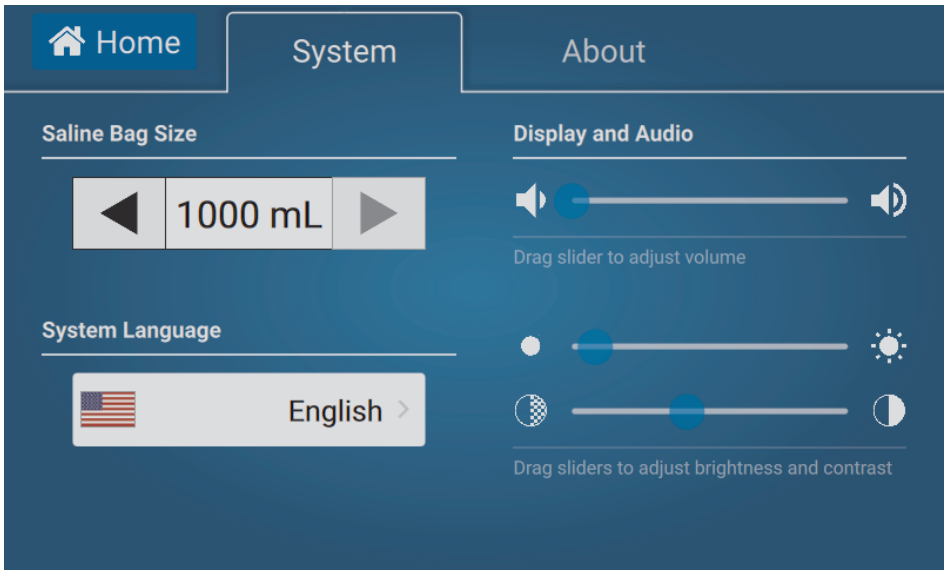
- The **System** Tab includes controls for changing the **Saline Bag Size** (used for the bag volume counter on the Home Screen), configuring the touchscreen display contrast and brightness, and adjusting audible notification volume.
- The **About** Tab shows the software version that is currently installed on the HexaFLOW™ Irrigation Pump.

Figure 20. HexaFLOW™ Irrigation Pump Home Screen



1 Reset the bag volume counter
2 Start Catheter Preparation Sequence
3 Run at Purge speed
4 Settings Screen

Figure 21. HexaFLOW™ Irrigation Pump Settings Screen



9 Periodic Maintenance and Service

9.1 System Cleaning and Disinfection

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

Use a dry microfiber cloth to clean the touch screen of the HexaGEN™ RF Generator, the Remote Control, and the HexaFLOW™ Irrigation Pump.

Use a dampened, lint-free cloth to clean the housing of the HexaGEN™ RF Generator, the Remote Control, the HexaPULSE™ PF Generator Module, the HexaFLOW™ Irrigation Pump, and accessories. Common hospital cleaning and disinfecting solutions may be used, such as 2% glutaraldehyde solution, green soap, 10% bleach solution, or 70% isopropyl alcohol. Make sure that no liquid penetrates the inside of the HexaGEN™ RF Generator, the Remote Control, the HexaPULSE™ PF Generator Module, or the HexaFLOW™ Irrigation Pump.

