

Synergy^{RF}™ System

User Manual

Important Product Information



DFU-0221-EO
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Symbols glossary can be found at arthrex.com/symbolsglossary



Synergy^{RF} System

The Synergy^{RF} system user manual provides safety operation information for all components of the Synergy^{RF} console (Model AR-9800), including accessories. All operating personnel must read this user manual thoroughly prior to using this system and follow all safety warnings, cautions, and notes.

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General Warnings, Training and Safety Notices - Read This First

 It is imperative that the symbols and conventions listed below be clearly understood. The Synergy^{RF} system *user manual* identifies critical, important, and useful information using these symbols and conventions.

Important Safety Conventions

Warnings and safety conventions follow International Electrotechnical Commission (IEC) 60601-1 and IEC 60601-2-2.

Users of this device are encouraged to contact their Arthrex representatives if they require a more comprehensive surgical technique.

 **WARNING!** The WARNING! is the most important safety symbol. It identifies **critical** information that must be followed precisely to avoid injury or death.

1.  Caution: Federal law restricts this device to sale by or on the order of a physician.
2.  This device is intended to be used by a trained medical professional.
3. **Failure** to follow the set-up instructions and/or continuing to use the console (AR-9800) without resolving an alarm could result in a serious patient adverse event.
4. **Failure** to adhere to the set-up instructions and use of Arthrex certified devices may result in inaccurate sensing and feedback by the device. It is imperative that the user is aware of the potential compromise in patient safety when an alarm on the console is ignored or silenced incorrectly. **NEVER** ignore or silence alarms. Follow appropriate troubleshooting procedures and carefully monitor the patient. **Only** Arthrex certified devices must be used.

5. This device is only for use in normal arthroscopic procedures as described in the user manual, under the supervision of a trained and licensed physician. This device should not be used by untrained personnel or used for indications other than those described in this user manual.
6. **No** modification of the console (AR-9800) or accessories are allowed.
7.  **DO NOT** open or attempt to service this system,  as this may void your warranty. There are no user-serviceable parts inside. Removing the cover may introduce an electric shock hazard by exposing you to dangerously high voltages or other risks. If the system malfunctions, return it for service immediately.
8. To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAIN with Protective Earth Terminal.
9. **DO NOT** stack or place equipment adjacent to the AR-9800 console, if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.
10. **Use only** Arthrex approved accessories. Other accessories may result in increased emissions or decreased immunity of the system. Contact your Arthrex representative for a complete list of accessories. **DO NOT** modify any accessory. Failure to comply may result in patient and/or operating room staff injury.
11.  **DO NOT** use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide, oxygen, or endogenous gases. All oxygen connections must be leak free for the duration of the surgical procedure.

12. Do not have the device in direct contact with the patient, if the patient requires defibrillation.
13. The safety and effectiveness of the AR-9800 is verified and documented; however, the AR-9800 must be used with an awareness of the risk of damage to surrounding tissue through iatrogenic injury.
14. Always start with the lowest possible power setting to achieve the desired effect.
15. Small electric arcs between the active electrode and tissue being resected can produce low-frequency current that may produce local neuromuscular stimulation. Per standard of care, ensure that the patient's arms and/or legs are supported appropriately.
16. Biohazard waste, such as explanted devices, needles, and contaminated surgical equipment, should be safely disposed of in accordance with the institution's policy.
17. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.



The PRECAUTION! symbol identifies methods and procedures that must be followed to avoid damaging the device or causing it to malfunction.

1. **DO NOT** – under any condition or for any reason – open the console (AR-9800) or any other accessory.
2. **DO NOT** disconnect the foot pedal unit from the console by pulling on the cable. Retract the connector tab and gently pull on the body of the connector to remove the cable from the console.
3. **Only use** replacement power cords that meet medical grade standards according to the International Electrotechnical Commission (IEC) 60320-1 Subclause 3.21, Detachable Power Supply Cords or electrical standards for the designated country where the AR-9800 is being used. Contact your Arthrex representative for further information.
4. **Avoid** positioning the console so that it is difficult to disconnect coupler or plug from supply main.
5. To prevent electrical shock, do not use extension cords or 2 to 3 pronged adaptors.
6. **Always** use fuses with the correct values to avoid allowing overcurrent to enter the system.
7. An incorrect fuse may increase the risk of electrical shock or fire hazard.

8. This device has passed testing for Electromagnetic Interference (EMI) / Radio Frequency Interference (RFI) radiation and susceptibility and Electromagnetic compatibility (EMC). This device may cause interference to other devices in the near vicinity if not set-up and used as Arthrex instructs.
9. **Do not** attach compatible disposable devices or footswitches during the Self Test or the Programming Modes.
10. **Do not** detach a disposable device or footswitch from the console while the disposable device or footswitch is activated. The disposable device will stop functioning if this is attempted.
11. **Only use** footswitches developed by Arthrex specifically for the AR-9800 Synergy^{RF} console.
12. **Only use** disposable devices developed by Arthrex specifically for the Synergy^{RF} console.
13. The footswitch cable connects and locks to the console to prevent accidental separation during use. To avoid damage, **always** disconnect the footswitch by pulling on the cable connector shell (plug) only.
14. The accessory device cable connects to the console. To avoid damage, **always** disconnect the accessory device by pulling on the cable connector shell (plug) only.
15. **Always** comply with the instructions issued by the manufacturer of the cleaning disinfectant regarding concentration, exposure times, temperature and material compatibility.
16. **NEVER** use liquid to clean the accessory device connector contacts. Remove dust regularly with dry compressed air.
17.  **Do NOT** clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.
18. **NEVER** allow the console receptacles to have any contact with liquids. If there is dust or moisture on the receptacles, remove with dry compressed air. **ONLY** dry connectors should be plugged into the console.
19. Liquid on the cable connector of the accessory device can damage the device. Before connecting the cable, ensure the receptacles are clean and dry.
20. For aspirating probes/disposable devices **ALWAYS** attach the suction tube connector to an adequate suction source. **ALWAYS** ensure the suction control valve on the device is open to ensure proper circulation of fluid.
21. Refer to the Directions for Use for the Apollo^{RF} disposable devices (DFU-0242-XX) for detailed device cleaning and sterilization instructions included with each device. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex Representative.

NOTE: This identifies information and training that can simplify the set-up and operation of this device.

1. *The user should be experienced in arthroscopic surgical techniques before using the Synergy^{RF} system.*
2. *Read this user manual thoroughly before operating the device, and save it for future reference. For additional information and training, contact your local Arthrex representative.*
3. *If required by local regulations, connect the console to the hospital equalization connector with an equipotential cable. Connect the power cord to a wall outlet having the correct voltage. Otherwise, product damage may result.*

(The equipotential connector provided complies with IEC 60601-1:2005/A1:2012. The proper use of equipotential cables and equipotential earthing systems must be governed by local hospital and regulatory requirements)

4. *The AR-9800 console incorporates a universal alternating current (AC) input power supply. A voltage selection switch is not required.*
5. *AR-9800 has been designed to accept EMC from other devices within the limitations as described in the **Electromagnetic Emissions** section.*
6. *Set-up for a footswitch is the same for all models. The console detects which version is attached and allows appropriate functions.*
7. *Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or contact your Arthrex representative for an onsite demonstration.*

Symbol Definitions

All of the symbols used on the labeling along with the title, description and standard designation number may be found on our website at www.arthrex.com/symbolsglossary.

	RF probe handpiece
	Time Burst

Shipping, and Unpacking Information



Carefully unpack and inspect all components for shipping damage. Do not use the disposable Apollo^{RF} device (probe) if packaging is damaged and sterile barrier has been compromised.

Any damage could compromise patient safety and should be reported immediately to Arthrex or any authorized Arthrex distributor. The warranty could be voided if shipping or first-installation damage is not reported within seven (7) business days of receiving the device. Refer also to our General Terms of Business.

The warranty is not valid if modifications are made to the product or repairs are completed outside of Arthrex or an authorized Arthrex distributor. Arthrex will answer any questions referring to the quality, reliability and/or shelf life of any product identified in this *user manual*.

Information

In CE Accepting Countries: Procedures carried out using these devices may be used on the general population.

In CE Accepting Countries: The clinical benefits associated with the use of these devices outweigh the known clinical risks.

In CE Accepting Countries: There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

Product Description and Intended Use

Product Description

The Synergy^{RF} generator is classified as an FDA Class II medical device. The Synergy^{RF} generator is an advanced electrosurgical generator utilizing feedback from the surgical site such as, voltage, current and power. It is designed to meet the needs of arthroscopic surgical procedures. The generator has an advanced output control algorithm using feedback systems that are capable of adjusting the output as the tissue characteristics change. This will result in a more consistent clinical effect at the surgical site.

The Supply Main is applied to the console from a detachable power cord.

The console is activated by a footswitch and/or hand switch.

The front panel display is a touch screen, back lit Liquid-crystal display (LCD) display that is used to select between ABLATE and COAG (coagulation) and provides a means for power adjustment, mode information, and warning/caution indicators of the generator status.

The AR-9800 Synergy^{RF} generator contains hardware for disposable device recognition.

