



Adapteur Power System II

User's Guide

The *Arthrex Adapteur Power System II User's Guide* provides important information for the safe operation of all components of the Arthrex Adapteur Power System II (Model AR-8300), including accessories. Read this *User's Guide* thoroughly prior to using this system and keep it in an easily accessible place for use by all operating personnel. Read and follow all safety warnings, cautions, and notes.

U.S. PATENT PENDING

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AR-8300S

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1.0 Read This First!

1.1 Important Symbols and Conventions

The *Adapteur Power System II User's Guide* identifies critical, important, and useful information using these symbols and conventions. Your familiarity with these symbols and conventions is required.

W A R N I N G !

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



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

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

1.2 Shipping, Unpacking, and Warranty Information

Prior to use in a surgical procedure, carefully unpack and inspect the components for any sign of damage that may have occurred during shipping. If shipping damage is suspected, notify Arthrex or any authorized Arthrex distributor immediately. Any such damage could compromise patient safety.

If transport or first-installation damage is not reported within seven business days of receiving the device, the warranty could be rendered void.

Refer also to our General Terms of Business.

Arthrex assumes a warranty to the first purchaser for a twelve month period with regard to defects or failure of its medical devices. All defective products covered by the warranty are repaired or replaced free of charge by Arthrex at Arthrex's discretion. The warranty does not cover any damage caused by unlawful use or improper handling of a particular product.

The warranty becomes invalid when Arthrex products are changed in any way or repairs are performed by any party other than Arthrex.

Arthrex will answer any questions referring to the quality, reliability, and/or shelf life of any product identified in this *User's Guide*.

1.3 Important Safety Information

W A R N I N G !

This device is to be used by or 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*.



U.S. Federal Law restricts this device to use only by or on order of a physician.



DO NOT—under any conditions or for any reason—open the console (AR-8300) or any other shaver accessory.

NOTE: Read this User's Guide thoroughly before attempting to operate the device and retain for future reference.

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

2.0 Product Description

2.1 Functional Description and Intended Use

The Arthrex Adapteur Power System II is a multi-functional system designed for many different orthopedic uses.

The system is microprocessor controlled and can operate several different handpieces. Handpieces are connected to the console by means of a cable and are operated by a waterproof footswitch or by the front panel switches.

The AR-8300 console is designed for continuous operation. The motorized 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 de-activated. When the fault is removed and the thermal fuse cools down (typically about 30 seconds) operation resumes, retaining the pre-failure settings.

The cable and all handpieces can be sterilized. This means that the handpieces can be changed during the surgical procedure without endangering surgical sterility.

The Adapteur Power System AR-8300S includes:

- AR-8300, Console with power cord
- Standard Footswitch
- Two Shaver Handpieces
- *User's Guide*

Optional Accessories:

- Gas Pedal Footswitch
- Corded Multi-Function Footswitch



- Wireless Multi-Function Footswitch
- Accessory Handpiece Cable
- Drill Handpiece with key for Jacobs chuck
- Sagittal Saw Handpiece with wrench

Save the packaging for later transport of the device.

W A R N I N G !

This device is to be used by or 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*.

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2.2 Product Features

2.2.1 AR-8300 Console: Front Panel

Figure 1 shows the front panel of the AR-8300 console. Features and symbols are identified in Table 1.

FIGURE 1 FRONT PANEL OF CONSOLE

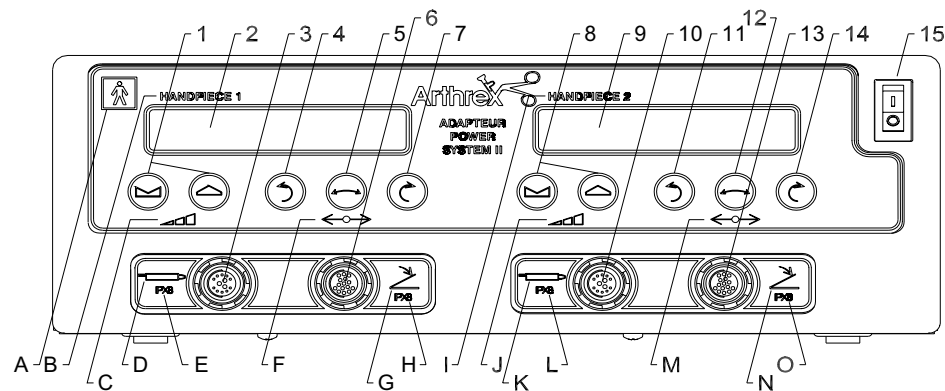


TABLE 1 FRONT PANEL ELEMENTS

FEATURES		SYMBOLS	
1	Handpiece 1 Speed Increase/Decrease switches	A	Protection plate TYPE BF
2	Handpiece 1 Operator Display	B	Handpiece 1 ID Label
3	Handpiece 1 Handpiece Receptacle	C	Handpiece 1 Speed Adjust
4	Handpiece 1 REVERSE Switch	D	Handpiece 1 Receptacle
5	Handpiece 1 OSCILLATE Switch	E	Handpiece 1 Classification
6	Handpiece 1 Footswitch Receptacle	F	Handpiece 1 Direction Adjust
7	Handpiece 1 FORWARD Switch	G	Footswitch 1 Receptacle
8	Handpiece 2 Speed Increase/Decrease switches	H	Footswitch 1 Classification
9	Handpiece 2 Operator Display	I	Handpiece 2 ID Label
10	Handpiece 2 Handpiece Receptacle	J	Handpiece 2 Speed Adjust
11	Handpiece 2 REVERSE Switch	K	Handpiece 2 Receptacle

