DrillSaw Highspeed 200™

User's Guide

The Arthrex DrillSaw Highspeed 200™ *User's Guide* provides safety operation information for all components of the Arthrex DrillSaw Highspeed 200, including accessories. All operating personnel must read this *User's Guide* thoroughly prior to using this system and follow all safety warnings, cautions, and precautions.

AR-200

CE 2797

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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.

Table of Contents

Table of Contents

Table of Contents

List of Figures

Table of Contents

List of Tables

1.0 General Warnings and Safety Notices - Read This First

It is imperative that the symbols and conventions listed below be clearly understood. The DrillSaw Highspeed 200 *User's Guide* identifies critical, important, and useful information using these symbols and conventions.

1.1 Important Safety Conventions

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

W A R N I N G !

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

1. Ensure that you comply with these instructions for use and the instructions pertaining to all instruments used (drills, saws etc.).
2. This device is only for use in normal orthopedic procedures as described in the User's Guide, 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.
3. The device is intended to apply mechanical force / rotational energy to the patient.
4. Check the console, the motor and the foot control with cables for damage and loose parts before each use. Correct any faults or refer to an authorized Arthrex service partner. Do not operate the AR-200 if it is damaged.
5. Before using the AR-200 for the first time, store it at room temperature for 24 hours.
6. Perform a test run before each use. All couplings and mechanical connections need to be fully secured or locked before the actuation of the system.
7. Check the parameter settings every time the device is restarted.
8. Never touch the open chuck mechanism of the motor during operation, or while the motor is still running.
9. Put the attachment onto the motor, only when the motor is at a complete stop. Never touch the rotating instrument when it is still moving.
10. Never touch the pump motor while the pump arm door is open
11. Always ensure adequate cooling and correct operating conditions are observed.
12. Avoid overheating at the treatment site.

13. Never touch the patient and the connection for the foot control simultaneously.
14. The ESD (electrostatic discharge) spring contact on the underside of the foot control must touch the floor during operation.
15. **Do not** open or attempt to service this system, as this may void your warranty. There are no user-serviceable parts inside. Removing the cover may introduce an electric shock hazard by exposing you to dangerously high voltages or other risks. If the system malfunctions, return it for servicing immediately.
16. Misuse may damage the AR-200 and may cause risks and hazards for patients, users and third parties.
17. Misuse, as well as unauthorized assembly and modifications or repairs to the AR-200 system, or non-compliance with our instructions relieves us of all liability for claims under warranty or other claims.
18. **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.
19. **Do not** modify the console or any accessory. Failure to comply may result in injury to the patient and/or operating room staff.
20. **Do not** use improper or damaged accessories.
21. **Do not** use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide, oxygen, or endogenous gases. All oxygen connections must be leak free for the duration of the surgical procedure.
22. After autoclaving, the accessory devices are VERY HOT. Handle with care to avoid burns.
23. The console, the motors with cable and the footswitch are not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anesthetic substances containing oxygen or nitrous oxide. Zone M is defined as a “medical environment” and constitutes the part of a room in which potentially explosive atmospheres may form, due to the use of anesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary. Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.
24. Zone G, also known as an “enclosed medical gas system”, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.
25. Never use the Arthrex AR-200 in areas close to strong magnetic fields.
26. Do not place the handpiece drive on the patient.

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

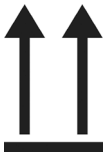
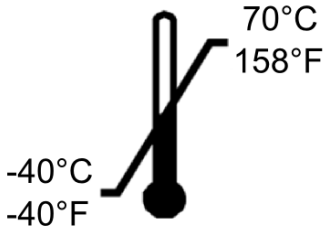
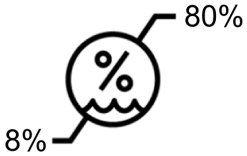
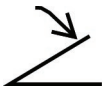
1. **Do not** disconnect the plug of the motors or foot control unit by pulling on the cable. Remove it by grasping and pulling on the body of the connector.
2. Only use replacement power cords that comply with medical grade standards, IEC 60320-1 Subclause 3.21, Detachable Power Supply Cords or electrical standards for the designated country where the AR-200C is being used. Contact your Arthrex representative for further information.
3. Avoid positioning the console so that it is difficult to disconnect the coupler or plug from the mains power supply.
4. To prevent electrical shock do not use extension cords or two-prong/three-prong adaptors.
5. Always use fuses with the correct values to avoid allowing overcurrent to enter the system. Only use Arthrex original fuses.
6. An incorrect fuse may increase the risk of electrical shock or fire hazard.
7. This device has passed testing for EMC compatibility. This device may cause interference with other devices in the near vicinity if not set up and used as instructed by Arthrex.
8. **Do not** attach the motor or the foot control unit during the Self Test.
9. NEVER use liquid to clean the accessory device connector contacts. Remove dust regularly using dry compressed air.
10. Liquid on the cable connector of the accessory device can damage the device. Before connecting the cable, ensure the receptacles are clean and dry.
11. Always comply with the instructions issued by the manufacturer of the cleaning disinfectant regarding concentration, exposure times, temperature, and material compatibility.
12. NEVER allow the console receptacles to have any contact with liquids. If there is dust or moisture on the receptacles, remove using dry compressed air. ONLY dry connectors should be plugged into the console.
13. **Do not** clean the device with abrasive cleaning agents or disinfectant compounds, solvents, or other materials that could scratch or damage the device.
14. The foot control unit is NOT suitable to be cleaned and disinfected in a thermo washer disinfector.
15. After sterilization in the autoclave, let the accessory device cool down slowly. NEVER use cold water to cool the remote control. This will damage the electronic components and seals.
16. Please note that at low speeds, it is more difficult to determine that the motor is running.
17. The motors must be used in compliance with the operation mode.
18. Please refer to the User's Guide DFU-0223-XX for more information about the DrillSaw Mini 300™ attachments that can be connected to the AR-200M motor.

19. The third conductor in the power supply cord is only a functional earth.
20. The console is NOT released for automatic cleaning.
21. Before starting operation again: Wait until the motor and cable are completely dry. Moisture in the plug or motor can lead to a malfunction. (short circuit).
22. Position the foot control unit, where it cannot be pushed unintended.
23. Caution: Federal law restricts this device to sale by or on the order of a physician.
24. This device is intended to be used by a trained medical professional
25. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.
26. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.

- 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.
- **In CE Accepting Countries:** Procedures carried out using these devices may be used on the general population.
- **In CE Accepting Countries:** The clinical benefits associated with the use of these devices outweigh the known clinical risks.
- **In CE Accepting Countries:** There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

1.2 Symbols Definition

	**Safety Sign Follow operating instructions**
	**On/Off (push-push)**
	**Caution / Precaution**
	**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**
	**Fuse**
	**Electrical waste**

R_x ONLY	**Caution: Federal law restricts this device to sale by or on the order of a physician.**
	**Fragile, handle with care**
	**This side up**
	**Temperature limits for storage and transport**
	**Atmospheric pressure limitation for storage and transport**
	**Humidity limits for storage and transport**
	**Foot control unit connection**
	**No user-serviceable parts inside** **Electrical hazard**

	**Manufacturer**
	**Non sterile**
REF	**Catalog number**
	**Quantity**
	**Do not use if package is damaged**

	**Date of manufacture; year and month.**
CE 2797	**The product meets the essential requirements of Medical Device Directive 93/42/EEC**
SN	**Serial number**
EC REP	**Authorized representative in the European Community**
	**Non-ionizing radiation**

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

[x] Square brackets that enclose a letter, number or lower-case Roman numeral reference a callout on a line drawing. The section for "Product Features" includes line drawings of products associated with the DrillSaw Highspeed 200. Each line drawing has its own callout system to identify important elements of each product.

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. The warranty could be voided if shipping or first-installation damage is not reported within seven business days of receiving the device. Refer also to our General Terms of Business.

All defective products will be repaired or replaced at the discretion of Arthrex at no charge. The warranty does not cover damage caused by unlawful use or improper handling of a product.

The warranty is not valid if modifications are made to the product or repairs are carried out 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.*

2.0 Product Description and Intended Use

2.1 Product Description

The DrillSaw Highspeed 200 is a console driven power tool for orthopedic surgeries. Two different motors can be connected. Only one motor can be used at a time. Both motors can be operated with the foot control unit. The motors will be reused. Different attachments can be connected to resect bone and tissue. A Spray Clip guides fluid to the tip of the drills/burrs. A fluid pump is integrated in the console.

2.2 Intended Use

The DrillSaw Highspeed 200 is an electrically-powered system to be used for treatment in orthopedic surgeries, as well as for surgery in the hand and foot, e.g. fracture treatment, drilling holes for plating, cutting bone for corrective osteotomies, and percutaneous surgery.

Intended User Profile: The DrillSaw Highspeed 200 is intended for use by suitably qualified and trained medical, technical and specialist staff only. The development and design of the AR-200 is based on the "physician" target group.

Patient Population: Whoever needs an orthopedic surgical intervention defined in the intended use demanding the use of a power tool.

Conditions of Use: The system is used in an operating room. The motors with connected attachments are intended to be used in the sterile field. The console is located in the operating room, close to the operation field, unsterile and shall stand stable on a non-vibrating surface.

2.3 Contraindications

The DrillSaw Highspeed 200 is contraindicated in any non-orthopedic surgery procedure and procedures disregarding the intended use.

- use by unskilled/untrained personnel
- disregarding the intended use
- non-compliance with the operation mode
- usage of improper accessories
- Not for use on spinal or neuro procedures

The functionality of implantable systems, such as cardiac pacemakers and ICD (implantable cardioverter defibrillator) can be affected by electric, magnetic and electromagnetic fields. Find out if patient and/or user have implanted systems before using the product and consider the application. Weigh the risks and benefits before using. Keep the product away from implanted systems. Make appropriate emergency provisions and take immediate action at any signs of health issues. Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD (implantable cardioverter defibrillator).

