Arthrex® Synergy Resection™

AR-8305

User's Guide

The *Arthrex Synergy Resection User's Guide* provides safety operation information for all components of the Arthrex Synergy Resection console (Model AR-8305), including the accessories. All operating personnel must read this User's Guide thoroughly prior to using this system and follow all safety warnings, cautions, and notes.

CE 2797

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1.0 General Warnings and Safety Notices - Read This First

1.1 Important Symbols and Conventions

It is imperative that the symbols and conventions listed below be clearly understood. The *Synergy*^{Resection} *User's Guide* identifies critical, important, and useful information using these symbols and conventions.

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

W A R N I N G !

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. Use this device only for purposes described in the User's Guide, under the supervision of a trained and licensed physician.
3. No modifications of the console (AR-8305) or accessories are allowed.
4. 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.
5. 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 dangerous high voltages or other risks. If the system malfunctions, return it for service immediately.

6. To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAIN with protective earth ground.
7. Do not have device in direct contact with patient if high-frequency devices are in use, or if the patient requires defibrillation.
8. DO NOT stack or place equipment adjacent to the AR-8305 console, if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.
9. 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.
10. This equipment is **NOT** suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen rich or nitrous oxide environment.
11. Do not have device in direct contact with patient if high-frequency devices are

in use or if the patient requires defibrillation.

12. After autoclaving, the accessory devices are VERY HOT. Handle with care to avoid burns.
13. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.
14. 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-8305) or any other shaver accessory.
2. **Only use** replacement power cords that meet medical grade standards according to IEC 60320-1, Detachable Power Supply Cords or electrical standards for the designated country where the AR-8305 is being used. Contact your Arthrex representative for further information.
3. **Avoid** position console so that it is difficult to disconnect coupler or plug from supply main.
4. C*onnecting an extension cord to the AR-8305 may result in a reduced level of safety.*
5. **Always** use fuses with the correct values to avoid allowing overcurrent to enter the system.
6. An incorrect fuse may increase the risk of electrical shock or fire hazard.
7. 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.
8. **Do not** attach handpieces or footswitches during the Self Test or the Programming Modes.
9. **Only use** footswitches developed by Arthrex specifically for the AR-8305 Synergy^{Resection} console.
10. **Only use** shaver handpieces and cables that have been developed by Arthrex specifically for the Synergy^{Resection} console.
11. **Only use** handpieces and cables that have been developed by Arthrex specifically for the Synergy^{Resection}. The footswitch cable connects and locks to the console to prevent accidental separation during use. To avoid damage, disconnect the footswitch by pulling on the cable connector shell (plug) only.
12. The accessory handpiece cable connects and locks to the console to prevent accidental separation during use. To avoid damage, disconnect the footswitch by pulling on the cable connector shell (plug) only.
13. **Always** comply with the instructions issued by the manufacturer of the **cleaning disinfectant regarding concentration, exposure times, temperature and material compatibility**.

14. **NEVER** clean the console with liquid cleaners. If there is dust, remove it with dry compressed air.
15. **Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.**
16. **The footswitch is NOT suitable to be cleaned and disinfected in a thermo washer disinfector.**
17. **NEVER** allow the console receptacles to have any contact with liquids. If there is dust or moisture on the receptacles, remove it with dry compressed air. ONLY dry connectors should be plugged into the console.
18. Refer to the Instructions for Use package insert for detailed shaver handpiece (DFU-0154-XX) and Adapteur Power System II Accessory Attachments (DFU- 0149-XX) cleaning and sterilization instructions included with each handpiece. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex representative.
19. **NEVER** place the shaver handpiece in Cidex or other aldehyde disinfectant solutions.
20. After sterilization in the autoclave, let the accessory device cool down slowly. **NEVER** use cold water to cool the handpieces. This will damage the electronic components and seals.
21. Liquid on the cable connector of the accessory device can damage the device. Before connecting the cable, ensure the receptacles are clean and dry.
22. Open the suction control completely to ensure proper circulation, if applicable.
23. Open the chuck completely to ensure proper circulation, if applicable.
24. Remove all accessories, including shaver blades, drill bits and saw blades before sterilizing a handpiece.
25. 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.

NOTE**: **This identifies information that can simplify the setup and operation of this device.

1. *Read this User's Guide thoroughly before operating the device and save it for future reference.*
2. *Extension cords must meet local electrical standard. Extension cords are not recommended to be used with the AR-8305.*
3. *The AR-8305 console incorporates a universal AC input power supply. A voltage selection switch is not required.*
4. AR-8305 has been designed to accept EMC from other devices within the limitations as described in section 14.0.
5. *The setup for a footswitch is the same for all models. The console detects which version is attached and allows the appropriate functions.*

6. While operating the handpieces, the settings can be changed without risk of damaging the motor or console.

In EU Only: Procedures carried out using these devices may be used on the general population.

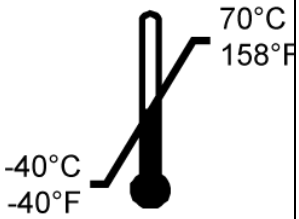
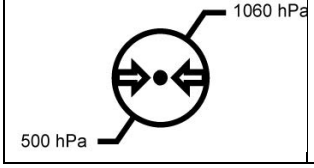
In EU Only: The clinical benefits associated with the use of these devices outweigh the known clinical risks.

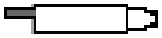
In the EU Only: There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

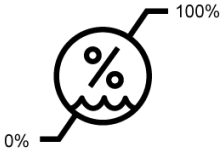
1.2 Symbol Definitions

All 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.

	**Safety Sign Follow Operating Instructions**
	**On / Off (push-push)**
	**Precaution of Warning Notice**
	**Keep Dry**
	**Electrical Hazard, Dangerous Voltages are Present. Never attempt to repair the equipment. Only Trained Service Personnel may remove the cover, or obtain access to system components.**
	**Alternating Current**

R_x ONLY	**Caution: Federal Law Restricts this device to sale by or on the order of a Physician.**
	**Type BF Equipment**
	**Fragile**
	**This Side Up**
	**Temperature Limits for Storage and Transport**
	**Pressure Limits for Storage and Transport**

	**Fuse**
	**Equipotential [Equipment Potential]**
	**WEEE [Waste Electronics and Electrical Equipment] Symbol. Regarding European Union End-of-Life of Product.**
	**Manufacturer**
	**Handpiece connection**
USB	**Universal Serial Bus [For use ONLY with thumb drive]**
REF	**Catalog number**
	**Serial number**
	**Quantity**
	**Consult Instructions for Use**
	**Authorized Representative in the European Community**

	**Humidity Limits for Storage and Transport**
	**Protective Earth Ground [Functional]**
	**RF Symbol. Non-ionizing Electromagnetic Radiation**
	**Date of Manufacture; year and month.**
	**Foot Pedal connection**
RS-232	**Serial Port [Arthrex Integration]**
CE 2797	**The product meets the essential requirements of Medical Device Directive 93/42/EEC**
	**Non Sterile**
	**Do not use if package is damaged**
	**No user-serviceable parts inside Electrical hazard**

1.3 Shipping, Unpacking, and Warranty Information

Carefully unpack and inspect all components for shipping damage. Any damage could compromise patient safety and should be reported immediately to Arthrex or any authorized Arthrex distributor. Warranty could be voided if shipping or first-installation damage is not reported within 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's Guide.*

This is not a warranty document. For all warranty information, including disclaimers, exclusions, terms, conditions and related provisions, refer to the "Arthrex U.S. Product Warranty" section of the Arthrex, Inc. website, found at www.arthrex.com whose provisions are incorporated herein by reference.

2.0 Product Description

2.1 Product Description and Intended Use

The Arthrex AR-8305 Synergy[Resection] Shaver System is a motorized, suction/cutting device used for the resection and aspiration of soft tissue, cartilage and bone during arthroscopic surgical procedures.