FEATURES		SYMBOLS	
12	Handpiece 2 OSCILLATE Switch	L	Handpiece 2 Classification
13	Handpiece 2 Footswitch Receptacle	M	Handpiece 2 Direction Adjust
14	Handpiece 2 FORWARD Switch	N	Footswitch 2 Receptacle
15	AC Mains POWER switch	O	Footswitch 2 Classification

2.2.2 AR-8300 Console: Rear Panel

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

FIGURE 2 REAR PANEL OF CONSOLE

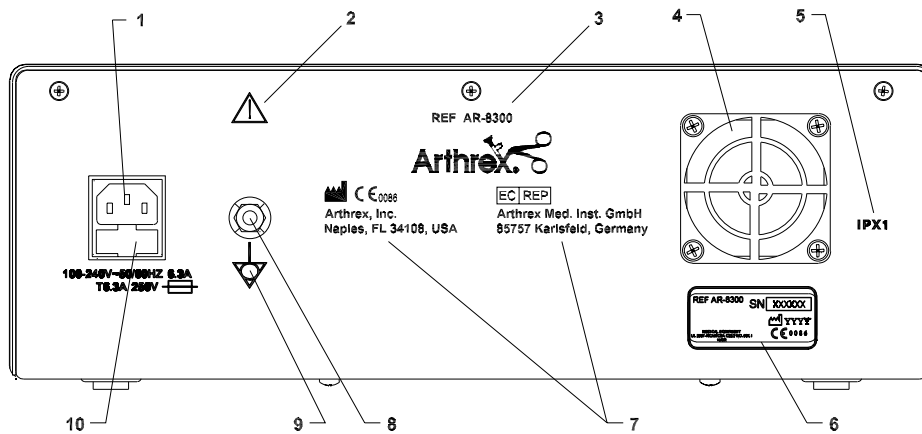


TABLE 2 REAR PANEL ELEMENTS

ELEMENT NUMBER	ELEMENT NAME
1	Main Power Input Plug
2	Comply with Operating Instructions Symbol
3	Model Number
4	Fan
5	Splash Proof Symbol
6	Serial Number Label
7	Address
8	Equipotential Bonding Pin
9	Equipotential Bonding Symbol
10	Fuse holder for the Power Entry Module

2.2.3 AR-8300 Console: Front Panel (With Software 5.01.00 or Higher)

Figure 3 shows the front panel of the AR-8300 console. Features and symbols are identified in Table 3.

FIGURE 3 FRONT PANEL OF CONSOLE (WITH SOFTWARE 5.01.00 OR HIGHER)

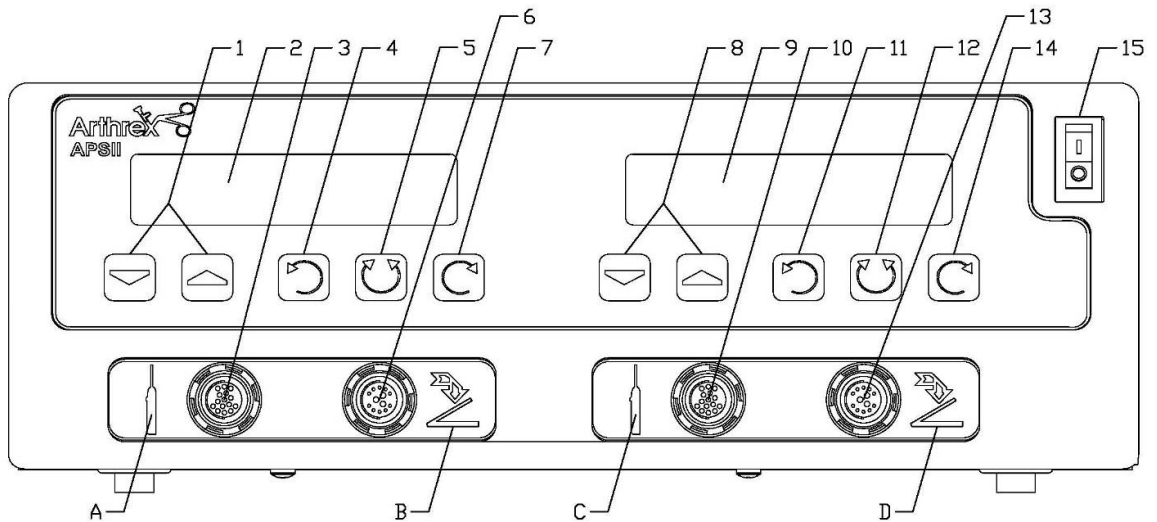


TABLE 3 FRONT PANEL ELEMENTS

FEATURES		SYMBOLS	
1	Handpiece 1 Speed Increase/Decrease switches	A	Handpiece 1 Receptacle
2	Handpiece 1 Operator Display	B	Footswitch 1 Receptacle
3	Handpiece 1 Handpiece Receptacle	C	Handpiece 2 Receptacle
4	Handpiece 1 REVERSE Switch	D	Footswitch 2 Receptacle
5	Handpiece 1 OSCILLATE Switch		
6	Handpiece 1 Footswitch Receptacle		
7	Handpiece 1 FORWARD Switch		
8	Handpiece 2 Speed Increase/Decrease switches		
9	Handpiece 2 Operator Display		
10	Handpiece 2 Handpiece Receptacle		
11	Handpiece 2 REVERSE Switch		
12	Handpiece 2 OSCILLATE Switch		
13	Handpiece 2 Footswitch Receptacle		
14	Handpiece 2 FORWARD Switch		
15	AC Mains POWER switch		