W A R N I N G !

Misuse may damage the AR-200 and may cause risks and hazards for patients, users and third parties.

W A R N I N G !

This device is only for use 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.

2.4 Set Composition

The AR-200 Set includes:

- AR-200C Console (CE2797)
- AR-200M Motor with cable, with AR-300 coupling (CE2797)
- AR-200SP Spray Clip (CE2797)
- OEM06202400 Foot Control Unit S-N1 with handle (CE0297)
- OEM04005900 Stand (CE2797)
- OEM06177800 Motor support (CE2797)
- WH013437000-01 Power Cord with a European Plug (CE2797)
- WH028214000-01 Power Cord with a US Plug (CE2797)

The AR-200M-ISO includes:

- AR-200M-ISO Motor with cable, for ISO saw attachments (CE2797)
- OEM04006800 Locking Pin (CE2797)

Accessories for AR-200M motor:

All attachments that can be used with AR-200M motor are listed in Table 26

Other optional accessories:

- OEM06290600 AR-200 - CLIPS (5 PIECES)
- OEM06352200 AR-200 - FUSE 250V-T1.6AH
- OEM07149200 AR-200 - CLEANING ADAPTER FOR SPRAY CLIP
- OEM01525000 AR-200 – SILICONE TUBING FOR CLEANING ADAPTER, 10 PIECES
- OEM04013500* AR-200 - STERILIZATION CASSETTE (CE)
- OEM04364100 Irrigation Tubing Set (6 pieces) (CE0481)
- AR-200H Handle for AR-200M (CE2797)
- 30264001 Footswitch for AR-200, wireless

* not for distribution in the U.S.

2.5 Product Features

2.5.1 AR-200C Console: Front View

Figure 1 uses a *numeric* callout system to identify the main elements of the console's front panel, which are listed and labeled in Table 1. These callouts are referenced throughout this *User's Guide*.

Figure 1 Front Panel of Console

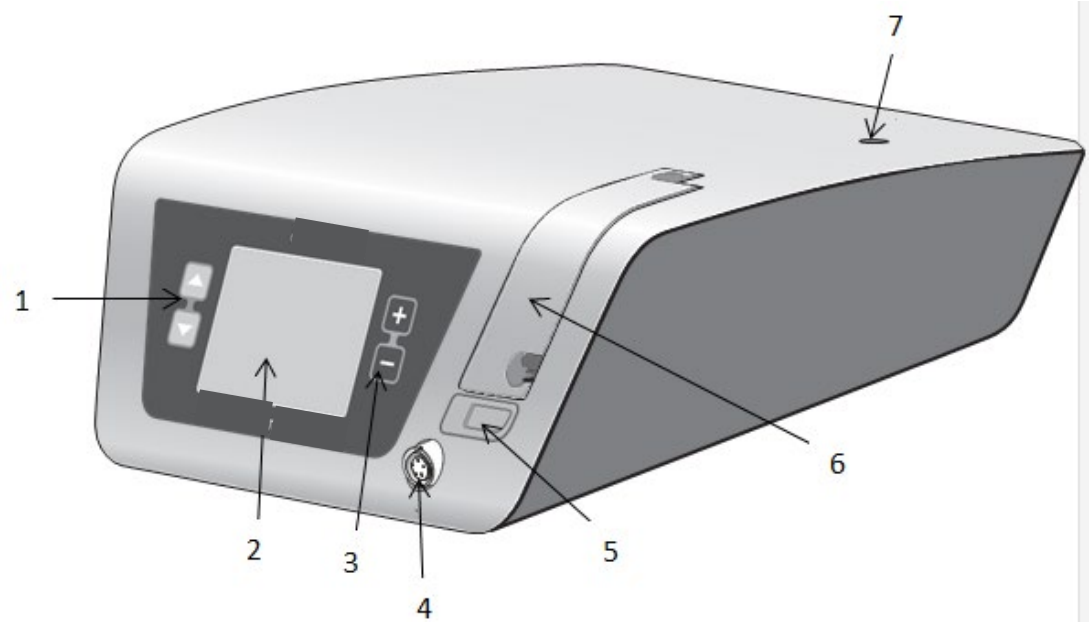


Table 1 Front Panel Elements

1.	Shift buttons
2.	Operator display
3.	PLUS / MINUS buttons
4.	Motor connecting socket
5.	Pump arm OPEN
6.	Pump arm
7.	Stand holder

2.5.2 AR-200C Console: Rear View

Figure 2 uses a *numeric* callout system to identify the main elements of the console's rear panel, which are listed and labeled in Table 2. These callouts are referenced throughout this *User's Guide*.

Figure 2 Rear Panel of Console

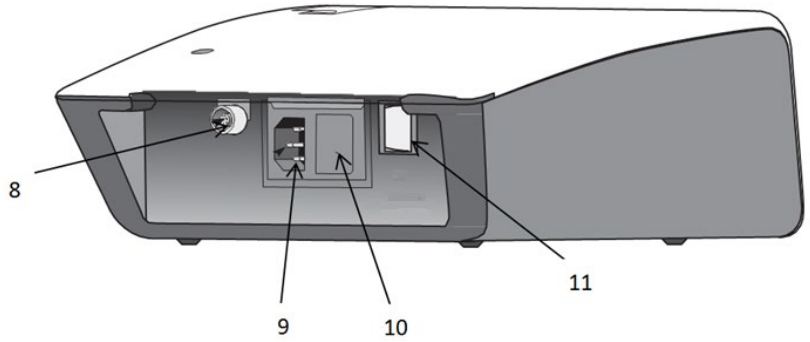


Table 2 Rear Panel Elements

8.	Connecting socket for foot control
9.	AC mains power input plug
10.	Main power input - Fuse holder (250V – T1,6AH)
11.	AC Mains power ON / OFF

2.5.3 AR-200C Console: Main Screen and Iconography

The console's Main Screen (Operator display) [2] provides information about the status of the AR-200 programs, speed, torque and coolant settings in real time. Table 3 describes each message or button, cause and explanation when the AR-200 is in the ready state.

Figure 3 Main Screen Overview

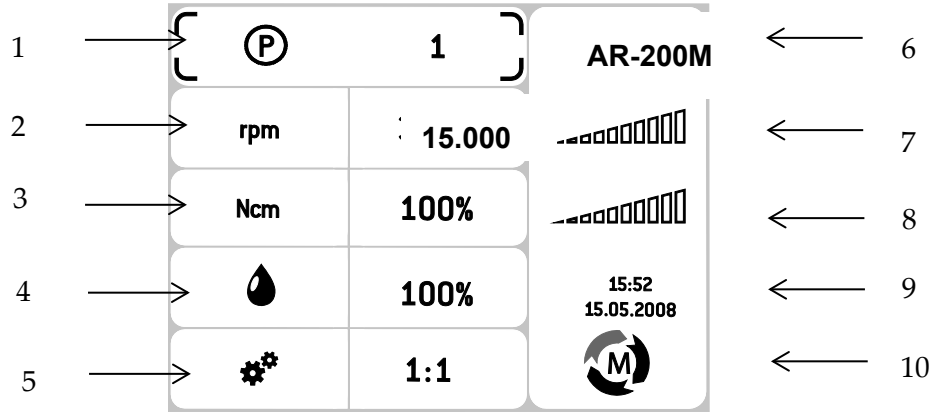


Table 3 Main Screen Elements

1.	Programs (P1-P6)
2.	Speed [rpm]
3.	Torque [% Ncm]
4.	Coolant [%]
5.	Transmission (always 1:1)
6.	Motor selected
7.	Speed displayed in bars
8.	Torque displayed in bars
9.	Time / Date
10.	Clockwise / counterclockwise rotation

2.5.4 Foot Control Unit (S-N1)

Figure 4 uses a *numeral* callout system to identify the main elements on the foot pedal unit, which are listed and labeled in Table 4. These callouts are referenced throughout this *User's Guide.*

Figure 4 Foot Control Unit (S-N1)

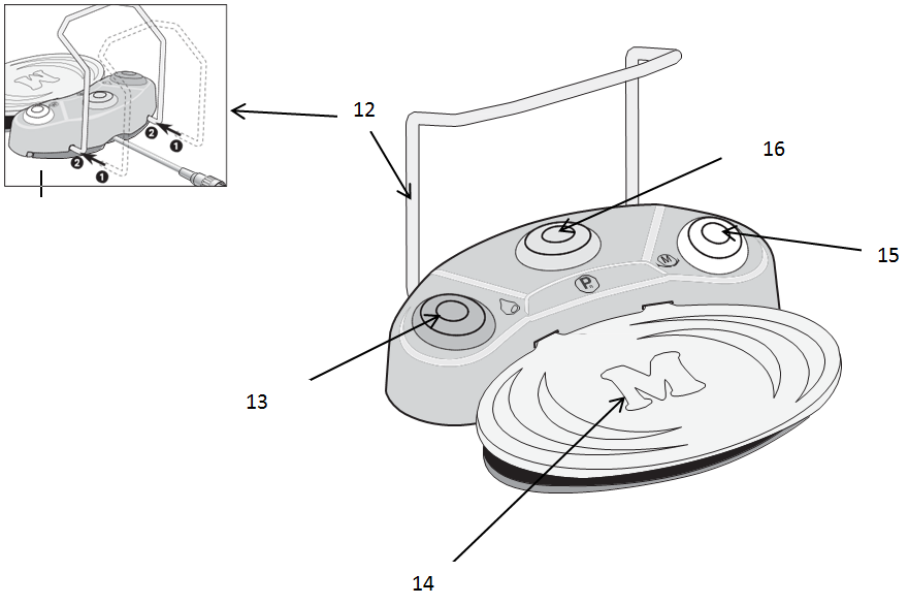


Table 4 Foot Control Unit Elements (S-N1)

12.	Handle for Foot Control Unit: – Attach: (1) Guide the ends of the Handle into the two holes of the Foot Control Unit. (2) Insert the Handle until the stop is reached. - Detach: Pull out the handle until completely removed.
13.	Green – Pump on/ off
14.	Grey – Start motor (pedal), variable or ON/OFF, factory setting = variable
15.	Yellow – Change motor direction, clockwise / counterclockwise rotation
16.	Orange – Change program, programs 1 to 6

When counterclockwise rotation is used, the motor panel emits a warning tone before the motor starts (after approximately 1 second).