The AR-9800 Synergy^{RF} generator, Applied Parts and accessories:

- AR-9800 Synergy^{RF} generator
- Power cord
- User's Guide
- Accessory Radio Frequency (RF) devices (probe, supplied separately)
- Synergy^{RF} system footswitch (supplied separately)

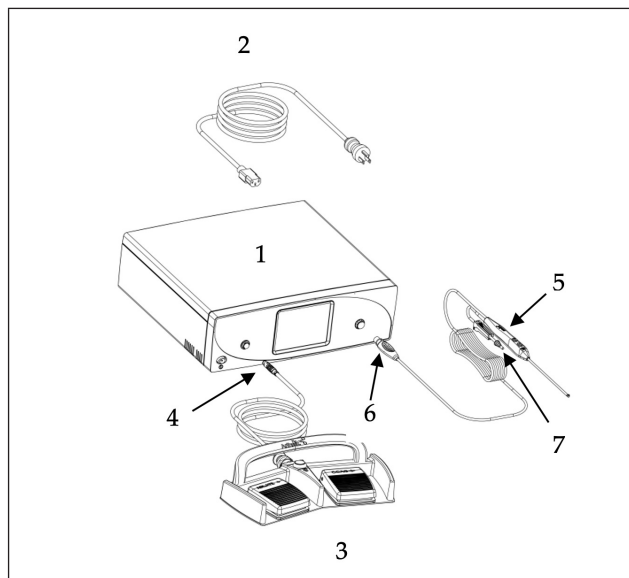


Figure 1 Connection Diagram

Table 1 Connection Elements

1	Generator/Console
2	Power cord
3	Footswitch
4	Footswitch cable connector
5	RF ablation device (probe)
6	Probe cable connector
7	Suction tube connector

Save the packaging for later transport of the device.

Indications for Use and Contraindications

Indications for Use

The Arthrex Synergy^{RF} System, when used with an Apollo^{RF} Ablation Device (Probe), is intended for use as a complete system in the resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures. Specifically, the ablation devices, electrosurgical generator and their accessories are used for arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, foot and ankle.

Contraindications

The Arthrex Synergy^{RF} system is contraindicated in any procedure where a conductive solution is not used. The system is also contraindicated for patients who have cardiac pacemakers or other electronic implants without specific instructions from the manufacturer of the pacemaker or implant. Please refer to the RF Probe Directions for Use for a comprehensive list of contraindications regarding specific procedures. The generator is not intended to be used with a neutral electrode.



WARNING! Use this device only under the supervision of a trained and licensed physician. This device should not be used by untrained personnel or used for indications other than those described in this *user's guide* and the RF ablation probe Directions for Use.

Product Features

AR-9800 Console - Front View

Figure 2 shows the front panel of the AR-9800 console. The features and symbols are identified in Table 2 below.

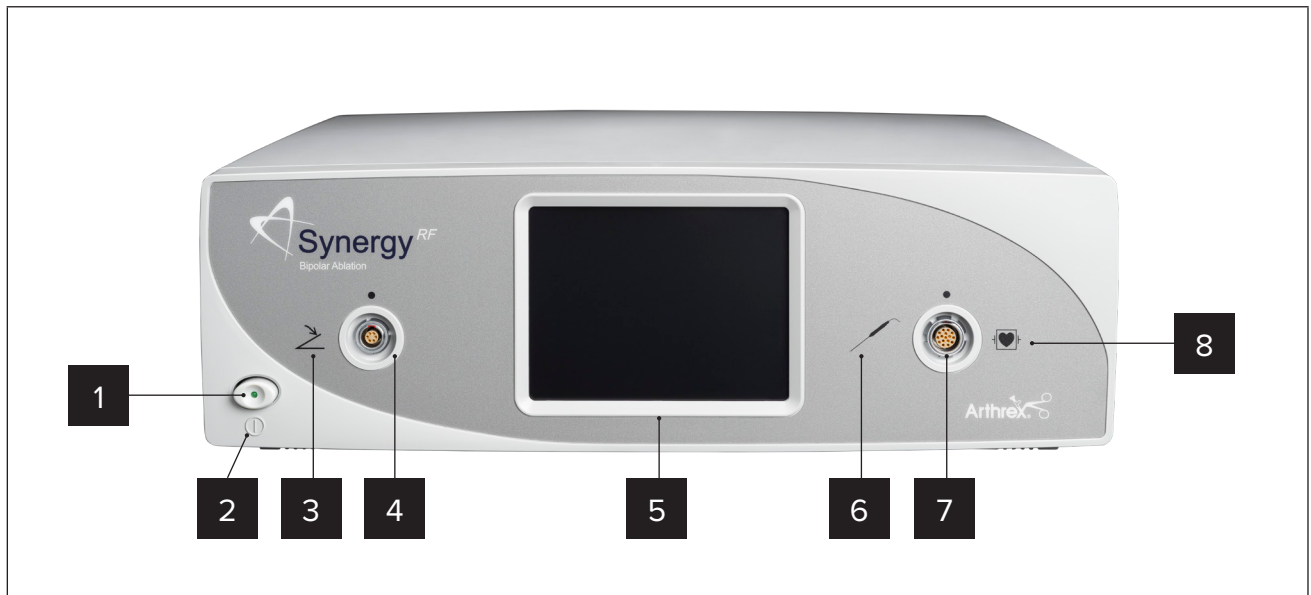


Figure 2 Front Panel of Console

Table 2 Front Panel Elements

1	On / Off power switch
2	Power switch IEC 60417-5010 symbol (On / Off)
3	Footswitch symbol
4	Footswitch connector
5	Touch screen display
6	Probe handpiece symbol
7	Probe handpiece connector
8	Type Cardiac Floating (CF) symbols (electric shock protection)

AR-9800 Console - Rear View

Figure 3 shows the rear panel of the console. The features and symbols are identified in Table 3 below.

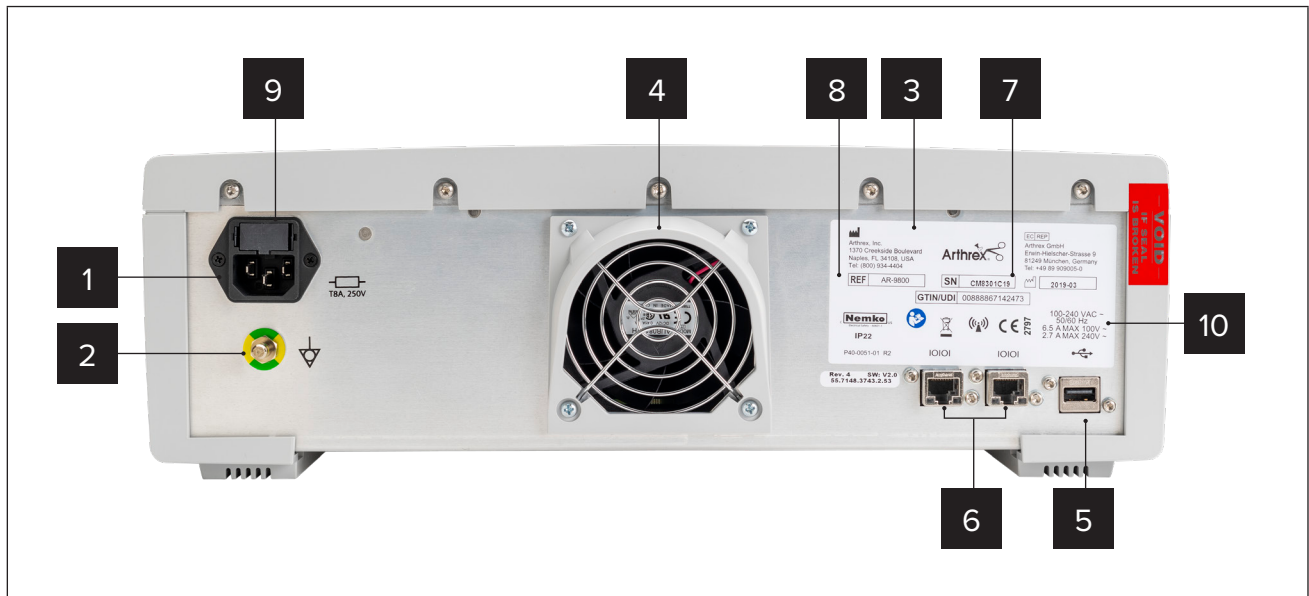


Figure 3 Rear Panel of Console

Table 3 Rear Panel Elements

1	Supply main input plug
2	Equipotential bonding pin with stamped equipotential bonding symbol
3	Address label
4	Fan
5	Universal serial bus (USB) port (For use ONLY by service technicians)
6	Serial ports for Arthrex integration (to only be connected to IEC 60601-1 approved equipment)
7	Serial number label
8	Model number label
9	Fuse holder for the Power Entry Module
10	Fuse label

AR-9800 Display Messages

The console's touch screen display Figure 2 [5] provides information about the status of the AR-9800 settings in real time. A list of informational and error messages is shown in Table 4. Error display messages reported to Arthrex technical services should include the Error Message and Error Code for reference (See Figure 4).

