AERIN CONSOLE

Model FG2045

Instruction for Use

English (US)

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Aerin Medical relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

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Rx ONLY Caution: Federal law restricts this device to sale by or on the order of a physician.

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DEFINITIONS OF SYMBOLS USED

Symbol	Description
	Warning: Dangerous Voltage
	Caution
	Manufacturer
	Country and Date of Manufacture
	Model Number
	Foot Switch
	Medical Device
	Catalogue number
	Quantity
	Consult instructions for use
	Serial Number
	Batch Code
	Type BF applied part
	Temperature Limit
	Humidity Limitation
	Please dispose properly by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment in accordance with applicable local and national legislation procedure and requirements.
	Earth Reference Point
	Non-Ionizing Radiation

Symbol	Description
	Back Button
	RF ON Button
	RF Stop Icon
	View Utilization Log Button
	Export Utilization Log Button
	Detail View Button
	Page Up Button
	Page Down Button
	User/Login Page Button
	Do Not Twist Icon
	Ohms, Unit of Impedance Measurement
	System Volume
	Temperature
	Alternating Current
	Power
	Treatment Duration
	Cooling Time
	Display Brightness
	Apposition Audible Indicator Icon

Symbol	Description
	Apposition Visual Indicator Icon
	Power-On Self Test (POST)
	Keep Away From Sunlight
	This End Up
	Keep Dry
	Fragile, Handle With Care
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.
	MRI Unsafe

SECTION A – OVERVIEW

1. SYSTEM DESCRIPTION

The Aerin Console is an AC (alternating current) radiofrequency generator. It incorporates user interface software to control, monitor and regulate RF power delivery to soft tissues via a cable-connected electrosurgical handpiece and electrode. The Aerin Console set consists of the following items (Figure 1.0):

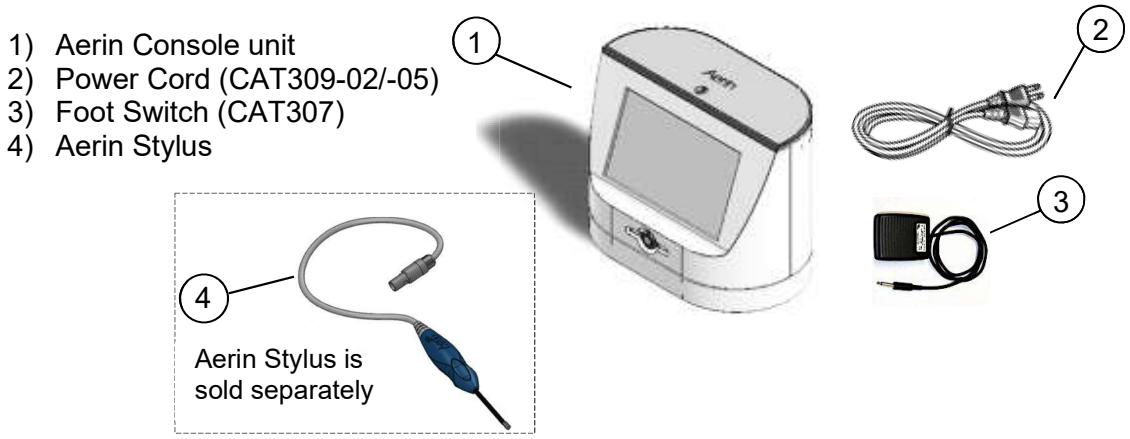


Figure 1.0 – Aerin Console

2. ADDITIONAL EQUIPMENT NEEDED

The Aerin Console is designed to be compatible with an Aerin Medical Stylus only. Refer to the Instructions for Use (IFU) for the particular Stylus for treatment settings and additional operating instructions.

3. INTENDED USE AND INDICATION FOR USE

The Aerin Console is an electrosurgical system intended to generate radiofrequency (RF) electrical current for the use of an Aerin Medical Stylus. The Aerin Console is indicated for use in small clinics, offices or hospital environments.

4. INTENDED USER

The Aerin Console is intended for use by, or under the direct supervision of, qualified medical personnel trained in the use of electrosurgical equipment.

5. CONTRAINDICATIONS (When should the device not be used)

- Aerin Console is not recommended for usage other than intended use.
- Aerin Console should only be used with an approved Aerin Medical Stylus.

6. WARNINGS & PRECAUTIONS

- The Console is intended for use with an Aerin Medical Stylus, Power Cord (CAT309-02/05) and the Foot Switch (CAT307) provided by Aerin Medical. The safety of use with other surgical ablation devices, catheters, or accessories has not been assessed.
- DO NOT attempt to operate the Console before thoroughly reading this Instructions For Use. It is vital that the operating instructions for the equipment is read, understood, and followed properly. For future reference, retain this IFU in a convenient, readily accessible place.
- Do not remove the cover of the Console. Removal of the cover may result in injury and/or damage to the Console.
- The Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Instruction For Use. Electromagnetic disturbance could affect the Console's RF power delivery, impedance and temperature accuracy.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Console including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The use of accessories and cables other than those specified by Aerin Medical, may result in increased emissions or decreased immunity of the Console.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

- Failure of the Console could result in an unintended increase of output power.
- DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- Only physicians trained on Aerin Medical products and techniques should perform RF procedures using the Console and an associated Aerin Medical stylus.
- DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
- DO NOT place the Console near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
- Patient should not come into contact with earthed metal parts or parts with appreciable capacitance to earth (e.g., operating table supports, etc.).
- Temporarily store unused active electrodes in a location isolated from patient. Inadvertent contact with the patient may result in burns.
- Aerin Medical relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of the Console.
- The mains power cord of the Console must be connected to a properly grounded receptacle.
- Inspect all components and cable insulation prior to each use for any obvious signs of damage that may have occurred during transit, storage and/or prolong usage. Insulation failures may result in burns or other injuries to the patient or operator.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.
- DO NOT activate the Stylus when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.
- Build-up of eschar may reduce the Stylus’s effectiveness. Do not initiate treatment while cleaning. Injury to user may result.
- This device has not been evaluated in the pediatric population.

- The power cord and foot switch may be a trip hazard. Ensure that all cords are out of areas where people may walk.
- **MRI SAFETY INFORMATION**– The Aerin Console has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Aerin Console in the MR environment is unknown. Performing an MR exam on a person while using this medical device may result in injury or device malfunction.
- **MAGNET WARNING:** Keep this medical device 6 inches (15cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, stents and shunts.
- **CALIFORNIA PROPOSITION 65 WARNING**

  WARNING: This product contains a chemical known to the State of California to cause cancer.

  WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

SECTION B – DESCRIPTION

1. PACKAGING INFORMATION

The Aerin Console Set shipping carton contains the following:

- 1 Console Unit
- 1 Power Cord
- 1 Foot Switch

Notify the distributor immediately if the shipment carton is damaged. If it is necessary to return and ship the Console back to the distributor or manufacturer, use the original shipping carton and packaging materials to repack the console and ensure that no breakage occurs. Disconnect the power cord and Foot Switch and place them into their respective locations in the carton.

2. CONTROLS AND CONNECTORS

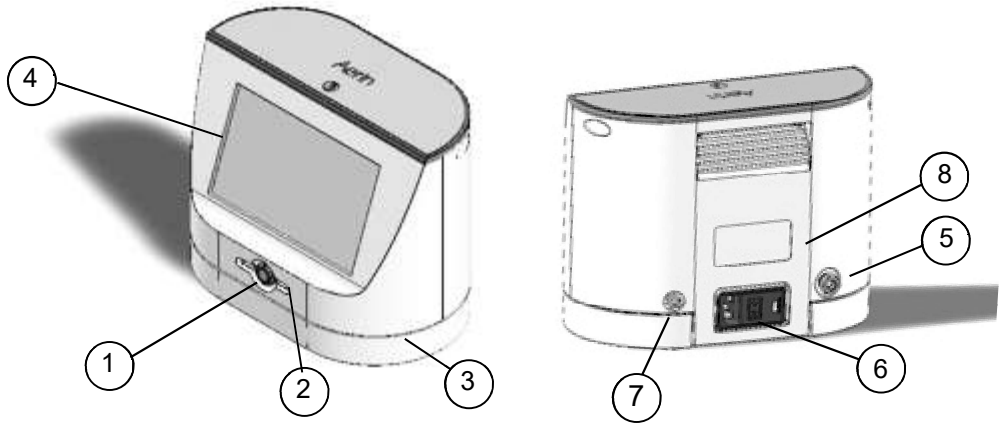


Figure 2.0 Aerin Console Controls and Connectors

1) Stylus Connection – Provides connection for the Aerin Stylus.
2) RF ON Indicator Light – Constant blue light indicates RF power is being delivered.
3) Power-ON Light Ring – Indicates the Power-ON status of the Console.
4) Touch Screen Display – Main user interface.
5) Foot Switch connection – Provides connection for the Foot Switch.
6) Main Power Switch and Connection – The power cord connects to the Main power connector, on the right side is the Main power switch for switching the Console ON or OFF.

7) Equipotential Ground Connection – This connector is attached to the chassis/earth ground reference. It is intended for earth reference connection in environments where equipotential ground cabling is used.

8) Label – Indicates required labeling information.

3. TOUCH SCREEN DISPLAY

The Console's touch screen display is intuitively designed for users to easily perform treatment with the default recommended settings. Once a Stylus is plugged in, the Console will automatically set the recommended treatment parameters for the device such as the temperature, power and time. The user has an option to access a Detail View page where the settings and actual treatment parameters can be viewed.

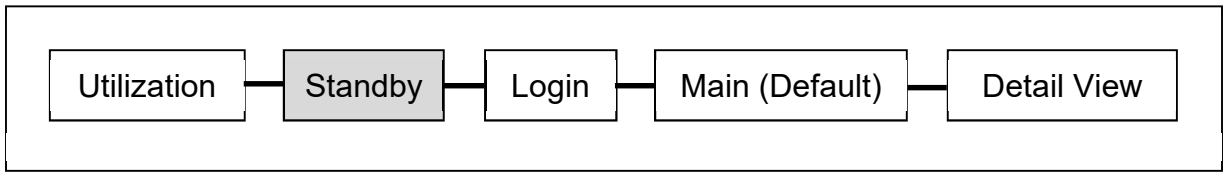


Figure 3.0 Console's Touch Screen Display User Interface Pages

3.1. Default Treatment Page

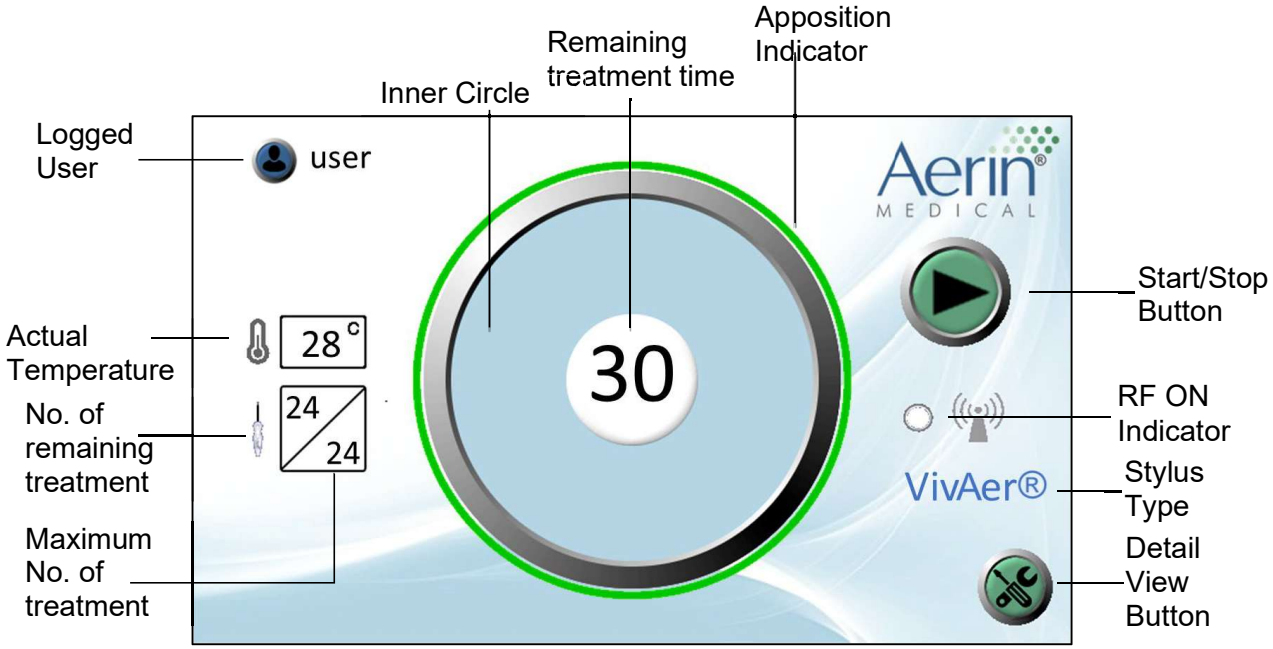


Figure 3.1 Default Treatment Page

- Actual Temperature – shows the temperature read by the Stylus.
- No. of remaining treatment – shows the remaining treatments for the connected Stylus.
- Maximum number of treatments – shows the maximum treatment allowed for the connected stylus.
- Inner Circle – Shows visual status of the treatment progress turns to Dark Blue when delivering RF energy and Gray during cooling time (if any).
- Remaining Treatment Time – Treatment time remaining, countdown until zero.
- Start/Stop Button – On-screen Button to Start or Stop the treatment.
- RF ON Indicator – Lights up when the treatment is in progress to show that the Console is delivering RF Power.
- Stylus Type – Shows the Product name of the connected Aerin Medical Stylus.
- Detail View Button – Goes to Detail View Page.
- Logged User – Shows the name of current user.
- Apposition Indicator (Green Ring) – Indicated good contact with tissue.