W A R N I N G !

The ESD (electrostatic discharge) spring contact on the underside of the foot control must touch the floor during operation.

W A R N I N G !

The console, the motors with cable and the footswitch are not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anesthetic substances containing oxygen or nitrous oxide. Zone M is defined as a "medical environment" and constitutes the part of a room in which potentially explosive atmospheres may form, due to the use of anesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary. Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.

W A R N I N G !

Zone G, also known as an "enclosed medical gas system", does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.

⚠ **Do not disconnect the plug of the foot pedal unit by pulling on the cable. Remove the foot control plug by grasping and pulling on the body of the connector.**

⚠ **Position the foot control unit, where it cannot be unintentionally pushed.**

Foot control: The foot control is approved for use in zone M (AP).

Regular checking of the foot control:

- Visual inspection for outside damage

- Visually inspect the ESD spring contact on the underside of the foot control (electrostatic discharge)

- Clean and inspect the ESD spring contact on the underside of the foot control on a regular basis.

2.5.5 AR-200M, AR-200M-ISO Motors with Cable

Two different, externally powered motors can be connected to the AR-200C Console

AR-200M:

Figure 5 AR-200M Motor with AR-300 Attachment Coupling

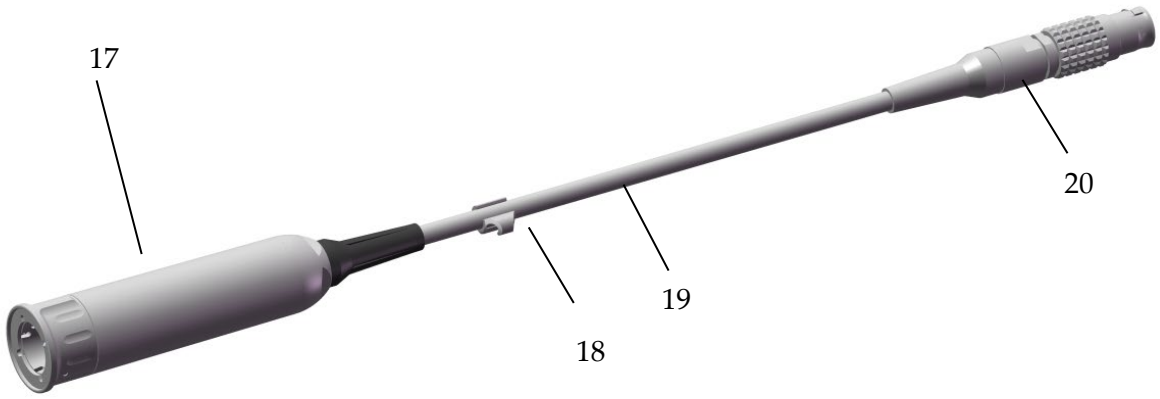


Table 5 AR-200M Motor Elements

17.	Motor chuck mechanism
18.	Clip for Irrigation Pump Tubing
19.	Motor cable
20.	Connector

The AR-200M motor can be connected to all AR-300 attachments, except the AR-300CA Offset Cannulation Adapter.

The motors with cable must not be disassembled.

The motors with cable must not be lubricated during their lifetime.

Please note that at low speeds, it is more difficult to determine that the motor is running.

The motors must be used in compliance with the operation mode.

Please refer to the User's Guide DFU-0223-XX for more information about the DrillSaw Mini 300 attachments that can be connected to the AR-200M motor.

Never touch the open chuck mechanism of the motor during operation, or while the motor is still running.

The maximum rotational speed of the DrillSaw Mini 300 attachments stated in the User's Guide DFU-0223-XX can only be reached when the AR-200M motor speed is set to 15,000 rpm on the AR-200C console.

Rotational energy: Fast deceleration of the bur can cause the selected torque to be overloaded as a result of the rotational energy stored in the drive system.

AR-200M-ISO:

Only use ISO saw attachments that are listed in this *User's Guide* as official DrillSaw Highspeed 200 accessories.

These ISO saw attachments provide their own *User's Guide*.

Coupling system according to ISO 3964 / DIN 13940

Please refer to the device specific *User's Guide* and safety notes for more information about the ISO saw attachments that can be connected to the AR-200M-ISO motor.

To prevent the ISO saw attachments from turning during transmission of high torques, the locking pin supplied can be pushed into the designated hole. See Figure 6.

Figure 6 AR-200M-ISO Motor with ISO Saw Attachment Coupling

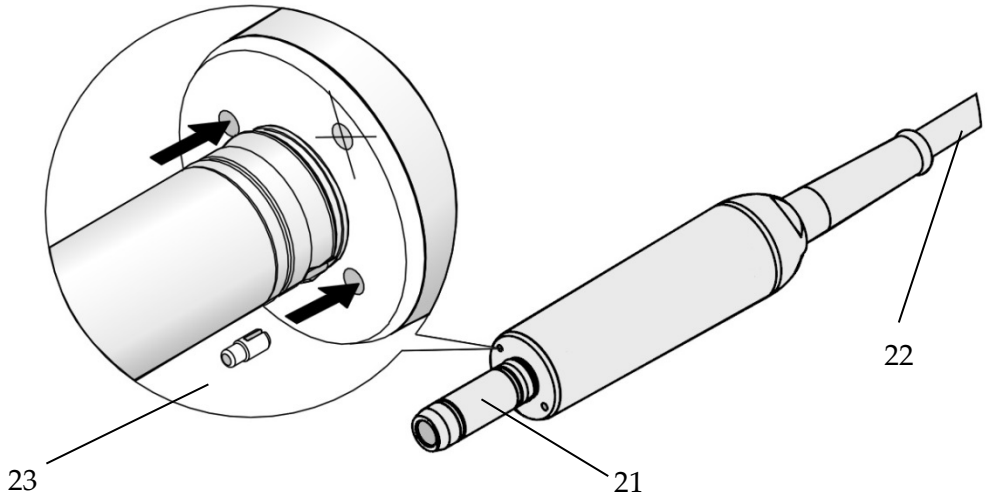


Table 6 AR-200M-ISO Motor Elements

21.	ISO Coupling
22.	Motor cable
23.	Locking Pin

2.5.6 AR-200SP Spray Clip

Figure 7 AR-200SP Spray Clip

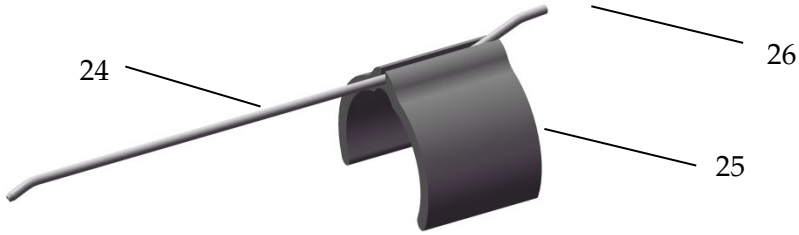


Table 7 AR-200SP Spray Clip Elements

24.	Coolant tube
25.	Clip mechanism
26.	Connection for Irrigation pump tubing

The Spray Clip can be attached to the AR-200M motor with cable, and leads the irrigation fluid to the tip of the connected burr.

The Spray Clip is not intended to be used with the motor AR-200M-ISO, since the ISO saw attachments have their own spray rod attached.

The irrigation tubing set can be connected on the proximal side [3] of the Spray Clip.

The fluid pump can be activated / deactivated on the AR-200C console or with the foot control unit S-N1.

3.0 Technical Specifications

3.1 Console AR-200C

Table 8	Console (AR-200C) Specifications
Width	256 mm (10 in.)
Height	109 mm (4.3 in.)
Depth	305 mm (12 in.)
Weight	7.0 kg (15.4 lbs.)
Maximum flow rate	≥ 90 mL/minute
Power supply	110-130 V / 220-240V, 50/60 Hz, 0.1-1.8A / 0.1-0.9A
Allowed voltage fluctuation	+/- 10%
Mains fuse	2 x 250V – T1.6AH
Power:	max 180 VA
Cleaning	Refer to Section 6.0 Cleaning and Disinfecting
Sterilization	No
Pollution level	2
Overvoltage category	II
Altitude	Up to 3000 m [9842 ft.] above sea level
Protection	IP22

Table 9	Ambient Conditions for Operation
Temperature	10° to 40 °C (50° to 104 °F)
Relative Humidity	15% to 80% (relative), non-condensing

Table 10	Ambient Conditions for Storage (in shipping packaging)
Temperature	-40° to +70°C (-40° to 158°F)
Relative Humidity	8% to 80% (relative), non-condensing
Atmospheric Pressure	700 hPa – 1060 hPa

In the event of a power failure, or if the AR-200C is switched off, or when switching between programs, the last set of values are saved and re-activated when the device is switched on again.

A total system failure does not constitute a critical fault. Simply switch the device off and on again.