Table 4 AR-9800 Display Messages

Message	Explanation
"Ablation Footswitch Stuck"	A button on the footswitch is stuck. Replace the footswitch.
"COAG Footswitch Stuck"	A button on the footswitch is stuck. Replace the footswitch.
"PROBE Already Used"	The RF device attached to the console has either been previously used, or has been disconnected and reconnected. Replace with a new device.
"PROBE Communication Failure"	Communication with the RF device has been lost. Check the connection and replace the device, if necessary.
"Replace Probe"	The RF disposable device attached to the console is malfunctioning.
"System Temperature Failure"	The console temperature is outside of normal parameters, contact Arthrex technical support.
"Turn off and let cool down"	The console has overheated. Power off the console for 10 minutes.
"WRAP Footswitch Stuck".	A button on the footswitch is stuck. Replace the footswitch.
"Contact Technical Services"	Contact Arthrex technical services.
"Configuration File Corruption"	Contact Arthrex technical services.
"Critical Failure"	A terminal fault has occurred, contact Arthrex technical services.
"LCD File Version Failure"	Touch panel failure, contact Arthrex technical services.
"LCD Communications Failure"	Touch panel failure, contact Arthrex technical services
"Main Calibration Required"	Contact Arthrex technical services.
"Power Supply Calibration Required"	Power supply self-check failure, contact Arthrex Technical Services.
"Power Supply Communications Failure"	Power supply self-check failure, contact Arthrex technical services.
"Power Supply POST Failure"	Power supply self-check failure, contact Arthrex technical services.
"Power Supply PFC Voltage"	Power supply self-check failure, contact Arthrex technical services.
"Power Supply Excessive Voltage"	Power supply is exceeding the voltage parameters, contact Arthrex technical services.
"Power Supply Excessive Power"	Power supply is exceeding the power parameters, contact Arthrex technical services.
"Relay Failure"	Power supply self-check failure, contact Arthrex technical services.
"RF Output Failure"	Power supply self-check failure, contact Arthrex technical services.
"Touchscreen Circuit Failure"	Touch panel failure, contact Arthrex technical services.

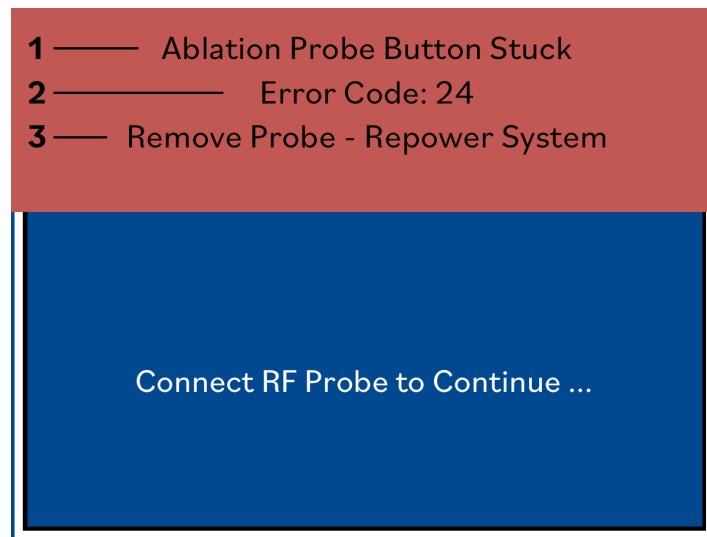


Figure 4 Error Screen Display

Table 5 Error Screen Display – Descriptions

1	Error Message	The description of the error/fault experienced in the system
2	Error Code	The Error Code specifies which error occurred for additional reference for Arthrex technical services
3	Explanation	Provides context of the error/fault

Technical Specifications

Console

Table 6 AR-9800 Console Specifications

Width	40.64 cm (16.00 inches)
Height	13.335 cm (5.250 inches)
Depth	37.338 cm (14.7 inches)
Weight	6.8 kg (15 lbs.)
Water protection	Ingress Protection (IP) IP22
Mains cable	10 A/250 V
Power entry module	IEC 320/C13
Fuse value	8.0 A, 250 V~, 2.0 cm (0.75 inches) Type T
AC input	100-240V~, 50 - 60 Hz, 8.0A, Class I
Applied Part Type	CF
Applied Part Max Length	3.81 m (12.5 feet) maximum cable length.
Peak Power Output	575 Watts (W) (ablate setting 9 with 218Ω load)

Ambient Conditions for Operation

Table 7 AR-9800 Ambient Conditions for Operation

Temperature	10° to 40 °C (50° to 104 °F)
Relative humidity	20% to 75%
Air pressure	700 Hectopascal Pressure unit (hPa) to 1060 hPa (21 in. Hg to 31.3 in. Hg)

Ambient Conditions for Storage (in shipping packaging)

Table 8 AR-9800 Ambient Conditions for Storage

Temperature	-40° to 70 °C (-40° to 158 °F)
Relative humidity	10% to 90%, non-condensing
Air Pressure	500 hPa to 1060 hPa (15 in. Hg to 31.3 in. Hg)

Synergy^{RF} System Footswitch

Table 9 Synergy^{RF} System Footswitch Specifications

Functions	Ablate, Coag, Power setting change
Width	33 cm (13 inches)
Height	7.6 cm (3 inches)
Depth	17.8 cm (7 inches)
Weight	2.77 kg (6.1 lbs.)
Water protection	IP68

Safety, EMC, and Regulatory Requirements

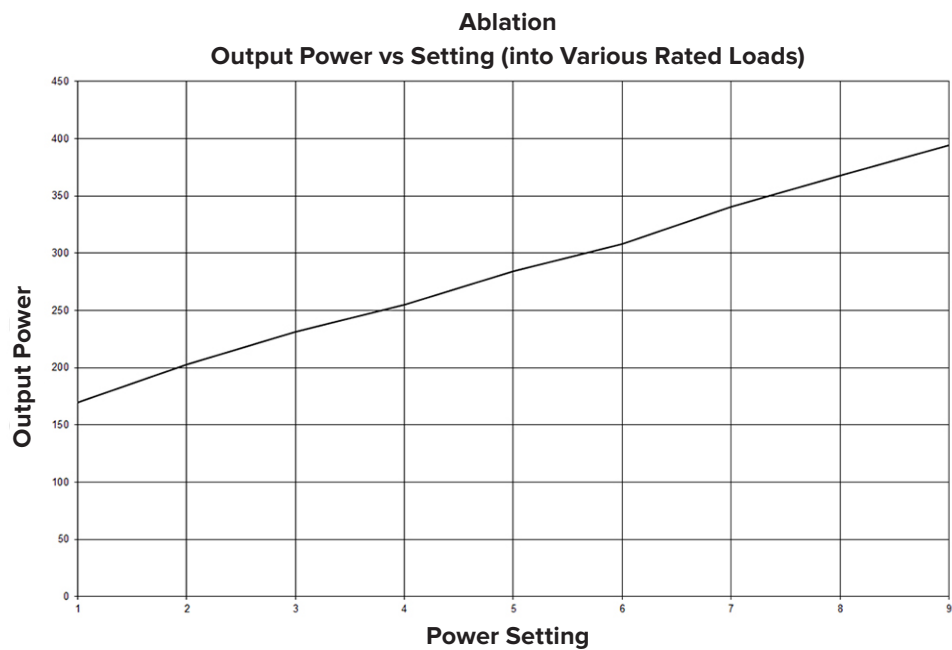
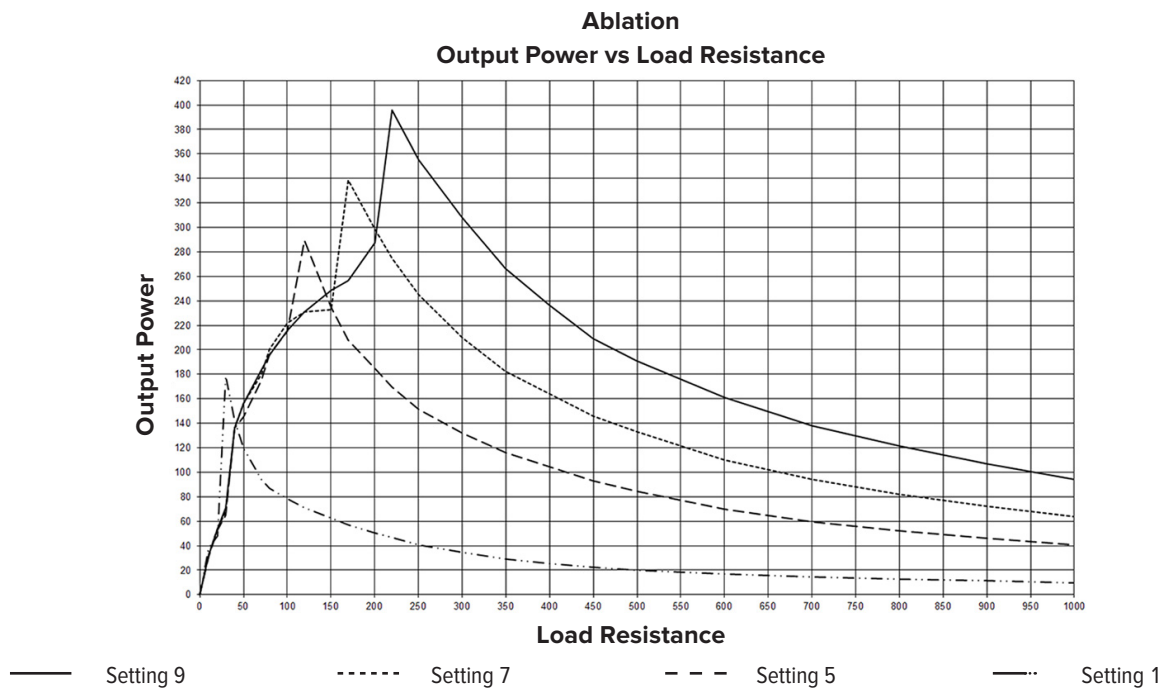
Table 10 Safety, EMC, and Regulatory Requirements