9.2 Periodic Maintenance

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

9.3 Service and Repairs

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

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

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

9.4 Disposal

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

10 Technical Description

10.1 Technical Specifications

Table 6. Ablation System Technical Specifications

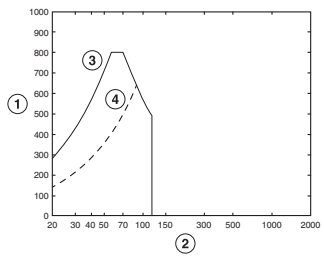
Technical Specifications	
HexaGEN™ RF Generator	
RF power output frequency	488 kHz
RF output voltage	0 - 240 V_{RMS}
RF output current	0 - 3.75 A_{RMS}
RF impedance operating range	20-120 Ω
RF impedance monitoring	8.5 µA, 488 kHz
RF impedance display accuracy	±10%
Return electrode contact quality monitoring	9 µA, 61 kHz
Temperature operating range	20-100 °C
Temperature measurement display accuracy	20 °C - 60 °C ± 1 °C 61 °C - 100 °C ± 2 °C
RF Power display accuracy	±10%
RF Energy display accuracy	±10%
RF Level (% of max I^2) display accuracy	±8%
Mains power	100-240 VAC, 50/60 Hz 1200 VA
Weight	17 kg
Operational Limits	Continuous operation at 50% output level; Operation at 100% output level and 50% duty cycle.
HexaPULSE™ PF Generator Module	
PF Output Voltage (peak)	3333 Vpeak
PF Output Current (peak)	57 A
PF Impedance operating range	20 - 120 Ω
PF Level (% of max Ip-p) display accuracy	±10%
Mains Power	100-240 VAC, 50/60 Hz 300 VA
Weight	11 kg
Operational Limits	Continuous operation at 50% output level; Operation at 100% output level and 50% duty cycle.
HexaFLOW™ Irrigation Pump	

Table 6. Ablation System Technical Specifications (continued)

Technical Specifications	
Flow rate	0-55 mL/min
Air bubble detection	≥2 µL
Maximum output pressure (occlusion)	110 psi
Flow rate accuracy	2-5 mL/min ± 1 mL/min 6-30 mL/min -5% / +15% 31-55 mL/min ± 25%
Mains Power	100-240 VAC, 50/60 Hz 150 VA
Weight	11 kg
Remote Control Power Supply	
Remote Control Power Supply input	100-240 VAC, 50/60 Hz 60 VA
Remote Control Power Supply output	24 VDC 2.5 A Medical grade isolation
Environmental Conditions	
Ambient operating range	10 °C - 40 °C 30% to 85% relative humidity (non-condensing)
Transportation conditions	-29 °C - 60 °C 30% to 85% relative humidity (non-condensing)

10.2 RF Output Characteristics

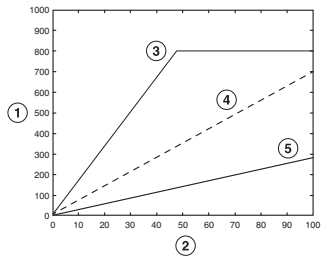
Figure 22. HexaGEN™ RF Generator Output Power vs. Load Impedance



1 Output Power [W]
2 Load Impedance [Ω]
3 Level = 100%
4 Level = 50%

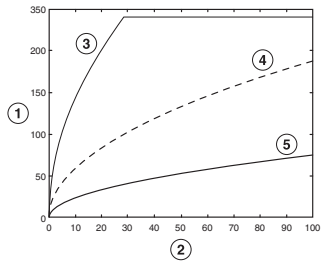
Note: Power delivery is prevented above 120 Ω.

Figure 23. HexaGEN™ RF Generator Output Power vs. Control Setting



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

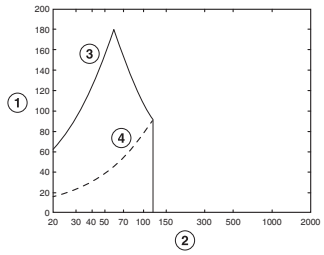
Figure 24. HexaGEN™ RF Generator Output Voltage vs. Control Setting



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

10.3 PF Output Characteristics

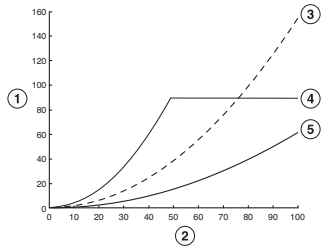
Figure 25. HexaPULSE™ PF Generator Module Output Power vs. Load Impedance



1 Output Power [W]
2 Load Impedance [Ω]
3 Level = 100%
4 Level = 50%

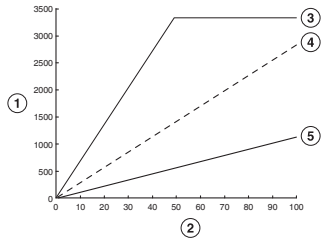
Note: Power delivery is prevented above 120 Ω.