2.2.4 AR-8300 Rear Panel: (With Software 5.01.00 or Higher)

Figure 4 shows the rear panel of the console. Features and symbols are identified in Table 4.

FIGURE 4 REAR PANEL OF CONSOLE (WITH SOFTWARE 5.01.00 OR HIGHER)

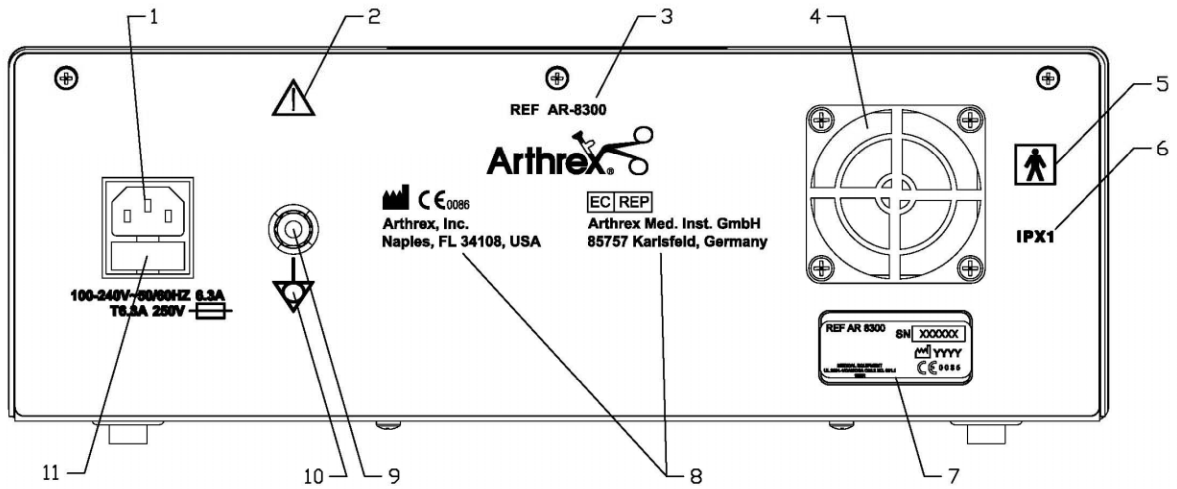


TABLE 4 REAR PANEL ELEMENTS

ELEMENT NUMBER	ELEMENT NAME
1	Main Power Input Plug
2	Comply with Operating Instructions Symbol
3	Model Number
4	Fan
5	Protection Plate Type BF
6	Splash Proof Symbol
7	Serial Number Label
8	Address
9	Equipotential Bonding Pin
10	Equipotential Bonding Symbol
11	Fuse holder for the Power Entry Module

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2.2.5 AR-8300 Display Messaging

A listing of informational and error messages is shown in Table 5

TABLE 5 AR-8300 DISPLAY MESSAGING

MESSAGE	EXPLANATION
<i>Arthrex</i>	Power on message, Handpiece 1 display
<i>APSII</i>	Power on message, Handpiece 2 display
<i>INACTIVE</i>	Handpiece disabled
<i>DFS</i>	Digital Footswitch Connected
<i>GFS</i>	Gas Pedal Footswitch Connected
<i>SFS</i>	Standard Footswitch Connected
<i>No Tool</i>	No tool connected on channel
<i>Shaver</i>	Shaver connected
<i>Drill</i>	Drill connected
<i>Sag Saw</i>	Sagittal Saw connected
<i>SJ Shaver</i>	Shaver connected
<i>rpm</i>	Speed designation, revolutions per minute
EEPROM Reset	Momentarily displayed first time microcontroller is programmed, or if internal memory has faulted and is reset.
Motor Fault	Momentarily displayed when motor fault condition occurs
Overload	Momentarily displayed when motor over-current condition occurs
Self Test Fail	Console has failed a critical power on test
CRUISE NOT ALLOWED	Momentarily displayed when cruise button pressed with tool that doesn't allow cruise control
FWD or REV ONLY	Momentarily displayed for tools that do not support OSC mode
Lock	Speed locked on cruise control
TOGGLE NOT ALLOWED	Momentarily displayed when toggle button pressed with two footswitches connected, or no tool on opposite channel.
<i>Agg</i>	Current mode: Aggressive oscillation mode (stopped)
<i>CC ON</i>	Cruise control enabled, about to lock
<i>Eff</i>	Current mode: Efficient oscillation mode (stopped)
<i>English</i>	Programming mode. Language set to English
<i>F/R</i>	Current mode: forward/reverse (stopped)
<i>French</i>	Programming mode. Language set to French
<i>Fwd</i>	Current mode: Forward (stopped)
<i>Fwd></i>	Current status: Motor is moving forward
<i>Gas Pedal Footswitch</i>	Momentarily displayed when gas pedal footswitch connected
<i>German</i>	Programming mode. Language set to German
<i>Italian</i>	Programming mode. Language set to Italian
<i>No Footswitch</i>	Momentarily displayed when footswitch disconnected
<i>Osc</i>	Current mode: oscillation (stopped)
<i>Osc~</i>	Current status: Motor is oscillating
<i>Prog Mode: BRIGHTNESS</i>	Console is in programming mode. Set the display brightness
<i>Prog Mode: LANGUAGE</i>	Console is in programming mode. Set the language
<i>Rev key changes mode</i>	Programming mode instructions to change function (currently LANGUAGE or BRIGHTNESS)
<i>Rev</i>	Current mode: Reverse (stopped)
<i>Rev<</i>	Current status: Motor is moving in reverse
<i>Run></i>	Current status: Motor is running (for saw)
<i>Spanish</i>	Programming mode. Language set to Spanish
<i>Standard Footswitch</i>	Momentarily displayed when standard footswitch connected
<i>Std</i>	Current mode: Standard oscillation mode (stopped)
<i>Use Speed Increase- to set</i>	Programming mode instructions to change parameter