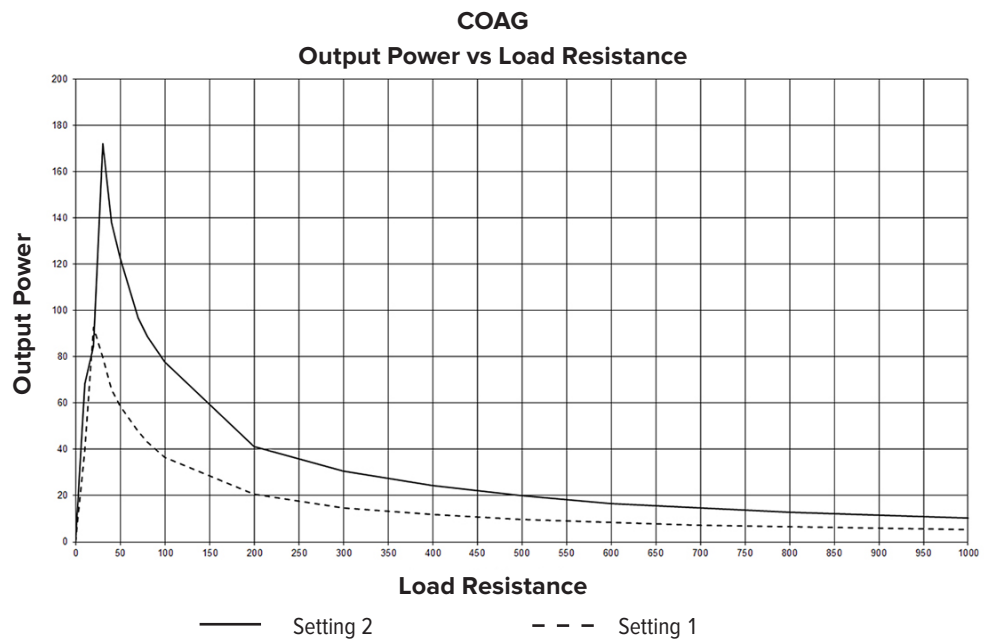
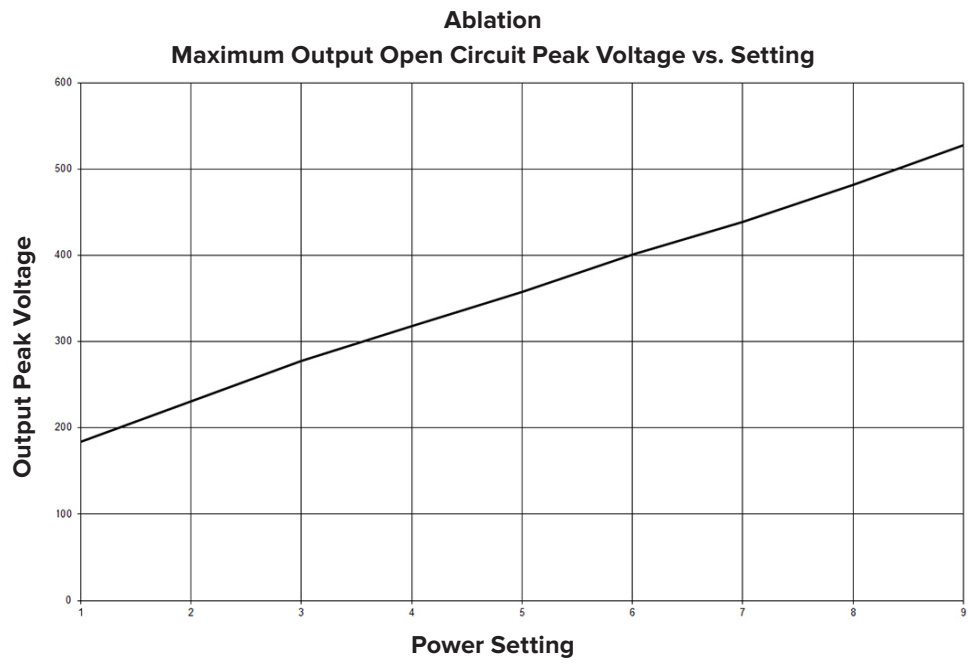
Parameter	Parameter Value	
System Classification	IEC 60601-1	Class I (protection against electric shock)
	Food and Drug Administration (FDA) class	Class II
	European Union (EU) class	Class IIb
	Health Canada Class	Class 3
Safety Certifications	Domestic Certification	ES60601-1:2005/A1:2012
	Canadian Certification	Canadian Standards Association (CAN/CSA) C22.2 No. 60601-1-08
	EU Certification	EN 60601-1:2006/A1:2013
EMC Certifications	International special committee on radio interference (CISPR) 11 EMC Class	Class A
	CISPR 11 EMC Group	Group 1
	EMC Certification	Certification to EN 60601-1-2:2015\ IEC 60601-1-2:2014, 4th edition
Safety Certification Marking	 	
CE Classification 93/42/EEC	Annex IX Rule 9	Class IIb

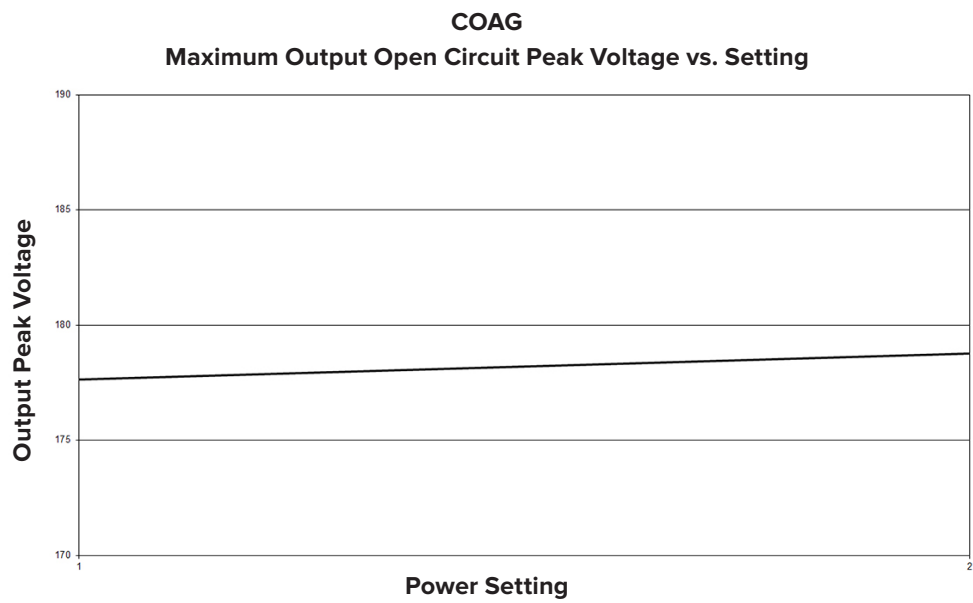
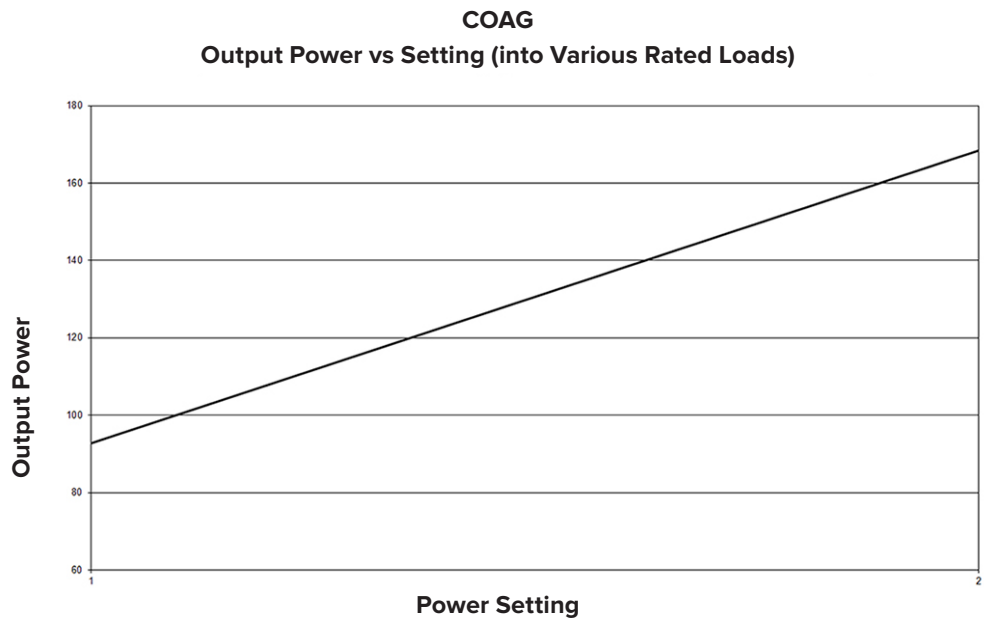
For all other accessories refer to the accompanying DFUs for more information.

Refer to the **Electromagnetic Emissions** section for further details on EMC Certification.

Power Curves







Set-up

How to Set-up the Console

Users are encouraged to contact their Arthrex representative if they require a more comprehensive surgical technique.