Figure 26. HexaPULSE™ PF Generator Module Output Power vs. Control Setting



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

Figure 27. HexaPULSE™ PF Generator Module Peak Output Voltage vs. Control Setting



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

10.4 Use Environment and Electromagnetic Compatibility (EMC)

The Affera Ablation System is intended for use in a cardiac catheterization laboratory or surgical suite environment by trained personnel only. The Affera Ablation System can be stacked with the Prism-1™ Mapping System HexaMAP™ Catheter Interface Unit on the Affera System Cart.

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

Table 7. Electromagnetic Emissions Environment

The Affera Ablation System is intended for use in the electromagnetic environment specified below. Users of the Affera Ablation System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR11	Group 1	The Affera Ablation System must emit RF energy for its intended function. Nearby electronic equipment may be affected. If necessary, increase the distance between the Affera Ablation System and the affected electronic equipment to reduce interference.
RF emissions CISPR11	Class A	The emissions characteristics of the Affera Ablation System make it suitable for use only in industrial areas and hospitals.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Warning: To maintain basic safety and essential performance of the Affera Ablation System throughout its service life, ensure the following:

- Do not operate the Affera Ablation System stacked on or in close proximity with other electrical equipment other than the Prism-1™ Mapping System. If adjacent or stacked use is necessary, the system should be observed prior to use to verify normal operation in the configuration in which it will be used.
- Use only compatible Affera accessories.
- Do not modify the Affera Ablation System or accessories in any way.
- Do not operate the Affera Ablation System if any components appear damaged.

The Affera Ablation System generates the following frequencies for its operation:

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

Table 8. Electromagnetic Immunity Environmental Guidance

The Affera Ablation System is intended for use in the electromagnetic environment specified below. Users of the Affera Ablation System 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 ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	±2 kV on AC Mains ±1 kV on signal and control lines	±2 kV on AC Mains ±1 kV on signal and control lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	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	Drop to 0 V for 0.5 Cycle Drop to 0 V for 1 Cycle 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Drop to 0 V for 0.5 Cycle Drop to 0 V for 1 Cycle 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the use of the Affera Ablation System requires continued operation during power mains interruptions, it is recommended that system be powered from an uninterruptible power supply or battery. Tested at 100 VAC/60 Hz and 240 VAC/50 Hz
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.

Warning: The Affera Ablation System may be interfered with/by other equipment, even if the other equipment complies with CISPR emission requirements.

Warning: Portable and Mobile RF Communications Equipment can affect the operation of the Affera Ablation System. Refer to the information provided in *Table 9* to ensure minimum safe operating distance is observed.

Table 9. Recommended Separation Distances Between Portable and Mobile RF Communications Equipment

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

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 V_{RMS}, 6 V_{RMS} from 150 kHz to 80 MHz 80% AM at 1 kHz	3 V_{RMS}, 6 V_{RMS} from 150 kHz to 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be separated from the Affera Ablation System by no less than the recommended separation distances calculated/listed below: $D = (3.5/3)\sqrt{P}$ 150 kHz to 80 MHz $D = (3.5/3)\sqrt{P}$ 80 MHz to 800 MHz $D = (7/3)\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum power rating in watts and *D* is the recommended separation distance in meters.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	E1 = 3 V/m	
Radiated RF Proximity fields IEC 61000-4-3	3 V/m - 28 V/m	3 V/m - 28 V/m	

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

Maximum Output Power of Adjacent Communications Equipment (W)	**Recommended Separation Distances** (m)		
	150 kHz to 80 MHz $D = 1.1667\sqrt{P}$	80 to 800 MHz $D = 1.1667\sqrt{P}$	800 MHz to 2.5 GHz $D = 2.3333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.378
100	11.667	11.667	23.333

10.5 Essential Performance

The essential performance of the Affera Ablation System is defined as the following:

HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module:

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

HexaFLOW™ Irrigation Pump:

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

10.6 Legend to Accompanying Symbols

The table below defines symbols used on this product and its packaging, as well as accessory products and associate packaging. Refer to the packaging and product labels to determine product-specific information, such as the date of manufacture and use-by date.