In the event of interruption/restoration of power, the device may lose settings or functions.

In the case of a display failure, the device must be taken out of service and returned to the service center.

3.2 Motor AR-200M

Table 11	Motor AR-200M Specifications
Diameter	26.3 mm (1.04 in.)
Length	96 mm (3.78 in.)
Weight	0.42 kg (0.93 lbs.)
Speed	300-15,000 rpm
Torque	7 Ncm
Length in Cable	3.5 m (137.8 in.)
Cleaning	Refer to Section 6.0 Cleaning and Disinfecting
Sterilization	Refer to Section 7.0 Sterilization
Mode of Operation	Non-continuous
Applied part type	Type BF
Operation Mode	30 sec ON, 60 sec OFF (max. 4 repetitions)

3.3 Motor AR-200M-ISO

Table 12	Motor AR-200M-ISO Specifications
Diameter	23 mm (0.91 in.)
Length	112 mm (4.41 in.)
Weight	0.38 kg (0.84 lbs.)
Speed	300-40,000 rpm
Torque	7 Ncm
Length in Cable	3.5 m (137.8 in.)
Cleaning	Refer to Section 6.0 Cleaning and Disinfecting
Sterilization	Refer to Section 7.0 Sterilization
Mode of Operation	Non-continuous
Applied part type	Type BF
Operation Mode	30 sec ON, 60 sec OFF (max. 4 repetitions)

3.4 Foot Control Unit

Table 13	Foot Control Unit (S-N1) Specifications
Width	207 mm (8.15 in.)
Height	45 mm (1.77 in.)
Depth	198 mm (7.79 in.)
Weight	1.15 kg (2.2 lbs.)
Cable length	3.5 m (137.8 in.)
Cleaning	Surface cleaning with mild detergent
Sterilization	No
Protection	IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529)

3.5 Safety, EMC, and Regulatory Requirements

Parameter	**Parameter Value**	
System Classification	IEC 60601-1	Class II (protection against electric shock)
	FDA class	Class I exempt
	EU class	Class IIa
	Health Canada Class	Class 2
Safety Certifications	Domestic Certification	ANSI/AAMI ES60601-1 (2005+C2+A2)
	Canadian Certification	CSA C22.2 No 60601.1 (2008)
	EU Certification	IEC 60601-1:2005+A1:2012
EMC Certifications	EMC Certification	EN 60601-1-2 :2015-09
Safety Certification Marking	UL	
CE Classification MDD 93/42/EEC	Annex IX Rule 9	Class IIa

Refer to section 14 for further details 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-200C 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 7/7 with the AR-200. Contact your Arthrex representative if you need a power cord that must meet the electrical standards of another country.

Only use replacement power cords that comply with medical grade standards, IEC 60320-1 Subclause 3.21, Detachable Power Supply Cords, or electrical standards for the designated country where the AR-200C is being used. Contact your Arthrex representative for further information.

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

To prevent electrical shock do not use extension cords or two-prong/three-prong adaptors.

The third conductor in the power supply cord is only a functional earth.

If required by local codes, connect the console to the hospital equalization connector with an equipotential cable. Connect the power cord to a wall outlet with the correct voltage. Otherwise, the product may be damaged.

The console is designed to meet power-saving guidelines. The console has an AC mains switch on the rear panel [11]. 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 operator display [2] shows the Main Display [Figure 3]. If the tests detect a problem, an error message is shown on the display. Refer to the section for Troubleshooting for a complete list of operator display messages.

Set up the device so that the power switch is easily accessible. In dangerous situations the device can be disconnected from the power supply using the power switch.

The power switch can also be used to safely stop the device. In dangerous situations the device can be disconnected from the power supply by disconnecting the mains-cable.

No excessive heat generation within the operation mode. The responsibility for the timely switch off of the motor is the responsibility of the user.

W A R N I N G !

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

4.3 Replacing the Fuses

The main fuse is replaced as follows:

1. Disconnect the device from the AC mains power supply.
2. Open the fuse tray in the AC inlet [10] by pinching the tabs and pulling outward.
3. Replace the fuses with 2 x 250V – T1.6AH Line Fuses as noted on the rear panel.
4. Push the fuse holder back into the AC inlet.
5. Ensure that the 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. Only use Arthrex original fuses.

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

The AR-200C console incorporates a universal AC input power supply.
A voltage selection switch is not required.

4.4 Electromagnetic Compatibility (EMC)

This device has passed testing for EMC compatibility. This device may cause interference with other devices in the near vicinity if not set up and used as instructed by Arthrex.

The AR-200 has been designed to accept EMC from other devices within the limitations as described in section 14.

To determine if the AR-200 is causing interference with other devices, power the AC mains power switch [11] OFF, 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 distance between the devices.
3. Connect the device to an outlet on a different circuit than the other device(s) are connected to.
4. Consult the manufacturer or field service technician for the receiving device for guidance.

4.5 Basic Setup Procedure for the AR-200

Place the AR-200C on a flat, dry and stable surface.

Figure 8 Set up the AR-200

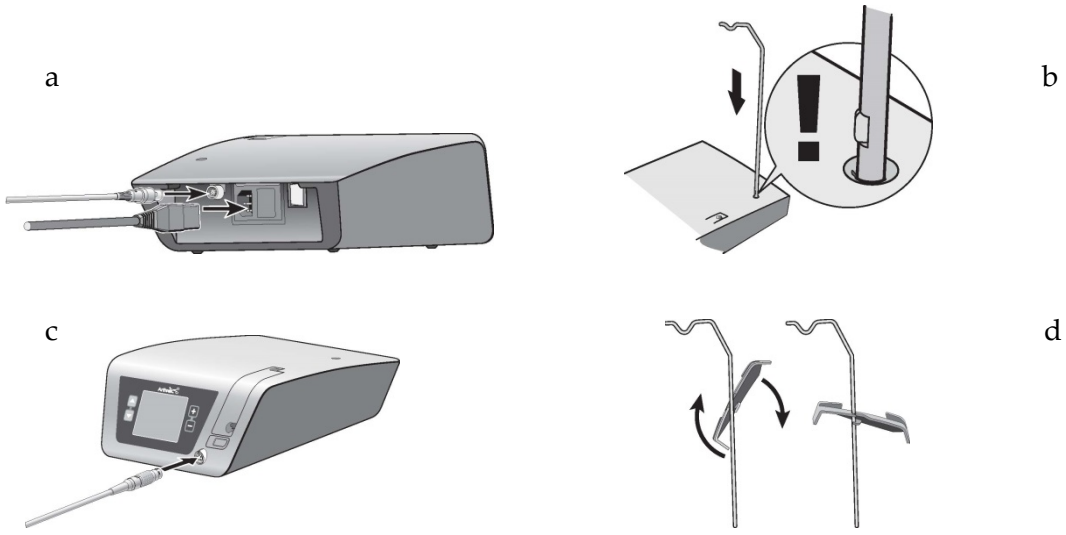


Table 14 Set up the AR-200

a	Connect the receiver end of the power cord for the AR-200C into the AC mains power socket [9] and connect the plug end into the facility AC mains supply. Additionally, connect the foot control unit cable to the console.
b	Connect one of the motors with cable.
c	Insert the Stand. Note the positioning! (maximum load capacity 1,5 kg / 3.3 lbs.)
d	Attach the motor support and lock it.

The motor connector plug cannot be properly inserted into the console receptacle if the corresponding red dots are not aligned.
The foot control unit connector plug cannot be properly inserted into the console receptacle if the corresponding black triangle of the console is not aligned with the black arrows of the cable plug.

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 injury to the patient and/or operating room staff.

W A R N I N G !

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

W A R N I N G !

Before using the AR-200 for the first time, store it at room temperature for 24 hours.

4.6 Motor Detection

The AR-200C detects when a motor with cable has been activated. The Motor Detection feature operates differently, depending on if an AR-200M or an AR-200M-ISO motor is connected to the AR-200C console.

4.7 Connecting and Removing Attachments to the AR-200M Motor

These instructions describe the procedure for connecting an attachment to the AR-200M motor.