2.2.6 Standard Footswitch

Figure 5 shows the Standard Footswitch. Features and symbols are identified in Table 6.

FIGURE 5 STANDARD FOOTSWITCH

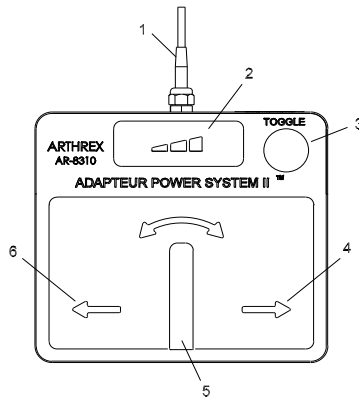


TABLE 6 ELEMENTS OF THE STANDARD FOOTSWITCH

ELEMENT NUMBER	ELEMENT NAME
1	Cable
2	Speed Increase Button
3	Toggle Button
4	Forward Pedal
5	Oscillating Pedal
6	Reverse Pedal

2.3 Technical Specifications

2.3.1 Console

TABLE 7 AR-8300 CONSOLE SPECIFICATIONS

Width	36.8 cm (14.5 inches)
Height	13.2 cm (5.2 inches)
Depth	32.5 cm (12.8 inches)
Weight	7.2 kg (16 lbs.)
Water protection	IPX1
Mains cable	10 A/250 V
Power entry module	IEC 320/C13
Fuse value	6.3 Amp, 250 VAC, 2.0 cm (0.75 inches)
AC input	87-264 VAC, 47-63 Hz
Cleaning, disinfection, and sterilization	Refer to Sections 5.0 and 6.0.

2.3.2 Standard Footswitch

TABLE 8 STANDARD FOOTSWITCH SPECIFICATIONS

<i>Functions</i>	Reverse, Forward, Oscillate, Speed Increase, and Toggle
<i>Width</i>	23.6 cm (9.3 inches)
<i>Height</i>	2.5 cm (1.0 inches)
<i>Depth</i>	20.8 cm (8.2 inches)
<i>Weight</i>	2.2 kg (5 lbs.)
<i>Water protection</i>	IPX8
<i>Cleaning, disinfection, and sterilization</i>	Refer to Sections 5.0 and 6.0

2.3.3 Ambient Conditions for Operation

TABLE 9 AR-8300S AMBIENT CONDITIONS FOR OPERATION

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

2.3.4 Ambient Conditions for Storage (in shipping packaging)

TABLE 10 AR-8300S AMBIENT CONDITIONS FOR STORAGE

<i>Temperature</i>	-40° to 70°C (-40° to 158°F)
<i>Relative humidity</i>	0% to 100%, non-condensing
<i>Air pressure</i>	500 hPa to 1160 hPa (15 in. Hg to 31.3 in. Hg)

3.0 Setup

3.1 How to Set Up the Console

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

3.2 AC Power Safety Considerations

The AR-8300 is powered by a medically rated universal AC input switching power supply, which allows the console to be connected to any local AC mains outlet provided that you use the appropriate plug and a reliable ground conductor.

Two power cords are supplied by default with the AR-8300: one for the electrical standards of the U.S. and one for the electrical standards of Germany. Contact your Arthrex representative if you need a power cord that must meet the electrical standards of another country.

The console has been 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 automatically executes a brief series of self-diagnostic tests. Upon successful completion of these self-diagnostic tests, the console displays the name and model number. If the tests discover a problem, you see

the problem displayed in the display. Refer to Table 5 for a listing of AR-8300 Display Messaging.

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

W A R N I N G !

If high-frequency devices are in use, or defibrillation of the patient is required, ensure that the device is not in direct contact with the patient.



This device has passed testing for EMI / RFI radiation and susceptibility and EMC compatibility. However, if not set up and used in accordance with the instructions provided by Arthrex, this device may cause interference to other devices in the near vicinity.

W A R N I N G !

