ArthroCare® Quantum™ (RF 12000) System and ArthroCare® Quantum™ 2 (RF 12000) System

User's Manual

This equipment has been tested and found to comply with the limits for medical devices to IEC/EN 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. If this equipment does cause harmful interference to other devices, which can be verified by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device,
- Increase the separation between the affected equipment and the Controller,
- Connect the affected equipment to an outlet or circuit different from that to which the Controller is connected, or
- Consult the manufacturer or field service technician for help.

High frequency surgical unit with respect to electrical shock, fire and mechanical hazards only in accordance with: IEC/EN 60601-1/CAN/CSA C22.2 No. 601.1, IEC/EN 60601-1-2, IEC/EN 60601-1-4, IEC/EN 60601-2-2, and IEC/EN 60601-2-18.

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Description

The ArthroCare® Quantum™ System (Model RF 12000) and ArthroCare® Quantum™ 2 System (Model RF 12000)are bipolar, radiofrequency (RF) electrosurgical systems designed for use in arthroscopic and orthopedic procedures. Each System consists of the following components:

1) a bipolar radiofrequency Controller;
2) a reusable, non-sterile Power Cord;
3) a reusable, non-sterile Foot Control;
3a) a reusable, non-sterile wireless Foot Control (optional);
4) a reusable, non-sterile Patient Cable (optional); and
5) a disposable, sterile ArthroWand®.

An optional reusable non-sterile Hand Control is also available for use with the System.

The Controller is the voltage source that delivers RF energy to the treatment site via a reusable Patient Cable and sterile Wand, or an integrated Cable Wand (ICW), or a sterile Wand/Cable combination.

The reusable Patient Cable (optional) is supplied non-sterile and is designed for sterilization prior to use.

The sterile disposable Wand is available in various single or multi-electrode configurations and is supplied separately.

The Controller is activated by either a reusable Foot Control, or an optional reusable Hand Control, or Wand with Integrated Finger Switches.

Indications for Use

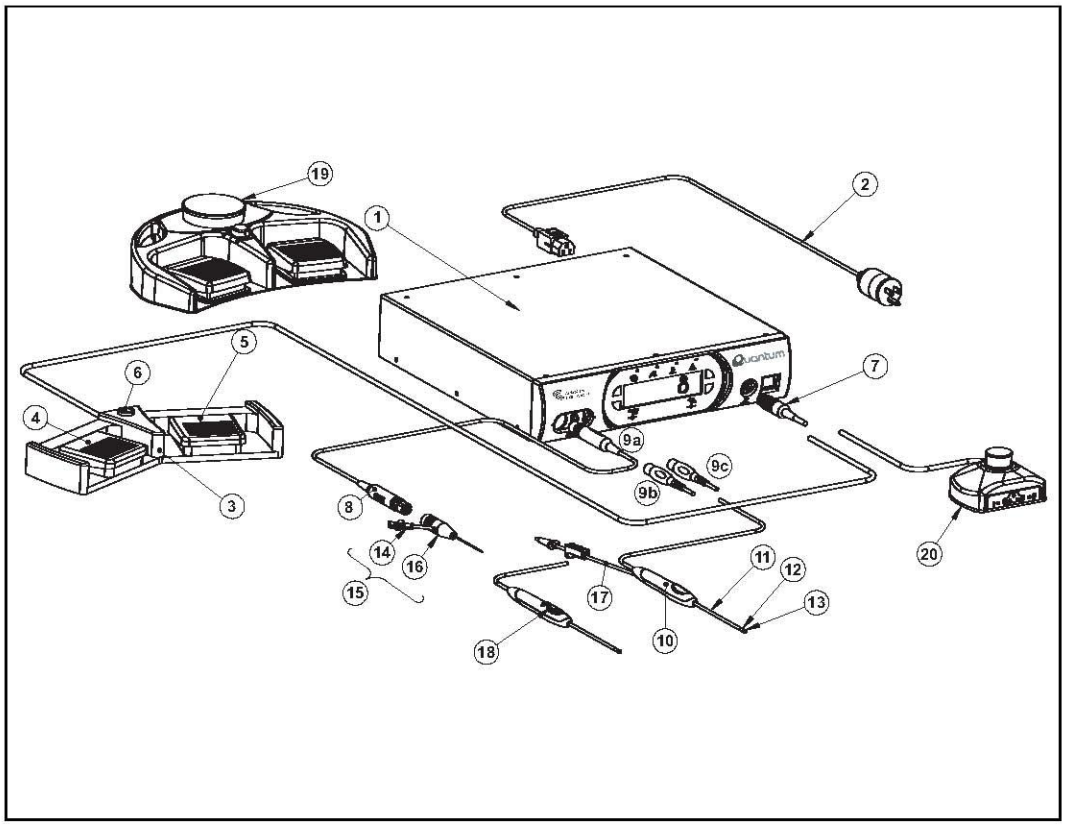
The ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 System (RF 12000) are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.

Contraindications

The ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 System (RF 12000) are contraindicated in any procedures where a conductive solution is not used. The System is also contraindicated for patients who have cardiac pacemakers or other electronic implants without specific instructions from the manufacturer of the cardiac pacemaker or implant. Please refer to the Wand Instructions for Use for a more comprehensive list of contraindications regarding specific procedures. The controller is not intended to be used with a neutral electrode.

System Overview

Connection Diagram



1. Controller
2. Power Cord
3. Foot Control
4. Ablation Pedal
5. Coagulation Pedal
6. Set Point Adjustment Button
7. Foot Control Connector
8. Patient Cable (optional)

9a. Patient Cable Connector
9b. Cable Connector with Gray Plug
9c. Cable Connector with Black Plug

10. Integrated Cable Wand (ICW)
11. Shaft (Wand)
12. Return Electrode (Wand)
13. Active Electrode Tip (Wand)
14. Irrigation Tube (optional on Wand Style)
15. Wand
16. Handle (Wand)
17. Suction Tube (optional on Wand Style)
18. Integrated Finger Switch Wand
19. Wireless Foot Control transmitter
20. Wireless Foot Control receiver

Principle of Operation

The ArthroCare Quantum (RF 12000) Controller and ArthroCare Quantum 2 System (RF 12000) are designed to deliver RF energy to the electrode elements located at the distal end of the sterile single-use Wands. Current flows between the active electrode elements and the return electrode element, both elements or poles located on the Wand itself in a bipolar configuration, providing a localized energy field. The result of this arrangement is controlled energy delivery with minimal collateral tissue damage.

The ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 System (RF 12000) work by passing RF energy through a conductive solution (such as normal saline or Ringer's lactate) in close proximity to or in contact with the tissue to be treated. The conductive solution forms a thin layer between the active and return electrode elements. In the ablation mode, when sufficient energy is applied, the conductive solution is converted into a vapor layer (plasma) containing energized charged particles. When the high-energy charged particles come in contact with tissue, they cause its disintegration through molecular dissociation.