Figure 9 Connecting and removing an attachment

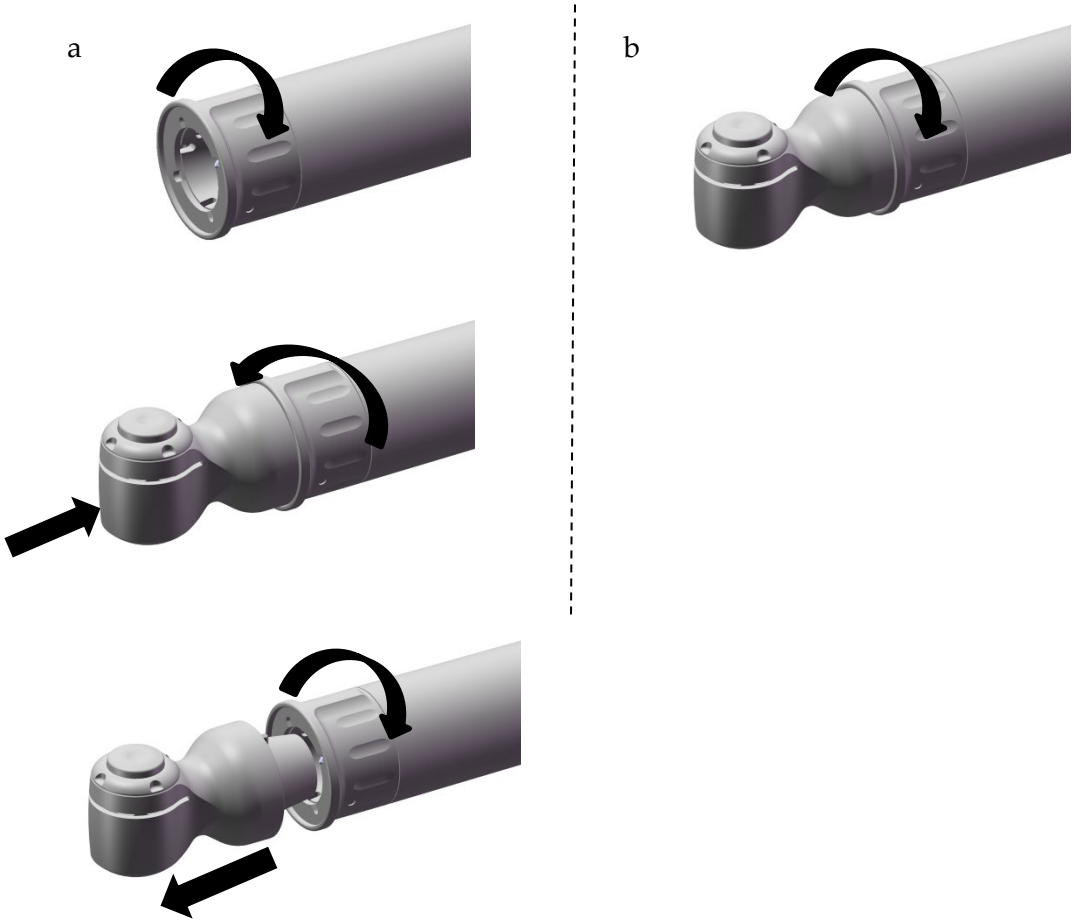


Table 15 Connecting and removing an attachment

a	To Insert the attachment: - Step 1: Turn the motor chuck mechanism - Step 2: Push the adaptor into the locking mechanism - Step 3: Loosen the chuck mechanism Note: For insertion only: Steps 1 and 2 can be combined
b	To Remove the attachment: - Turn the motor chuck mechanism - Pull out the adaptor

4.8 Pump Tubing

These instructions describe the setup of the AR-200 irrigation pump tubing.

Figure 10 Irrigation Pump Tubing Setup

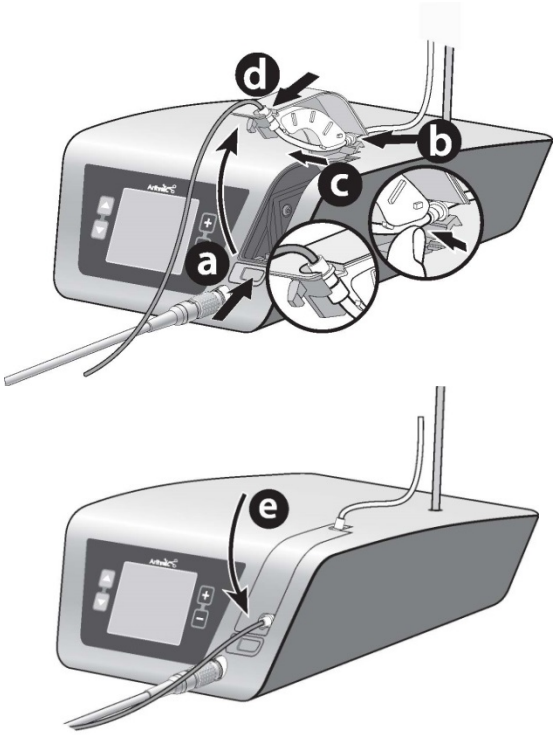


Table 16 Irrigation Pump Tubing Configuration

	Install the bag and spike the bag with the irrigation pump tubing
a	Open the Pump arm door
b, c, d	Insert the irrigation pump tubing
e	Close the pump arm door. It is confirmed by physically hearing and feeling the latching mechanism. The surface of the door is flush with the surface of the front panel.
	Follow the sequences a - e when removing the irrigation tubing

The AR-200 is designed for use with physiological saline solution. Use only suitable irrigation fluids and follow the manufacturer's medical information and instructions.

Sterile irrigation pump tubing is supplied with the equipment. These irrigation pump tubing is disposable and must be discarded after each use.

Please note the expiration date and the relevant regulations for disposal of irrigation pump tubing.

Only use disposable irrigation pump tubing with undamaged packaging/ sealing.

W A R N I N G !

Never touch the pump motor while the pump arm door is open

4.9 AR-200SP Spray Clip

These instructions describe the setup of the AR-200M with the AR-200SP Spray Clip

Figure 11 Connection of AR-200SP Spray Clip to the Motor AR-200M

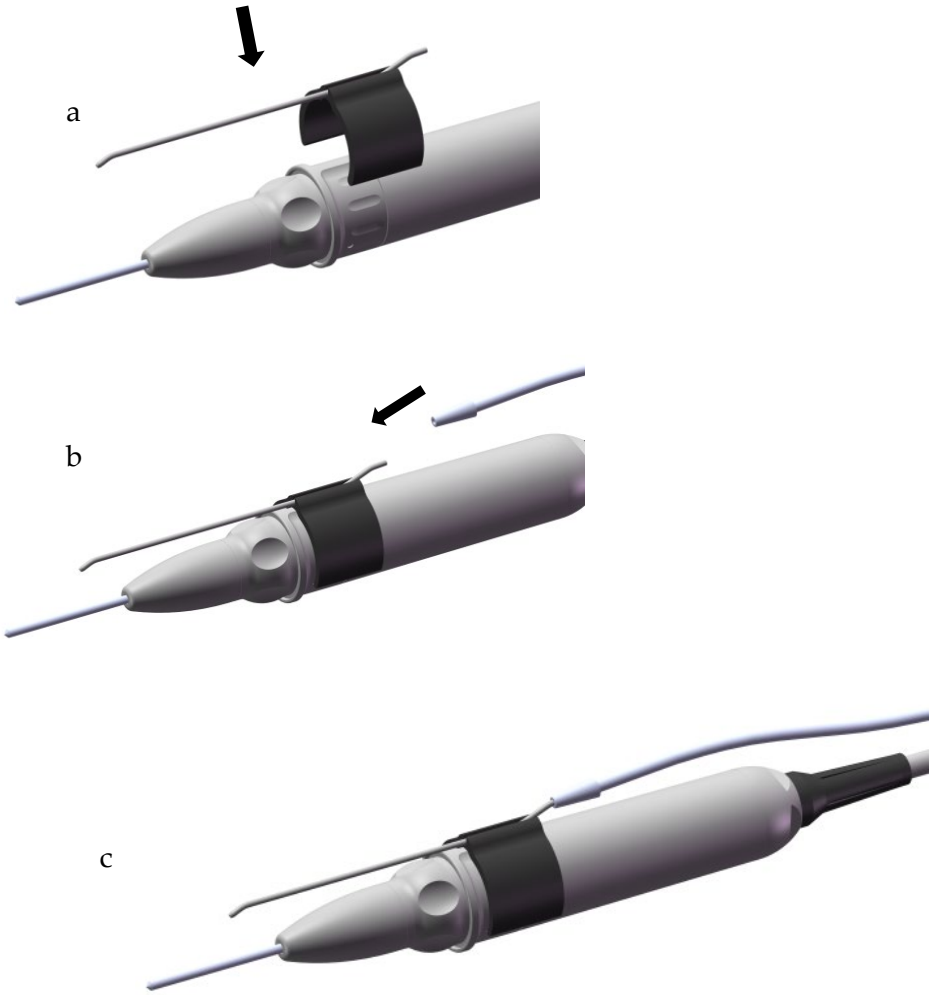


Table 17	One-Piece Tubing Configuration
a.	Attach the Spray Clip to the motor The Spray Clip groove matches with the coupling ring of the motor
a.	Insert the tubing end onto the proximal rod end of the Spray Clip
c.	If needed: Fix the irrigation tubing in the clips of the motor cable