DO NOT stack or place equipment adjacent to the AR-8300 console if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.

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 will result in patient and/or operating room staff injury.

3.3 How to Set Up a Footswitch



Only use footswitches that have been developed by Arthrex specifically for the AR-8300 Adapteur Power System II.

NOTE: Setup for a footswitch is the same for all models. The console will detect which version is attached and allow functions as appropriate.

Insert the 15-pin connector from the footswitch into the footswitch receptacle of the console so that the red dots on the connector and receptacle align and they engage easily.

3.4 How to Set Up the Shaver Handpieces



Only use shaver handpieces and cables that have been developed by Arthrex specifically for the Adapteur Power System II.

Insert the 15-pin connector from the handpiece into the handpiece receptacle of the console so that the red dots on the connector and receptacle align and engage easily.

3.5 How to Set Up Other Accessory Handpieces



Only use handpieces and cables that have been developed by Arthrex specifically for the Adapteur Power System II.

Other accessory handpieces are available for use with the Adapteur Power System II and may require the use of an accessory cable. Specific instructions for use of a particular accessory handpiece are packaged with the handpiece. The procedure for setting up the handpiece and accessory cable is described below.

Insert one end of the accessory cable connector (13-pin) into the cable receptacle of the accessory handpiece so that the red dots on the connector and receptacle align and engage easily.

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

3.6 How to Adjust the System



Do not attach handpiece(s) or footswitch(s) during Self Test or during the following Programming Modes.

3.6.1 Brightness Adjustment

This display allows the operator to vary the display brightness by using the **FORWARD** and **REVERSE** switches. These switches increment or decrement the brightness and cycle around from the minimum to the maximum setting.

1. Press and hold the **Handpiece 2 FORWARD** and **REVERSE** Switches during **power up**.
2. Depress the **Handpiece 1 Speed Increase** or **Speed Decrease** Switches to increase/decrease brightness setting respectively.
3. Once desired brightness is reached, depress the **Handpiece 1 Reverse** switch twice and system is ready for use.

3.6.2 Language Selection

This display allows the user to select one of five languages. The language is selected by using the **FORWARD** and **REVERSE** switches. The switches will scroll through the selected choices and wrap around at the beginning and end of the list.

You can view the display text in English, French, German, Italian, or Spanish. The default language is English. To select a different language, follow these steps.

NOTE: Reference Figure 1 or Figure 3 for a diagram of front panel. Do not switch the unit off or disconnect the main power plug, until final step is finished, otherwise all changed settings are lost.

1. Depress the **Handpiece 2** FORWARD and REVERSE switches during power up.
2. Depress the **Handpiece 1** Reverse switch once to enable Language selection.
3. Depress the **Handpiece 1** Speed Increase or Speed Decrease switches to select the desired Language.
4. Once you choose the Language, depress the **Handpiece 1** Reverse switch. The system is ready for use.

4.0 Operation

4.1 Console (AR-8300) Speed Adjustment

To power on the console, toggle the "POWER SWITCH" button to the ON position. The console initiates a series of self-diagnostic checks.

Figure 6 shows the layout for the two independent displays: one display for each attachment channel. The two displays operate exactly the same for their respective channel.

FIGURE 6 LAYOUT OF THE AR-8300 DISPLAY

Tool Name			Channel Inactive or Pedal Type	Tool Name			Channel Inactive or Pedal Type
HANDPIECE 1				HANDPIECE 2			
S a g	S a w		INACTIVE	S h a v e r			GFS
1 8 0 0 0 RPM	F / R			8 0 0 0 RPM	FWD >		* LOCK*
Speed		Mode or Motor Status	Cruise Control Status	Speed		Mode or Motor Status	Cruise Control Status

The top line is split into two areas. The left side displays the name of the device, and the right side displays either the footswitch attached (or blank if no footswitch), or "INACTIVE" if the channel is disabled (see Section 4.3.4, "Toggle Function").

The bottom line is divided into three areas:

1. Speed, which reflects the RPM of the output shaft for the device attached

2. When the motor is stopped, the mode is Forward (FWD) or Reverse (REV) or the current Oscillate Mode (STD, EFF or AGG), as described in section 4.2. When the motor is running, the direction is: Forward (FWD), Reverse (REV) or Oscillating (OSC).
3. Cruise Control Status: *Lock* or Cruise Control ON (CC ON)

The bottom line is also used to display momentary status or error messages.

4.2 Console (AR-8300) Oscillation Mode Adjustment

The AR-8300 console with Revision 5.00.00 or higher software has three different oscillation modes: Standard (STD), Efficient (EFF) and Aggressive (AGG). The current mode will be shown in the bottom line of the display as either STD, EFF or AGG when the AR-8300 console is powered up and an accessory shaver handpiece is installed.

To change oscillation modes:

1. Press and hold 'speed up' and 'speed down' buttons for 3 seconds.
2. When the program menu appears, press 'speed up' to change the mode.
 - a. The menu display will cycle between the three modes from Standard to Efficient to Aggressive then back to Standard.
3. Once the desired oscillation mode is displayed, press 'speed down' to save the selected mode and exit the program menu.