This mode of operation results in relatively low treatment site temperatures when compared to conventional electrosurgical and monopolar RF systems, thus yielding limited collateral thermal damage to the surrounding untreated tissue.

The system can also function when a lower voltage is applied between the active and return electrodes. In this case, the electrical field is below the threshold required to create a plasma layer and resistive tissue heating occurs. This mode is useful when a greater thermal effect is needed, i.e. for coagulation of blood vessel. The appropriate voltage setting will depend on the design of the Wand used, tissue type, and desired tissue effect.

Warnings, Precautions, and Adverse Events

The following is a list of Warnings and Precautions that apply to the general operation of the ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 System (RF 12000). For specific warnings and precautions, please refer to the Wand and the Patient Cable Instructions for Use.

⚠ WARNINGS

- The Quantum (RF 12000) System and Quantum 2 System (RF 12000) are intended for use by healthcare professionals only. The Quantum (RF 12000) System and Quantum 2 System (RF 12000) may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Quantum (RF 12000) System or Quantum 2 System (RF 12000) or shielding the location.
- Failure to follow all applicable instructions may result in serious surgical consequences.
- Explosion Hazard: The following substances will contribute to increased fire and explosion hazards in the operating room: flammable substances (such as alcohol-based skin prepping agents and tinctures), flammable anesthetics, naturally occurring flammable gases which may accumulate in body cavities such as the bowel, oxygen enriched atmospheres, and oxidizing agents such as nitrous oxide (N2O) atmospheres.
- Fire Hazard: **DO NOT** place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).
- Electrosurgical accessories, which are activated or hot from use, can cause a fire.
- Accessory tips may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of Wands outside the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrosurgical current carried through other instruments and conductive objects.
- Electrosurgical current may be generated in conductive objects by direct contact with the active electrode or by the active or return electrode being in close proximity to a conductive object.
- If excessive heating or physical forces cause damage to the Wand tip, foreign body fragments may result, possibly requiring extended surgery for removal.
- **DO NOT** use the ArthroCare Quantum (RF 12000) System or ArthroCare Quantum 2 System (RF 12000) with non-conductive media (e.g. sterile water, dextrose, air, gas, glycine, etc.). Use only conductive media such as normal saline or Ringer's lactate.
- Electric Shock Hazard: **DO NOT** connect wet accessories to the Controller.
- Controller failure could result in an unintended increase in output power.

. ⚠ PRECAUTIONS

- Prior to initial use, ensure that all package inserts, warnings, precautions, and Instructions for Use are read and understood.
- Safe and effective electrosurgery is dependent not only on equipment design, but also, to a large extent, on factors under the user's control. Only persons having adequate training and familiarity with orthopedic surgery should perform procedures with the ArthroCare Quantum (RF 12000) System or ArthroCare Quantum 2 System (RF 12000).
- Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
- Evaluate patients for predisposing medical problems that may be aggravated by the stress of surgery.
- A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or Controller grounding is not compromised.
- When instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- When not in use, remove the Wand from the surgical site and place away from metallic objects. Wands should remain separated from other electrosurgical equipment to avoid inadvertent electrical coupling between devices. Inadvertent activation may cause injury to patient and/or user or equipment damage.
- **DO NOT** wrap Patient Cable around metal objects. Wrapping cords around metal objects may induce currents that could lead to shocks, fires, or injury to the patient or surgical personnel.

- Use caution when using Wand tips to probe or manipulate tissue. Forceful contact between Wand tips and tissue or other instruments may result in damage to the instrument.
- **DO NOT** use the Wand as a lever to enlarge surgical site or gain access to tissue.
- **DO NOT** allow fluid to contact any electrical connectors on the Wands, Controller, or Cables during use.
- Maintain the lowest Controller Set Point necessary to achieve the desired tissue effect.
- Confirm proper activation of the Wand if a Controller Set Point is chosen outside of the selected, default settings.
- **DO NOT** allow patient contact with grounded conductive objects, such as a surgical table frame or an instrument table, to avoid risk of shock. Grounding pads should not be used.
- **DO NOT** contact metal objects with an activated Wand.
- Observe fire precautions at all times. Sparking and heating associated with electrosurgery may be an ignition source.
- **DO NOT** use flammable agents for cleaning and disinfection of the Controller or Cables.
- As with other electrosurgical units, electrodes and Cables can provide paths for high frequency current. Position the cables to avoid contact with the patient or other electrical leads.
- High frequency (HF) electrosurgical equipment such as the ArthroCare Quantum (RF 12000) System or ArthroCare Quantum 2 System (RF 12000) may adversely affect the operation of other electronic equipment.
- Electrodes should remain separated from other electrosurgical equipment to avoid inadvertent electrical coupling between devices.
- Monitoring electrodes should be positioned as far as possible from the surgical electrodes when HF surgical equipment and physiological monitoring equipment are used simultaneously on a patient. Monitoring electrodes are not recommended.
- Monitoring equipment incorporating high frequency current-limiting devices is recommended.
- **DO NOT** remove the cover of the Controller. Refer servicing to qualified personnel.
- **DO NOT** obstruct the exhaust fan (located at rear of Controller).
- **DO NOT** touch the Controller's fan and/or speaker while touching the patient.
- Before each use, check that all Controller indicator lights and audio signals are functional. Make sure that the power cable plug is properly connected to the Controller receptacle.
- To avoid risk of fire, only replace the Controller fuses with the same type and rating.
- The ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 System (RF 12000) are designed to be operated exclusively as a unit. Only use accessories provided by ArthroCare.
- ArthroCare fully warrants the safety and efficacy of our devices when used as intended for indications for which they are approved. ArthroCare cannot verify the safety of single use Wands that have been reprocessed or reused.
- The Quantum (RF 12000) System and Quantum 2 System (RF 12000) is certified to IEC60601-1-2, class A, and should not be used adjacent to or stacked with other equipment. If the system is used adjacent to or stacked with other equipment, the system should be verified that it is operating in its intended configuration.
- **DO NOT** use other ArthroCare Foot Controls. Use only the Foot Control provided with the Quantum (RF 12000) System and Quantum 2 System (RF 12000) or the optional wireless Foot Control (P/N H4001-0X).
- When endoscopes are used with endoscopically-used accessories, the patient leakage currents may be additive.
- **DO NOT** use controller if the alarms during system check are not audible**.**
- If a Power Cord other than the ArthroCare Power Cord is used, please ensure the Power Cord complies with the voltage and current rating listing on the back panel of the Controller. Failure to do so may alter the performance of the Controller.

ADVERSE EVENTS

As a consequence of electrosurgery, damage to surrounding tissue through iatrogenic injury could occur.