4.10 AR-200H Handle

These instructions describe the setup of the AR-200M with the AR-200H Handle

Figure 12 Connection of AR-200H handle to the AR-200M motor

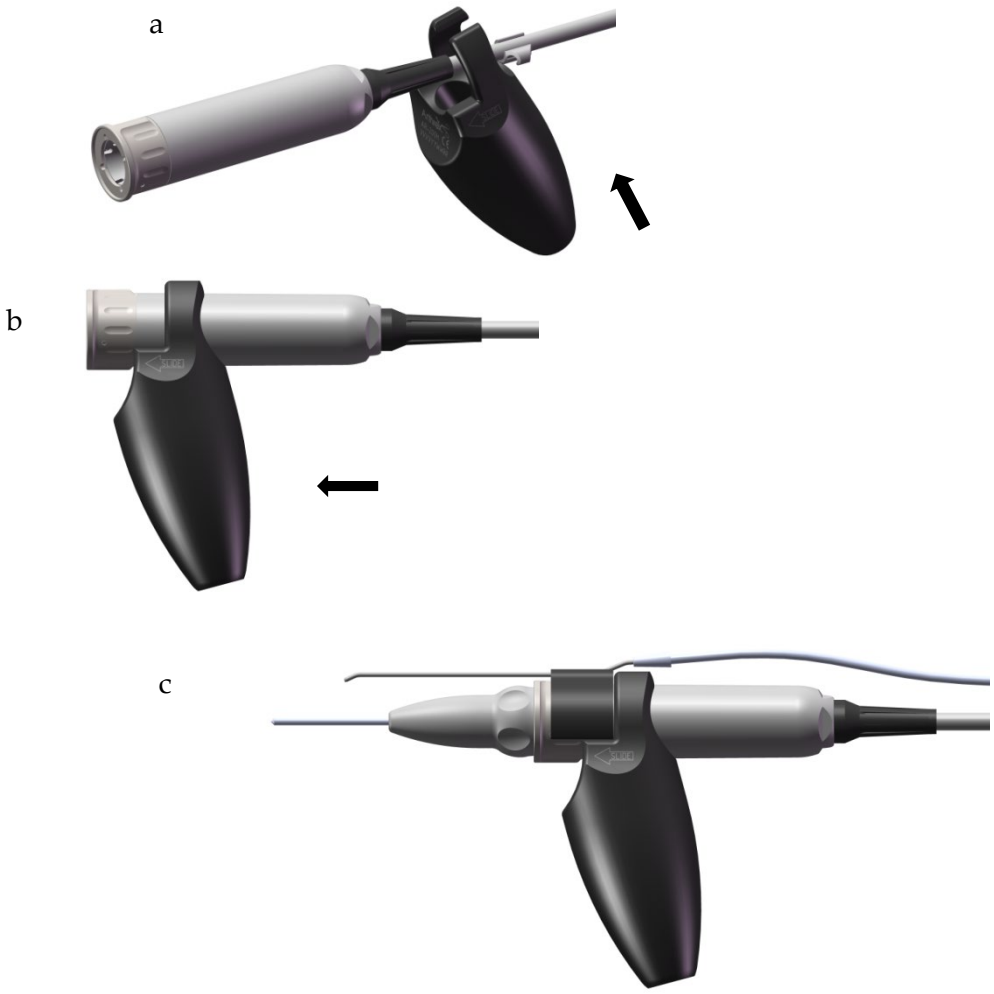


Table 18	AR-200H handle connection to AR-200M motor
a.	Attach the handle to the AR-200M motor cable Pay attention to the orientation. The arrow on the handle indicates the correct direction
b.	Slide the handle up the motor until it reaches the coupling ring
c.	The handle can also be used with the Spray Clip. This configuration is shown with a drill attachment.

The AR-200H handle can only be used with the AR-200M motor not with the AR-200M-ISO motor.

4.11 Screen Navigation Overview

Figure 13 Overview of different screens

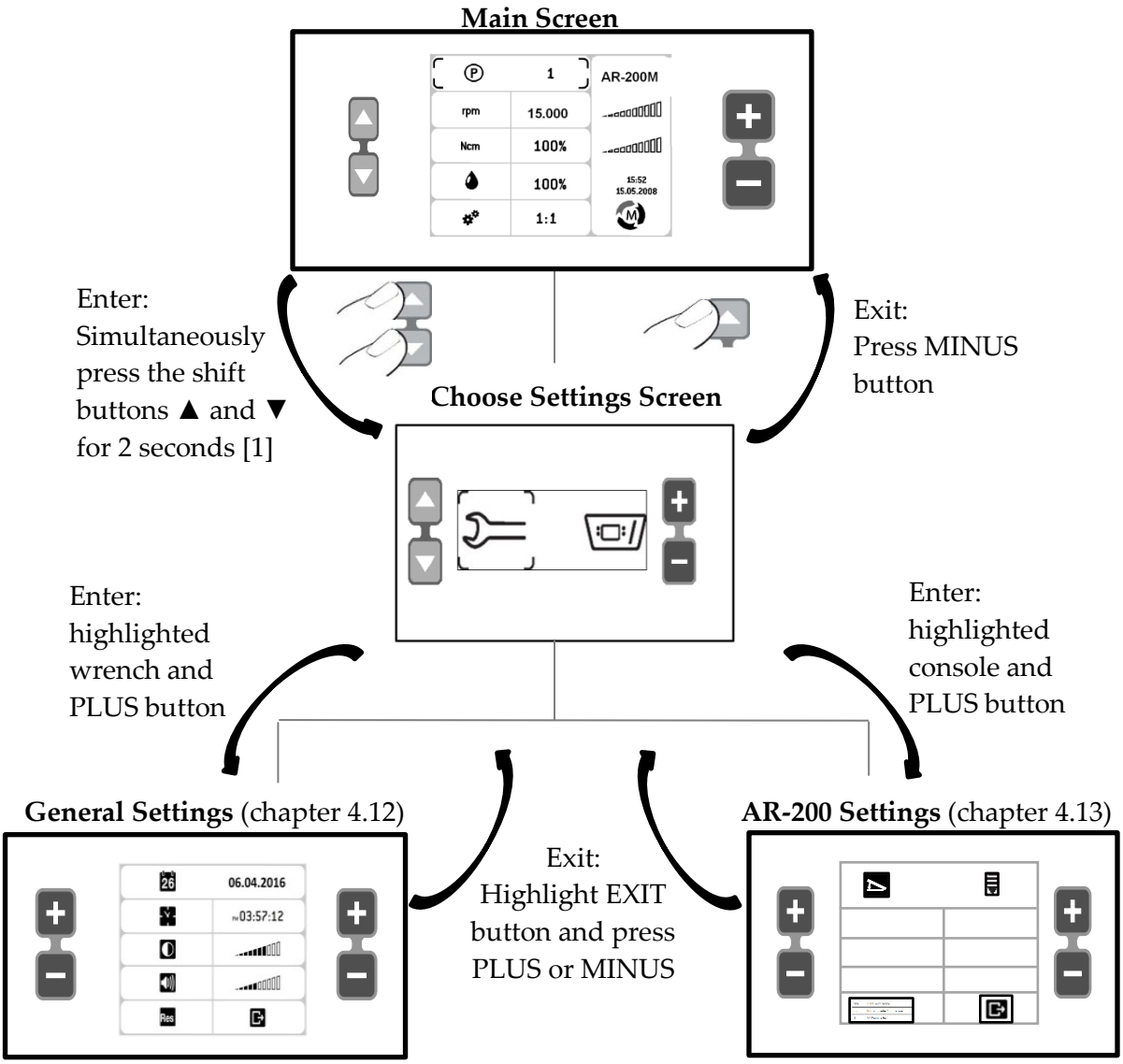


Table 19 Calling Up the Settings Screens

1	Simultaneously press the shift buttons ▲ and ▼ for 2 seconds [1]
2	General settings are highlighted in Choose Settings Screen: Confirm by pressing the PLUS button. For a description of the general settings see chapter 4.12
3	AR-200 settings are highlighted in Choose Settings Screen: Confirm by pressing the PLUS button. For a description of the AR-200 settings see chapter 4.13

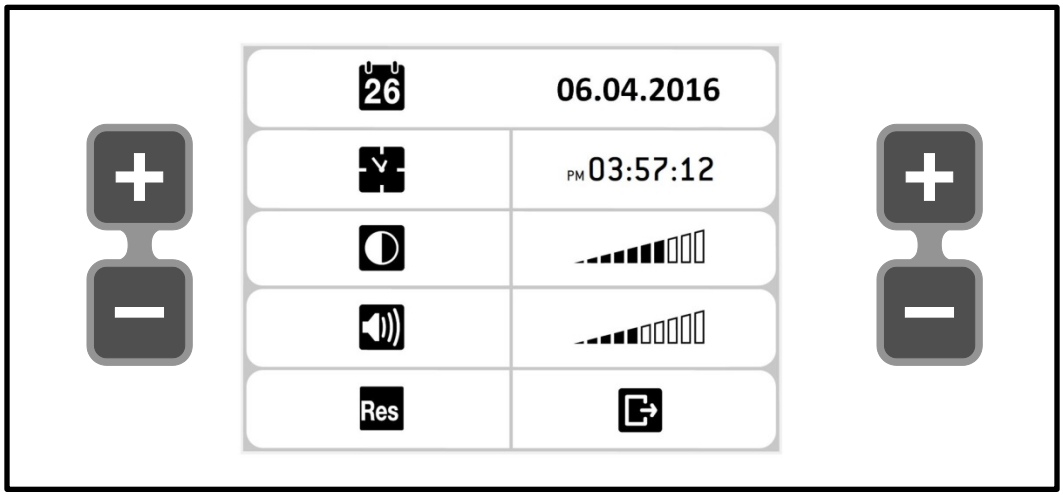
Press the MINUS button [3] to move from the Choose Setup Screen to the main screen.

Highlight the EXIT button: and press PLUS or MINUS to move from the General Settings or AR-200 Settings screens back to the Choose Settings Screen.

The LED buttons and the display of the AR-200 must light up fully before use.

4.12 General Settings

Press shift button ▲ or ▼ [1] to select the desired menu. Press the PLUS / MINUS button [3] to set the menu functions. The selected functions light up in green.



To exit the general settings, select Return with shift button ▼.
Confirm with the PLUS / MINUS button.