Table 10. Symbols used on Labeling

	Consult user manual
	Caution
	Start/Stop button
	Return electrode connection
	Isolated High Frequency Patient Circuit
	Defibrillator-proof Type CF patient connection
	System interconnect link
	Auxiliary PF
	Input connection

Table 10. Symbols used on Labeling (continued)

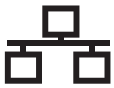
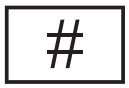
	Output connection
	Serial data connection
	System communication connection
	Foot pedal connection
	Equipotential connection
	Serial number
	Catalog reference number
	Component model number
	Manufacturer
	Date of manufacture
	European authorized representative
	Contact manufacturer for disposal instructions
	Do not reuse
	Do not use if package is damaged

Table 10. Symbols used on Labeling (continued)

	“Use By” date
	Contains 1 product
	Consult instructions for use
	Lot or batch number
	Unique Device Identifier
	Medical device
	Alternating current
	Fuse
	Non-ionizing electromagnetic radiation
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
	Importer
RF Generator	RF Generator
PF Generator	PF Generator Module
Irrigation Pump	Irrigation Pump
Remote Control	Remote Control

11 Notifications

The following notifications may be encountered during use of the Affera Ablation System. If the problem persists, please contact Affera.

11.1 HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications

Error Code	Title	Description / Recommended Action
0000	**Ablation Current Too High**	Verify appropriate impedance and adequate stability of the ablation catheter. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or the ablation catheter.
0001	**Ablation Voltage Too High**	Verify appropriate impedance and adequate stability of the ablation catheter. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter.
0002	**Impedance Too High**	Ablation impedance is higher than the maximum limit specified in Settings. Impedance limits can be adjusted in Settings. Verify the return electrode placement and contact quality. Verify appropriate ablation catheter location. Disconnect and reconnect the return electrodes, return electrode adapter, and ablation return link. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter.
0003	**Impedance Too Low**	Ablation impedance is lower than the minimum limit specified in Settings. Stop ablation and contact support.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0004	**Ablation Power Too High**	Verify appropriate impedance and adequate stability of the ablation catheter. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter. Power cycle the RFG and PFG.
0005	**RF Ablation: Low Output Efficiency**	Stop ablation and contact support.
0006	**Catheter Temperature Too High**	Catheter temperature is higher than the maximum limit specified in Settings. Allow the ablation site to cool. Ensure adequate ablation catheter contact and stability. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter.
0007	**Pump Stopped: Bubble Detected**	Remove the ablation catheter from the patient. Verify adequate supply of irrigation solution. Verify the tubing set mounting. With the ablation catheter outside the patient, clear bubbles using **PURGE**.
0008	**Catheter Temperature Acquisition Error**	Power cycle the RFG and PFG.
0010	**Internal System Temperature Too High**	Pause ablation and wait for the system to cool. Ensure the RFG and PFG side and back panels are not obstructed and are properly ventilated. Power cycle the RFG and PFG.
0011	**RF Ablation: No Temperature Increase**	Temperature increase was not detected during RF delivery. Verify adequate ablation catheter contact and stability. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter. Power cycle the RFG and PFG.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0012	**Impedance Change Rate Too High**	Impedance change during RF delivery exceeded maximum limit specified in Settings. Verify adequate ablation catheter contact and stability.
0013	**Return Electrode Fault Detected**	Verify return electrode placement and contact quality. Disconnect and reconnect return electrodes, return electrode adapter, and ablation return link. Power cycle the RFG and PFG.
0014	**Ablation Current Measurement Fault**	Verify appropriate impedance and adequate stability of the ablation catheter. Power cycle the RFG and PFG.
0015	**Ablation Voltage Measurement Fault**	Verify appropriate impedance and adequate stability of the ablation catheter. Power cycle the RFG and PFG.
0016	**Catheter Reference Temp Too High**	Ablation catheter reference temperature is too high. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter. Power cycle the RFG and PFG.
0017	**Catheter Reference Temp Too Low**	Ablation catheter reference temperature is too low. Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter. Power cycle the RFG and PFG.
0018	**Patient Temperature Too High**	Patient temperature measured with ablation catheter is too high. Verify patient temperature using other means (thermometer). Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0019	**Patient Temperature Too Low**	Patient temperature measured with ablation catheter is too low. Ensure the ablation electrode is outside the sheath and in the blood pool. Verify patient temperature using other means (thermometer). Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter.
0020	**No Pre Ablation Temp Decrease**	No temperature decrease detected just prior to energy delivery. Repeat the energy delivery. Verify patient temperature using other means (thermometer). Fully disconnect and reconnect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter.