Controls, Indicators, and Alarms

Controls & Indicators

The Quantum (RF 12000) Controller and Quantum 2 System (RF 12000) incorporates the following controls and indicators:

FRONT PANEL

1. On/Off Switch

This switch turns the AC power on and off. When the switch is on,the LCD display on the Controller will be active. This display may remain active for up to 5 seconds following power turn-off.

2. Warning Indicator

A red indicator illuminates and an audible signal alarms when a Controller-specific failure or malfunction occurs.

3. Foot Control / Hand Control /Wireless Foot Control Connected Indicator

A green Foot Control / Hand Control Connector Indicator will illuminate when a Foot Control or Reusable Hand Control is properly connected.

4. Coagulation Activation Indicator

A blue indicator will illuminate when the Foot Control or Hand Control or Wand finger switch Coagulation function is depressed with a Wand attached.

5. Wand Connected Indicator

A green Wand Connector Indicator will illuminate when the Patient Cable and the Wand are properly connected.

6. Coagulation Set Point Adjustment

Increment and Decrement Arrow buttons control the Coagulation Set Point. Refer to the Instructions for Use section of this manual for the corresponding voltage levels for each setting.

7. Ablation Set Point Adjustment

Increment and Decrement Arrow buttons control the Ablation Set Point. The Ablation output adjustment is only enabled on wands where this feature is allowed. The Ablation output level can also be adjusted from the Ablation Set Point Adjustment function on the Foot Control or the Hand Control or the Wand's integrated finger switch. Refer to the Instructions for Use section of this manual for the corresponding voltage levels for each setting.

8. LCD Display Window

This display indicates the output level for ablation and coagulation. Nominal settings will automatically be displayed when the System is powered up with a Wand attached or when a new Wand is connected. When the Controller is turned on, and prior to connection of a Wand, this display will show "Connect Wand".

9. Ablation Activation Indicator

A yellow indicator will illuminate when the Foot Control or Hand Control or Wand finger switch Ablation function is depressed with a Wand attached.

10. Plasma Mode Indicator

The Plasma Mode Active Indicator will illuminate when the Ablation output is active and the Quantum (RF 12000) and Quantum 2 (RF 12000) detects that the wand is actively cutting or resecting tissue.

11. Foot Control / Hand Control Receptacle

The Foot Control / Hand Control / Wireless Foot Control Receiver plugs into the tan receptacle located on the front of the Controller.

12. Symbol for Defibrillator-Proof Type BF Equipment

This equipment provides a degree of protection against electric shock to TYPE BF applied parts as defined in IEC/EN 60601-1, it also has an F type applied part capable of withstanding the effects of defibrillator discharge.

13. Black Cable Receptacle

The Cable Receptacle with the black ring will accept cable wands with black mating end.

14. Tan Cable Receptacle

The Cable Receptacle with the tan ring will accept the reusable Patient Cable and cable wands with gray mating end.

15. Sliding Door

This door slides left and right and allows access to either the Black Cable Receptacle or the Tan Cable Receptacle.

BACK PANEL

16. Tone Volume Control

The Tone Volume Control regulates tone volume. To increase volume, turn the knob clockwise. To reduce volume, turn the knob counterclockwise.

17. Non-Ionizing Radiation Symbol

This symbol indicates that this equipment intentionally emits RF energy during activation.

18. Fuse Rating Symbol

This symbol indicates that only fuses with the appropriate rating should be used. Check the Controller back label for the appropriate fuse rating. See Maintenance and Troubleshooting section for fuse replacement instructions.

19. Power Cord Receptacle / Fuse Holder

The Controller Power Cord plugs into this receptacle. The fuse holder is behind the receptacle.

20. Equipotential Ground Symbol

This symbol identifies the conductor that is used to bond the equipment to earth ground.

21. TÜV Nord Classified Mark

The TÜV Nord Classified Mark indicates compliance with applicable international IEC 60601 series safety standards.

22. Attention Symbol

This symbol alerts the user to read and understand this manual and accompanying instructions before operating the equipment.

23. No Disposal Symbol

This symbol indicates that this equipment should not be discarded in any waste container.

24. Serial Communication Port

This port allows the Quantum (RF 12000) system and Quantum 2 (RF 12000) to communicate to remote accessory devices, such as arthroscopy pumps, that use the RS-232 serial communication protocol.

25. CE Mark - European Certification Symbol

This indicates compliance with the European Commission Medical Device Directive (93/42/EEC).

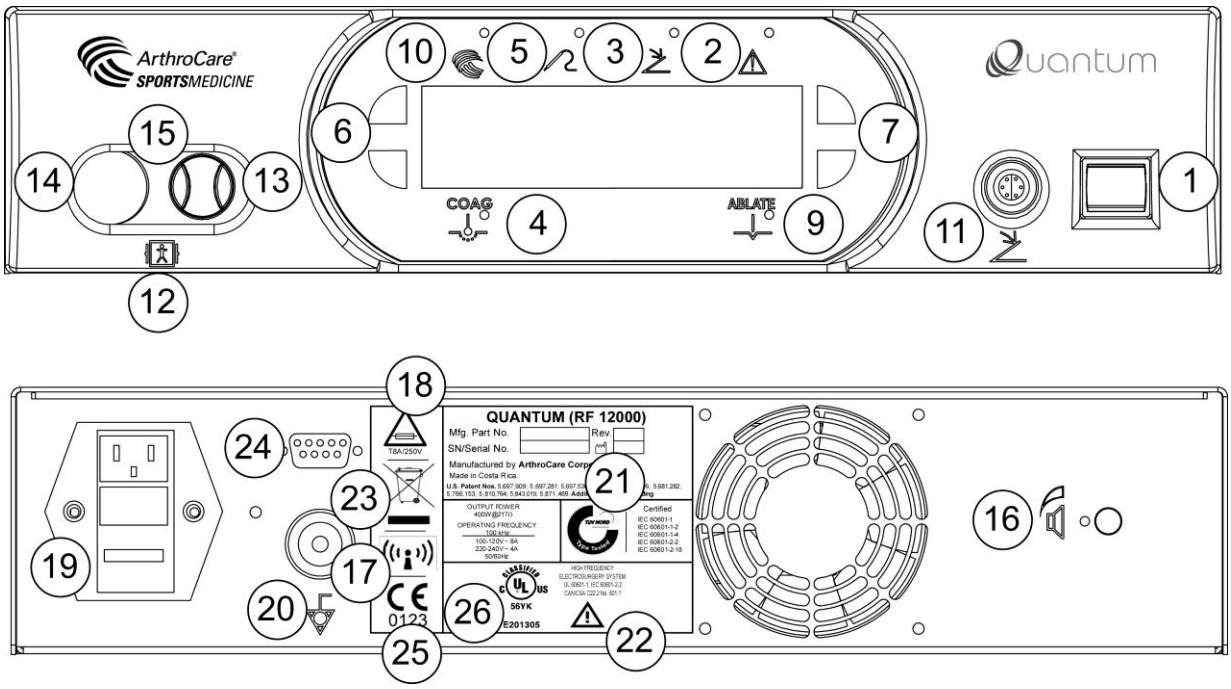
26. UL Classified Mark

The UL Classified Mark indicates compliance with applicable Safety Standards for the United States and Canada by Underwriters Laboratories, Inc. (UL).