AC Power Safety Considerations

The AR-9800 is powered by a medically rated universal AC input switching power supply. This power supply allows users to connect the console to any local AC mains outlet. Please use the appropriate plug and a reliable ground conductor.

Arthrex supplies separate power cords for the U.S. and Europe with the AR-9800. Contact your Arthrex representative if you need a power cord that must meet the electrical standards of another country.

 **Only use replacement power cords that comply with medical grade standards, IEC 60320-1 Subclause 3.21, Detachable Power Supply Cords or electrical standards for the designated country where the AR-9800 is being used. Contact your Arthrex representative for further information.**

 **Avoid positioning the console so that it is difficult to disconnect coupler or plug from supply main.**

 **To prevent electrical shock, do not use extension cords or 2 to 3 pronged adaptors.**

NOTE: If required by local regulations connect the console to the hospital equalization connector with an equipotential cable. Connect the power cord to a wall outlet having the correct voltage. Otherwise, product damage may occur.

NOTE: The probe and console will reset to the factory setting, if there is a power interruption of 30-90 seconds or longer.

NOTE: Maintain the console volume to a level that will be audible in a normal operating room environment. The activation tone is heard from the console while the foot pedal and hand controls are pressed.

Audible tones are also emitted from the console during initial set-up and making changes to the console settings.

The console is designed to meet power-saving guidelines. The console has an AC mains switch on the front panel. When the supply main switch is OFF, no electrical power is drawn by the console.

When the supply main switch is ON, the console executes a series of self-diagnostic tests. Upon successful completion of these tests, the console displays the name and model number. If the tests discover a problem, the problem is shown on the display. Refer to Table 4 for a listing of AR-9800 Display Messages.

 **WARNING!** To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAIN with protective earth ground.

Do not have the device in direct contact with the patient if the patient requires defibrillation.

Replacing the Fuses

The main fuse is replaced with T8.0AL250v as follows:

1. Disconnect the device from the Supply Main.
2. Open the fuse tray in the AC inlet, by pulling out on the tabs.
3. Replace the fuses with T8.0AL250v line fuses as noted on the rear panel.
4. Push the fuse holder back into the AC inlet.
5. Ensure that fuse holder is fully seated and that the tabs snap back

 **Always use fuses with the correct values to avoid allowing overcurrent to enter the system.**

 **An incorrect fuse may increase the risk of electrical shock or fire hazard.**

NOTE: The AR-9800 console incorporates a universal AC input power supply. A voltage selection switch is not required.

Electromagnetic Compatibility

 **This device has passed testing for EMI / RFI radiation and susceptibility and EMC compatibility. This device may cause interference to other devices in the near vicinity if not set up and used as Arthrex instructs.**

AR-9800 has been designed to accept EMC from other devices within the limitations as described in the **Electromagnetic Emissions** section.

To determine if the AR-9800 is causing interference to other devices, power OFF the supply main switch and then ON again.

Try to correct the interference by following one or more of these measures:

1. Reorient or relocate the receiving device.
2. Increase the separation between devices.
3. Connect the device to an outlet on a different circuit than the other device(s) are connected.
4. Consult the manufacturer or field service technician for receiving devices for guidance.
5. Power off any other RF devices not being used in the procedure
6. Eliminate any points where the RF cords contact or cross cords of the receiving device e.g., arthroscopic imaging system.

Basic Set-up Procedure for the AR-9800 Console

*NOTE: The **Operation and Frequently Used Functions** section, explains how to use the console.*

 **Inspect all cords for cracks, nicks and breaks. Inspect all connectors for damaged or missing parts.**

1. Place the AR-9800 on a flat, dry surface, such as the AR-6481 Arthrex arthroscopy cart.
2. Connect the receiver end of the power cord for the AR-9800 into the AC Supply main input socket and the plug end to the facility AC mains supply.
3. Power ON console.
4. Allow to fully initialize.
5. Attach a single-use Arthrex, disposable Apollo^{RF} device (probe).

Note: For probes with suction, attach the suction adapter to the standard hospital suction system or pump equipment. Sterile suction tubing is **required** for use with the Apollo^{RF} probes that aspirate. Please review the probe DFU for the appropriate suction range and other operational parameters.

6. Attach a footswitch, if applicable.

 **WARNING! DO NOT** stack or place equipment adjacent to the AR-9800 console if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.

 **Do not attach handpieces or footswitches during the Self Test or the Programming Modes.**

 **WARNING!** Use only Arthrex approved accessories. Other accessories may result in increased emissions or decreased immunity of the system. Contact your Arthrex representative for a complete list of accessories. **DO NOT** modify any accessory. Failure to comply may result in patient and/or operating room staff injury.

 **WARNING! Do not** use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide, oxygen, or endogenous gases. All oxygen connections must be leak free for the duration of the surgical procedure.

Setting up a Footswitch

 **Only use footswitches developed by Arthrex specifically for the AR-9800 Synergy^{RF} console.**

NOTES: Set-up for a footswitch is the same for all models. The console detects which version is attached and allows appropriate functions.

The footswitch connector cannot be properly inserted into the console receptacle if the corresponding black dots are not aligned.

The pins of the footswitch connector may be damaged if the black dots are not aligned before the footswitch is fully inserted.

The user may experience intermittent operation of the footswitch if the connector is not fully seated into the console receptacle.

Insert the footswitch connector into the console's footswitch receptacle. Align the black dots on the connector and receptacle so they engage easily.

Setting up the Arthrex single-use, disposable Apollo^{RF} device (probe)

⚠ WARNING! Check that the disposable RF device packaging and sterile barrier is intact before opening the product and introducing it to the sterile surgery field.

⚠ If the packing has been compromised **DO NOT** use the product.

⚠ During the electrosurgical procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as surgical table frame, instrument table, etc. which may lead to patient injury.

⚠ When not in use, place the probe in a clean, dry, non-conductive and highly visible area not in contact with the patient. Inadvertent activation while in contact with the patient may cause burns.

⚠ Do not wrap probe handpiece, footswitch, or generator power cord around metal objects. Wrapping cables around metal objects may induce currents that could lead to shock, fire or injury to patient or surgical personnel.

⚠ Only use Arthrex RF devices (probes) that have been developed by Arthrex specifically for the Synergy^{RF} console.

⚠ Introducing the probe into tissue without an instrument cannula may result in tissue injury and/or product damage.

⚠ Do not insert, withdraw or touch the tip of the probe when the device is activated.

⚠ Do not use the probe as a lever to enlarge the surgical site or gain access to tissue.

⚠ Observe extreme caution when using electrosurgery in proximity or direct contact with metal objects or metal implants; possible hazards exist due to the concentration or re-direction of electrical currents. The majority of arthroscopes and instruments are metal. Do not activate the probe when any portion of the metal tip is in contact with another metal object; localized heating of the metal tip and the adjacent metal object may result in damage to the patient and or operator. In case of doubt, qualified advice should be obtained.

⚠ The probe tip should be completely surrounded by irrigation solution during use. A continuous flow of irrigation fluid is recommended. Fluid flow assists in removing ablated tissue, as well as reducing the temperature of the probe tip between activations.

NOTES: The disposable RF device (probe) connector cannot be properly inserted into the console receptacle if the corresponding black dots are not aligned.

The pins of the device connector may be damaged if the black dots are not aligned before the device connector is fully inserted.

The user may experience intermittent operation of the disposable RF device (probe) if the connector is not fully seated into the console receptacle.

Insert the device connector into the console's receptacle. Align the dots on the connector and receptacle so they engage properly.

Operation and Frequently Used Functions

Users of this device should contact their Arthrex representative if they require a more comprehensive surgical technique.

⚠ WARNING! The safety and effectiveness of the AR-9800 is verified and documented; however, the AR-9800 must be used with an awareness of the risk of damage to surrounding tissue through iatrogenic injury.