0021	**RF Ablation: Output Voltage Fault**	RF output voltage is too high. Power cycle the RFG and PFG.
0022	**Hardware Error: Input Voltage Too High**	Power cycle the RFG and PFG.
0023	**Hardware Error: Input Voltage Too Low**	Power cycle the RFG and PFG.
0024	**Return 1 Contact Quality Poor**	Return electrode 1 contact impedance is too high. Verify the return electrode placement and contact quality. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Use the recommended return electrodes. Replace the return electrode.
0025	**Return 1 Contact Quality Invalid**	Return electrode 1 contact impedance is too low. Use the recommended return electrodes. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Replace the return electrode.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0026	**Return 2 Contact Quality Poor**	Return electrode 2 contact impedance is too high. Verify the return electrode placement and contact quality. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Use the recommended return electrodes. Replace the return electrode.
0027	**Return 2 Contact Quality Invalid**	Return electrode 2 contact impedance is too low. Use the recommended return electrodes. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Replace the return electrode.
0028	**Return 3 Contact Quality Poor**	Return electrode 3 contact impedance is too high. Verify the return electrode placement and contact quality. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Use the recommended return electrodes. Replace the return electrode.
0029	**Return 3 Contact Quality Invalid**	Return electrode 3 contact impedance is too low. Use the recommended return electrodes. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Replace the return electrode.
0030	**Return 4 Contact Quality Poor**	Return electrode 4 contact impedance is too high. Verify the return electrode placement and contact quality. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Use the recommended return electrodes. Replace the return electrode.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0031	**Return 4 Contact Quality Invalid**	Return electrode 4 contact impedance is too low. Use the recommended return electrodes. Disconnect and reconnect the return electrode, return electrode adapter, and ablation return link. Replace the return electrode.
0032	**High-Frequency Leakage**	Power cycle the RFG and PFG.
0033	**Return 1 Current Balancing Fault**	Verify the return electrode contact quality and placement near the heart. Power cycle the RFG and PFG.
0034	**Return 2 Current Balancing Fault**	Verify the return electrode contact quality and placement near the heart. Power cycle the RFG and PFG.
0035	**Return 3 Current Balancing Fault**	Verify the return electrode contact quality and placement near the heart. Power cycle the RFG and PFG.
0036	**Return 4 Current Balancing Fault**	Verify the return electrode contact quality and placement near the heart. Power cycle the RFG and PFG.
0037	**Return 1 High Voltage**	Verify the return electrode contact quality and placement near the heart.
0038	**Return 2 High Voltage**	Verify the return electrode contact quality and placement near the heart.
0039	**Return 3 High Voltage**	Verify the return electrode contact quality and placement near the heart.
0040	**Return 4 High Voltage**	Verify the return electrode contact quality and placement near the heart.
0041	**Internal Monitoring Out of Range**	Internal system voltage or temperature is out of range. Pause ablation and wait for the system to cool. Ensure the RFG and PFG side and back panels are not obstructed and are properly ventilated. Power cycle the RFG and PFG.
0042	**Internal Communication Error**	Power cycle the RFG and PFG.
0043	**Return 1 Excessive Heating Factor**	Return electrode 1 Heating Factor is too high. Increase the waiting time between RF deliveries.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0044	**Return 2 Excessive Heating Factor**	Return electrode 2 Heating Factor is too high. Increase the waiting time between RF deliveries.
0045	**Return 3 Excessive Heating Factor**	Return electrode 3 Heating Factor is too high. Increase the waiting time between RF deliveries.
0046	**Return 4 Excessive Heating Factor**	Return electrode 4 Heating Factor is too high. Increase the waiting time between RF deliveries.
0047	**Temperature Calibration Failed**	Fully disconnect and reconnect the Catheter Extension Cable. Power cycle the RFG and PFG.
0048	**Catheter Temperature Sensor Fault**	One of the catheter temperatures is out of range. Fully disconnect and re-connect the Catheter Extension Cable. Replace the Catheter Extension Cable and/or ablation catheter.
0051	**Pump Housing Open**	Close the door on the Pump.
0052	**Pump Communication Failure**	Ensure the communication cable is properly connected between the Pump and RFG. Power cycle the RFG, PFG, and Pump.
0053	**Pump Flow Mismatch**	Power cycle the Pump.
0054	**Pump Stopped**	Start the Pump.
0055	**No Pump Flow**	Start the Pump.
0057	**No Sound During Ablation**	Try ablating again. Power cycle the RFG and PFG.
0059	**Internal Communication Error**	Power cycle the RFG and PFG.
0060	**Impedance Check Disabled**	Impedance change detection was disabled due to high impedance variability. Verify appropriate impedance and adequate stability of the ablation catheter.