Alarms

1. Intermittent dual tone: power limit alarm or overload
2. Intermittent monotone: connection fault alarm (Patient Cable, Wand, Cable Wand, Over Temperature Condition, Over Power Condition)

Diagram of Controls, Indicators, and Alarms



Unpacking, Assembly, and System Check

Unpacking

Verify that all items have been received and are not damaged. Damage should be reported at once to the Customer Service Department. Save all containers and packaging material; they will be required if it is necessary to return the equipment.

Assembly and System Check

1. Connect the Power Cord to the receptacle on the rear panel of the Controller. Connect the other end of the Power Cord to the electrical outlet. If it is necessary to use a Power Cord other than the one supplied with the System, the alternate Power Cord should comply with appropriate electrical standards and be suitable for hospital use.
2. Turn the On/Off Switch on the front panel of the Controller to the 'On' position. The system should go through a Power On Self Test routine, and the ArthroCare logo and software version number should be displayed. During this sequence, verify that the displays and indicator lights are properly working and that the warning alarm is audible. The Display should indicate "Connect Wand". If the display indicates "PRESS ANY BUTTON", press the yellow or blue set point adjustment keys on the front of the controller or press the foot pedal adjustment button to return controller to standby mode.
3. Attach the Foot Control or Hand Control or Wireless Foot Control Receiver to the tan receptacle on the front of the Controller. The Foot Control / Hand Control / Wireless Foot Control Connected Indicator on the front panel of the Controller should illuminate.
4. Depress the Ablation function on the Foot Control or the Hand Control. The red Warning Indicator on the front panel of the Controller should illuminate and the Controller should emit an intermittent monotone alarm. The yellow Ablation Activation Indicator on the front panel should be off.

   CAUTION: DO NOT use controller if the alarms during system check are not audible.

   NOTE: Use only the Foot Control authorized by ArthroCare for use with RF 12000 System.
5. Attach Patient Cable and Wand or Integrated Cable Wand to appropriate cable receptacle (tan receptacle for tan connector Wands and black receptacle for black connector Wands).The green Wand Indicator should illuminate. See System Preparation and Care section of this manual for additional information.

   CAUTION: DO NOT contact metal objects with an activated Wand.

   CAUTION: DO NOT place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).

   CAUTION: Electrosurgical accessories, which are activated or hot from use, can cause a fire.

   CAUTION: Accessory tips may remain hot enough to cause burns after the electrosurgical current is deactivated.

   CAUTION: Localized burns to the patient or physician may result from electrosurgical current carried through other instruments and conductive objects.
6. Taking care not to touch the Wand end, depress the Ablation (yellow) pedal of the Foot Control or button on the Hand Control or Wand's integrated finger switch. The yellow Ablation Activation Indicator should illuminate. If the Controller does not function as described above, please contact Customer Service immediately.

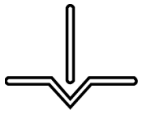
Instructions for Use

Operator Training Requirements

The operator should be experienced in electrosurgical techniques. It is recommended that the user remain current with advances in orthopedic procedures. Additional training on the use of the ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 (RF 12000) from an ArthroCare representative is recommended.

General System Operation

Wands are activated using either the Foot Control or the Hand Control or the Wand's integrated finger switch. Depending on the type of Wand that is connected, the RF will either be activated continuously as long as any of these switches are pressed, or the RF delivery will be limited to a predetermined time interval. The Quantum (RF 12000) System and Quantum 2 (RF 12000) automatically detects Wands that include this feature. When this type of Wand is detected, the system activates the Timer icon on the LCD display to indicate to the operator that the RF delivery time will be automatically limited. Refer to the Wand IFU for further information. The Foot Control, the Hand Control, and the Wand's integrated finger switch have three functions (ablation, coagulation, and ablation set point adjustment) as described below:



Ablation Activation

Pressing the Ablation Activation function operates the Controller's normal ablation mode and will activate the Wand.

Coagulation Activation

Pressing the coagulation function will activate the Controller's preset coagulation mode and will activate the Wand for hemostasis of blood vessels.

Ablation Set Point Adjustment

Pressing the Ablation Set Point Adjustment function will adjust the Ablation voltage level on the Controller. Each time the Ablation Set Point Adjustment function is pressed, the Ablation voltage level increases by one level up to the maximum set point for each Wand style. Once the maximum level for the connected Wand has been reached, the System will cycle back to Set Point 1.

Timer Icon

A Wand that limits the RF delivery time to a predetermined value has been connected to the system.

NOTE: The Foot Control, the reusable Hand Control, and the Wand with Integrated Finger Switches may be used in the same procedure but cannot be used simultaneously.

Quantum 2 (RF 12000) System

Some Wands include an integrated thermocouple that allows the temperature of the irrigating fluid to be monitored during use. These Wands are only to be used with the Quantum 2 (RF 12000) System. The Quantum 2 System automatically detects Wands that include this function and enables the temperature display. When these Wands are used, the operator can select a temperature alarm set point by using the COAG adjustment buttons when the system is in the standby mode. During use, if the measured temperature exceeds this set point, an audible and a visual alarm are activated to alert the operator. Refer to the Wand IFU for more information on this feature. Wands with the Ambient™ feature are not compatible with other controllers including Quantum (RF 12000) controllers.

Temperature Monitor Display

A Wand that includes the temperature monitor feature has been connected to the Quantum 2 (RF 12000) System. An audible and a visual alarm are activated if the measured irrigation temperature exceeds the alarm set point.

Voltage Outputs

The voltage outputs correspond to the Ablate or Coag Set Points as listed in the Table below. Depending on the particular Patient Cable in use, the display corresponds to the output voltage in open circuit as follows:

Tan Patient Cable Receptacle

Display	Output Voltage (Vrms ±10%)
1	100
2	126
3	154
4	180
5	207
6	234
7	260
8	287
9	314
10	Not allowed
Coag 0	0
Coag 1	65
Coag 2	100

Black Patient Cable Receptacle

Display	Output Voltage (Vrms ±10%)
1	100
2	126
3	154
4	180
5	207
6	234
7	260
8	287
9	314
10	320
Coag 0	0
Coag 1	65
Coag 2	100

When the Controller is first powered on with no Wand attached, after the self tests are completed, a "Connect Wand" message will be displayed on the controller front panel. If a Wand is attached at power-up, the Controller will display "Press any key". After a wand is connected or a key pressed, the output levels will be set automatically by the system to the default values for the particular Wand. These settings will usually provide the best effect in most situations. Press any key on the controller front panel or the set point adjustment button on the Foot Control or Hand Control or the Wand's integrated finger switch to adjust the display to the nominal settings.