4.12.1 Changing the Date

1.  Select function Date
2.  Activate date settings

3.  Select the day, month or year, or exit the date settings

4.  Adjust settings for day, month or year

4.12.2 Changing the Time

1.  Select function Time

2.  Activate time settings

3.  Select time format (am, pm, 24h), select hours, minutes or seconds or exit the time settings

4.  Adjust the settings for time format, hours, minutes and seconds

4.12.3 Changing the Contrast

1.  Select function Contrast

2.  Increase contrast

3.  Decrease contrast

4.12.4 Changing the Volume

1.  Select function Volume

2.  Increase volume

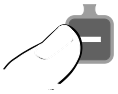
3.  Decrease volume

 Mute

4.12.5 Reset Factory Setting

1.  Select function Reset

2.  Start reset countdown [3]

3.  The reset countdown can be interrupted within 5 seconds by pressing the MINUS button

4.12.6 Exit setting

1.  Select function Exit

2.  Confirm with PLUS or MINUS button [3]

4.12.7 Factory Settings (P1-P6)

Table 20 Factory Settings AR-200C

For AR-200M motor with cable

Program	Speed [rpm]	Torque [Ncm]	Coolant supply volume	Coolant	Transmission ratio	Motor direction
P1	15,000	100 %	100 %	disabled	1 : 1	clockwise
P2	8,000	100 %	100 %	disabled	1 : 1	clockwise
P3	3,000	100 %	100 %	disabled	1 : 1	clockwise
P4	15,000	100 %	100 %	disabled	1 : 1	clockwise
P5	15,000	100 %	100 %	disabled	1 : 1	clockwise
P6	15,000	100 %	100 %	disabled	1 : 1	clockwise

For AR-200M-ISO motor with cable

Program	Speed [rpm]	Torque [Ncm]	Coolant supply volume	Coolant	Transmission ratio	Motor direction
P1	40,000	100 %	100 %	disabled	1 : 1	clockwise
P2	40,000	100 %	100 %	disabled	1 : 1	clockwise
P3	30,000	100 %	100 %	disabled	1 : 1	clockwise
P4	15,000	100 %	100 %	disabled	1 : 1	clockwise
P5	15,000	100 %	100 %	disabled	1 : 1	clockwise
P6	15,000	100 %	100 %	disabled	1 : 1	clockwise

4.13 AR-200 Settings

4.13.1 Changing the Foot Controller Mode

To change from VARIABLE to ON / OFF

Switching between variable and ON / OFF is only possible in this menu

1.  Select function Foot control
2.  Select setting

VARIABLE (factory setting) -Continuously variable motor control

ON/OFF -motor runs either with 100% speed (grey pedal [14] is pushed) or 0% speed (grey pedal [14] is not pushed)

4.13.2 Show Hardware / Software / Production Date and Serial Number

In the down-left corner of the display 3 numbers can be seen

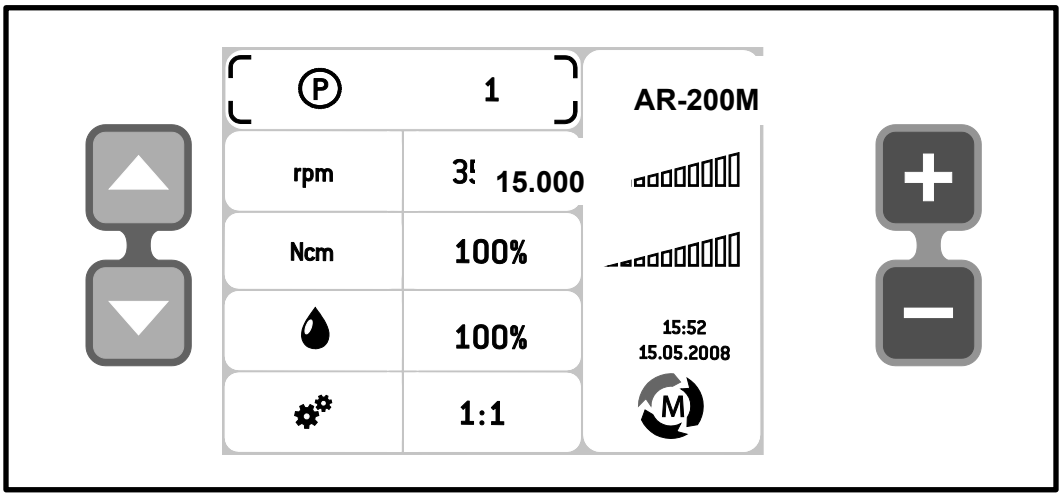
mmi:	Front Board number
mot:	Motor controller Board number
cfg:	SD Card number

Technical Support may request the software version of the console. Please note the three numbers that are displayed and submit them to the technical support.

5.0 Operation and Frequently Used Functions

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

Press shift button▲ or ▼ to select the desired menu. Press the PLUS / MINUS button to set the menu functions. The selected functions light up in green.



When changing settings no separate confirmation is necessary.

W A R N I N G !

Check the console, the motor and the foot control unit with cables for damage and loose parts before each use. Correct any faults or refer to an authorized Arthrex service partner. Do not operate the AR-200 if it is damaged.

W A R N I N G !

Perform a test run before each use.

5.1 Changing the Program

1.  Select menu - Program
2.  Next program - press PLUS button
3.  Previous program - press MINUS button

5.2 Changing the Speed

When the safety speed (15,000 rpm for AR-200M / 40,000 rpm for AR-200M-ISO) is reached, an audible signal (safety stop) sounds.

Keeping PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

1.  Select menu - Speed
2.  Increase speed - press PLUS button
3.  Decrease speed - press MINUS button

5.3 Changing the Torque

Settings range from 10 % to 100 %.

Keeping PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

1. 

Select menu - Torque

2. 
Increase torque in 10% steps - press PLUS button

3. 
Decrease torque in 10% steps – press MINUS button

5.4 Changing the Coolant Flow

Adjustable range: 0 % – 100 %.

By keeping PLUS / MINUS depressed the values are continuously increased / decreased.

1. 
Select menu - Coolant

2. 
Increase flow rate in 20% steps – press PLUS button

3. 
Decrease flow rate in 20% steps – press MINUS button

5.5 Changing Settings with the Foot Control Unit

Changing the program

Press the ORANGE button [16] to select programs 1 to 6 in ascending order.

Hold the ORANGE button [16] down to select programs 6 to 1 in descending order.

With each program change, the motor direction is automatically set to clockwise rotation.

Pump ON / OFF

Only when the motor is stationary can the pump be switched on or off by operating the GREEN button [13] of the foot control. When the pump is switched off, the pump symbol on the display is crossed out.

Counterclockwise rotation

Press the YELLOW button [15] to change from clockwise rotation to counterclockwise rotation.

When selecting counterclockwise rotation, an audible signal can be heard before the motor starts running and the counterclockwise symbol flashes.

Before the motor starts running an audible warning signal is given.

5.6 System Shutdown

1. Turn the power switch to the OFF position on the rear side of the console.
2. Disconnect the power cord from the wall outlet.
3. Disconnect the Spray Clip and irrigation pump tubing, if applicable.
4. Disconnect the motor with cable from the console.
5. Disconnect the foot control unit, if applicable.

5.7 Backup System

A second system that is ready for use must always be available during the surgical procedure.

5.8 Infrequently Used Functions

Before changing infrequently used functions/settings, the description within this User's Guide must be read and understood

6.0 Cleaning and Disinfecting

Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.

Always wear proper PPE (Personal Protective Equipment) such as: gloves, eye protection, face shields, gowns, etc.

To make cleaning and disinfecting easier, always clean and disinfect the Arthrex DrillSaw Highspeed 200 System immediately after use; do not allow bodily fluids and tissue to dry on any of the system components.

6.1 Console (AR-200C) and Foot Control Unit (S-N1)

The AR-200C console and S-N1 foot control unit are provided **non-sterile** and **must not** be sterilized.

The AR-200C console and S-N1 foot control unit must be adequately cleaned and disinfected prior to use or re-use.
Always place the main power switch in the "Off (O), position" and disconnect the power before cleaning and disinfecting the AR-200C console.
Disconnect the S-N1 foot control unit cord from the console prior to cleaning and disinfecting.

To clean and disinfect:

1. Using a disinfecting towelette or a low-linting cloth dipped in disinfectant solution, gently wipe down all surfaces of gross contamination.
2. Using a second (fresh) towelette or cloth, thoroughly wet the surface of the aseptic battery pack and ensure it remains visibly wet for the contact time recommended by the disinfectant manufacturer. The use of additional towelettes or cloths may be used to ensure the surface remains visibly wet for the entire contact time.
3. If required by the disinfectant manufacturer, rinse per instructions; otherwise, allow to air dry.
4. Inspect for visual cleanliness and ensure there is no remaining gross contamination. If gross contamination remains, repeat the procedure and re-inspect.

   Always comply with the instructions issued by the manufacturer of the disinfectant regarding concentration, exposure times, temperature, and material compatibility.
   Do **NOT** immerse the console or the foot control unit in cleaning/disinfecting solution, and do **NOT** utilize automated cleaning in a washer/disinfector.

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

6.2 Motor with Cable (AR-200M, AR-200M-ISO) and Spray Clip (AR-200SP

6.2.1 Detergent Selection

Consider the following points during selection of the cleaning detergent:

1. Suitability of the cleaning agent for ultrasonic cleaning (no foam development), where applicable.
2. Compatibility of the cleaning agent with the instruments. Arthrex recommends the use of neutral pH or enzymatic cleaning agents. Alkaline agents may be used to clean devices in countries where required by law or local ordinance, or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) or Creutzfeldt - Jakob disease (CJD) are a concern (applies only outside of the US). Arthrex does not recommend the use of a specific brand of cleaning agent. Enzol® and neodisher® MediClean forte were utilized during the validation of these instructions. Do **NOT** use abrasive cleaning or disinfecting compounds, solvents, or other materials that could scratch or damage the device.
3. **Caution: Highly acidic or highly alkaline (>pH 10.8) solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise plastics. If non-neutral pH cleaning chemistries are utilized, care should be taken to ensure appropriate rinsing, as validated by the end-user facility, and neutralization steps are taken so as to not negatively impact the fit, finish, or function of the device.**
4. Pay attention to the instructions of the detergent manufacturer with respect to neutralization and post-rinsing.
5. Follow the instructions of the detergent manufacturer regarding use concentration and temperature for either preliminary or automated cleaning. Use only freshly prepared solutions as well as only purified/highly purified water at least for final rinse, and a soft, low-linting cloth and/or filtered medical grade air for drying, respectively.

6.2.1.1 Preliminary Cleaning

The motor with cable and spray clip are provided non-sterile and must be adequately cleaned, disinfected, and sterilized prior to use or re-use. Preliminary cleaning should be performed prior to automated cleaning and disinfection.