3.2. Detail View Page

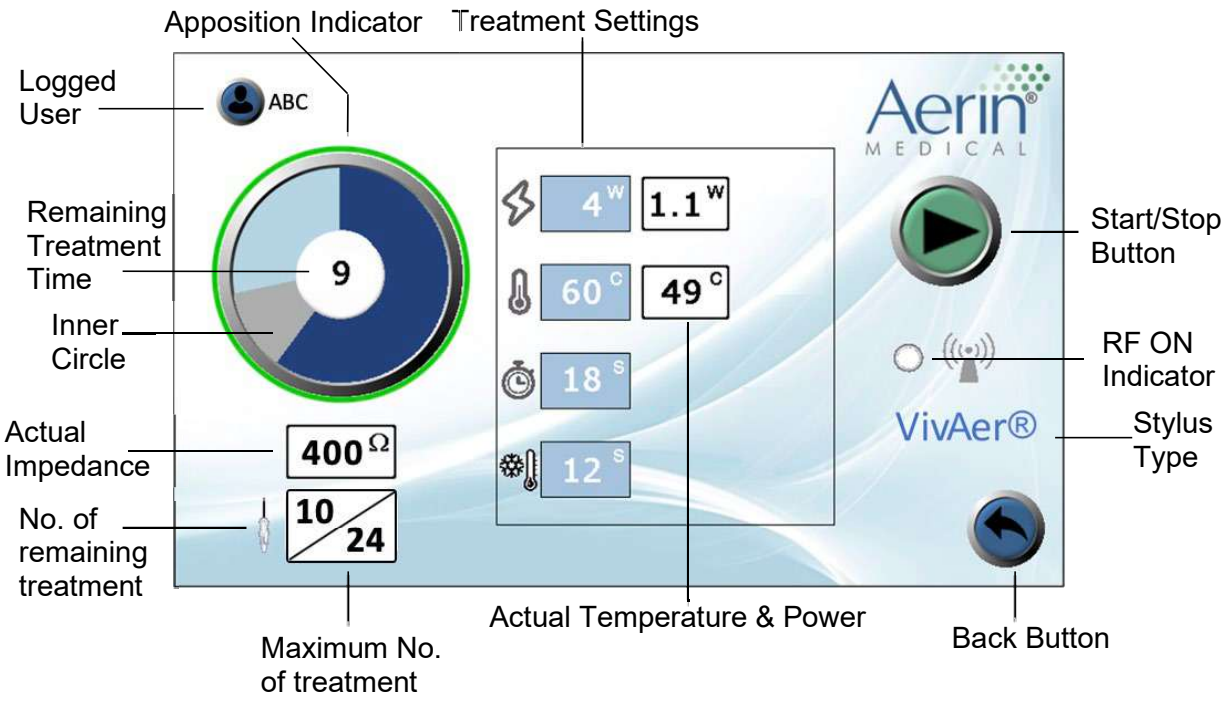


Figure 3.2 Detail View Page

- Remaining Treatment Time – Treatment time remaining, countdown until zero.
- Inner Circle – Shows visual status of the treatment progress turns to Dark Blue when delivering RF energy and Gray during cooling time (if any).
- Actual Impedance – Displays the actual impedance reading.
- No. of remaining treatment – shows the remaining treatments for the connected Stylus.
- Maximum number of treatments – shows the maximum treatment allowed for the connected stylus.
- Treatment Settings – Displays the settings for power, temperature, treatment duration and cooling duration.
- Actual Temperature and Power – Displays the actual Power delivered and Temperature read.
- Start/Stop Button – On-screen Button to Start or Stop the treatment.
- RF ON Indicator – Lights up when the treatment is in progress to show that the Console is delivering RF Power.

- Stylus Type – Shows the Product name of the connected Aerin Medical Stylus.
- Back Button – Goes to Main default treatment page.
- Logged User – Shows the name of current user
- Apposition Indicator (Green Ring) – Indicates good contact with tissue

3.3. Login Page

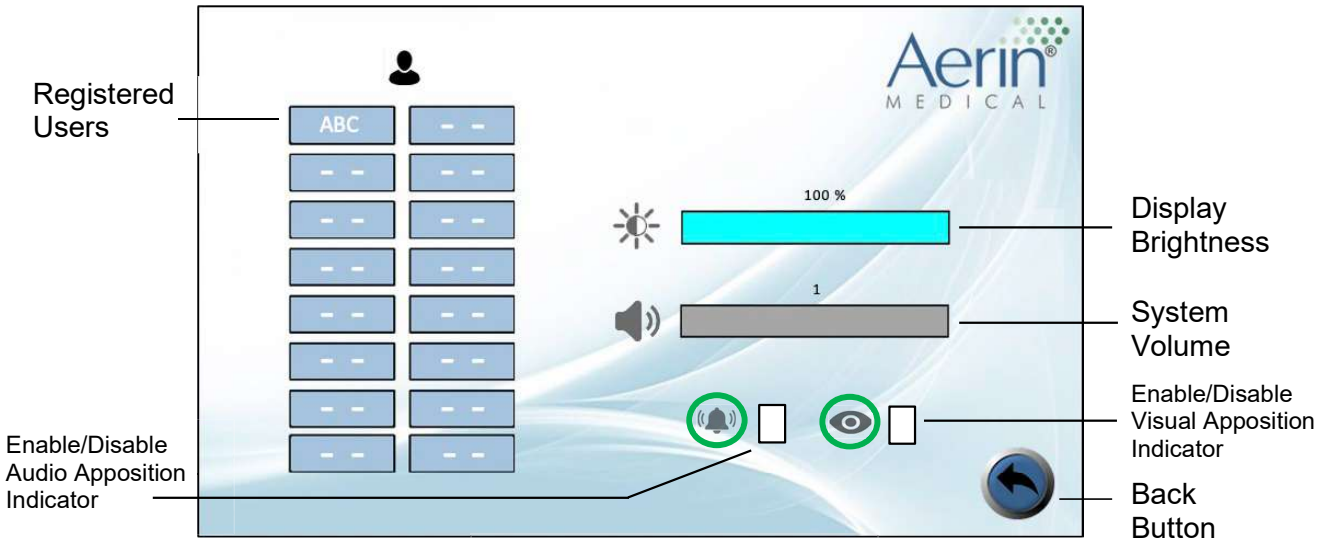


Figure 3.3 Login Page

- Display Brightness – User adjustable display brightness
- System Volume – User adjustable system volume
- Back Button – Goes to Standby Page (see Figure 3.4) if no Stylus is connected.
- Registered Users – List of registered users.
- Apposition indicator options
    - If Visual indicator is ON, option to toggle off Audible indicator
    - If Visual indicator is OFF, Audible indicator is grayed out