NOTE: If a Set Point is selected outside of the default range (between the initial Set Point and maximum Set Point), proper activation of the Wand should be confirmed.

Once a Wand has been properly connected, the Ablation or Coagulation voltage level can be increased or decreased by pressing the voltage level adjustment button located on the front panel. Ablation level can also be adjusted by pressing the Ablation set point adjustment function on the Foot Control or the Hand Control or the Wand's integrated finger switch. The ablation setting levels may be adjusted to levels throughout the appropriate range, depending on the maximum voltage permitted by the particular Wand in use. In general, the higher set point values will result in more aggressive tissue ablation, low set point values (e.g. 1 or 2) will result in the Wand maintaining a resistive heating mode.

Wands also have adjustable coagulation functionality which can be adjusted using coagulation set point buttons on the controller front panel. Nominal coag is "1" and enhanced coag is "2".

System Preparation and Care

System Preparation

1. Prior to each use, inspect the ArthroCare Quantum (RF 12000) System or ArthroCare Quantum 2 (RF12000) System for possible damage to the Controller Casing and cables.
2. Insert the receptacle end of the Power Cord into the Power Cord Receptacle located at the rear of the Controller. Insert the plug end of the Power Cord into an appropriately grounded electrical outlet. Position the Controller so that the exhaust fan located in the rear of the Controller is unobstructed and directed away from the patient.
3. Press the On/Off Switch on the front panel of the Controller to the 'On' (I) position. The system should go through a Power On Self Test routine, and the ArthroCare logo and software version number should be displayed. During this sequence, verify that the displays and indicator lights are properly working and that the warning alarm is audible. The LCD should indicate "Connect Wand".
4. Connect the Foot Control or the reusable Hand Control or wireless Foot Control Receiver to the Foot Control / Hand Control Receptacle on the front of the Controller. The Foot Control / Hand Control Connected Indicator (green) on the Controller front panel will illuminate.
5. a. If using the reusable Patient Cable, ensure that the Patient Cable has been cleaned and sterilized and that the connectors are DRY before use. Slide the sliding door to the right and connect the Patient Cable to the tan Receptacle on the front of the Controller. Connect the appropriate Wand to the other end of the Patient Cable.

   NOTE: If sliding door has been removed, contact Customer Service.

   b. If using an ICW with gray mating or tan end, slide the sliding door to the right and connect the ICW to the Tan Receptacle (27 pin) on the Controller.

   c. If using an ICW with black mating end, slide the door to the left and connect the ICW to the Black Cable Receptacle (18 pin) on the front of the Controller.

   NOTE: Refer to each Wand Instructions for Use for specific instructions regarding surgical preparation and procedures.

6. Set appropriate Set Point Display required to obtain desired effects.

Wand Selection

Select the Wand type most appropriate for the procedure. The Quantum (RF 12000) Controller and Quantum 2 (RF 12000) Controller will default to a recommended ablation set point and coagulation set point for each Wand style to serve as a guide for safe and effective operation.

NOTE: Initial and maximum Set Points are suggested settings. Proper activation of the Wand should always be confirmed.

In order to adjust the ablation set points, the Wand and Patient Cable must be connected to the Controller.

System Shut Down

1. Turn the power switch to the 'OFF' (0) position. After a brief (less than 4 seconds) delay, all lights on the Controller and the Set Point Display will go off.
2. Disconnect the suction tubing if appropriate.
3. If using the reusable Patient Cable, remove the Wand from the Patient Cable and disconnect the Patient Cable from the Controller. Dispose of the Wand and prepare the Patient Cable for sterilization and further use.
4. If using the ArthroWand with Integrated Cable, disconnect the Wand cable connector from the Controller. Do not attempt to separate the ArthroWand from the Cable component. Discard the Wand with Integrated Cable.

System Environmental Requirements

All ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 (RF 12000) components may be safely stored and transported at an ambient temperature range of -40°C (-40° F) to +70°C (158° F) and atmospheric pressure of 500 hPa (7.2 psi) to 1060 hPa (15.3 psi). The relative humidity should be between 10 and 85%. The ArthroCare Quantum (RF 12000) and ArthroCare Quantum 2 (RF 12000) may be safely operated at an ambient temperature range of +10° C (+50° F) to +40° C (104° F), atmospheric pressure of 700 hPa (10.1 psi) to 1060 hPa (15.3 psi) and relative humidity of 10% to 85%.

Equipment Disposal

The ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 (RF 12000) System contains electronic printed circuit board assemblies and should not be disposed in any waste container. It should be disposed of in accordance with any applicable national or institutional policies relating to obsolete electronic equipment. Contact ArthroCare for return of the Quantum (RF 12000) or Quantum 2 (RF 12000) Controller for proper disposal. Dispose of the Wand and the Patient Cable according to normal institutional practices for potentially contaminated items.

Cleaning and Sterilization

Surface Cleaning & Disinfection of Controller and Foot Control

DO NOT sterilize or immerse in liquid. Wipe clean with a soft cloth and mild detergent as needed. Clean with detergents and disinfectants according to standard practices. Disinfect with liquid chemical disinfectants such as chlorine solutions, iodophors, glutaraldehydes and hydrogen peroxides. Follow manufacturer guidelines for concentration and length of exposure.

Cleaning and Sterilization of Patient Cable

The Patient Cable is supplied NON-STERILE. It is reusable if cleaned and sterilized prior to each use. Ensure that a validated and approved steam sterilization process is used during the sterilization process.

Surface Cleaning and Disinfection

- Before cleaning, secure the protective caps over the Patient Cable connectors to protect them from possible damage. The protective caps should fit snugly over the Patient Cable connector. If the protective caps are loose, check to see if the silicone o-ring is positioned within the groove on the cable connector. Replacement o-rings are available through ArthroCare. The Patient Cable should then be wiped down with a mild, disinfecting detergent solution using a soft brush or sponge to remove any gross contaminants from the Patient Cable. The Patient Cable can be rinsed under running water to remove any cleaning residue. The Patient Cable should not be immersed in water or any other solution. Remove the protective caps from the Patient Cable connectors and inspect the Patient Cable for any damage such as cuts or nicks. Damaged Patient Cable should not be reused. Sterilize the clean Patient Cable by following one of the recommended sterilization methods:

Pre-Vacuum Steam Sterilization

If the pre-vacuum steam sterilizer has a prefixed cycle, use the "Hard Goods" cycle. If it does not have a prefixed cycle, the following parameters are recommended:

- Set temperature at 270-272°F (132-133°C);
- Set exposure time for 10 minutes for wrapped Patient Cables;
- Set exposure time for 4 minutes for unwrapped Patient Cables;
- Set drying time for 5 minutes minimum.