The console is microprocessor controlled and features two fully functional channels that allow optional simultaneous handpiece operation. Both channels can be operated with a single foot switch or individually when a second foot switch is attached to the console. The Synergy[Resection] has a maximum speed of 8,000 revolutions per minute providing precise burr control during surgical procedures.

The Synergy[Resection] console is designed for continuous operation. The handpieces are individually protected by a resetting thermal fuse. In the event of a motor overload fault (e.g., excess current) the fuse heats up and the device is deactivated. When the fault is removed and the fuse cools down (typically about 30 seconds) operation resumes at the pre-failure settings.

The cable and all handpieces can be sterilized, so handpieces can be changed during the surgical procedure without endangering surgical sterility.

The AR-8305 Synergy[Resection] Console and included Applied Parts and Accessories:

- AR-8305 Console with power cord
- User's Guide Optional

Applied Parts

- Footswitch Controlled (FC) Shaver Handpieces
- Handpiece Controlled (HC) Shaver Handpieces
- Drill Handpiece with key for Jacobs chuck
- Sagittal Saw Handpiece with wrench
- Small Joint Shaver

Other Optional Accessories:

- Accessory Handpiece Cable
- Gas Pedal Footswitch
- Corded Multi-Function Footswitch
- Wireless Multi-Function Footswitch

Save the packaging for later transport of the device.

W A R N I N G !

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*.

2.2 Product Features

2.2.1 AR-8305Console - Front View

Figure 1 shows the front panel of the AR-8305 console. Features and symbols are identified in Table 1 below.

Figure 1 Front Panel of Console

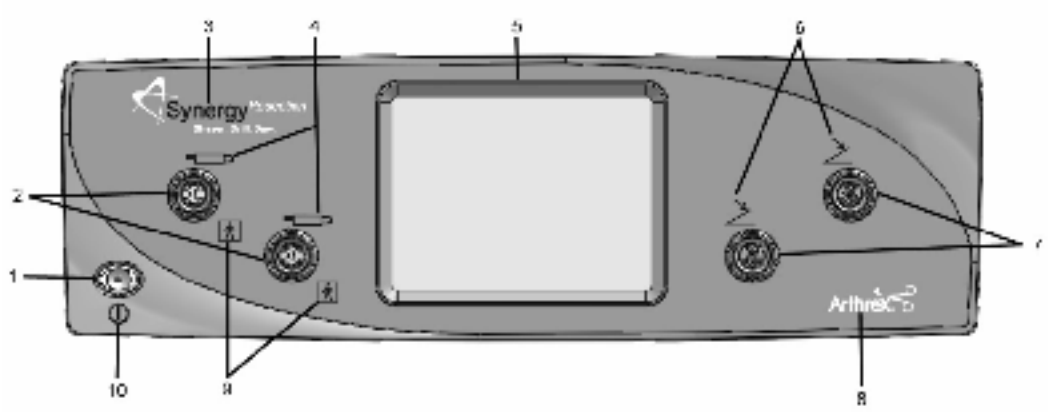


Table 1 Front Panel Elements

1.	On / Off Power Switch
2.	Handpiece Connectors
3.	Synergy Product Logo
4.	Handpiece Symbols
5.	Touch Panel Visual Display
6.	Footswitch Symbols
7.	Footswitch Connectors
8.	Arthrex Logo
9.	Type BF Symbols (Electric Shock Protection)
10.	Power Switch IEC 60417-5010 symbol (On / Off)

2.2.2 AR-8305 Console - Rear View

Figure 2 shows the rear panel of the console. Features and symbols are identified in Table 2 below.

Figure 2 Rear Panel of Console

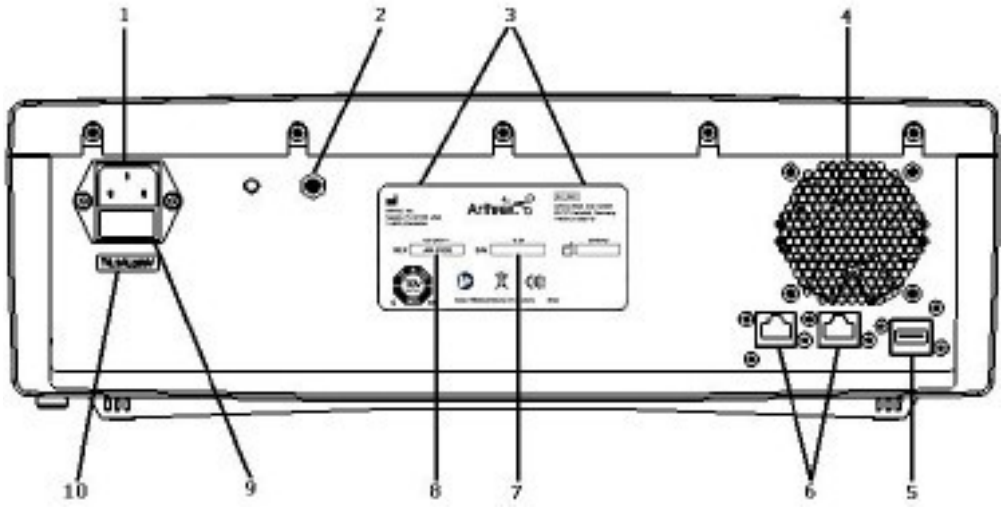


Table 2 Rear Panel Elements

1.	Main power input Plug
2.	Equipotential Bonding Pin with Stamped Equipotential Bonding Symbol
3.	Address
4.	Fan
5.	USB port (For use **ONLY** with thumb drive)
6.	Serial ports for Arthrex integration
7.	Serial number label
8.	Model number label
9.	Fuse holder for the Power Entry Module
10.	Fuse label

2.2.3 AR-8305 Display Messages

The console's Touch Panel Visual Display (TPVD) [5] provides information about the status of the AR-8305 settings in real time. A list of informational and error messages is shown in Table 3 and 4 below. Messages that represent the active motor states are displayed in green on the TPVD.

Table 3 AR-8305 Display Messages

Message	Explanation
EEPROM Reset	Temporarily displayed first time micro-controller is programmed, or if internal memory has faulted and is reset.
Motor Fault	Temporarily displayed when motor fault condition occurs.
Overload	Temporarily displayed when motor over-current condition occurs.
Self Test Fail	Console has failed a critical power on test.
CRUISE NOT ALLOWED	Temporarily displayed when cruise button pressed with tool that doesn't allow cruise control.
FS PEDAL STUCK Remove FS, Repower System	Either a footswitch pedal is being pressed or is stuck while connecting to console. Communication error results. Remove the footswitch and repower the system to reset the console.
FWD or REV ONLY	Temporarily displayed for tools that do not support OSC mode.
HP BUTTON STUCK Remove HP, Repower System	Either a handpiece button is being pressed or is stuck while connecting to console. Communication error results. Remove the handpiece and repower the system to reset the console.
TOGGLE NOT ALLOWED	Temporarily displayed when toggle button pressed with tool that doesn't allow oscillation mode.
TOOL FAILURE ERROR, XXX (Where "XXX" is an error code as defined in Table 4.)	Critical Tool Failure caused either by a faulty sensor or an over current condition. Remove and replace tool or repower console to reset.
Unable to Install	Handpiece is not recognized.
[CC][1]	Speed locked on cruise control.
CC	Cruise control enabled, about to lock.
AGG	Current mode: Aggressive oscillation mode (stopped).
Communication Error	Internal data communication error.
Critical Error	Critical error, unit will shut down.
DFS	Digital Footswitch Connected.
Drill	Drill connected.