0061	**Temperature Spread Too High**	Large spread in catheter temperature measurements. Move the ablation catheter. Fully disconnect and reconnect the Catheter Extension Cable. Power cycle the RFG and PFG. Replace the Catheter Extension Cable and/or ablation catheter.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0062	**RF Output Error**	Verify appropriate impedance and adequate stability of the ablation catheter. Try ablating again. Power cycle the RFG and PFG.
0064	**Too Few Return Electrodes**	Verify that all four (4) return electrodes are connected. Disconnect and reconnect the return electrodes, return electrode adapter, and ablation return link.
0065	**Voltage Below Target**	PF output voltage was too low. This may be caused by impedance variability. Verify appropriate impedance and adequate stability of the ablation catheter. Do not deliver PF energy near other intracardiac devices. Try ablating again.
0066	**Voltage Above Target**	PF output voltage was too high. This may be caused by impedance variability. Verify appropriate impedance and adequate stability of the ablation catheter. Do not deliver PF energy near other intracardiac devices. Try ablating again.
0068	**Current Below Target**	PF output current was too low. This may be caused by impedance variability. Verify appropriate impedance and adequate stability of the ablation catheter. Do not deliver PF energy near other intracardiac devices. Try ablating again.
0069	**Current Above Target**	PF output current was too high. This may be caused by impedance variability. Verify appropriate impedance and adequate stability of the ablation catheter. Do not deliver PF energy near other intracardiac devices. Try ablating again.
0070	**PF Ablation: Internal Error**	Try ablating again. Power cycle the RFG and PFG.
0071	**RFG to PFG Communication Error**	Disconnect and reconnect the RFG-PFG back panel communication cable on both ends, and then power cycle the RFG and PFG.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0072	**Target Level Too High**	Ablation impedance is too high for the specified Level. Verify appropriate ablation location. Verify return electrode contact quality and placement near the heart. Disconnect and reconnect the return electrodes, return electrode adapter, and ablation return link.
0073	**PFG Hardware Fault**	Power cycle the RFG and PFG.
0074	**Pump Hardware Fault**	Power cycle the Pump.
0076	**PF Invalid Configuration**	Invalid combination of PF ablation parameters applied. Review PF ablation parameters. Try a different PF preset. Reset to Factory.
0078	**PF Ablation: Return 1 or 2 Disabled**	No user action.
0081	**RFG to PFG Communication Error**	Disconnect and reconnect the RFG-PFG back panel communication cable on both ends, and then power cycle the RFG and PFG.
0082	**PF Ablation: Internal Error**	Review PF ablation parameters. Try a different PF preset. Reset to Factory.
0083	**PF Ablation: Internal Error**	Review PF ablation parameters. Try a different PF preset. Reset to Factory.
0084	**PFG Power On Test Failed**	Power cycle the RFG and PFG.
0085	**PF Current Too High**	PF output current was too high. This may be caused by impedance variability. Verify appropriate impedance and adequate stability of the ablation catheter. Do not deliver PF energy near other intracardiac devices. Try ablating again.
0086	**PF Ablation: Internal Error**	Power cycle the RFG and PFG.
0087	**PF Current Measurement Fault**	Verify appropriate impedance and adequate stability of the ablation catheter. Power cycle the RFG and PFG.
0088	**Pump Purge Active**	Release the **PURGE** button to return to idle flow.
0089	**Catheter Prep. Sequence Running**	Wait until the catheter preparation sequence is complete or press the Start/Stop Button on the Pump to stop.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
0090	**RFG to PFG Communication Error**	Disconnect and reconnect the RFG-PFG back panel communication cable on both ends, and then power cycle the RFG and PFG.
0091	**PFG to CIU Communication Error**	Disconnect and reconnect the PFG-CIU back panel communication cable on both ends. Power cycle the RFG and PFG.
0092	**Remote Internal Error**	Power cycle the Remote Control.
0093	**Remote Internal Error**	Power cycle the Remote Control.
0094	**RFG to Remote Communication Error**	Disconnect and reconnect the Ethernet or fiber optic communication cable between the RFG and the Remote Control on both ends. Power cycle the RFG, PFG, and Remote Control.
0095	**Unsupported Catheter Type**	Replace the Catheter Extension Cable and/or ablation catheter.
0096	**PF Output Detected When Not Ablating**	Power cycle the RFG and PFG.
0098	**Ablating in High Impedance Site**	PF current may be below target. Verify appropriate ablation catheter location and impedance. Modify PF ablation preset to stop ablation when impedance is too high.
0099	**Generator Internal Error**	Power cycle the RFG and PFG.
0102	**Start/Stop Button Not Fully Pressed**	Clear alarm to continue. Apply more force to the center of the RFG Start/Stop Button.
0103	**Foot Pedal Not Fully Pressed**	Clear alarm to continue. Apply more force to the Foot Pedal.
2200	**Generator Low Disk Space**	Contact Affera support.
2201	**Generator Low Memory**	Contact Affera support.
2202	**Generator High CPU Temperature**	Contact Affera support.
2203	**Generator Low CPU Frequency**	Contact Affera support.
2400	**Remote Low Disk Space**	Contact Affera support.
2401	**Remote Low Memory**	Contact Affera support.
2402	**Remote High CPU Temperature**	Contact Affera support.