Gravity Displacement Steam Sterilization

The following parameters are recommended for gravity displacement steam sterilization:

- Set temperature at 270-272°F (132-133°C);
- Set exposure time to 15 minutes for wrapped or unwrapped Cables;
- Set drying time for 8 minutes minimum.

Or

- Set temperature at 250-254°F (121-123°C);
- Set exposure time to 30 minutes for wrapped or unwrapped cables;
- Set drying time for 8 minutes.

⚠ **CAUTION:** Failure to properly clean the Patient Cable may lead to inadequate sterilization.

Cleaning and Sterilization (Cont.)

⚠ **CAUTION:** The recommended sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

⚠ **CAUTION:** To ensure adequate sterilization, make sure that the protective caps do not cover the cable connectors during sterilization.

⚠ **CAUTION:** Make sure Cable is thoroughly DRY before use. Wet Cable may damage the Cable and Controller.

Wand

The Wand is supplied sterile. The Wand is intended **for single use only. DO NOT clean, resterilize, or reuse the Wand as this may result in product malfunction, failure, or patient injury, which may also expose the patient to the risk of transmitted infectious diseases.** Please refer to the Instructions for Use associated with each Wand type for specific information concerning Wand use.

Maintenance and Troubleshooting

Maintenance

Other than fuse replacement, the Controller has no user-serviceable parts. It is designed to provide consistent output levels and is calibrated by clock crystals, voltage references, and fixed resistors. There are NO internal adjustments in the instrument and, due to the calibration methods, no annual maintenance check is required. If any component malfunctions, call Customer Service for a return authorization.

Fuse Replacement

The fuse holder is located on the back of the Controller. To replace a fuse, turn off the power to the Controller and unplug the Power Cord from the power receptacle at the rear of the Controller. After waiting at least 10 seconds for internal circuitry to discharge, use a screwdriver or similar tool to remove the fuse holder by depressing the locking tabs. Replace both fuses with the same type and rating as specified on the rear panel of the Controller. Reinsert the fuse holder until the locking tabs snap into place. Reconnect the Power Cord and restore power to the Controller. If a fuse fails again, disconnect all power to the Controller and contact Customer Service.

Troubleshooting Guide

If you are experiencing problems with the ArthroCare Quantum (RF 12000) System or ArthroCare Quantum 2 (RF 12000) System, you may want to use the following troubleshooting guide to help identify or eliminate the problem before contacting Customer Service:

- **System does not power up after the power switch is pressed.**
  Check that the Power Cord is properly connected to the Controller and plugged into an appropriately grounded outlet. If the unit is plugged in properly, check if the fuses have blown. To change the fuses, follow the instructions for Fuse Replacement.
- **System powers up and controller is unresponsive.**
  There are some controller self-tests that are performed immediately after the power is applied to the unit and prior to the initialization of the user interfaces. If one of these self tests fails to complete successfully, it is possible for the controller to go into the idle mode, without an error message or alarm tone being displayed. If this occurs, turn the controller off and then on again and check for proper operation. If the problem persists, return the System for Service.
- **Green Foot Control / Hand Control Connected Indicator light does not illuminate**
  Check that the Foot Control / Hand Control / Wireless Foot Control Receiver is properly connected to the Controller and that the cord is not nicked, cut or frayed. Do not use the Foot Control / Hand Control if the cord has been damaged. If the problem persists, change the Foot or Hand Control. If the Foot Control/Hand Control Connected Indicator Light is still not illuminated, return the System for Service.
- **Green Wand Connected Indicator light does not illuminate when a Wand is connected to the reusable Patient Cable.**
  Make sure that the Wand is securely seated in the Patient Cable, and that the Patient Cable is properly connected to the Controller. If the problem persists, first change the Patient Cable and then the Wand. If the Wand indicator light is still not illuminated, return the System for service.

Maintenance and Troubleshooting (Cont.)

- **Nothing happens when one of the device activation functions on the Foot Control or the reusable Hand Control or Wand's integrated finger switch is depressed.**
  Verify that both the Foot Control / Hand Control Connected Indicator light and the Wand Connected Indicator light are illuminated when the Foot Control or Hand Control is depressed. Or that the Wand Connected Indicator light is illuminated when a Wand with integrated finger switches is used. Check if the voltage level has been adjusted to a level appropriate for operation (usually 1 or greater). Confirm that the Wand tip and shaft are covered by a conductive irrigant. Make sure that the Wand is securely seated in the Patient Cable, and that the Patient Cable is properly connected to the Controller. If the problem persists, first replace the Patient Cable and then the Wand. If the System still fails to operate, return for service.

- **The Wand does not activate; an intermittent monotone alarm sounds and a red warning light illuminates.**
  This generally indicates a connection problem. Either the Wand is not fully seated in the Patient Cable, or the Patient Cable is not properly connected to the Controller. Check all connections. If the alarm continues to sound when the Foot Control or the Hand Control button or Wand's integrated finger switch is depressed, first replace the Patient Cable and then the Wand. Return the System for service if the problem continues.

- **A dual tone alarm sounds and a red warning light illuminates when the Wand is activated.**
  This is a safety feature of the ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 (RF 12000) System and may occur if the Wand is activated for an extended period of time without contacting tissue. To reset the unit, step off the foot pedal if the System is connected to the Foot Control. If the System is connected to the Hand Control, release the button from the Hand Control. Or, if the finger switch on the Wand is activated, release the finger switch on the handle to reset the unit. Make sure that the Wand is in close proximity or contact with the target tissue, and depress the Foot Control or Hand Control again. If the alarm continues to sound, first replace the Patient Cable and then the Wand. If the problem persists, return the System for service.

Error Messages

Fault/Error	Fault Description	LCD Message
Error	Both CUT/COAG buttons pressed simultaneously	E1: Cut and Coag simultaneously activated
Error	Wand disconnected while RF active	E2: Wand disconnected
Error	Use-limiting time expired	E3: Wand error
Error	Shorted wand	E4: Wand short
Error	Re-used wand detected	E5: Wand error
Error	Open T/C circuit	E6: Open T/C
Error	Re-used wand detected	E7: Wand error
Error	Controller powered on with re-used wand	E8: Wand error
Fault	Integrity of stored program compromised (calculated CRC differs from loaded value)	F1: Hardware failure
Fault	Integrity of RAM space compromised (RAM test failed)	No LCD message can be displayed
Fault	COP watchdog timer not strobed	F3: Hardware failure
Fault	Output of the DC-DC converter out of specification	F4: Hardware failure
Fault	Analog measurement failure (measured value out of specification)	F5: Hardware failure
Fault	Footswitch, fingerswitch or front panel switch pressed during power on	F6: Switch stuck on
Fault	Over temperature of internal electronics	F7: Internal overtemp

Product Specifications

Technical Specifications

Patient Cable (optional)