3.4. Standby Page

Figure 3.4 Standby Page

- Utilization Log Button – Goes to the Utilization Log Page (Figure 3.6)
- Do Not Twist Symbol – Informs users not to twist the Stylus when inserting or while it is plugged in the Console.
- Logged User – Shows the name of current user (if any)

3.5. Error/Fault Page

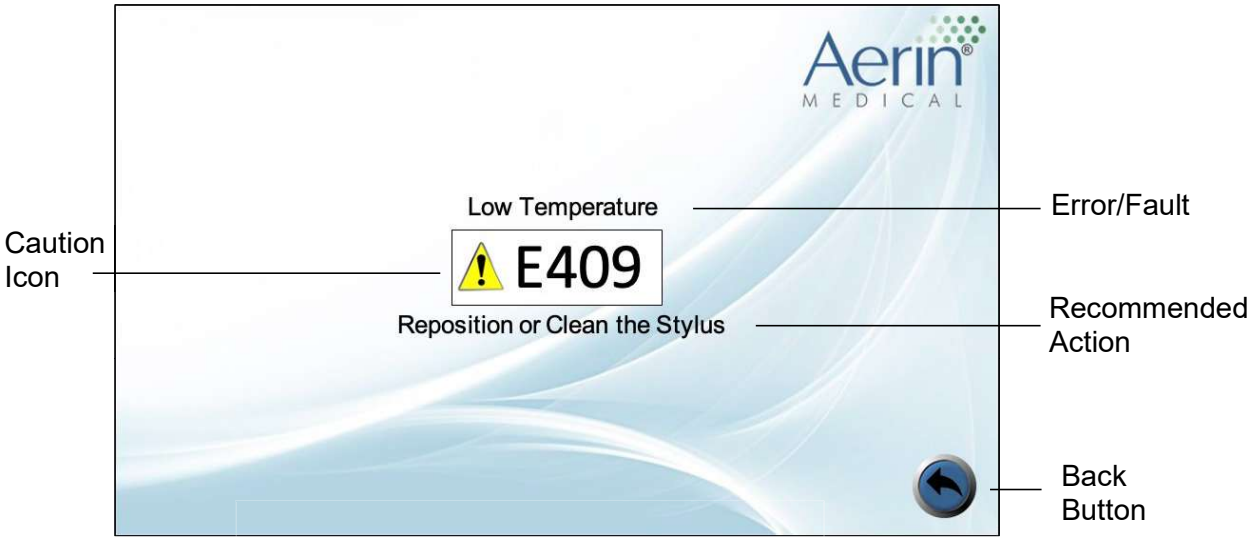


Figure 3.5 Error/Fault Page

- Error/Fault Code – Refer to Table 2 for the error and fault code descriptions.
- Error/Fault – Displays the type Error or Fault

- Back Button – Goes to the previous page before the error/fault occurred.
- Recommended Action – Possible steps that can be taken by the user to resolve the issue.

Notes:

- To exit the Error page, press on the foot switch or tap the Back Button
- To exit the Fault page, restart the Console by pressing the power switch Off then On.

3.6. Utilization Log Page

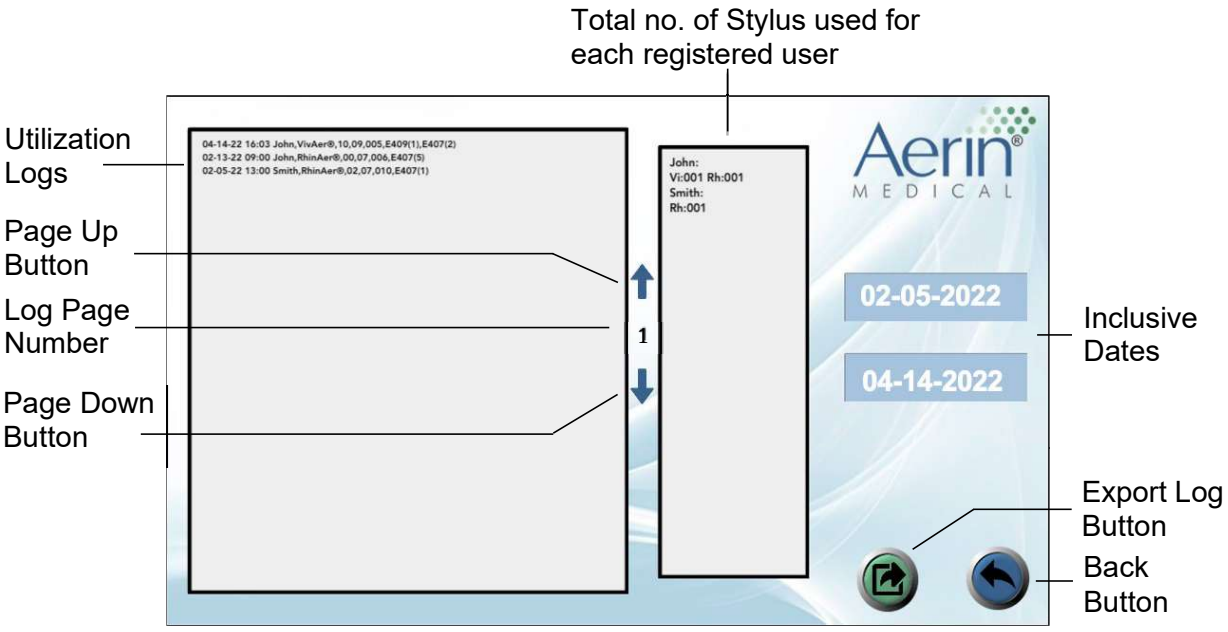


Figure 3.6 Utilization Log Page

- Utilization Logs – Displays the following utilization log data for each Stylus:

  "Date of first use (MM-DD-YY hh:mm), User, Stylus Product Name, No. of partial treatment, No. of full treatment, Total Case duration, Errors"