EFF	Current mode: Efficient oscillation mode (stopped).
FC Shaver	Footswitch Controlling Shaver connected.
Fwd	Current mode: Forward (stopped).
Fwd[1]	Current status: Motor is moving forward.
Gas Pedal Footswitch	Temporarily displayed when gas pedal footswitch connected.
GFS	Gas Pedal Footswitch Connected.
HC Shaver	Handpiece Controlling Shaver connected.
No Footswitch	Temporarily displayed when footswitch disconnected.
Osc[1]	Current status: Motor is oscillating.
Power Failure	Power supply error.
Rev	Current mode: Reverse (stopped).
Rev[1]	Current status: Motor is moving in reverse.
Run[1]	Current status: Motor is running (for saw).
Safe Mode	Excessive HP communication errors have occurred.
Sag Saw	Sagittal Saw connected.
SFS	Standard Footswitch Connected.
SJ Shaver	Small Joint Shaver connected.
Standard Footswitch	Temporarily displayed when standard footswitch connected.
STD	Current mode: Standard oscillation mode (stopped).

[1] Displayed in green, denoting an active tool.

Table 4 *TOOL FAILURE* Error Code Definitions

Message	Explanation
# $ @ Example: 022 Sensor 3 = Stuck Low Sensor 2 = No Errors Found Sensor 1 = No Errors Found	Represents Handpiece Sensor Failures # = Sensor 3, $ = Sensor 2, @ = Sensor 1 0 = Stuck Low, 1 = Stuck High, 2 = No Errors Found.
H13	Multiple sensors shorted
H14	Multiple sensors stuck high/low
H15	Invalid Hall sensor states detected
C31	Over current 7.5A during retries
C32	Over current 5.0A during retries
C33	Over 5.0A for 6 seconds
C34	Over 7.0A for 3 seconds
C35	Over 7.5A for 1 second
C36	Over 8.0A for 250ms
C37	Over 8.1A in INT0
C38	Over 8.1A in A/D ISR
C39	Over 8.0A in FWD/REV ramp up
S51	Invalid Gear Ratio
S52	Over restart tries
S54	General system failure

2.3 Applied Parts and Accessory Features

2.3.1 Standard Footswitch (AR-8310)

Figure 3 shows the Standard Footswitch. Features and symbols are identified in Table 5 below.

Figure 3 Standard Footswitch - Description

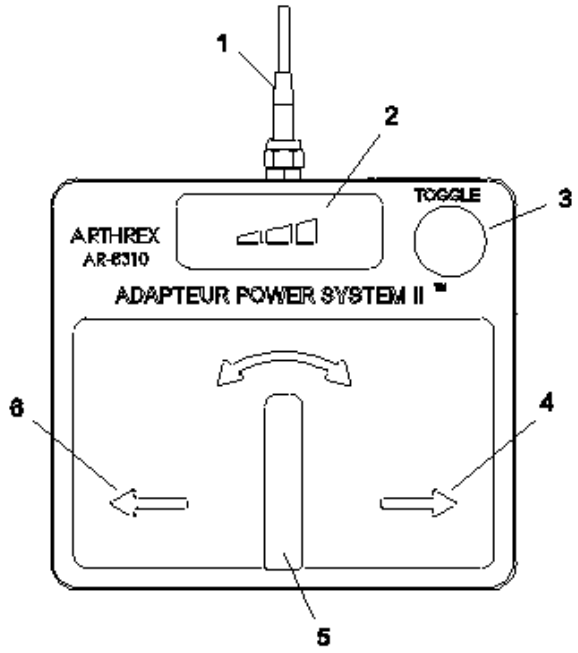


Table 5 Elements of the Standard Footswitch

1.	Cable
2.	Speed Increase button
3.	Toggle button
4.	Forward pedal
5.	Oscillation pedal
6.	Reverse pedal

3.0 Technical Specifications

3.1 Console

Table 6 AR-8305 Console Specifications

Width	40.64cm (16.00 inches)
Height	13.335cm (5.250 inches)
Depth	30.686cm (12.081 inches)
Weight	6.8kg (15 lbs.)
Water protection	IP22
Mains cable	10 A/250 V
Power entry module	IEC 320/C13
Fuse value	6.3 A, 250 V~, 2.0 cm (0.75 inches) Type T
AC input	100-240V~, 50/60Hz, 6.3A
Applied Part Type	BF
Cleaning, disinfecting and sterilization	Refer to Sections 6.0 Cleaning and Disinfecting and 7.0 Sterilization

3.2 Standard Footswitch

Table 7 Standard Footswitch Specifications

Functions	Reverse, Forward, Oscillation, Speed Increase, and Toggle
Width	23.6 cm (9.3 inches)
Height	2.5 cm (1.0 inches)
Depth	20.8 cm (8.2 inches)
Weight	2.2 kg (5 lbs.)
Water protection	IP68
Cleaning, disinfecting, and sterilization	Refer to Sections 6.0 Cleaning and Disinfecting and Section 7.0 Sterilization

3.3 Ambient Conditions for Operation

Table 8 AR-8305 Ambient Conditions for Operation

Temperature	10° to 40°C (50° to 104°F)
Relative humidity	30 % to 75 %
Air Pressure	700 hPa to 1060 hPa (21 in. Hg to 31.3 in. Hg)

3.4 Ambient Conditions for Storage (in shipping packaging)

Table 9 AR-8305 Ambient Conditions for Storage

Temperature	-30° to 70°C (-22° 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)

3.5 Safety, EMC, and Regulatory Requirements

Table 10 Safety, EMC, and Regulatory Requirements

Parameter	Parameter Value	
System Classification	FDA Class	Class 1
	EU Class	Class IIA
	Health Canada Class	Class 2
Safety Certifications	Domestic Certification	UL 60601-1:2003
	Canadian Certification	CAN/CSA C22.2 No. 60601-1-2008-02
	EU Certification	EN 60601-1:2006 IEC 60601-1 3rd Ed. + AM1 (2012)
EMC Certifications	CISPR 11 EMC Class	Class A
	CISPR 11 EMC Group	Group 1
	EMC Certification	IEC 60601-1-2:2014 Class A
Safety Certification Marking		
CE Markings	MDD Classification	CE Marking for MDD93/43/EEC Class IIA
	MDD Marking	Rule 9

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

Refer to Section 14.0 Electromagnetic Emissions for further detail on EMC Certification

4.0 Setup

4.1 How to Set Up the Console

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

4.2 AC Power Safety Considerations

The AR-8305 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 CEE 7/7with the AR-8305. 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, Detachable Power Supply Cords or electrical standards for the designated country where the AR-8305 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.

NOTE: Extension cords must meet the local electrical standard. Extension cords are not recommended to be used with the AR-8305.

Connecting an extension cord to the AR-8305 may result in a reduced level of safety.

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

When the AC mains 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 Tables 3 and 4 for a listing of Display Messages.

In the event of an AC power interruption, the console can run continuously without a fault for up to 10 milliseconds. If an AC power failure lasts for longer than 10 milliseconds, the system will return to the **default settings** when AC power is restored.

W A R N I N G !

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

W A R N I N G !

Do not have the device in direct contact with patient if high-frequency devices are in use, or if the patient requires defibrillation.

4.3 Replacing the Fuses

The mains fuse is replaced with T6.3AL250v as follows:

1. Disconnect the device from the AC mains.
2. Open the fuse tray in the AC inlet, by pulling out on the tabs.
3. Replace the fuses with T6.3AL250v 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-8305 console incorporates a universal AC input power supply. A voltage selection switch is not required.*

4.4 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-8305 has been designed to accept EMC from other devices within the limitations as described in section 14.0.

To determine if the AR-8305 is causing interference to other devices, power OFF the AC main power 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.