Overall Length……..3.3 m (10 ft.)
Sterilization Method……Steam

Controller

Input Power Requirements

Voltage……..100 -120/220-240 V~
Frequency…….....50/60 Hz
Input Current…….8 / 4 A
Fuse Rating……..T8 A /250V

Output Power

Fundamental Frequency……100 kHz
Voltage Range……0-320 Vrms @100 kHz
Max. Output Power……400 W @ 217 Ω

Operating Temperature……10° C to 40° C

Controller Dimensions

Weight (max)…… < 5 kg (< 11 lbs)
Height……10.2 cm (4.0 inches)
Width……40.6 cm (16.0 inches)
Length……40.9 cm (16.1 inches)

Controller Measuring Function (ArthroCare Quantum 2 System only)

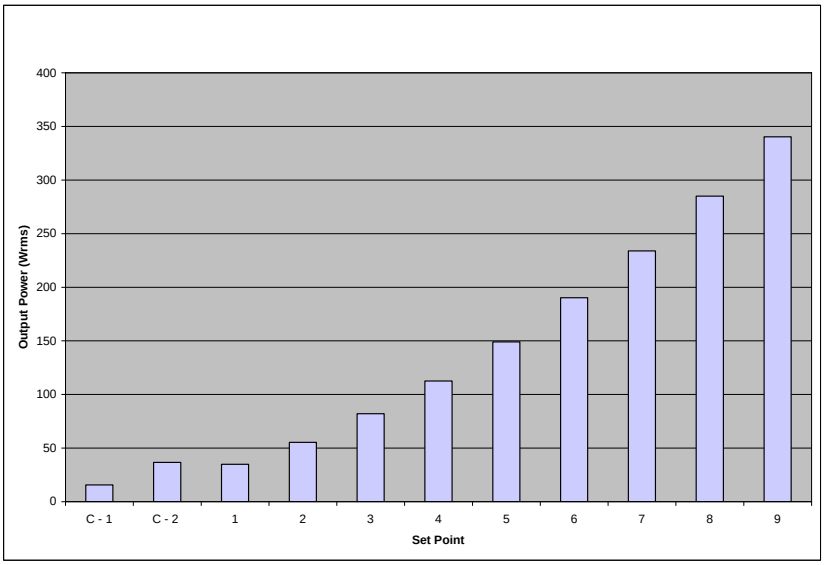
Temperature range……..20 to 60°C
Temperature resolution……1°C
Calibrated accuracy……±3°C

Foot Control and Hand Control

Foot Control Cable Length ……4.7 m (15 ft.)
Hand Switch Cable Length…….....3.0 m (10.0 ft.)
Sterilization (Hand Control only)…… Steam

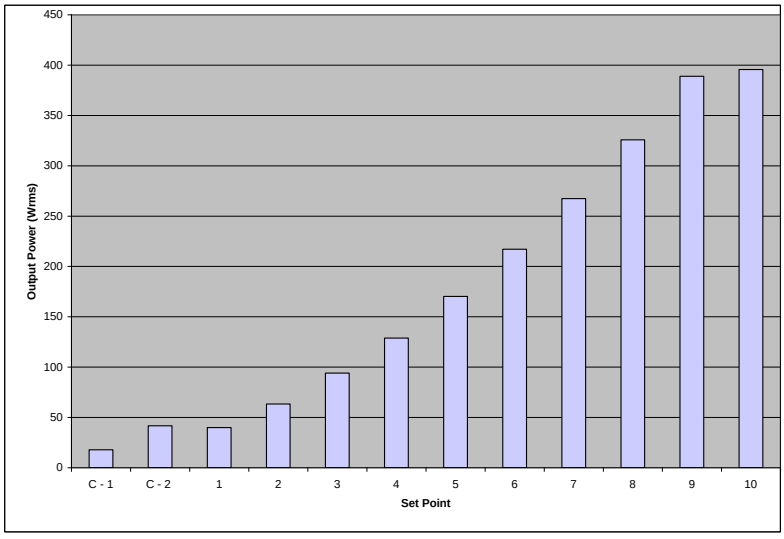
Controller Output Graphs

The Output Power at each specified set point is shown for the tan patient cable receptacle of the instrument in the graph below. The used load was 248 Ohms for all set points, except set point nine, where the resistance used was 219 Ohms (per IEC/EN 60601-2-2, subclause 6.8.3).



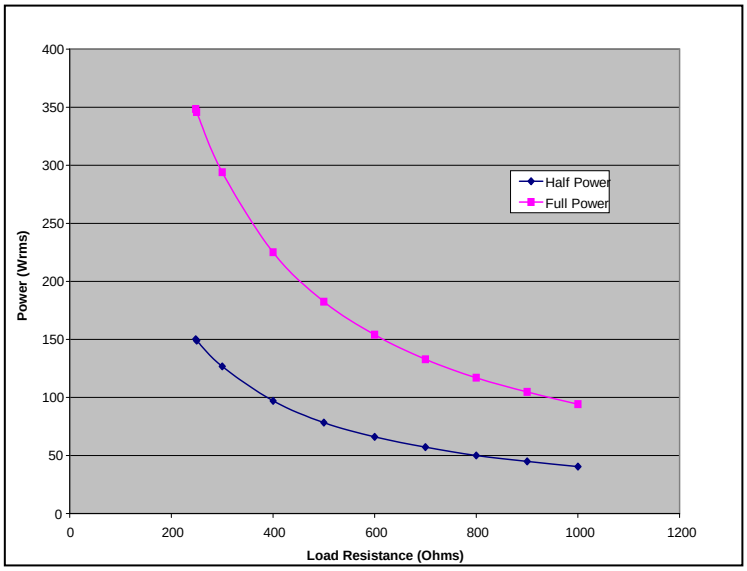
Output Power vs. Set Point at 248 Ohms Resistive Load, Tan Patient Cable Receptacle

The Output Power at each specified set point is shown for the black patient cable receptacle of the instrument in the graph below. The load used was 200 Ohms for all set points, except set point nine, where the resistance used was 217 Ohms (per IEC/EN 60601-2-2, subclause 6.8.3).