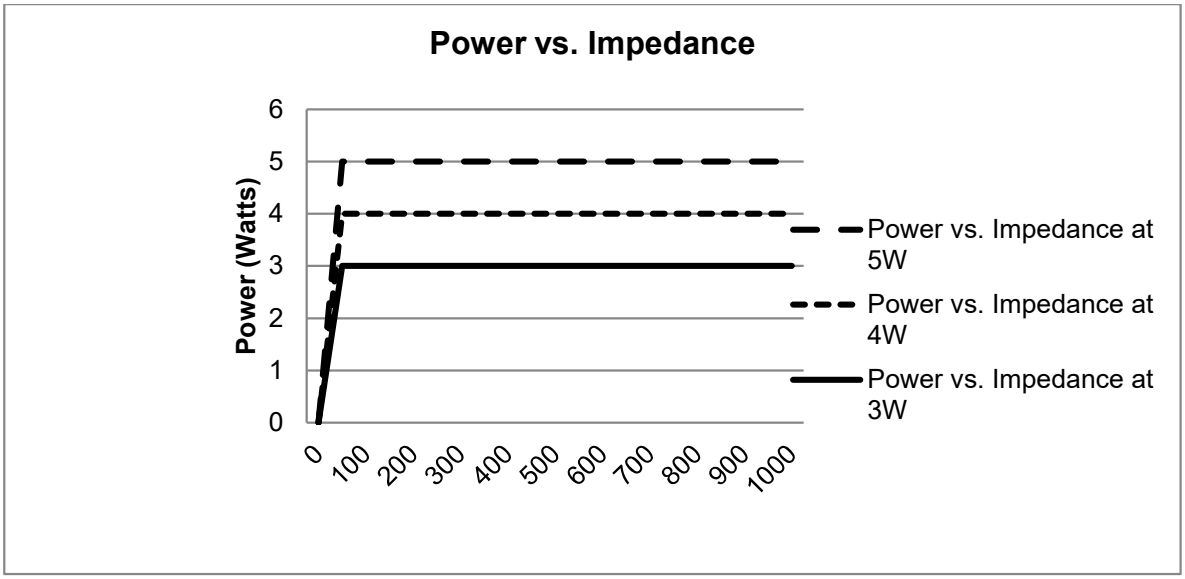
- Total no. of Stylus per user – Summary of all the Stylus used per user within the inclusive dates. Only the current registered users are listed.
- Inclusive Dates – Dates when the first and last recorded Stylus usage.
- Export Button – Tap to export the utilization log to an external memory dongle. (Used by Aerin Medical Personnel only).
- Log Page Number – Shows the page number of the log (1-10)

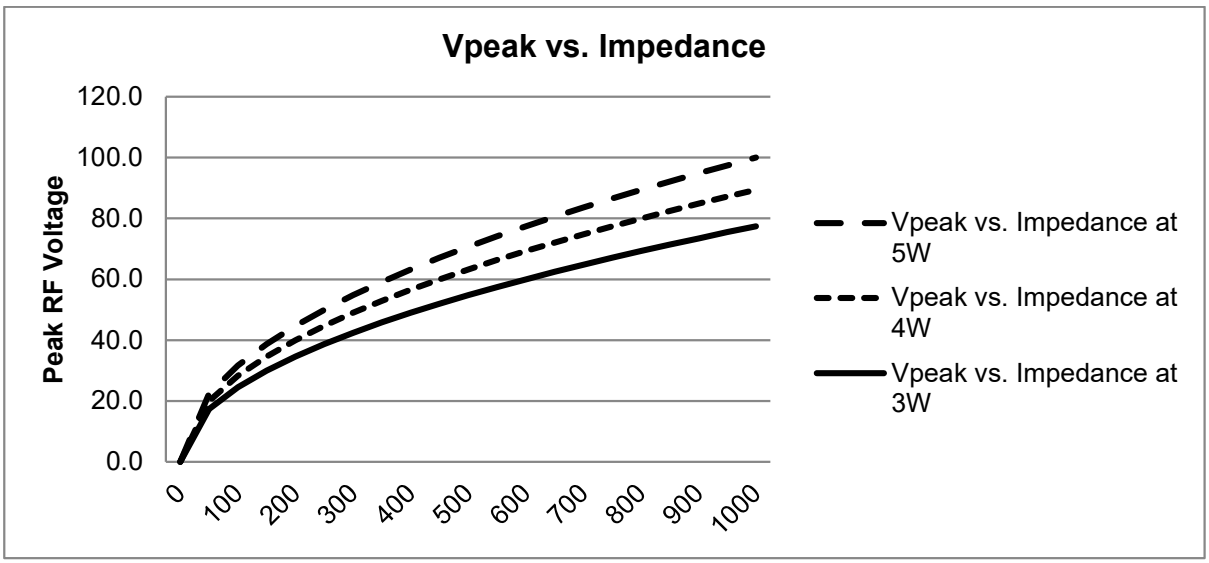
- Page Up Button – Scrolls up the utilization logs displayed on the Console, each page contains 40 records.
- Page Down Button – Scrolls down the utilization logs displayed on the Console, each page contains 40 records.

4. GENERAL SPECIFICATIONS

Line Power		100-240 VAC 50/60 Hz
Current Rating		3A RMS
Fuse Rating		3A
Power Cord Length		8 or 15 ± 1 ft (2.44 or 4.57 ± 0.3 meters)
Stylus Connector		Quick Connect female 8-pin
Temperature Accuracy		± 5°C
RF Output	Power	3 – 5 W ± 20%
	Frequency	460 ± 5 kHz
Impedance Range		100-700 ohms ± 20%
Count Down Timer Display Resolution		1 second
Accessory Rated Voltage		70.7Vrms
Dimensions	Length	6.5” (16.51cm)
	Width	10” (25.40 cm)
	Height	7.5” (19.05 cm)
Weight		< 22 lb (10 kg)