4.5 Basic Setup Procedure for the AR-8305 Console

NOTE: Section 5.0*, Operation, explains how to use the console.*

1. Place the AR-8305 on a flat, dry surface, such as the AR-6481 Arthrex Arthroscopy pump cart.
2. Connect the receiver end of the power cord for the AR-8305 into the AC socket and the plug end to the facility AC mains supply.
3. Power ON the console.
4. Allow it to fully initialize.
5. Attach the shaver handpiece.
6. Attach a footswitch, if applicable.

W A R N I N G !

DO NOT stack or place equipment adjacent to the AR-8305 console, if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that the electromagnetic interference does not degrade the performance.

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

W A R N I N G !

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.

W A R N I N G !

This equipment is NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen rich or nitrous oxide environment.

4.6 Setting up a Footswitch

Only use footswitches developed by Arthrex specifically for the AR-8305 Synergy[Resection] console.

NOTE: *Setup for a footswitch is the same for all models. The console detects which version is attached and allows the appropriate functions.*

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

4.7 Setting up the Shaver Handpieces

Only use shaver handpieces and cables that have been developed by Arthrex specifically for the Synergy[Resection] console.

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

4.8 Setting up Other Accessory Handpieces

Only use handpieces and cables that have been developed by Arthrex specifically for the Synergy[Resection].

Other accessory handpieces are available with the SynergyResection and may require an accessory cable. Specific instructions for use of an accessory are packaged with that handpiece.

Insert one end of the accessory cable connector into the cable receptacle of the accessory handpiece. Align the red dots on the connector and receptacle so they engage easily.

Connect the other end of the accessory cable to the handpiece receptacle of the console. Align the red dots on the connector and receptacle so they engage easily.

4.9 Shutdown Procedure

The AR-8305 can be safely shut down at any time by powering down the console.

5.0 Operation and Frequently Used Functions

5.1 Main Screen

Figure 4 Main Screen Display - One Tool Attached

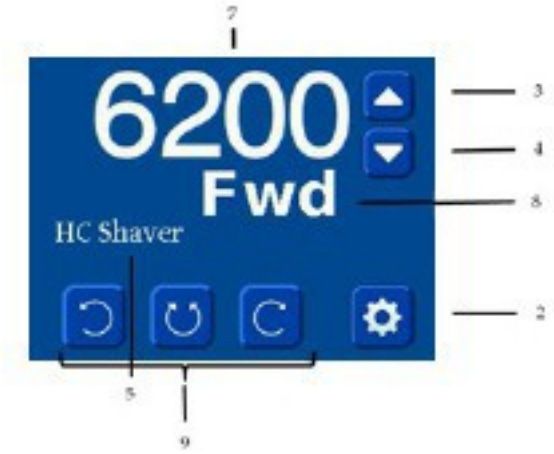


Figure 5 Main Screen Display - Two Tools Attached

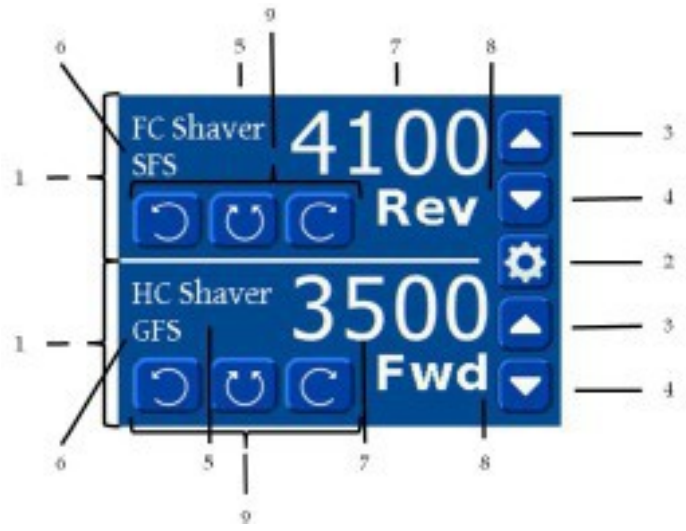


Table 11 Main Screen Display Elements

1.	The **main screen**, divided into two sections when two tools are attached
2.	**Settings** button (on the lower right corner in the single screen mode)
3.	**Up** button
4.	**Down** button
5.	**Tool** name
6.	**Footswitch**, displayed in green if Footswitch Override is disabled (SFS = Standard Footswitch, GFS – Gas Footswitch)
7.	**Speed** setting
8.	**Direction** or **Mode** indicator, displayed in green if active

9. **Direction** and **Oscillation** buttons

- The main screen is divided horizontally into two sections, one for each channel, when tools are connected to both channels.
- Each section contains a display area for messages and five buttons.
- The Settings button on the right configures both main screens. It is on the lower right corner in the single screen mode or between the two sections' **Up** and **Down** buttons in dual screen mode.
- The **tool name** is positioned as depicted in the above diagrams.
- **Footswitch data** is positioned below the tool name.
- The **speed setting** is displayed in large numeric digits. They are visible from a distance by the surgeon in the OR.
- **Direction or mode indicators** are below the speed setting in large characters. They are visible from a distance by the surgeon in the OR.
- **Direction** and **oscillation buttons**.
- **Cruise control status** is positioned next to the footswitch data.

5.2 Settings Menu Main Screen

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

Figure 6 Settings Menu Display - Operation

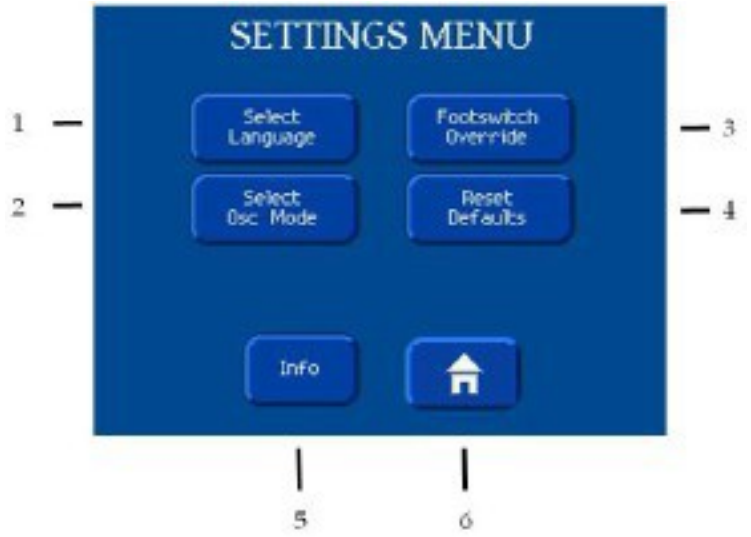


Table 12 Settings Menu Display - Operation

1.	**Select Language** button	When the Select Language button is pressed, the software displays the Language Selection screen, section 5.3 below.
2.	Select **Oscillation Mode** button	When the **Select Oscillation Mode** button is pressed, the software displays the **Oscillation Mode** screen, section 5.4 below.
3.	**Footswitch Override** button	When the **Footswitch Override** button is pressed, the software displays the **Footswitch Override** screen, section 5.5 below.
4.	**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, section 5.6 below.
5.	**Information** button	When the **Information** button is pressed, the software displays the **Information** screen, section 5.7 below.
6.	**Home** button	When the **Home** button is pressed, the software displays the **Main** screen, section 5.1 above.