Main Screen

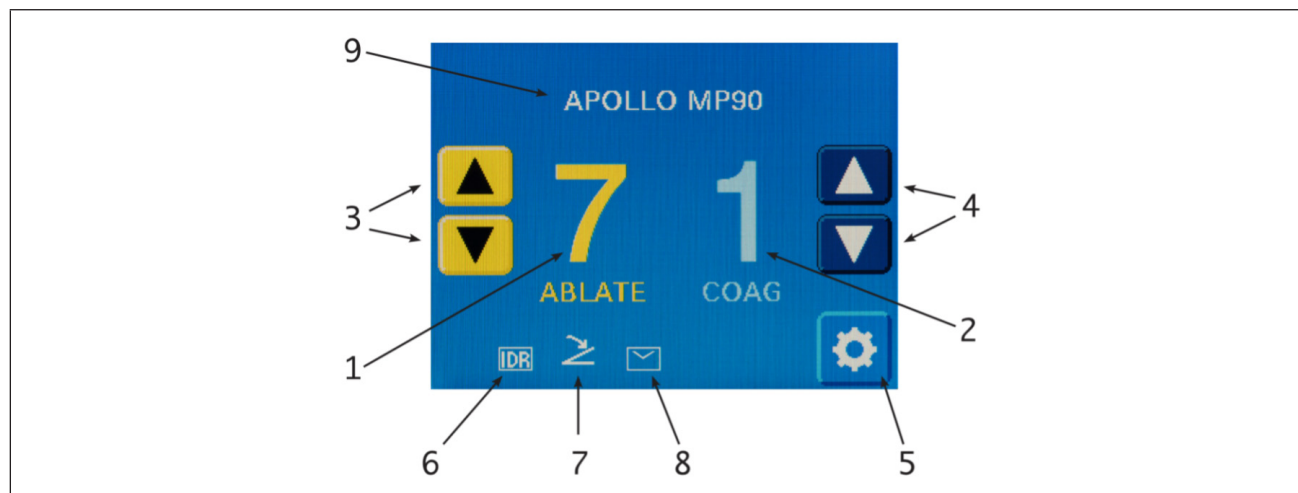


Figure 5 Main Screen Display

Table 11 Main Screen Display Elements

1. ABLATE Power Setting	Ablate – means to remove or cut. The ABLATE power settings range from 0-9. When an accessory device is plugged into the console, it will be recognized and the recommended ABLATE Power setting will appear. If an alternate setting is desired, use the UP and DOWN ABLATE power adjustment buttons to choose the desired setting. The Ablate Power Change button on the Synergy ^{RF} footswitch (see Figure 12) or Apollo ^{RF} probe (see Figure 13) can also adjust the Ablate Power setting . Each activation of the Ablate Power Change button increases the Ablate Power setting by 1 unit, in a positive direction only.
2. COAG Power Setting	COAG (coagulate) – means to seal bleeding blood vessels. The COAG POWER settings range from 0-2. When an accessory device is plugged into the console, it will be recognized and the recommended COAG Power setting will appear. If an alternate setting is desired, use the UP and DOWN COAG power adjustment buttons to choose the desired setting.
3. Ablate Power Adjustment buttons	The yellow up and down arrows adjust the ABLATE power setting . An audible tick is emitted from the console for each setting unit changed.
4. Coag Power Adjustment buttons	The blue up and down arrows adjust the COAG power setting . An audible tick is emitted from the console for each setting unit changed.
5. MENU button	The MENU button allows access to various settings and defaults.
6. Intelligent Device Recognition	Displays the probe name and recommended probe settings.
7. Footswitch	Footswitch is connected.
8. Time Burst	Time burst function is active.
9. Probe Name	Name of RF probe that is currently connected to console.

Settings Menu Main Screen

The Settings Menu provides access to settings and information screens. There are seven buttons described in Table 12 below.

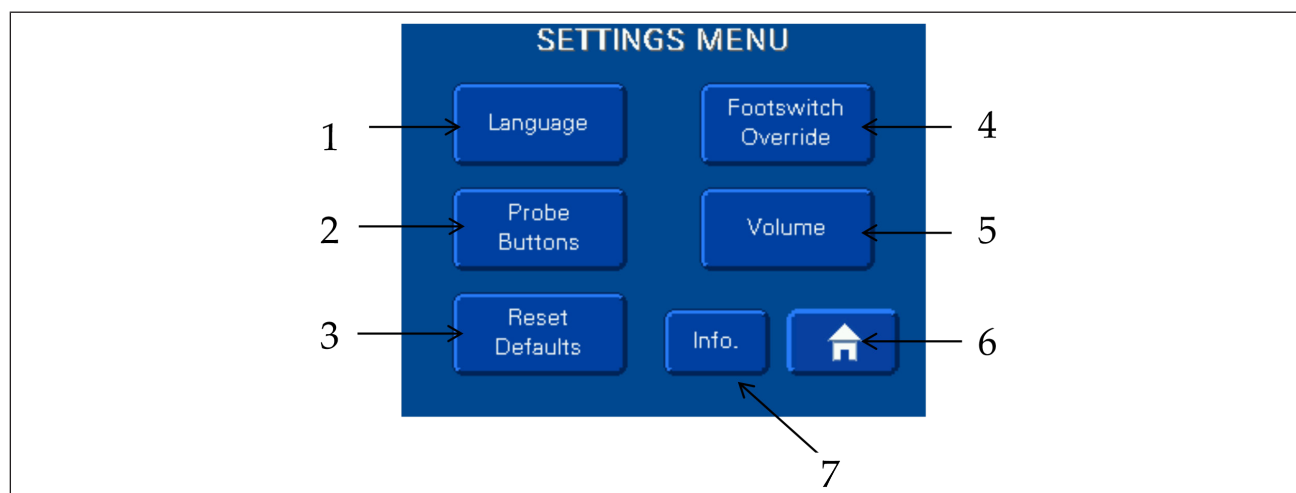


Figure 6 Settings Menu Display - Operation

Table 12 Settings Menu Display - Operation

1. Select Language button	When the Language button is pressed, the software displays the Language Selection screen. See the Language Selection Screen section.
2. Probe Buttons	When the Probe Buttons option is pressed, the software displays the Power Change Button screen to enable or disable the ablation setting button on the Apollo [®] probe handpiece, see the Probe Buttons section. <i>* This function is only available on software version 3.0 or greater.</i>
3. Reset Defaults button	When the Reset Defaults button is pressed, the software displays the Reset Defaults Screen which asks for confirmation before resetting all settings to the factory defaults.
4. Footswitch Override button	When the Footswitch Override button is pressed, the software displays the Footswitch Override Screen .
5. Volume button	When the Volume button is pressed, the software displays the Volume control screen.
6. Home button	When the Home button is pressed, the software displays the Main screen. See the Main Screen section.
7. Information (Info.) Button	When the Info. Button is pressed, the software displays the Information screen. See the Information Screen section.

Language Selection Screen

The **Language Selection** screen displays a list of available languages with radio buttons. The software supports the following languages: English, German, French, Italian and Spanish. It also includes three navigation buttons: Menu, Home and Cancel as described in Table 13 below.

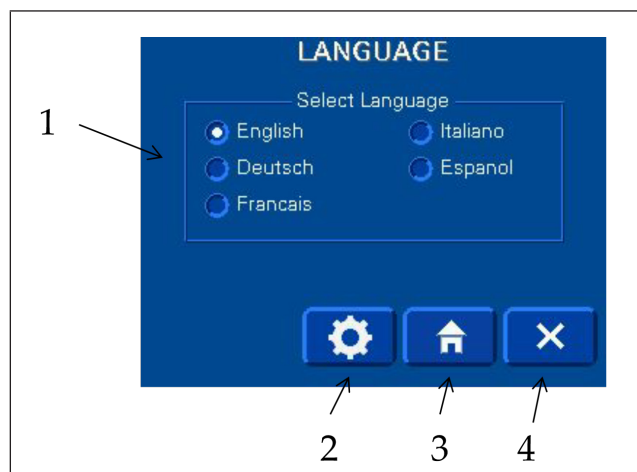


Figure 7 Language Selection Display - Operation

Table 13 Language Menu Display - Operation

1. Select Language radio buttons	Select the language of choice.
2. Menu button	When pressed, the software stores the selected language and returns to the Menu screen.
3. Home button	When pressed, the software stores the selected language and returns to the Main screen.
4. Cancel button	When pressed, the software returns to the Menu screen without making any changes.

Information Screen

The **Information** screen displays the Model, Software Versions and Builds for each controller, along with Menu and Home buttons as described in Table 14 below:

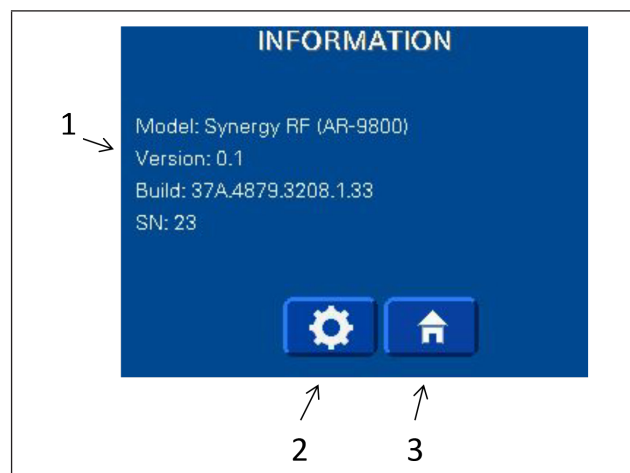


Figure 8 Information Screen - Operation

Table 14 Information Screen Display - Operation

1. Model, Software Versions & Builds for each controller.	
2. Menu button	Returns to the menu screen.
3. Home button	Returns to the main screen.

Apollo^{RF} device (Probe) Limits - IDR

The Synergy^{RF} generator has built in intelligent device recognition (IDR) for Apollo^{RF} probes. When attached, the recommended setting will be automatically applied, but individuals that desire an alternate setting can use the **ABLATE** power, **COAG** power, or **Ablate power change button** (see Figure 13) on the device to change the settings. Some power settings may be not be allowed, depending on the RF probe attached.

Reset Defaults Screen

The **Reset Defaults** screen prompts the user to confirm resetting to factory defaults. This screen is displayed when the Reset Defaults button is pressed on the **Settings** screen.

The software displays two buttons that allows the user to confirm resetting of factory defaults as described in Table 15 below. The defaults that are reset include: Language, Footswitch Override, Volume, probe ablation and coag settings.