5. POWER DELIVERY





6. SOFTWARE FLOWCHART

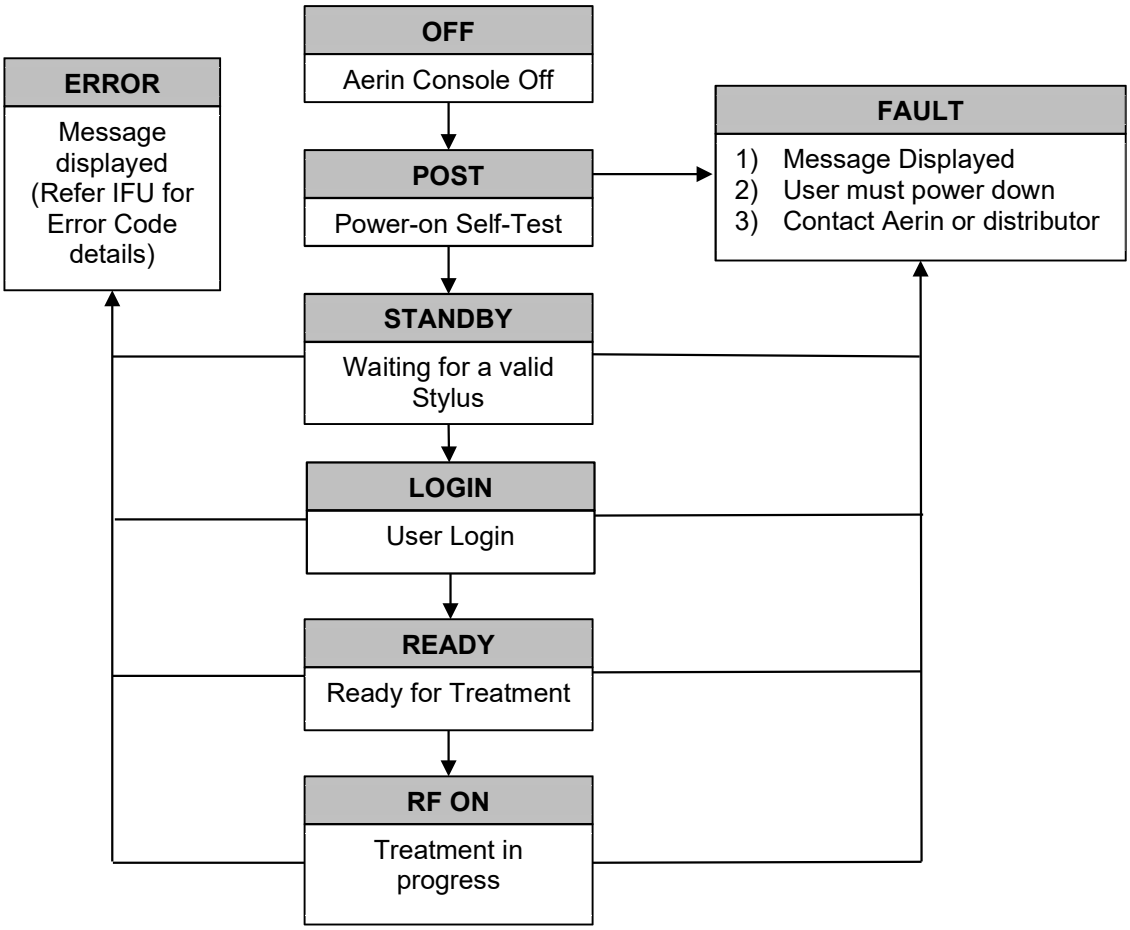


Figure 6.0 Console Software Flowchart

6.1. P.O.S.T

The power-on-self-test mode is initiated when the Console is turned ON. The Power-On-Self-Test (POST) icon is displayed during POST. In this mode, the LED light at the base of the Console will light up white followed by amber/yellow, red and blue at the Stylus connection port LED momentarily.

6.2. STANDBY

The Console will enter into Standby mode if the system has no faults and no Stylus connected. The “Standby – Insert Stylus” image can be seen at the screen (Fig. 3.4). The start button & Foot Switch are disabled.

6.3. READY

The Console will enter Ready mode and the LED at the Stylus connection port will start flashing blue. If there is a valid Stylus connected the screen automatically goes to the default treatment page. The Console is now ready for treatment. The start button & Foot Switch are enabled.

6.4. LOGIN

The Console will enter Login mode if a valid stylus is inserted. The user must choose a registered user from the list or create a new one. If there is only 1 registered user, the screen automatically goes to the default treatment page. The start button & Foot Switch are enabled.

6.5. RF ON

The “RF ON” indicator on Figure 3.1 and 3.2. is displayed while the RF power is being delivered and the blue LED light at the Stylus connection port will be constantly on.

6.6. FAULT

The Console will enter Fault mode in a safe state when the software determines an unrecoverable fault within the system. The caution icon is displayed with the fault code and symbol, the Stylus connection port LED light will also light up red.

6.7. ERROR

The Console will enter Error mode if there is an operational error that can be recovered by the user, the caution icon is displayed on the screen with the error code and symbol, the Stylus connection port LED light will also light up amber.

6.8. HALT

The Console will enter Halt mode when a catastrophic system failure is detected by the Software or CPU. In this state the Software ensures RF delivery is off and the Stylus connection port LED light will light up orange. Restart the Console by turning power off and on again. Contact Aerin Distributor or Customer Service if the issue persists.

Refer to Table 1 below for the indications of the LED light.

LED Color	Indication	LED location
White	Console Power On	Around base of Console
Amber/Yellow	Error	Stylus Connection Port
Red	Fault	
Orange	Halt	
Blue	Flashing: Ready for RF delivery Non-Flashing: RF delivery in progress	

Table 1 – LED light Indications

7. APPLICABLE STANDARDS

The Console fullfils the requirements of IEC 60601-1:2005+A1:2012, IEC 60601-1:2005/AMD2:2020, ANSI/AAMI ES60601-1:2005/ (R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, EN 60601-1:2006+AC:2010+A11:2011+A1:2013, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD), IEC/EN 60601-1-2:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020, CAN/CSA-C22.2 No. 60601-1-6:11, IEC/EN 60601-2-2:2017, IEC/EN 60601-2-2:2017/AMD1:2023, IEC/EN 62304:2006/A1:2015, IEC/EN 62366-1:2015/AMD1:2020, IEC 61000-4-39:2017

SECTION C – OPERATION

1. SETUP INSTRUCTION

1.1. Read Instructions for Use

Do not operate the Console or accessories before reading their respective Instructions For Use (IFU). It is crucial that the Instructions For Use for the equipment are read, understood, and followed properly.

1.2. Connect the Console Power Cord

Connect the Console's power cord plug into a properly grounded AC electrical outlet. Never use an outlet without a grounding connection. Place the Console on a solid surface and for easy viewing of the front panel touch screen display.

1.3. Connect the Foot Switch

Connect the Foot Switch to the Foot Switch connector located at the back panel of the Console (see Fig. 2.0).

1.4. Turn the Console "ON"

Turn the Console "ON" by pressing the rocker switch located on the back panel (See Fig. 2.0) to the "I" position. The base of the Console will light up indicating that the Power switch has been turned on.

The Console first performs a self-test of the power generation, measurement, and control circuitry. The Console will NOT operate unless the initial self-test is successfully completed. If all is satisfactory, the Console enters STANDBY or LOGIN mode if a valid stylus connected.

If the self-test fails, it enters into the FAULT mode, a "FAULT" error type and description will be displayed on the screen, in addition, a rapid burst of audible tones will be emitted.

If the FAULT mode is entered (i.e., a system malfunction is detected during self- test), the Console should not be used. To clear any malfunctions found during the self-test, the Console must be powered "OFF" and then back "ON" with the self-test repeated. If it fails again, the Console cannot be used properly, contact Aerin Medical for service or replacement.