5.3 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

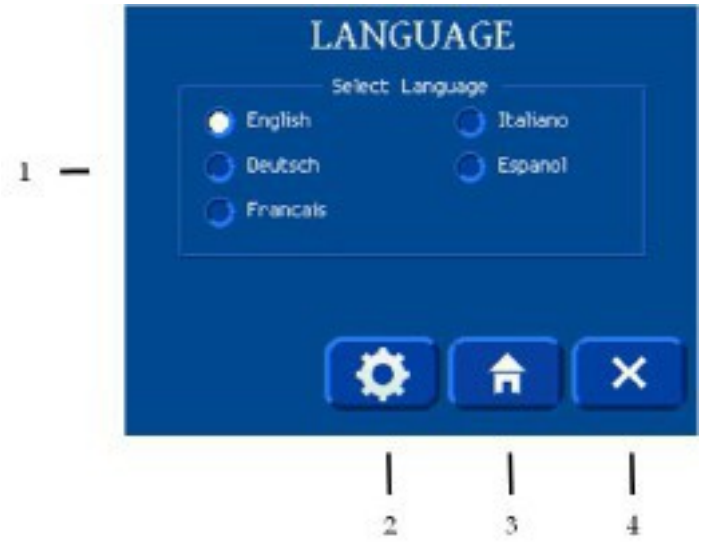


Table 13 Language Menu Display - Operation

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.

5.4 Oscillation Mode Selection Screen

The **Oscillation Mode** selection screen has radio buttons for available oscillation modes for each channel. This screen also includes Menu, Home and Cancel buttons as described in Table 14 below:

Figure 8 Oscillation Mode Selection Screen - Operation

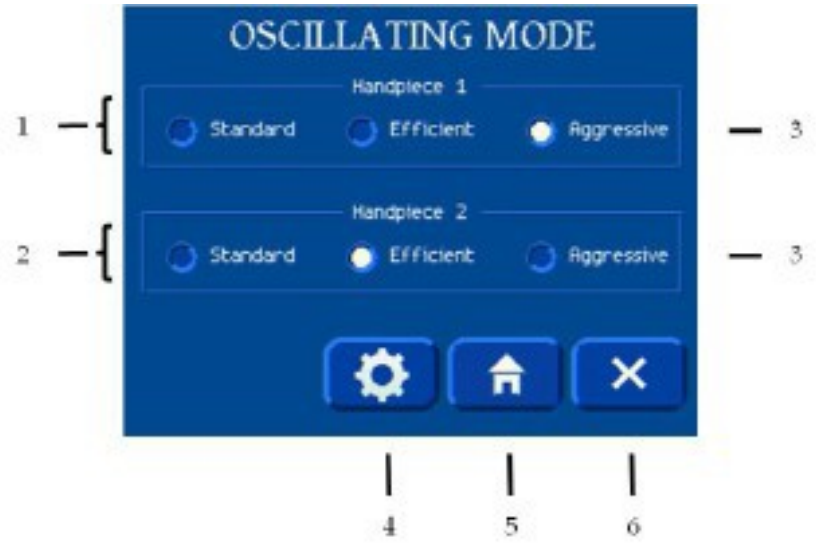


Table 14 Oscillation Mode Display - Operation

1.	**Channel 1**	The software supports each handpiece channel **with its own oscillation mode.**
2.	**Channel 2**	
3.	**Oscillation Mode** radio buttons	Select the oscillation mode: Standard, Efficient or Aggressive.
4.	**Menu** button	When pressed, the software stores the selected mode and returns to the Menu screen.
5.	**Home** button	When pressed, the software stores the selected mode and returns to the Main screen.
6.	**Cancel** button	When pressed, the software returns to the Menu screen without making any changes.

5.5 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 Shaver Handpiece 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, the Footswitch control will be dominant.

In the default (enabled) mode, the buttons on the hand-control shaver handpiece will not function when a footswitch is attached to the console. When disabled, both buttons on the handpiece and the footswitch will function. This screen also includes Menu, Home and Cancel buttons as described in Table 15 below:

Figure 9 Footswitch Override Selection Screen - Operation

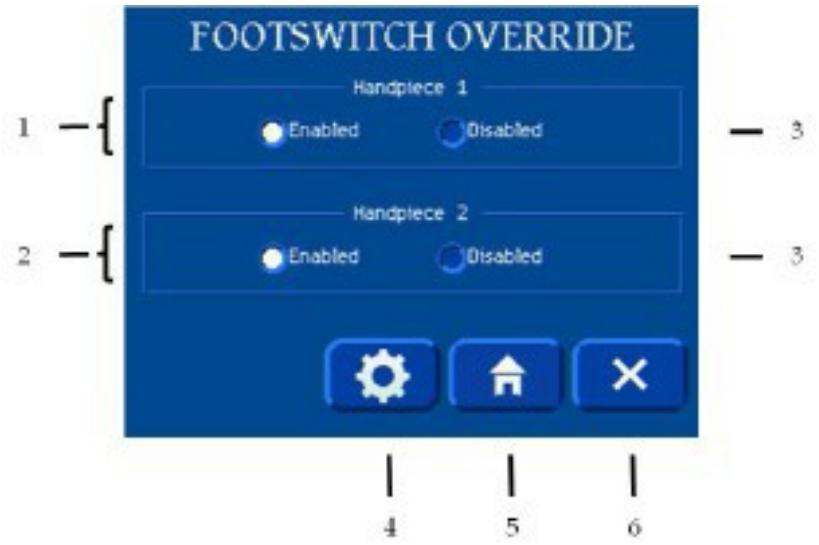


Table 15 Footswitch Override Display - Operation

1. **Channel 1** 2. **Channel 2**	The software displays the current settings for footswitch override for each channel with two sets of radio buttons.
3. **Footswitch Override** radio buttons	Each channel has an Enabled and Disabled radio button, with the factory default set to Enabled.
4. **Menu** button	When pressed, the software stores the selected mode and returns to the Menu screen.
5. **Home** button	When pressed, the software stores the selected mode and returns to the Main screen.
6. **Cancel** button	When pressed, the software returns to the Menu screen without making any changes.

5.6 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.

Figure 10 Reset Defaults Screen - Operation

The software displays two buttons that allows the user to confirm resetting of factory defaults as described in Table 16 below.

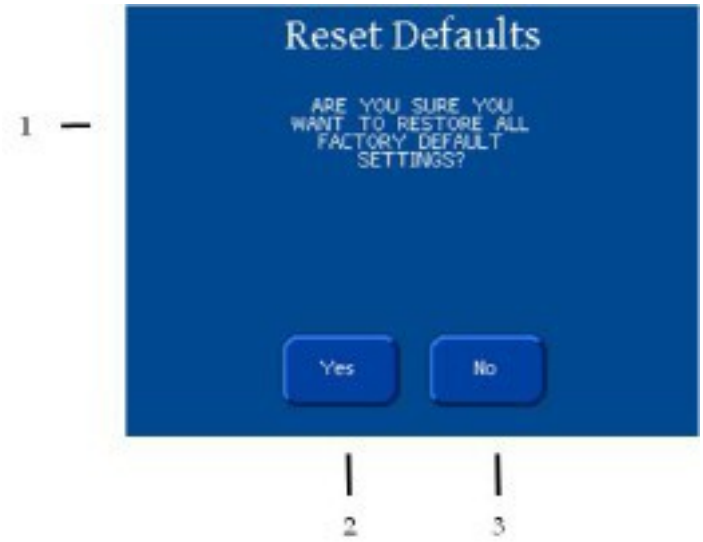


Table 16 Reset Defaults Display - Operation

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

5.7 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 17 below:

Figure 11 Information Screen - Operation

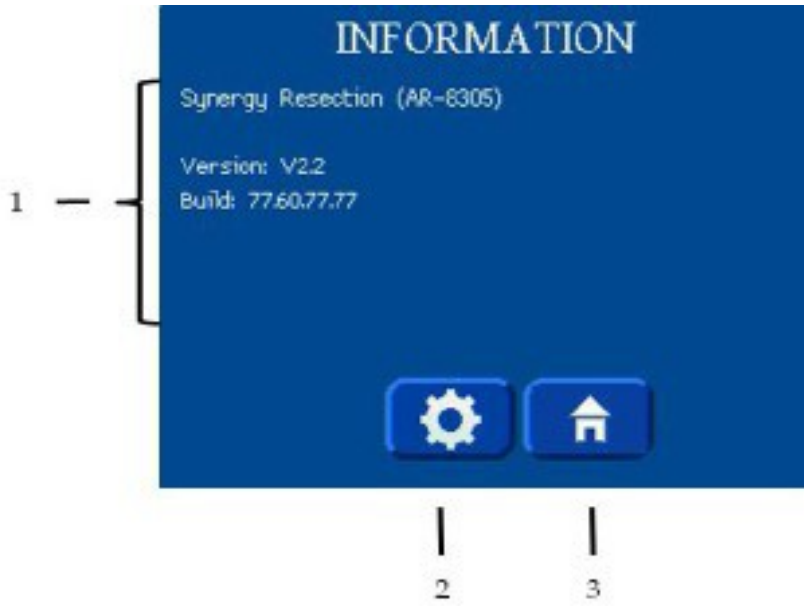


Table 17 Information Screen Display - Operation

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

5.8 Buttons

Most buttons send a message to the controller when activated and/or released. The **Up** and **Down** speed buttons auto repeat when pressure is maintained. The selected speed is not sent to the controller until the button is released.

5.8.1 Buttons - Main Screen

The Main Screen is displayed in one of two configurations depending on how many handpieces are connected to the system. A single handpiece screen is displayed with a single screen while a two handpiece screen has two equally sized sections, top and bottom. A single handpiece screen has the same content as a dual handpiece screen section, with the exception of the OSC Mode  button on a single handpiece screen.

Figure 12 Single Handpiece Screen Oscillation Mode Location

Table 18 Oscillation Mode - Operation

1.	**Oscillation Mode** button	The OSC Mode button is only displayed when a single handpiece is installed and the device is in OSC mode. When displayed, it can be pressed to toggle between the different OSC modes. This button is not displayed on a dual handpiece screen.

Figure 13 Two Handpiece Buttons - Operation

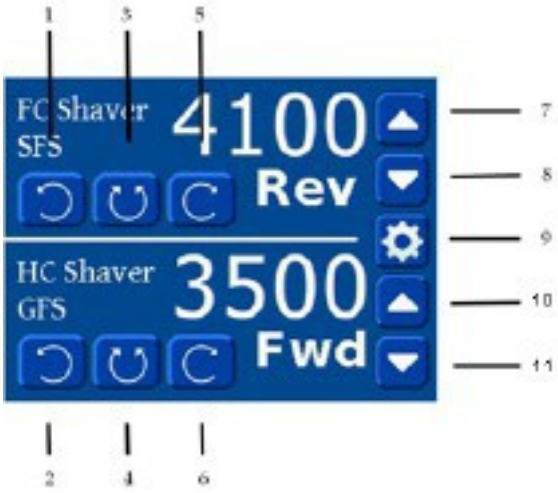


Table 19 Two Handpiece Buttons - Operation

1. 2.	Channel 1 **Reverse** button Channel 2 **Reverse** button	When the **Reverse** button is pressed, the handpiece motor moves in a counterclockwise direction when observed from the tip of the shaver.
3. 4.	Channel 1 **Oscillation** button Channel 2 **Oscillation** button	When the **Oscillation** button is pressed, the handpiece motor moves in an alternating clockwise/counterclockwise direction. The duration of each direction is specified in the Shaver Controller SRS document.
5. 6.	Channel 1 **Forward** button Channel 2 **Forward** button	When the **Forward** button is pressed, the handpiece motor moves in a clockwise direction when observed from the tip of the shaver.
7. 8.	Channel 1 **Up** button Channel 2 **Up** button	When the **Up** button is pressed, the speed of the motor increases. The increase of the motor speed depends on the type of handpiece. When the **Up** button is initially pressed, during the first second, the speed changes by one increment. If the **Up** button is still pressed after the initial second, the speed continues to increase until the limit is reached.

9. Channel 1 **Down** button	When the **Down** button is pressed, the speed of the motor decreases.
10. Channel 2 **Down** button	The decrease of the motor speed depends on the type of the handpiece. When the **Down** button is initially pressed, during the first second, the speed changes by one increment. If the **Down** button is still pressed after the initial second, the speed continues to decrease until the limit is reached.
11. **Settings** button	The **Settings** button is not displayed if either of the two motors are in motion. When the motors are not in motion, the **Settings** button is displayed between the Up and Down buttons for both sections in a dual screen mode, or in the lower right corner in a single screen mode. When the **Settings** button is pressed for 3 seconds, the software switches the controller into speed test mode. See Speed Test Mode.

5.9 Speed Test Mode

The software enters the Speed Test mode when the Menu button is pressed and held for 3 seconds until a triple beep is sounded.

5.10 Speed Adjustment

The **Up** and **Down** speed buttons auto-repeat when pressure is maintained. The selected speed is not sent to the controller until the button is released.

5.11 Oscillation Mode Adjustment

The **OSC Mode** button is only displayed when a single handpiece is installed and the device is in OSC mode.

When displayed, it can be pressed to toggle between the different OSC modes. This button is not displayed on a dual handpiece screen.

5.12 Accessory Handpiece Speed Limits and Deltas

The console supports individual handpiece motor-speed limits, defaults, and speed increment and decrement "deltas". These are defined below for the supported handpieces.

Table 20 Accessory Handpiece Speed Limits and Delta

	Forward / Reverse Speeds (RPM)			Oscillation Speeds (RPM)		
Handpiece	**Min.**	**Max.**	**Speed Delta**	**Min.**	**Max.**	**Speed Delta**
Shaver	500	8000	300	500	3000	250
Drill	100	1400	See Drill Speeds Section	N/A	N/A	N/A
Sag Saw	18000	18000	N/A	N/A	N/A	N/A
SJ Shaver	500	6200	300	500	3000	250

5.12.1 Drill Speeds

The drill supports only 100, 300, 500, 900, and 1400 (RPM). It does not cycle through regular increments.

NOTE: While operating handpieces, the settings can be changed without risk of damaging the motor or console.

W A R N I N G !

Do not have the device in direct contact with patient if high-frequency devices are in use or if the patient requires defibrillation.

5.12.2 Console Speed Controls

The Speed Increase and Speed Decrease buttons adjust the speed. Each time a button is pressed, the speed is adjusted as shown in Table 20. The commands are ignored if multiple buttons are pressed simultaneously.

To make the handpiece speed increase or decrease automatically, press the Speed Increase or Speed Decrease button for more than 1 second. The values will not exceed the minimum and maximum values defined for the attachment.

Table 21 Handpiece Accuracy

Handpiece	ACCURACY
All Shavers	±5 % OR ±100 RPM (greater of the two)
Drill	±5 % OR ±20 RPM (greater of the two)
Sag Saw	±6 %

5.13 Attachment Motor Control

5.13.1 Definition of Direction

The definition of direction as viewed looking from the proximal to the distal (top of the tip) of the shaver handpiece.

1.	Reverse	Counterclockwise (CCW)
2.	Forward	Clockwise (CW)
3.	Oscillation	CW then CCW
4.	Stop	No rotation

5.13.2 Forward, Reverse and Oscillation Modes

The buttons and pedals for the Reverse, Forward, and Oscillation modes select which direction the motor rotates. If the Reverse and Forward buttons or pedals are detected simultaneously then the motor defaults to Oscillation mode. During Oscillation mode, the motor will rotate forward, then backward. Any other combination of simultaneous button and pedal activations are ignored by the device. This operation applies to both the console front-panel buttons and the supported footswitch pedals.