4.3 Accessory Handpiece Speed Limits and Deltas

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

TABLE 11 ACCESSORY HANDPIECE SPEED LIMITS AND DELTA

Handpiece	Forward / Reverse Speeds (RPM)			Oscillation Speeds (RPM)		
	Min	Max	Speed Delta	Min	Max	Speed Delta
<i>Shaver</i>	500	8000	500	500	3000	250
<i>Drill</i>	100	1400	See Section 4.3.1.1	N/A	N/A	N/A
<i>Sag Saw</i>	18000	18000	N/A	N/A	N/A	N/A

4.3.1 Drill Speed Table

The drill is an exception to the regular increments in speed that the other attachments cycle through. The drill supports these speeds only: 100, 300, 500, 900, and 1400 (RPM).

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

W A R N I N G !

If defibrillation of the patient is required or the surgical process entails working with high frequency instruments, ensure that the patient is not in direct contact with the equipment.

4.3.2 Front Panel Switches

The **Speed Increase** and **Speed Decrease** panel switches adjust the speed. Each time the switch is actuated the speed is adjusted as shown in Table 11. If multiple switches are pressed simultaneously, the switch commands are ignored.

If the **Speed Increase** or **Speed Decrease** switches are continuously actuated for more than 1.0 seconds then the speed will auto-increment or decrement accordingly. The values will not exceed the minimum and maximum values defined for the attachment.

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4.4 Attachment Motor Control

4.4.1 Definition of Direction

The definition of direction as viewed looking from the proximal to the distal of the shaver handpiece:

I -	Reverse	Counterclockwise (CCW)
II -	Forward	Clockwise (CW)
III -	Oscillate	CW then CCW
IV -	Stop	No rotation

4.4.2 Forward, Reverse and Oscillate Modes

Reverse, **Forward**, and **Oscillate** buttons/pedals select which direction the motor rotates. If the **Reverse** and **Forward** buttons/pedals are detected simultaneously then the motor defaults to oscillation mode. The motor will rotate in a forward direction first when oscillation is entered. If any other combination of button/pedal activations is detected simultaneously, then the commands are ignored. This operation applies to the console front-panel buttons as well as to the supported footswitch pedals.

4.4.3 Cruise Control

The cruise control function is engaged from the Gas Pedal Footswitch, which is available as an optional system accessory. Cruise control operation is as follows:

1. **CRUISE SET** - When you select the Cruise Control Switch, the Cruise function becomes ARMED (signified by a single audible 1 second alarm/beep) but the LOCK IN period does not start until one of the three pedals is actuated. If a pedal is not actuated within 15.0 seconds then the Cruise function becomes DISARMED (signified by a single audible 1 second alarm/beep). If the Cruise switch is actuated on an attachment that does not allow cruise control, an error

alarm (beep) occurs (3 fast tones), and a momentary message is displayed “*CRUISE NOT ALLOWED*”.

2. **CRUISE LOCK** - The LOCK IN period lasts for up to 15.0 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/reverse, and ± 400 RPM for oscillation. If the pedal is held steady, the Shaver Console emits an audible double alarm/beep) (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 (signified by a single audible 1 second alarm (beep).
3. **REMOVE FOOT** - The operator is allowed to 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 3 seconds has elapsed, whichever comes first, then the system again responds to this pedal and disables the Cruise function. At any time during or after this 3 second period (i.e., during the Cruise Lock state) if any OTHER pedal, footswitch or panel switch is activated for that channel, the Cruise function becomes DISARMED.
4. **DISABLE CRUISE LOCK** - If any other footswitch or front-console panel button is activated while in the LOCKED state, the Cruise function becomes DISARMED (with the exception noted in item 3 “Remove Foot”).
5. **DISABLE CRUISE SET** - If the Toggle, Cruise Control, or Front Panel buttons are actuated at any time after the Cruise Control button is selected (i.e. in the ARMED or LOCKED condition) then the Cruise function becomes DISARMED.

4.4.4 Toggle Function

The toggle function is a button on footswitches that allows the operator to control the other handpiece without having to physically move the footswitch connection. Toggle is allowed when there is one footswitch connected and two handpieces connected. When the user presses the toggle switch and the conditions are met for a valid toggle, a long alarm (beep) indicates the footswitch has been toggled, and now the user can control the opposite handpiece with the footswitch. Additionally, the original handpiece that the user was previously controlling becomes inactive, which means it cannot be operated from either the footswitch or front panel controls.

When the user presses toggle again, the footswitch goes back to controlling the original handpiece, and the opposite handpiece becomes inactive.

When a toggle function occurs, the footswitch indicator moves to the display channel that the user is controlling, and the other channel is shown as “INACTIVE”.

The toggle function is not allowed if there are two footswitches installed. An error alarm (beep) occurs, and the momentary message “TOGGLE NOT

ALLOWED” is displayed when the user attempts to toggle with two footswitches installed.

The toggle function is not allowed if only one handpiece is attached. An error alarm (beep) occurs, and the momentary message “TOGGLE NOT ALLOWED” is displayed when the user attempts to toggle when there is only one handpiece attached to the console.



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.

4.5 Footswitches

4.5.1 Standard Footswitch

The **Speed Increase** button adjusts the speed in the positive direction only. Each time the switch is actuated, the speed is adjusted as shown in the Table 11. When the maximum speed is reached, the next time the switch is actuated, the speed setting cycles and returns to the minimum setting. If multiple switches are detected simultaneously then the switch commands are ignored.