1.5. Connect the Stylus

Connect the Stylus to the Stylus connector port located on the front panel of the Console. The Console will validate the Stylus, if successful, the Login Page will be shown. Select a user or create a new one. Press the Username box for more than 1 second to edit the username field. If only 1 user is registered/ selected, the Console will automatically apply the correct treatment settings and go to the default treatment screen bypassing the Login step (auto login).

1.6. Confirm the Console and Accessories

Prior to delivering RF power to the Stylus, check that all the connections have been made properly. Confirm that all of the requirements specified in the Stylus Instructions for Use have been met. Only when all the above conditions are met should one proceed to deliver RF power.

2. OPERATING INSTRUCTIONS

2.1. Treatment Instructions

2.1.1. Carefully read the Instructions For Use (IFU) of the Stylus.

2.1.2. Connect the Stylus to the Stylus connector located on the front panel of the Console.

2.1.3. Select the user from the Login Page or create a new one by pressing the user field for more than 1 second. Press Enter to save the user. The user will be logged out if the Console is turned off or if the user navigates to the Login page by pressing the Registered User button.

2.1.4. The Console will verify if the inserted Stylus is valid.

2.1.5. The Console will automatically detect the Stylus Model and apply the default treatment settings.

2.1.6. Apply conductive media (e.g., saline gel) to the Stylus tip then position the electrode-containing portion of the tip of the Stylus against the target tissue and exert gentle pressure.

2.1.7. If apposition indicator (visual and audible) is toggled on, a visual indicator will display (green ring will appear) along with audible sound signaling good contact with tissue to initiate treatment.

2.1.8. Continuously press the Foot Switch or the On-Screen Start Button to start the treatment, releasing the Foot Switch/Start Button will pause the treatment, the treatment will completely stop if the Foot Switch/Start Button is not pressed within 2 seconds.

2.1.9. Apply consistent pressure with the Stylus against the tissue for the entire duration of the treatment.

2.1.10. The total treatment duration countdown timer (including the cooling time) will be displayed inside the treatment circle together with a visual indicator of the overall treatment progress.

2.1.11. Remove the Stylus tip from the treatment area once the treatment is completed. Inspect the electrodes for eschar or material build-up; if necessary, gently wipe the tip with sterile gauze.

CAUTION: Build-up of eschar may reduce the Stylus's effectiveness. Do not initiate treatment while cleaning. Injury to the user may result.

2.1.12. Repeat Steps 2.1.5 to 2.1.9 for additional treatment cycles.

NOTE: If an Error is presented, refer to section 3 to troubleshoot. The Error may be cleared by pressing the foot switch or pressing the Back Button.

2.1.13. Upon completion of desired treatment cycle(s), turn off the Console by pressing the Main AC power switch to "0" position located at the rear panel. Dispose of the Stylus according to its Instructions For Use.

3. TROUBLESHOOTING, SERVICE AND MAINTENANCE

Displayed Error Text	Displayed Code	Recommended Action Text	Description	State
High Power	**E402**	Restart Treatment	RF power measurement is above 10 Watts for 500 milliseconds	During RF Delivery
Low Impedance	**E403**	Reposition or Clean the Stylus	Stylus resistance measurement is below 100Ω for one second	
Phase Limit	**E404**	Restart Treatment	Measured RF phase is above 2500 ADC counts for one second	
High Internal Temperature	**E405**	Check ambient temperature (too low/high)	Internal Console temperature is outside the range 15°C to 47°C	
Data Failure	**E406**	Restart Treatment	Background data acquisition did not occur at expected rate	
High Impedance	**E407**	Reposition or Clean the Stylus	Stylus resistance measurement is above 800Ω for one second	
High Temperature	**E408**	Reposition or Clean the Stylus	Stylus temperature measurement is more than 5°C over the temperature set point for 500 milliseconds	
Low Temperature	**E409**	Reposition or Clean the Stylus	Stylus temperature measurement did not reach the temperature set point within the first 10 seconds or anytime during the RF delivery time when the temperature is below 5°C of the temperature set point	

Displayed Error Text	Displayed Code	Recommended Action Text	Description	State
Abnormal Temperature	**E410**	Check or Reposition Stylus	Stylus temperature decreases or did not change within the first 3 seconds	
Invalid stylus	**E490**	Replace Stylus	Stylus is invalid (corrupt or invalid data in its Stylus Data Blocks)	During VALIDATE state. Condition is cleared by Disconnecting stylus.
Usage limit	**E491**	Replace Stylus	Stylus has reached its number of uses limit	
Disconnect Limit	**E492**	Replace Stylus	Stylus has performed at least one complete RF delivery cycle and has been disconnected from a Console for longer than 20 minutes	
Initialization Failure	**F504**	Restart Console	Background data acquisition did not occur at expected rate during RF Delivery test	At end of Self-Test
RF Test Failure	**F505**	Restart Console	Diagnostic Mode exited normally (not user-accessible)	Continuously after Self-Test has finished
Self-Test Power Failure	**F506**	Restart Console	RF power measurement outside expected range during RF Delivery test	At end of Self-Test
Self-Test Resistance Failure	**F509**	Restart Console	Electrode resistance measurement outside expected range during RF Delivery test	At end of Self-Test
Self-Test Internal Temperature Failure	**F511**	Check ambient temperature (too low/high)	Internal Console temperature is outside the range 15°C to 47°C during Self-Test	At end of Self-Test

Displayed Error Text	Displayed Code	Recommended Action Text	Description	State
Self Test Footswitch Error	**F512**	Check Footswitch	Footswitch ON at end of Self Test	At end of Self Test
Clock Failure	**F513**	Restart Console	Real-Time Clock battery dead or date/time setting invalid	At end of Self Test
Memory Failure	**F514**	Restart Console	Non-volatile settings bad (CRC failed or on-board EEPROM bad)	At start of Self Test
CPU Error	**F515**	Restart Console	CPU watchdog expired; software failed to reset the watchdog timer within 500 milliseconds	Continuously checked
Corrupt Memory	**F516**	Restart Console	CPU attempted to execute an illegal instruction opcode; this can be an indication of software error or corrupt program memory.	Continuously checked
Clock Failure	**F517**	Restart Console	Real-time clock time reading is not advancing as expected.	At end of Self-Test
Display Failure	**F518**	Restart Console	Display initialization failure, or Communication failures that persist for one second	During Self-Test or During RF Delivery

Table 2: Error and Fault Code List

3.1. Service & Maintenance

The Console requires no routine service or maintenance. If the Console fails to operate (in Fault Mode) when plugged into a proper AC power receptacle and the POWER Switch is turned “ON”, contact Aerin Medical. The Console contains no user-serviceable parts. Disassembly and attempted repair by unqualified personnel may create a hazardous condition and will void the warranty.

DO NOT remove the cover of the Console. Removing the cover may result in personnel injury and/or damage to the Console.