1. Remove any attachments or accessories prior to cleaning.
2. Prepare a detergent solution using cool utility (tap) water according to the manufacturer's recommended concentration.
3. Using a soft-bristled brush or cloth that has been dampened with the detergent solution, remove all visible gross soil from the surface of the device.
4. After the completion of preliminary cleaning, the end user should proceed to Machine (Automated) Cleaning and Thermal Disinfection.

The Spray Clip can be cleaned and sterilized with the suggested cleaning devices provided by Arthrex:

- AR-200 - CLEANING ADAPTER FOR SPRAY CLIP
- AR-200 – SILICONE TUBING FOR CLEANING ADAPTER, 10 PIECES

Please use dedicated cleaning adapters and tubing defined as accessories in this *User's Guide*, for cleaning and sterilization of AR-200SP Spray Clip.

6.2.2 Automated Cleaning and Thermal Disinfection

1. After preliminary cleaning is complete, load the devices in the washer-disinfector such that all design features of the device are accessible to cleaning and such that cannulated and recessed parts will drain accordingly during the wash cycle.
2. If using alkaline cleaning agents, a neutralization step should be utilized as appropriate.
3. Run an automated wash cycle with fundamentally approved efficiency of the washer-disinfector (for example, CE marking according to EN ISO 15883 or FDA approval/clearance/registration). The following minimum recommended wash cycle parameters were utilized by Arthrex during the validation of these instructions.

RECOMMENDED WASHING CYCLE PARAMETERS			
Phase	**Recirculation Time**	**Temperature**	**Detergent**
Pre-Wash	3 Minutes	Cold Water	N/A
Cleaning Wash	10 Minutes	Follow detergent manufacturer's recommendation	Enzymatic or alkaline agent
Rinse 1	3 Minutes	Follow detergent manufacturer's recommendation	Neutralizing agent (as needed)
Rinse 2	3 Minutes	Cold Water	N/A
Thermal Disinfection Rinse	5 Minutes	194°F (90°C)	N/A
Drying	Minimum 6 Minutes or until visibly dry	Minimum 239°F (115°C)	N/A

4. Remove the devices from the washer-disinfector following the completion of the program and check devices for visible soil. Repeat cleaning if soil is visible and re-inspect; otherwise, proceed to Sterilization section.

Before starting operation again: Wait until the motor and cable are completely dry. Moisture in the plug or motor can lead to a malfunction. (short circuit)

7.0 Sterilization

Sterilization is to be performed following cleaning, disinfection, and sterile packaging prior to use.

After sterilization in the autoclave, let the accessory device cool down slowly. NEVER use cold water to cool the motor. 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 that the receptacles are clean and dry.

The control unit AR-200C and the foot control unit S-N1 are not approved for sterilization.

Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. If a wrap is utilized, it should be completed following AAMI double-wrap or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body).

Only Arthrex devices should be included in the trays. These validated instructions are not applicable to trays that include devices not intended to be used with Arthrex trays.

7.1 Approved Sterilization - Motor with Cable (AR-200M, AR-200M-ISO) and Spray Clip (AR-200SP)

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

RECOMMENDED STEAM STERILIZATION PARAMETERS			
Cycle Type	**Minimum Exposure Temperature**	**Minimum Exposure Time**	**Minimum Drying Time**
Pre-Vacuum	132°C (270°F)	4 minutes	30 minutes
Gravity-Displacement	121°C (250°F)	30 minutes	30 minutes
Gravity-Displacement	132°C (270°F)	15 minutes	30 minutes

W A R N I N G !

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

Allow to cool down to ambient temperature before using.

7.2 Irrigation pump tubing

The tubing is supplied pre-packaged **sterile,** by EO sterilization. **Do not resterilize.**

Sterile devices must be stored in the original unopened packaging, in a cool place, away from moisture and should not be used after the expiration date.

All pump tubing is single use.

The irrigation pump tubing should be accepted only if the factory packaging and labeling arrive intact.

Contact Customer Service if the sterile irrigation package has been opened or altered.

7.3 Transmissible Spongiform Encephalopathy Agents

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

The agents for transmission of Creutzfeldt-Jakob disease are believed to be resistant to normal disinfection and sterilization processes. 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. Refer to AAMI ST79 for further information.

8.0 Maintenance

Regular and proper maintenance of your DrillSaw Highspeed 200 is the best way to protect your investment and avoid non-warranty repairs.

Recommended care and handling of the DrillSaw Highspeed 200 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 console, foot control unit, cables, connectors, and display before each use.

Your authorized Arthrex service department is extremely knowledgeable about the Arthrex DrillSaw Highspeed 200, motors and/or foot control unit and will provide a competent and efficient service. Any services and/or repairs carried out by any unauthorized repair facility may result in reduced performance of the instruments or instrument failure.

8.1 Periodic Maintenance

The product should be inspected prior to and after each use to ensure that the console, foot control unit, motor, cables, connector contacts, display, Spray Clip and accessories are not damaged or worn. If it becomes necessary to return the motor and or foot control unit to Arthrex for service, please sterilize the motor before shipping.

9.0 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-(888) 420-9393, Monday through Friday from 9:00 AM to 5:00 PM EST; or at +49 89 90 90 05 8800 or techsupport@arthrex.de from 8:00 AM to 5:00 PM CET.

9.1 Additional Technical Information

Contact your Arthrex representative if you require more comprehensive technical information. Other information will be provided upon request by Arthrex APPROVED SERVICE PERSONNEL.

10.0 Troubleshooting

Refer to Table 21 for device troubleshooting if problems occur after cleaning, transporting, or changing operating staff.

Table 21 Troubleshooting: Faults, Causes, and Solutions

Message	Cause	Solutions
	Foot control not recognized	Make sure foot control is connected properly.
	Foot control error	Connect a functioning foot control unit or release the engaged button on the foot control
	Motor not recognized	Connect motor
	Motor error	Connect a functioning motor
	Motor faulty	Connect a functioning motor
	Shift buttons or PLUS/MINUS buttons activated when switching on the device	Release the activated button, switch off the device and restart
	Electronics overheating Safety shutdown	Switch off the device, and allow to cool for at least 10 minutes, then restart
	Electronics overloaded	Switch off the device and restart
	Call service	Switch off the device and restart. If the error message appears again, contact an authorized Arthrex service partner.

If the problems persist, disinfect the DrillSaw Highspeed 200 and send it to Arthrex using the original packaging. Always send the corresponding console together with the foot control unit and motor. Please enclose a brief explanation of the detected malfunction.

10.1 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 the devices.
- Connect the device to an outlet on a different circuit than the other device(s) are connected to.
- Consult the manufacturer or field service technician for the receiving device for assistance.

11.0 Repair Policy

Contact Arthrex for a return authorization number and instructions prior to returning the device.

12.0 End of Life, Environmental Directives

WEEE Directive [2002/96/EC] 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.

Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.

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.

13.0 Electromagnetic Emissions

Table 22 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The DrillSaw Highspeed 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the DrillSaw Highspeed 200 should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The DrillSaw Highspeed 200 uses RF energy only for its internal function. Therefore its RF emissions are very low and not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The DrillSaw Highspeed 200 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Table 23 System Cables

Type	Use	Shielded	Ferrite	Maximum Length
Power Cords	Supply line power to the console	No	No	3.1 m (10 ft.)

Table 24 Guidance and Manufacturer's Statement - Electromagnetic Immunity

The AR-200 DrillSaw Highspeed 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the DrillSaw Highspeed 200 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical 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	<5 % Uτ (>95 % dip in Uτ) for 0.5/1/250 cycle 70 % Uτ (30 % dip in Uτ) for 0,5/1/5/10/25 cycles	<5 % Uτ (>95 % dip in Uτ) for 0.5/1/250 cycle 70 % Uτ (30 % dip in Uτ) for 0,5/1/5/10/25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the DrillSaw Highspeed 200 requires continued operation during power mains interruptions, it is recommended that the DrillSaw Highspeed 200 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	100 A/m	100 A/m	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.			

Table 25 Guidance and Manufacturer's Statement - Electromagnetic Immunity (cont'd)

The DrillSaw Highspeed 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the DrillSaw Highspeed 200 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	10 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the DrillSaw Highspeed 200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [3.5 / V1]\sqrt{P}$ = 1.2 $\sqrt{P}$ $d = [3.5 / V1]\sqrt{P}$ =1.2 $\sqrt{P}$ 80 MHz to 800 MHz $d = [7 / E1]\sqrt{P}$ = 2.3 $\sqrt{P}$ 800 MHz to 2.7 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 DrillSaw Highspeed 200 is used exceeds the applicable RF compliance level above, the DrillSaw Highspeed 200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DrillSaw Highspeed 200.

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

Table 26 Attachments for AR-200M motor for DrillSaw Highspeed 200

AR-300SAG	Saw attachment sagittal
AR-300SR	Saw attachment reciprocating
AR-300DK30	Drill Keyless Chuck 0-3.0 mm
AR-300DK45	Drill Keyless Chuck 2.0-4.5 mm
AR-300DJ	Drill Jacobs Chuck 0-4.0 mm
AR-300DAO-2	Drill Attachment Style AO
AR-300DJH	Drill Jacobs Chuck Hybrid 0-5.0 mm
AR-300B	Burr Attachment 2.35mm
AR-300B-2	Drill Attachment 2.35mm
AR-300RAO	Reamer Attachment – Style AO
AR-300RJ	Reamer Jacobs Chuck 0-4.0mm
AR-300WD16	Wire Driver Attachment 0.6-1.6 mm
AR-300PD24	Pin Driver Attachment 1.0-2.4 mm
AR-200CA	Cannulated Adapter for AR-200M
AR-200H	Handle for AR-200M

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