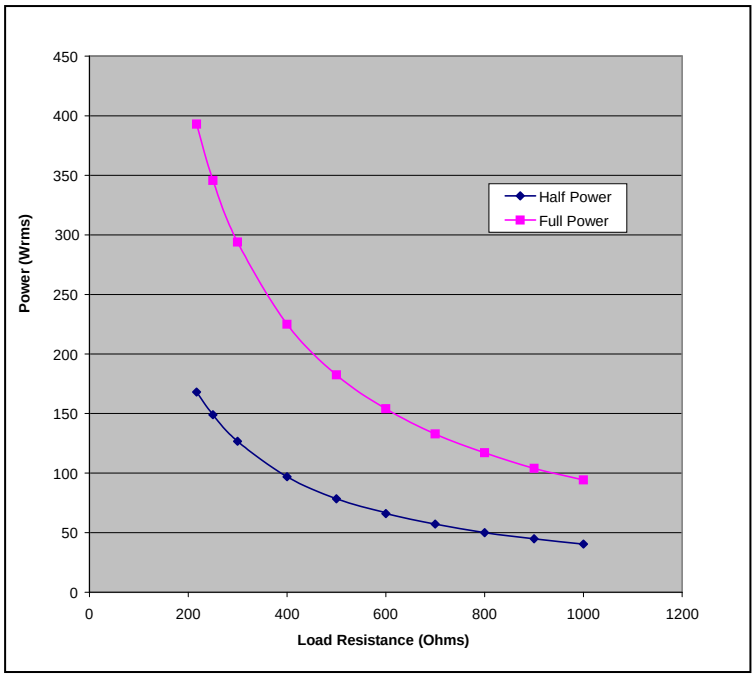


Output Power vs. Set Point at 217 Ohms Resistive Load, Black Patient Cable Receptacle

The output power (at full and half settings) versus load resistance (per IEC/EN 60601-2-2, subclause 6.8.3) is given in the graphs below:



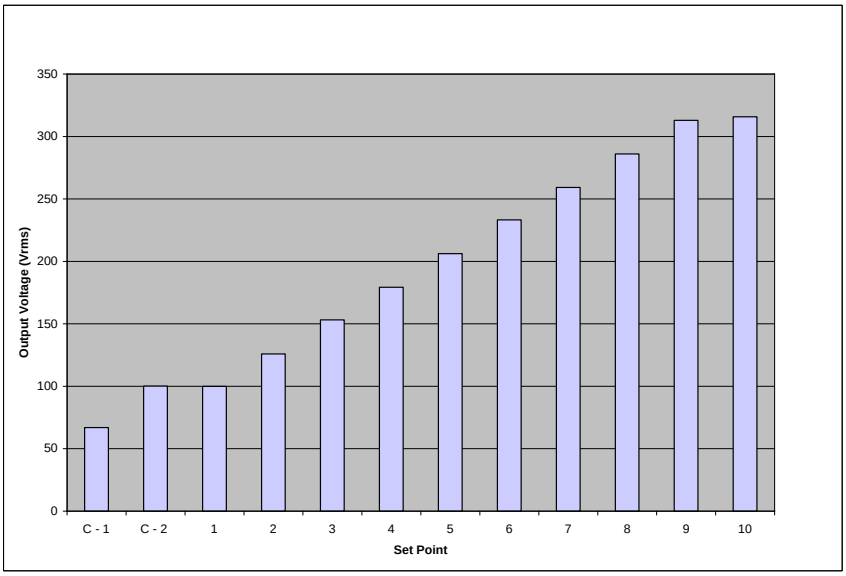
Output Power vs. Load Resistance, Tan Patient Cable Receptacle



Output Power vs. Load Resistance, Black Patient Cable Receptacle

Note: at 50 Ohms, full power setting of the black patient cable receptacle, the current limiting circuit of the instrument suppressed the output, and thus the output power registered a low value.

The following plot illustrates the relationship between instrument set points and output RMS voltage.



Output Voltage vs. Set Point, Tan and Black Patient Cable Receptacle

Controller Classification and Safety Verification

Classification

According to IEC/EN 60601-2-2, Specification for High Frequency Surgical Equipment, the Controller is classified as follows:

- Type of protection against electrical shock:
  Class I equipment.
- Degree of protection against electrical shock:
  Defibrillation proof, type BF (Isolating/floating).
- Degree of protection against harmful ingress of water:
  - Controller meets requirements of IEC/EN 60601-2-2, subclause 44.6.
  - Foot Control meets requirements of IEC/EN 60601-2-2, subclause 44.6, watertight construction (IPX8).
- Equipment not suitable for use in the presence of a flammable anesthetic mixture.
- Mode of operation: capable of continuous operation.

Safety Verification

The ArthroCare Quantum (RF 12000) System and ArthroCare Quantum 2 (RF 12000) meet the requirements of IEC/EN 60601-1, IEC/EN 60601-1-2, IEC/EN 60601-1-4, IEC/EN 60601-2-2, CSA 22.2 No. 601.1,and IEC/EN 60601-2-18. It is recommended that the biomedical engineering department test the System to ensure that it meets the following leakage levels:

- Leakage current……..≤100μA at 100-120/220-240 V~, 50/60 Hz isolated patient connections
- Leakage current…….≤500μA at 100-120/220-240 V~, 50/60 Hz non patient applied parts

If the System fails to meet the specifications listed above, please contact ArthroCare Customer Service for a return merchandise authorization.

Parts List

Part Number	Description
P/N H3000-01	Foot Control
P/N H4001-XX	Wireless Foot Control
P/N H0970-02	Patient Cable
P/N 10720 Product List	Wands

Customer Service

Warranty Information

The ArthroCare Quantum (RF 12000) Controller, ArthroCare Quantum 2 (RF 12000) Controller, and Foot Control are warranted for one year and the warranty for the reusable Patient Cable extends for a period of 90 days from the date of shipment to the original purchaser. Any component of the System, which develops defects resulting from defective material or workmanship during these time periods will be replaced or repaired without charge.

Product Complaints

All questions or concerns related to the quality, reliability and/or durability of this product should be directed to Customer Service or an authorized ArthroCare representative. Please contact Customer Service or an authorized ArthroCare representative for a return authorization.

Manufacturer

ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA U.S.A.
Toll Free: (800) 797-6520 (Customer Service)
www.arthrocare.com

Authorized European Representative

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111 30 Stockholm, Sweden
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Symbols Key

A	Caution, Consult accompanying documents / Caution
	Manufacturer
EC REP	Authorized representative in the European Community
	Date of Manufacture
	Coagulation
	Ablation
	Wand connected
	Foot Control/Hand Control Connected
	Defibrillator –Proof Type BF Equipment
	Fuse Rating
	Non-Ionizing Radiation
	Equipotential Ground
	Tone Volume Control
	Fragile, Handle with Care
	Temperature Limitations
	Keep Dry
	Do not dispose in waste container
	Timer
	Temperature measurement in degrees Celsius
	Humidity Range: 10% - 85% R.H., Non-condensing
CE 0123	CE mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive (93/42/EEC).
Rx only	CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

The ArthroCare Quantum System and ArthroCare Quantum 2 System are covered by the following U.S. Patents: 5,697,909; 5,697,281; 5,697,536; 5,697,882; 5,683,366; 5,681,282; 5,766,153; 5,810,764; 5,843,019; 5,871,469. Additional patents issued and pending.

ArthroCare, ArthroWand, Quantum, and Ambient are registered trademarks or unregistered trademarks of ArthroCare Corporation.

Rx only

CE 0123

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