Table 11. HexaGEN™ RF Generator and HexaPULSE™ PF Generator Module Notifications (continued)

Error Code	Title	Description / Recommended Action
2403	**Remote Low CPU Frequency**	Contact Affera support.
2600	**Pump Low Disk Space**	Contact Affera support.
2601	**Pump Low Memory**	Contact Affera support.
2602	**Pump High CPU Temperature**	Contact Affera support.
2603	**Pump Low CPU Frequency**	Contact Affera support.

11.2 HexaFLOW™ Irrigation Pump Notifications

Table 12. HexaFLOW™ Irrigation Pump Notifications

Error Code	Description	Action
000	**Bubble detected**	Hold **PURGE** until bubble is cleared from the Tubing Set.
001	Door open	Close the pump housing door.
002	Hardware Error, B001	Bubble Sensor Error. Restart Pump.
003	Hardware Error, H001	Door Sensor Error. Restart Pump
004	**Saline bag low**	Replace the saline bag and reset the counter.
005	**Saline bag empty**	Replace the saline bag and reset the counter.
006	Hardware Error, M001	Motor IO Error. Restart Pump.
007	Hardware Error, M002	Motor Data Error. Restart Pump.
008	Hardware Error, M003	Motor Program Error. Restart Pump.
009	Hardware Error, M004	Motor Communication Error. Restart Pump.
010	Hardware Error, M005	Motor System Error. Restart Pump.
011	Hardware Error, M006	Motor Motion Error. Restart Pump.
012	Hardware Error, M007	Motor Watchdog Error. Restart Pump.
013	Hardware Error, S001	SBC Watchdog Error. Restart Pump.
014	Hardware Error, C001	Pump Watchdog Error. Restart Pump.
015	Hardware Error, O001	Hardware Error. Restart Pump.
016	**Internal Connection**	Cannot communicate with microcontroller. Restart Pump.

12 Disclaimer of warranty

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