If the **Speed Increase** switch is continuously actuated for more than 1.0 seconds 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 again.

4.5.2 Gas Pedal Footswitch

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

4.5.3 Multi-Function Footswitches

Available as optional accessories, both the 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/SFS”.

4.6 Accessory Handpieces



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

5.0 Cleaning and Disinfection

5.1 Console (AR-8300)

Clean and disinfect the console with a commercially available surface disinfectant.



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



NEVER clean the console receptacles with liquid cleaners. Remove dust, if necessary, with dry compressed air.

5.2 Footswitches

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

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.



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



NEVER allow the console receptacles to have any contact with liquids. Remove dust or moisture, if necessary, with dry compressed air. ONLY dry connectors should be plugged into the console.

5.3 Accessory Cable

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

Rinse the cable thoroughly after cleaning.

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

Thoroughly rinse the cable under lukewarm water.

See Section 6.0 for sterilization information.



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



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

5.4 Accessory Handpieces

Remove any accessories in the device, such as shaver blades, saw blades or drill bits.

Open the suction control fully, if applicable.

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

Clean the suction control connection with a cleaning brush, if applicable.

Rinse the handpiece thoroughly after cleaning.

Disinfect the handpiece with a commercially available disinfectant.

Thoroughly rinse the handpiece under lukewarm water.

See Section 6.0 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, if necessary, with dry compressed air. ONLY dry connectors may be plugged into the console.

6.0 Sterilization

Sterilization does not eliminate the need for proper cleaning and disinfection of instruments prior to sterilization. Sterilization capabilities, cleaning, disinfecting, handling, and storage of instrumentation are the responsibility of qualified facility/user personnel.

Reusable accessories that are provided non-sterile may be sterilized by one of the following methods:

Gravity displacement cycles:

- 270°F – 275°F (134°C): exposure time 18 minutes (minimum)
- 250°F (121°C): exposure time 60 minutes

Prevacuum cycle:

- 270°F – 275°F (134°C): 5 minutes

Sterilizers vary in design and performance characteristics, so cycle parameters should always be verified against the sterilizer manufacturer's instructions for the specific sterilizer and load configuration being used. It is recommended that the user perform appropriate validation tests.

Drying - It is recommended to use a dry-cycle of a minimum of 4 minutes.

Cooling - The device must be adequately cooled, after being removed from the sterilizer.

6.1 Accessory Cable



After sterilization in the autoclave, let the cable cool down slowly. **NEVER** use cold water to cool the cables down, as this can damage the cable, connections, and seals.



Liquid on the cable receptacle or connection of the handpiece can cause damage to the device. Before connecting the cable, ensure the receptacles are clean and dry.

W A R N I N G !

After autoclaving, the cable is **VERY HOT**. Careless handling can result in burns.

6.2 Accessory Handpieces



After sterilization in the autoclave, let the handpieces cool down slowly. **NEVER** use cold water to cool the handpieces, as this can damage the electronic components and seals.



Liquid on the cable connector of the handpiece can cause damage to the device. Before connecting the cable, ensure that the receptacles are clean and dry.

W A R N I N G !

After autoclaving, the handpieces are **VERY HOT**. Careless handling can result in burns.

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



Open the suction control completely to ensure proper circulation, if applicable.



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



Do not sterilize a handpiece with accessories, such as shaver blades, drill bits or saw blades attached.

7.0 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 Agents.

The agents for transmission of Creutzfeldt-Jakob Disease are believed to be resistant to normal processes of disinfection and sterilization and 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 orthopaedic surgical instruments are those of low TSE infectivity. However, particular precautions should be taken when handling instruments that have been used on known, suspected, or at risk patients.

References

ANSI/AAMI ST46: Good Hospital Practice: Steam sterilization and sterility assurance.

8.0 Maintenance

The Adapteur Power System requires no routine maintenance. There are no operator repairable components and no scheduled intervals for mechanical inspection. If any system component malfunctions, please contact Arthrex.

9.0 Troubleshooting

If problems occur after cleaning, after transporting to other operation sites or when there is a change of operating staff, simple remedies are listed in Table 12.

TABLE 12 TROUBLESHOOTING: FAULTS AND THEIR CAUSES AND REMEDIES

Fault	Cause and remedy
Unit does not power on	<ol style="list-style-type: none"> 1. Check the main power plug and wall receptacle. 2. Check the fuses. 3. Send in for repairs.
Handpiece does not work	<ol style="list-style-type: none"> 1. Check whether the connector is plugged into the correct channel receptacle. 2. Check that both connectors are plugged in properly. 3. Liquid in the receptacle or connector. Dry thoroughly. 4. Connector is damaged. Replace the cable. 5. Footswitch is defective: operate the device using the console unit. Footswitch is functional: replace the footswitch. 6. Handpiece is too hot after sterilization. Allow it to cool down per the WARNING in Section 6.0. 7. Handpiece over-current is detected. Allow 30 seconds for the console to re-set the affected channel. 8. Defective handpiece. Send in for repairs.
Motor runs but shaver blade does not work	<ol style="list-style-type: none"> 1. Not inserted properly. Insert the shaver blade so that it engages and close the locking mechanism fully. 2. Hub is damaged. Replace the shaver blade. 3. Sleeve is bent. Replace the shaver blade.
No suction	<ol style="list-style-type: none"> 1. Suction connection is clogged. Rinse with a syringe. 2. Shaver blade or burr is clogged. Clean with a brush. 3. Suction Control is closed. Open Suction Control. 4. Suction control is damaged. Send in for repairs.
System runs with the control unit but not with the footswitch	<ol style="list-style-type: none"> 1. Check the connector from the footswitch to the control unit. 2. Liquid in receptacle or connector. Dry thoroughly. 3. Footswitch defect. Send in for repairs.
Connected handpiece not shown on display	<ol style="list-style-type: none"> 1. Check that both connectors are plugged in properly. 2. Check the connector with another handpiece. 3. Connector is damaged. Replace. 4. Defective handpiece. Send in for repairs.