4. THERMAL PROFILE DATA

When used with an Aerin Stylus the Thermal Profile of the lesions is representative of the following settings: 4W/60°C/18s which are the programmed settings for VivAer Stylus.

Example of lesion profile on different tissues with VivAer Stylus

Tissue Type	Average Lesion Volume ($mm^{3)}$ L x W x D	Approximate Lesion Dimensions		
		Length (mm)	Width (mm)	Depth (mm)
Bovine Liver	31.9	6.3	4.5	1.2
Porcine Ear	16.5	6.1	4.2	0.6
Chicken Breast	46.0	6.6	5.4	1.2

5. CLEANING

The outer surface of the Console may be cleaned with a mild soapy solution. DO NOT immerse the Console or its accessories in any liquid. Avoid caustic or abrasive cleaners. If disinfecting is required, isopropyl alcohol may be used to clean outer surfaces.

The Aerin Console enclosure and touch screen display are constructed of polycarbonate, ABS plastics and glass. Refer to the material safety data sheet (MSDS) or material specification for alternate cleaners or disinfectants to ensure compatibility with the above materials.

Typical disinfectants used to wipe down similar medical equipment are generally compatible with the materials mentioned above.

The following list of products have undergone limited testing by Aerin Medical and have been found to be safe for use for on the exterior surfaces of the Aerin Console. Should any damage, degradation, or discoloration to the Aerin Console be observed using these products, please discontinue the use and notify Aerin Medical.

1. PDI Super Sani-Cloth Germicidal Disposable Wipe (P/N: Q55172)
2. PDI AF3 Sani-Cloth Germicidal Disposable Wipe (P/N: H59200)

6. SAFE DISPOSAL

Disposal of Console shall be in accordance with applicable local and national legislation and requirements.

7. PERMISSIBLE ENVIRONMENTAL CONDITIONS

Parameters	Transport/Storage	Usage
Temperature	-20°C to 60°C	10°C to 40°C
Relative Humidity	10% to 85%	Max 80% RH (non-condensing)
Pressure	59.5 kPa – 101.3 kPa	18.7 kPa – 101.3 kPa

7. ELECTROMAGNETIC EMISSIONS AND IMMUNITY DECLARATION

7.1. Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Aerin Console FG2045 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Aerin Console should ensure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Console uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The Console is suitable for use in industrial areas, hospitals and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations/ Flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 3.1 Electromagnetic Emissions

7.2. Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Aerin Console FG2045 is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerin Console should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	*U*T = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) *U*T = 40%; 10 cycle *U*T = 70%; 25 cycles *U*T = 0%; 250 cycle	< *U*T = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) *U*T = 40%; 10 cycle *U*T = 70%; 25 cycles *U*T = 0%; 250 cycle	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the Console requires continued operation during power mains interruptions, it is recommended that the Console be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 3.2 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Aerin Console FG2045 is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerin Console should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Console, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms & 6Vrms 150 kHz to 80 MHz	3 Vrms & 6 Vrms 150 kHz to 80 MHz	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz
	Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an

			electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Console is used exceeds the applicable RF compliance level above, the Aerin Console should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Aerin Console. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 3.2 Electromagnetic Immunity, IEC/EN 60601-1-2 Table 204

Recommended separation distances between portable and mobile RF communications equipment and the Console			
The Aerin Console FG2045 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Aerin Console can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aerin Console as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 3.3 Recommended separation distances between portable and mobile radio frequency (RF) communication equipment and the Aerin Console. IEC/EN 60601-1-2 Table 206

8. CYBERSECURITY

The Aerin Console (FG2045) contains a 4G cellular module. The cellular function is not used to support the intended use or performance of the medical device.

The 4G cellular module is used solely for the device manufacturer to send utilization logs to a secure cloud database. This cellular interface is restricted allowing communications to the Aerin Medical secure cloud; and is not networked to any hospital environment. The cellular interface does not affect device operations. This console does not contain any protected health information (PHI) data. Alternatively, the utilization logs may be retrieved via the serial I2C interface within the Stylus port with a proprietary dongle, which is used only by the device manufacturer.

If you detect a security vulnerability, please refer to our Coordinated Vulnerability Disclosure Policy at *http://aerinmedical.com/cybersecurity/*.

An SBOM is available upon request, send request to *security@aerinmedical.com*.

Additional information can be found in the MDS2 form provided upon request, send request to *security@aerinmedical.com*.

9. WIRELESS INFORMATION

The Aerin Console (FG2045) contains a 4G Cellular Module with functionality limited to transmitting device Utilization Logs generated during normal operations to a secure cloud database. The Aerin Console does not rely on healthcare delivery organization infrastructure for networking, as it features its own dedicated cellular connection for log transmission. The Aerin Console does not require the use of the cellular function; the device will continue to perform as intended without interruption, without 4G wireless connectivity. The specifications for the 4G Cellular Module are listed below:

Transmitter Frequency Band	LTE (CAT-M1): Band 4: 1710 – 1775 MHz Band 13: 777 – 787 MHz
Modulation Type	LTE: QPSK/16-QAM
Antenna Type and Gain	Internal
Antenna Gain (Transmit Power)	LTE Band 4: 2 dBi , LTE Band 13: 0 dBi
Maximum Transmit Power	Band 4: 164.44 mW, Band 13: 200.91 mW

The Aerin Console (FG2045) complies with FCC Part 15 Subpart B:2024, ICES-001 Issue 5.

Standards	Description	Severity Level or Limit	Criteria	Test Result
FCC Part 15 Subpart B:2024, ICES-001 Issue 5	Radiated Emissions	Class A, 30 - 1000 MHz Class A, 1000 - 18000 MHz	Limit	**Complies**
FCC Part 15 Subpart B:2024, ICES-001 Issue 5	Conducted Emissions	Class A, 150 kHz - 30 MHz	Limit	**Complies**

- The levels of radiated spurious emissions from the Aerin Console (FG2045) were evaluated for the potential for the device to cause radio frequency interference to other electronic devices. The Aerin Console (FG2045) complies with CFR Title 47, Subchapter B §Part 27.
- **RF Exposure Safety**
  The Aerin Console (FG2045) complies with the FCC RF exposure limits and has been evaluated in compliance with single RF source device exposure conditions.
- **Class A Device Notice**
  The Aerin Console (FG2045) has been tested and found to comply with the limits for a Class A device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in business, industrial and commercial environments only. This device generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications.

8. DISCLAIMER AND LIMITATION OF LIABILITY

No agent, employee or representative of Aerin Medical has the authority to bind the Company to any other warranty, affirmation or representation concerning the product. This warranty is valid only to the original purchaser of Aerin Medical products directly from an Aerin Medical authorized agent. The original purchaser cannot transfer the warranty.