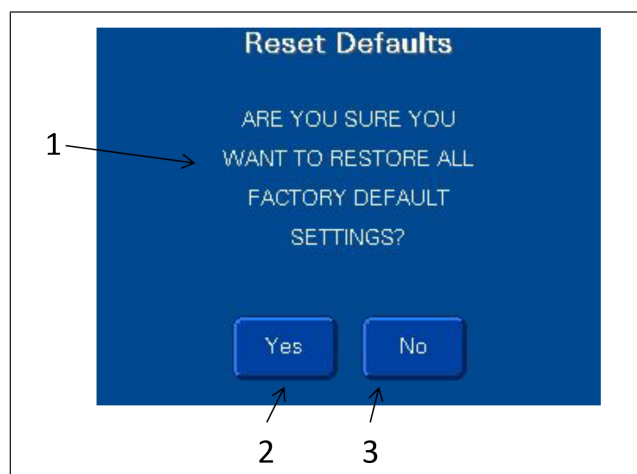


Figure 9 Reset Defaults Screen - Operation

Table 15 Reset Defaults Display - Operation

1.	Prompt to confirm resetting to factory defaults.
2.	Yes to reset to factory defaults.
3.	No to exit without resetting.

Probe Buttons

The **Probe Buttons** screen has radio buttons to enable or disable the **ablate power change button** on the Apollo^{RF} probe handpiece (See Figure 13). *This function is only available on software version 3.0 or greater.*

At the End User's discretion, the **ablate power change button** on the probe handpiece can be disabled to prevent inadvertent activation while using the hand controls. **In factory default mode, the ablate power change button is enabled.**

This screen also includes Menu, Home and Cancel buttons as described in Table 16 below.

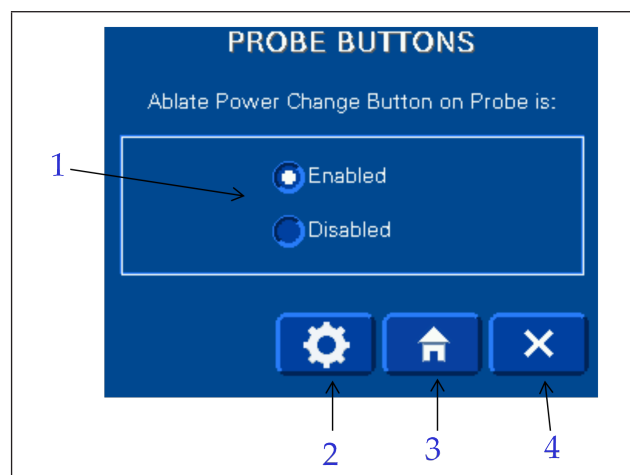


Figure 10 Power Change Button Screen – Operation

Table 16 Probe Buttons Display - Operation

1.	Power Change radio buttons	Enable or Disable the ablation setting button on the Apollo ^{RF} probe handpiece (See Figure 13).
2.	Menu button	When pressed, the software stores the selected language and returns to the Menu screen.
3.	Home button	When pressed, the software stores the selected language and returns to the Main screen.
4.	Cancel button	When pressed, the software returns to the Menu screen without making any changes.

Footswitch Override Screen

The **Footswitch Override** screen has radio buttons to select the footswitch override mode for each channel.

At the End User's discretion, the default setting can be changed so that the Apollo^{RF} device (probe) can be controlled by both the footswitch and/or the hand controls, as described below. If both the footswitch and the hand controls are enabled and activated simultaneously, whichever button is activated first will take precedence and other inputs will be ignored while that button is activated.

⚠ WARNING! When the Footswitch Override function is disabled the disposable RF device (probe) hand controls are active. Care must be taken not to activate the device inadvertently.

In the default mode, the buttons on the hand-control of the Apollo^{RF} probe will not function when a footswitch is attached to the console. The End User may select both the footswitch and hand controls option and the buttons on the Apollo^{RF} probe and the footswitch will both operate the probe. This screen also includes Menu, Home and Cancel buttons as described in Table 17 below.

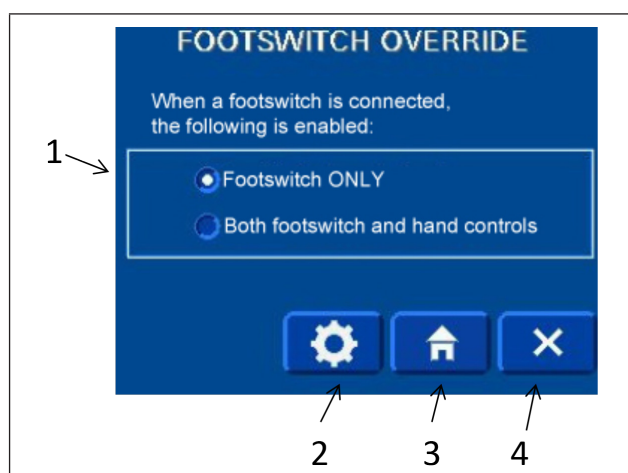


Figure 11 Footswitch Override Selection Screen - Operation

Table 17 Footswitch Override Display - Operation

1. Footswitch Override radio buttons	When a footswitch is connected, select the footswitch ONLY or both footswitch and hand controls radio button. (The factory default is set to footswitch ONLY mode).
2. Menu button	When pressed, the software stores the selected mode and returns to the Menu screen.
3. Home button	When pressed, the software stores the selected mode and returns to the Main screen.
4. Cancel button	When pressed, the software returns to the Menu screen without making any changes.

Footswitches

⚠ The footswitch cable connects and locks to the console to prevent accidental separation during use. To avoid damage, always disconnect the footswitch by pulling on the cable connector shell (plug) only.

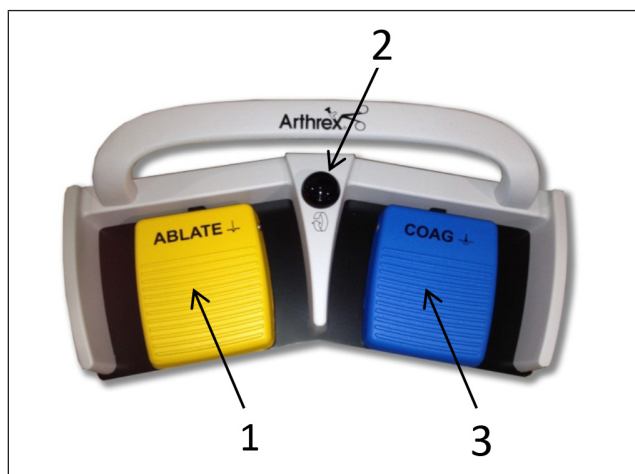


Figure 12 Synergy^{RF} System Footswitch - Description

Table 18 Elements of the Synergy^{RF} System Footswitch

1	Ablate button
2	Ablate power change button
3	Coag button

Synergy^{RF} System Footswitch – Ablate Power Change button

The **Ablate power change button** adjusts the power in the positive direction only. Each time the button is pressed, the ablate setting increases by 1 unit. When the device is at maximum power setting, the user can return to the minimum setting by pressing the Power button one more time. An audible tick is emitted from the console for each setting unit changed. A different audible tick is emitted from the console when the maximum setting has been reached.

If the **Ablate power change button** is continuously pressed for more than 1 second, then the power setting auto-increments accordingly. The power setting will not wrap when auto-incrementing. Release the **ablate power change button** and then press it again to get the **Ablate Power setting** to cycle to the minimum setting.

The **ABLATE button** will activate the **ABLATE** function as long as the button is depressed. The **COAG button** will activate the **COAG** function as long as the button is depressed. If two buttons are depressed, the button that was depressed first will take precedence and the second button to be depressed will be ignored.

Accessory Apollo^{RF} devices (probe)

⚠ The accessory device cable firmly connects to the console to prevent accidental separation during use. To avoid damage, always disconnect the device by pulling on the cable connector shell (plug) only.

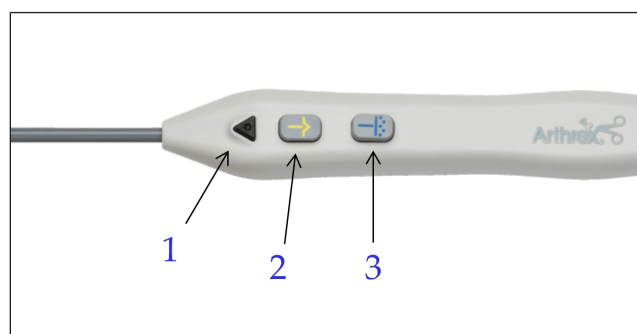


Figure 13 Apollo^{RF} probe - Description

Table 19 Apollo^{RF} probe - Description

1. Ablation Power Change button	Each time the button is pressed, the Ablation setting increases by 1 unit. Activation increases ablation in a positive direction only. When the device is at maximum power setting, the user can return to the minimum setting by pressing the Ablation Power Change button one more time.
2. Ablate button	Activates ablation at the tip of the Apollo ^{RF} probe.
3. Coagulation button	Activates coagulation at the tip of the Apollo ^{RF} probe.

Normal Operation

Normal operation mode for Ablation and Coag is 10 seconds on, 30 seconds off.

This console only provides output setting ranges compatible with the Apollo^{RF} probes (Arthrex DFU-0242-XX).

System Shutdown

1. Turn the power switch to the off position on the console.
2. Disconnect the power cord from the wall outlet.
3. Disconnect the suction tubing, if applicable.
4. Disconnect the probe from the console.
5. Dispose of the single-use probe.
6. Disconnect the footswitch, if applicable.

Cleaning and Disinfecting

Console AR-9800



The AR-9800 console is provided non-sterile and should not be sterilized. The AR-9800 console can be cleaned/disinfected using a cloth and commercially available surfactants or surface disinfectants only.

 The AR-9800 must not be submersed in any liquid.