If the problems persist, disinfect the Adapteur Power 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 11.0 for more information.

9.1 Replacing the Fuses

The mains fuses can be replaced 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 the proper values as noted on the rear panel.
4. Push the fuse holder back into the AC inlet.



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

NOTE: The AR-8300 console incorporates a universal AC input power supply. A voltage selection switch is not required.

9.2 Troubleshooting Interference to Other Devices

To correct the interference, try one or more of these suggestions:

- § Reorient or relocate the receiving device.
- § Increase the separation between devices.
- § Connect the device into an outlet on a circuit different from that to which the other device(s) are connected.
- § Consult the manufacturer or field service technician for the receiving device for guidance.

10.0 Limited Warranty

For a period of one (1) year after delivery of the Equipment and subject to the terms hereof, Arthrex warrants the Equipment to be free from manufacturers' defects in material and craftsmanship under normal use and service. The Warranty does not apply to any Equipment that has been repaired, serviced or altered outside of the manufacturer's or Arthrex's facility or to Equipment that has been subjected to abuse, misuse, neglect, accident or negligence in use, storage or handling. Arthrex's obligation, and the Customer's sole and exclusive remedy, is limited to the replacement or repair of any Equipment which Arthrex's examination shall disclose, in its sole discretion, to be defective or inoperative, and will be conditioned upon Arthrex's receiving written notice of any alleged nonconformity or defect during the applicable warranty period and the return of defective products to Arthrex, F.O.B. Arthrex's facility. If Arthrex determines that any product or service is not defective or that Arthrex is not liable for the defect, the Customer will be notified; thereafter, Arthrex will repair or replace such product upon the Customer's written consent and at prevailing prices. Arthrex may, in its discretion, provide reasonable use of loaner Equipment while repair or replacement is underway. This warranty applies only to the original Customer and is not transferable except at the discretion of Arthrex. Repairs and replacements made under this warranty are not warranted beyond the remainder of the warranty period. ARTHREX'S LIABILITY SHALL BE LIMITED SOLELY, AT ARTHREX'S OPTION, TO REPAIR OR REPLACEMENT OF THE GOODS OR COMPONENT PARTS NOT MEETING THE QUALITY AND SPECIFICATIONS WARRANTED. THERE ARE NO WARRANTIES, IMPLIED OR STATUTORY (INCLUDING THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR INTENDED USE, NON-INFRINGEMENT, OR ARISING OUT OF A COURSE OF PERFORMANCE, DEALING OR TRADE USAGE) THAT EXTEND BEYOND THIS EXPRESS WARRANTY. IN THE EVENT THAT APPLICABLE LAW PREVENTS THE DISCLAIMER OF ANY IMPLIED WARRANTIES, THEN SUCH IMPLIED WARRANTIES SHALL BE LIMITED TO THE CONTENTS AND DURATION OF THIS EXPRESS WARRANTY.

11.0 Repair Policy

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

12.0 Electromagnetic Emissions

TABLE 13 GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS


The AR-8300S Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-8300S Shaver 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-8300S Shaver System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The AR-8300S Shaver 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 14 GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The AR-8300S Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-8300S Shaver System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply	<5 % U _T (>95 % dip in U _T) for 0.5 cycle 40% U _T	95% Reduction (10ms) 60% Reduction (100ms)	Mains power quality should be that of a typical commercial or hospital environment. If the AR-8300S Shaver System requires continued operation during power mains interruptions, it is recommended that the AR-8300S Shaver System be powered from an

input lines IEC 61000-4-11	(60 % dip in U_T) for 5 cycles 70% U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	30% Reduction (500ms) 95% Reduction (5s)	uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 a.c. mains voltage prior to application of the test level.			

TABLE 15 GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The AR-8300S Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-8300S Shaver System should assure 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 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the AR-8300S Shaver System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17P^{1/2}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.17P^{1/2}$ 80 MHz to 800 MHz $d = 2.33P^{1/2}$ 800 MHz to 2.5 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) Interference may occur in the vicinity of equipment marked with the following symbol: 

13.0 Contact Information

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13.1 Compliance Information

The Adapteur Power System II (AR-8300S) is designed and tested in accordance with EN 60601-1.

According to EN 60601 the console is Type BF, Class 1, IPX1 rating. Accessories are Type BF, Class 1, IPX 8.

According to MDD93/42/EEC, Annex IX, Rule 9 this device is classified as a Class IIa device.