5.13.3 Cruise Control

Use the Gas Pedal Footswitch to engage the cruise control function. The Gas Pedal Footswitch is available as an optional system accessory. To operate the cruise control, you must:

5.13.3.1 Cruise Set

When you select the Cruise Control Button, the Cruise function becomes ARMED (signaled by a single audible 1 second alarm) but the LOCK IN period does not start until one of the three pedals is pressed. If a pedal is not pressed within 15 seconds then the Cruise function becomes DISARMED (signaled by a single audible 1 second alarm).

If the Cruise button is pressed on an attachment that does not allow cruise control, an error alarm occurs (3 fast tones), and displays the message "*CRUISE NOT ALLOWED*".

5.13.3.2 Cruise Lock

The LOCK IN period lasts for up to 15 seconds. During the LOCK IN period the operator adjusts the speed and must hold the pedal steady for 3 seconds in order for the LOCKED state to occur. Steady is defined as ±500 RPM for forward or reverse, and ±400 RPM for oscillation. If the pedal is held steady, the Shaver Console emits an audible double alarm (2 brief tones) that indicates the LOCKED state has been entered, and "*Lock*" is displayed. If the pedal was not held steady within the 15 second LOCK IN period, then the Cruise function becomes DISARMED (signaled by a single audible 1 second alarm).

5.13.3.3 Remove Foot

The operator can move the same pedal for the next 3 seconds without leaving the LOCKED state. This is necessary, since the act of taking the foot off of the pedal moves the pedal position. Once the pedal is fully released, or after 3 seconds have elapsed, the system again responds to this pedal and disables the Cruise function.

5.13.3.4 Disable Cruise Lock

If any other footswitch or console panel button is activated while in the LOCKED state, the Cruise function becomes DISARMED (with the exception noted in item Remove Foot).

5.13.3.5 Disable Cruise Set

If the Toggle, Cruise Control, or Front Panel buttons are pressed at any time after the Cruise Control button is selected (i.e. in the ARMED or LOCKED state) then the Cruise function becomes DISARMED.

5.13.4 Toggle Function

A Toggle switch is available on both the Standard and the Gas Pedal footswitches. The toggle function is performed by pressing a button on the footswitch. The toggle function is available when one footswitch and two handpieces are connected to the Synergy^{Resection} console. The toggle function allows the operator to control the handpieces in channel 1 and channel 2, without moving the footswitch connection.

At power on, or at first connection, the footswitch controls the attachment which is on the same channel as the one the footswitch is connected to. When the user presses the Toggle switch, a beep indicates the footswitch has been toggled to the attachment on the opposite channel. The handpiece on the same channel as the footswitch is controlled by the front panel buttons only.

When the user presses Toggle again, the footswitch returns control to the handpiece on the same channel as the footswitch. The channel on the opposite side as the footswitch is controlled by front panel buttons only.

When controlled by the footswitch, the **HC shaver** is controlled by the Footswitch Override setting. When not controlled by the footswitch, the handpiece buttons and control panel are enabled.

If there is a connected attachment for each installed footswitch, and the attachment supports oscillation mode, the toggle button switches to the next oscillation mode in this sequence: efficient mode, aggressive mode, standard mode and then back to efficient mode.

If two footswitches are installed with only one connected attachment, the footswitch without a connected attachment is inactive.

If the Toggle switch is activated when only one attachment is connected and this attachment does not support oscillation modes, an error beep sounds and "TOGGLE NOT ALLOWED" message is temporarily displayed.

Table 22 Toggle Function

Installed Handpieces	Installed Footswitches	Action	Beep type
0	1	None	None
0	2	None	None
1	1	Change oscillation mode	Single
1	2	Change oscillation mode (footswitch on installed HP channel)	Single
		None (footswitch with no installed HP)	None
2	1	Move control to next channel	Single
2	2	Change oscillation mode	Single

5.14 Footswitches

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

5.14.1 Standard Footswitch

The Speed Increase button adjusts the speed in the positive direction only. Each time the button is pressed, the speed adjusts as shown in Table 20. When the device is at maximum speed setting, the user can return to minimum speeds by pressing the Speed Increase button one more time. The commands are ignored if multiple buttons are pressed simultaneously.

If the Speed Increase button is continuously pressed for more than 1 second then the speed auto-increments accordingly. The speed setting will not wrap when auto-incrementing. Release the Speed Increase button and then press it again to get the speed setting to cycle to the minimum setting.

5.14.2 Gas Pedal Footswitch

The Forward, Reverse, and Oscillation pedals linearly adjust the speed. When the pedal is pressed, it returns an analog signal that is converted to a corresponding RPM between the minimum and maximum speed of the attachment connected to the footswitch.

5.14.3 Multi-Function Footswitches

Wireless and Corded Multi-Function Footswitches can operate as either a Standard Footswitch or as a Gas Pedal Footswitch, as described in the preceding sections. Function selection is made by pressing the button on the Multi-Function Footswitch labeled "GFS" or "SFS'. These footswitches are available as optional accessories. For more information on the Synergy^{Resection} Wireless Footswitch (AR-8315W), please see DFU-0320-XX. For the Synergy^{Resection} Wireless Footswitch Quick Start Guide, please see DFU-0323-XX-SUB.

5.15 Accessory Handpieces

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

6.0 Cleaning and Disinfecting

6.1 Console AR-8305

The AR-8305 console is provided non-sterile and must not be sterilized.

The AR-8305 console can be cleaned/disinfected using a cloth and commercially available surfactants or surface disinfectants only. Use a commercially available cleaning disinfectant for surfaces. Alkaline agents with a pH value > 8 are to be avoided Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device. The AR-8305 must not be submersed in any liquid.

Always place the Main Power Switch to "Off (O), position" and disconnect the power before cleaning the AR-8305 console.

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

NEVER clean the console with liquid cleaners. If there is dust, remove it with dry compressed air.

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

6.2 Footswitches

The footswitch is provided non-sterile and must not be sterilized.

To clean and disinfect, unplug the cord from the console and add the protective cap to the connector. Use a commercially available cleaning disinfectant for surfaces. Alkaline agents with a pH value > 8 are to be avoided. 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.

Refer to the Multifunction Wireless Footswitch Operator's Manual, LM0659 for additional cleaning instructions.

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 it 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 footswitch is NOT suitable to be cleaned and disinfected in a thermo washer disinfector.

6.3 Accessory Cable

Clean the cable with an enzymatic cleaner without subsequent acid neutralization. Use a commercially available cleaning disinfectant for surfaces. Alkaline agents with a pH value > 8 are to be avoided Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.

Rinse the cable thoroughly after cleaning.

After cleaning, disinfect the cable with a commercially available surface disinfectant.

Thoroughly rinse the cable under lukewarm distilled water or preferably demineralized sterile water. See Section 7.0 for sterilization information.

Refer to the Instructions for Use package insert for detailed Adapteur Power System II Accessory Attachments (DFU-0149-XX) cleaning and sterilization instructions included with each cable. Additional copies of this insert can be obtained from the Arthrex website at www.Arthrex.com, or by contacting your local Arthrex Representative.

Always comply with the instructions issued by the manufacturer of the disinfectant.

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

6.4 Accessory Handpieces

Refer to the Instructions for Use package insert for detailed shaver handpiece (DFU-0154-XX, or DFU-0240-XX) and Adapteur Power System II Accessory Attachments (DFU-0149-XX) cleaning and sterilization instructions included with each handpiece. Additional copies of this insert can be obtained from the Arthrex website at www.Arthrex.com, or by contacting your local Arthrex Representative.

Remove any accessories in the device. This includes shaver blades, saw blades or drill bits.

If the handpiece has suction control, make sure it is fully open.

Clean the handpiece with an enzymatic cleaner without subsequent acid neutralization.

If the handpiece has suction control, clean the connection with a cleaning brush. Rinse the handpiece thoroughly after cleaning.