Always allow adequate time for flammable solvent used for cleaning and disinfecting to evaporate before using the high frequency device during surgery.

Always place the Main Power Switch to the “Off position” and disconnect the power before cleaning the AR-9800 console.

 **Always comply with the instructions issued by the manufacturer of the cleaning disinfectant regarding concentration, exposure times, temperature and material compatibility.**

 **NEVER allow the console receptacles to have any contact with liquids. If there is dust or moisture on the receptacles, remove with dry compressed air. ONLY dry connectors should be plugged into the console.**

 **Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.**

Footswitches

Clean the footswitch with an enzymatic cleaner without subsequent acid neutralization. Rinse the footswitch thoroughly after cleaning.

After cleaning, disinfect the footswitch with a commercially available surface disinfectant. Thoroughly rinse the footswitch under lukewarm water (please refer to DFU-0203-XX for additional information).

 **Always comply with the instructions issued by the manufacturer of the cleaning disinfectant regarding concentration, exposure times, temperature and material compatibility.**

 **NEVER allow the console receptacles to have any contact with liquids. If there is dust or moisture on the receptacles, remove with dry compressed air. ONLY dry connectors should be plugged into the console.**

 **Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.**

 **The foot pedal is NOT suitable to be cleaned and disinfected in a thermo washer disinfectant.**

Sterilization

All Apollo^{RF} disposable devices are supplied sterile. Sterilization is not necessary.

 **Refer to the Instructions for Use package insert for detailed Apollo^{RF} disposable devices (DFU-0242-XX) cleaning and sterilization instructions included with each device. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex Representative.**

Transmissible Spongiform Encephalopathy Agents

It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy (TSE) Agents.

The agents for transmission of Creutzfeldt-Jakob disease (CJD) are believed to be resistant to normal processes of disinfection and sterilization. Therefore, the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk.

In general, the tissues that come into contact with orthopedic surgical instruments are those of low TSE infectivity. However, take particular precautions when handling instruments that have been used on known, suspected, or at risk patients.

References:

ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Maintenance

Regular and proper maintenance of your Synergy^{RF} system is the best way to protect your investment and avoid non-warranty repairs.

Recommended care and handling of the Synergy^{RF} system includes proper day-to-day operation and cleaning which are extremely important to ensure safe and efficient operation. It is important to visually inspect the foot pedal, accessory devices, cable and connectors before each use.

Your authorized Arthrex service department is the most knowledgeable about the Synergy^{RF} systems, accessory devices and foot pedals and will provide competent and efficient service. Any services and/or repairs done by any unauthorized repair facility may result in reduced performance of the instruments or instrument failure.

Periodic Maintenance

The product should be inspected prior to and after each use to ensure that there is no damage. If it becomes necessary to return the console or accessory devices to Arthrex for service, please clean and disinfect them before shipping. If fluid or particles splash on the display, clean with a micro-fiber cloth by gently wiping in a circular motion.

A Field Service Preventative Maintenance Inspection Form can be supplied separately, by request to assist with the periodic maintenance.

Service Manual

The Synergy^{RF} Service Manual can be supplied separately, by request for additional information on servicing the system.

Annual Calibration

Annual calibration of the Synergy^{RF} console is **NOT** required. If the user experiences a calibration error message (see Table 4), please contact Arthrex technical services.

Technical Support

For assistance in using the products identified in this user manual, contact an Arthrex representative or call the **Arthrex Technical Support Hotline** at ☎+1 888 420 9393, Monday through Friday from 9:00 AM to 5:00 PM EST; at ☎+49 89 909005-0 or techsupport@arthrex.de from 8:00 AM to 5:00 PM CET.

How to Display the Software Version

Technical Support may request the software version of the console. Follow these instructions to display the software version.

1. Power On the AC mains power switch Figure 2 [1] on the AR-9800. The software version is displayed during the power up sequence.
2. Refer to the **Information Screen** section to display the full software version.

Troubleshooting

Refer to Table 20 for device troubleshooting if problems occur after cleaning, transporting or changing operating staff.

Table 20 Troubleshooting: Faults, their Causes and Solutions

Fault	Cause	Solution
Unit does not power on.	1. Not receiving power from the wall receptacle or the power strip. 2. Blown fuses. 3. Console has an internal power failure.	1. Check the main power plug and wall receptacle. 2. Check the fuses. 3. Return to Arthrex for repairs.
Accessory RF probe does not work.	1. Probe not recognized by console 2. Defective footswitch (if used) 3. Defective probe	1. Disconnect and reconnect probe. 2. Turn off console, wait 30 seconds and turn the power back on. 3. If used, disconnect and connect footswitch. Replace, if not functioning properly. 4. Open new RF probe.
Yellow fault message	1. User correction is required	1. Refer to Table 4 for proper disposition.
Red Fault Message	2. Critical failure	1. Make note of message displayed. 2. Call Arthrex Service.

If the problems persist, disinfect the Synergy^{RF} system and send in to Arthrex using the original packaging. Always send the corresponding accessory device and if applicable, the footswitch together with the console. Please enclose a brief explanation of the malfunction. Refer to the **Repair Policy** section for more information.

Troubleshooting Interference with Other Devices

Try one or more of the following to correct interference:

- Reorient or relocate the receiving device.
- Increase the distance between devices.
- Connect the device to an outlet on a different circuit than the other device(s).
- Consult the manufacturer or field service technician for the receiving device for assistance.

Repair Policy

Contact Arthrex for a Return Authorization Number and instructions, prior to returning the device.

End of Life, Environmental Directives



WEEE Directive [2012/19/EU] on Waste Electrical and Electronic Equipment

The Directive on Waste Electrical and Electronic Equipment obliges manufacturers, importers, and/or distributors of electronic equipment to provide for recycling of the electronic equipment at the end of its useful life.

Do not dispose of WEEE in unsorted municipal waste.

The WEEE symbol on the product or its packaging indicates that this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your medical electronic equipment at the end of its useful life for recycling, please contact Arthrex Customer Service Department.

Electromagnetic Emissions

Table 21 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The AR-9800 Synergy^{RF} system is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-9800 Synergy^{RF} system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The AR-9800 Synergy ^{RF} system uses RF energy only for its internal function. Therefore its RF emissions are very low and not likely to cause any interference in nearby equipment. The AR-9800 Synergy ^{RF} system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 22 System Cables

Type	Use	Shielded	Ferrite	Maximum Length
Power Cords	Supply Line Power to the Console	No	No	3.048 m (10 feet)

Table 23 Guidance and Manufacturer's Statement - Electromagnetic Immunity

The AR-9800 Synergy^{RF} system is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-9800 Synergy^{RF} system 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 100kHz Cycling Frequency	± 2 kV for power supply lines ± 1 kV for input/output lines 100kHz Cycling Frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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	U _T = 0%, 0.5 cycle (0,45,90,135,180,225,270 and 315°) U _T = 0%, 1 cycle U _T = 70%; 25/30 cycles (@ 0 degrees) U _T = 0%; 250/300 cycles	U _T = 0%, 0.5 cycle (0,45,90,135,180,225,270 and 315°) U _T = 0%, 1 cycle U _T = 70%; 25/30 cycles (@ 0 degrees) U _T = 0%; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the AR-9800 Synergy ^{RF} system requires continued operation during power mains interruptions, it is recommended that the AR-9800 Synergy ^{RF} system be powered from an uninterruptible power supply.
Power frequency (50 - 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m @ 50 - 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

Table 23 (cont.) Guidance and Manufacturer's Statement - Electromagnetic Immunity

The AR-9800 Synergy^{RF} system is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-9800 Synergy^{RF} system should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Model AR-9800, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5 / V1] \sqrt{P} = 1.2 \sqrt{P}$ $d = [3.5 / V1] \sqrt{P} = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = [7 / E1] \sqrt{P} = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz @ 1kHz AM modulation	3 V/m	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 Model AR-9800 is used exceeds the applicable RF compliance level above, the Model AR-9800 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model AR-9800.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 24 Guidance and Manufacturer's Statement – Recommend Separation

Recommended separation distances between portable and mobile RF communications equipment and the Model AR-9800

The Model AR-9800 Synergy^{RF} system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model AR-9800 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model AR-9800 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be 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.

Contact Information

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the health authority where the incident occurred.

 Arthrex, Inc.	1370 Creekside Blvd. Naples, FL 34108, USA ☎+1 800 934-4404 arthrex.com arthrex.com/eDFU
Customer Service	☎+1 866 267 9138
Technical Support	☎+1 888 420 9393
 Arthrex GmbH	Erwin-Hielscher-Strasse 9 81249 München, Germany ☎+49 89 90 90 05-0 arthrex.de info@arthrex.de
 Arthrex Distribution Hub EMEA B.V.	Ampèrestraat 9 5928 PE Venlo, Netherlands ☎+31 88 712 9800 arthrex.nl info@arthrex.nl
 Arthrex Ltd.,	Unit 1 Bessemer Park Shepcote Lane Sheffield S9 1DZ United Kingdom ☎+44 0 114 232 9180
 confinis ch-rep ag,	Hauptstrasse 16, 3186 Düringen, Switzerland ☎+41 26 494 8 494
Manufacturer's Australian Sponsor Arthrex Australia Pty Ltd	Suite 501, 20 Rodborough Road Frenchs Forest, NSW, 2086 Australia ☎+1 800 950 637 arthrex.com.au csAU@arthrex.com



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