Disinfect the handpiece with a commercially available disinfectant.

Thoroughly rinse the handpiece under lukewarm distilled water or preferably demineralized sterile water.

See Section 7.0 for sterilization information.

Always comply with the instructions issued by the manufacturer of the disinfectant.

NEVER place the shaver handpiece in Cidex or other aldehyde disinfectant solutions.

NEVER allow the console plug pins to have any contact with liquids. Remove dust or moisture with dry compressed air. Only DRY connectors may be plugged into the console.

7.0 Sterilization

Sterilization capabilities, cleaning, disinfecting, handling, and storage of instrumentation are the responsibility of qualified facility and/or user personnel. Qualified personnel must still properly clean and disinfect the instruments prior to sterilization.

⚠ **Refer to the Instructions for Use package insert for detailed Shaver Handpiece (DFU-0154-XX or DFU-0240-XX) and Adapteur Power System II Accessory Attachments (DFU-0149-XX) cleaning and sterilization instructions included with each handpiece. Additional copies of this insert can be obtained from the Arthrex website at www.Arthrex.com, or by contacting your local Arthrex Representative.**

⚠ **After sterilization in the autoclave, let the accessory device cool down slowly. NEVER use cold water to cool the handpieces. This will damage the electronic components and seals.**

⚠ **Liquid on the cable connector of the accessory device can damage the device. Before connecting the cable, ensure the receptacles are clean and dry.**

W A R N I N G !

After autoclaving, the accessory devices are VERY HOT. Handle with care to avoid burns.

The following special instructions are to be observed when sterilizing accessory handpieces.

⚠ **Open or remove the suction control completely to ensure proper circulation, if applicable.**

⚠ **Open the chuck completely to ensure proper circulation, if applicable.**

⚠ **Remove all accessories, including shaver blades, drill bits and saw blades before sterilizing a handpiece.**

8.0 Transmissible Spongiform Encephalopathy (TSE) 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 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: Good Hospital Practice: Steam sterilization and sterility assurance.

9.0 Maintenance

Regular and proper maintenance of your Synergy[Resection] System is the best way to protect your investment and avoid non-warranty repairs.

Recommended care and handling of the Synergy[Resection] System includes proper day- to-day operation, cleaning, and sterilization which are extremely important to ensure safe and efficient operation. It is important to visually inspect the foot pedal and handpiece, cable and connectors before each use.

Your authorized Arthrex service department is the most knowledgeable about the Arthrex Medical Resection Systems and/ foot pedal and handpiece, 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.

9.1 Life Expectancy

Life expectancy for the console is approximately 5 years under normal use and standard of care.

9.2 Periodic Maintenance

The product should be inspected prior to and after each use to ensure that the foot pedal, handpiece, cable, strain relief, overmold, or connector contacts are not damaged or worn. If it becomes necessary to return the foot pedal and / or handpiece to Arthrex for service, please disinfect the foot pedal and/or sterilize the handpiece before shipping.

10.0 Technical Support

For assistance in using the products identified in this *User's Guide*, contact an Arthrex representative or contact the **Arthrex Technical Support Hotline** at 1 (800) 391-8599, Monday through Friday from 8:00 AM to 8:00 PM EST; at +49 89 909005-0 or techsupport@arthrex.de from 8:00 AM to 5:00 PM CET

10.1 How to Display the Software Version

Technical Support may request the software version of the AR-8305. Follow these instructions to display the software version.

1. Power On the AC mains power switch [3] on the AR-8305.
2. The software version is displayed on the TPVD during the power-up sequence.

10.2 Additional Technical Information

Contact your Arthrex representative if require more comprehensive technical information. Circuit diagrams, component part lists, descriptions, calibration instructions, or other information will be provided upon request by Arthrex APPROVED SERVICE PERSONNEL

11.0 Troubleshooting

Refer to Table 23 for device troubleshooting if problems occur after cleaning, transporting or changing operating staff.

Table 23 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. Send in for repairs.
Handpiece does not work.	1. Handpiece is not connected to the correct channel. 2. Not fully or properly connected or connector is damaged. 3. Liquid in the receptacle or connector. 4. Connector is damaged. 5. Footswitch is defective. 6. Footswitch is functional. 7. Handpiece is too hot after sterilization. 8. Handpiece over-current is detected. 9. Defective handpiece.	1. Check the connector is plugged into the correct channel receptacle. 2. Check both connectors are plugged in properly. 3. Dry thoroughly. 4. Replace the cable. 5. Operate the device using the console unit. 6. Replace the handpiece. 7. Allow it to cool down as indicated in the WARNING in Section 7.0. 8. Allow 30 seconds for the console to reset the affected channel. 9. Send in for repairs.
Motor runs but shaver blades/burrs do not work.	1. Shaver blade/burr incorrectly inserted. 2. Damaged hub. 3. Bent sleeve.	1. Insert the shaver blade so that it engages. Fully close the locking mechanism. 2. Replace the shaver blade/burr. 3. Replace the shaver blade/burr.
No suction.	1. Clogged suction connection. 2. Clogged shaver blade or burr. 3. Closed Suction Control. 4. Damaged Suction Control.	1. Rinse with a syringe. 2. Clean with a brush. 3. Open Suction Control. 4. Send in for repairs.

Fault	Cause	Solution
System runs with the control unit but not with the footswitch.	1. Not fully, properly connected or damaged connector. 2. Liquid in receptacle or connector. 3. Defective Footswitch.	1. Check the connector from the footswitch to the control unit. 2. Dry thoroughly. 3. Send in for repairs.
Connected handpiece not shown on display.	1. Not fully or properly connected or connector is damaged. 2. Defective handpiece or connector. 3. Connector is damaged. 4. Defective handpiece.	1. Check that both connectors are plugged in properly. 2. Check the connector with another handpiece. 3. Replace. 4. Send in for repairs.

If the problems persist, disinfect the Synergy[Resection] System and send in to Arthrex using the original packaging. Always send the corresponding handpiece together with the console, footswitch and cable. Please enclose a brief explanation of the detected malfunction. Refer to Section 12.0 for more information.

11.1 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.

12.0 Repair Policy

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

13.0 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.

14.0 Electromagnetic Emissions

Table 24 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The AR-8305 Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-8305 Shaver System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1	AR-8305 Synergy[Resection] 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.
RF emissions CISPR 11	Class A	The AR-8305 Synergy[Resection] 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 25 System Cables

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

Table 26 Guidance and Manufacturer's Statement - Electromagnetic Immunity

The AR-8305 Synergy[Resection] System is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-8305 Synergy[Resection] 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 100	± 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 315^0) U_T= 0%;1 cycle U_T= 70%;25/30 cycles (@0 degrees) U_T= 70%; 250/300 cycles	U_T= 0%,0.5 cycle (0, 45, 90,135, 180, 225, 270, and 315^0) U_T= 0%;1 cycle U_T= 70%;25/30 cycles (@0 degrees) U_T= 70%; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the AR-8305 Synergy[Resection] System requires continued operation during power mains interruptions, it is recommended that the AR-8305 Synergy[Resection] 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: UT is the AC mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Model AR-8305, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [3.5/V1]\sqrt{P}_{=1.17}\sqrt{P}$ $d = [3.5/V1]\sqrt{P}_{=1.17}\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}_{=2.33}\sqrt{P}$ 800 MHz to 2.7 GHz 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 8305is used exceeds the applicable RF compliance level above, the Model AR-8305 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-8305

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

Table 27 Guidance and Manufacturer's Statement – Recommend Separation Distance between portable and mobile RF communications equipment and the Model AR-8305

Recommended separation distances between portable and mobile RF communications equipment and the ModelAR-8305

The ModelAR-8305 Synergy[Resection] 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-8305 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model AR-8305 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.

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