Symbols

⚠ ATTENTION, SEE INSTRUCTIONS FOR USE.

REF CATALOG NUMBER

SN SERIAL NUMBER

📅 DATE OF MANUFACTURE

LOT LOT NUMBER

⚠️ DANGER: DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS: RISK OF EXPLOSION!

⚠️ DANGER: NOT DEFIBRILLATOR PROOF! CAUTION: POSSIBLE INTERFERENCE TO OTHER MEDICAL ELECTRICAL EQUIPMENT.

⚠️ DANGER: MAY CAUSE INTERFERENCE TO ACTIVE IMPLANTS OR CARDIAC PACEMAKERS!

⚠️ PRESENCE OF UNINSULATED HIGH VOLTAGE INSIDE THE EQUIPMENT. RISK OF ELECTRIC SHOCK. DO NOT REMOVE EQUIPMENT COVER.

⚠️ TYPE “BF” APPLIED PART, PATIENT APPLIED PART ISOLATED FROM PROTECTIVE AND FUNCTIONAL EARTH GROUND.

⚠️ “I” SYMBOL ON MAIN SWITCH INDICATES MAIN POWER IS ON.

⚠️ “O” SYMBOL ON MAIN SWITCH INDICATES MAIN POWER IS OFF.
SINGLE PHASE ALTERNATING CURRENT.

FOOT SWITCH: PROTECTED AGAINST THE EFFECTS OF IMMERSION IN FLUIDS.

FOOT SWITCH CONNECTOR

FUSE

RF OUTPUT CONNECTOR

VARIABLE AUDIO OUTPUT
Customer Service

U.S. CUSTOMER SERVICE
General customer service and technical support are available toll-free:
800-535-4646 or 904-296-9600
Monday-Friday
8:00 a.m. - 6:00 p.m. E.S.T.
www.medtronicophthalmics.com

MICROELECTRONICS REPAIR
Technical Support:
Phone: 800-535-4646
Fax: 904-279-7533
Monday-Friday
8:00 a.m. - 5:00 p.m. E.S.T.

Return Address:
Medtronic Ophthalmics
4102 Southpoint Boulevard
Jacksonville, FL 32216-0980
ATTN: Customer Repair Department

CUSTOMER SERVICE INFORMATION
For further information regarding the use of this product or to report any problems, please contact Medtronic Ophthalmics using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

THE WET-FIELD COAGULATOR HELPLINE
Should you need immediate help with a technical question or guidance through the appropriate protocol, just call the Wet-Field Coagulator Help Line at 800-535-4646.

NOTE: When contacting our Customer Service and Technical Support, please have the appropriate product number, product serial number, date of purchase, and nature of inquiry available.

Product Number______________________________
Serial Number______________________________
Date of Purchase______________________________
SECTION 1
Introduction

1.1 Overview

1.1.1 Description

The Wet-Field® Coagulator (see Figure 1-1) is a high frequency electrosurgical unit supplied in a sturdy console which is easily transportable. Accessories to perform coagulation include bipolar hemostatic eraser instruments, bipolar forceps, and either reusable or disposable cables.

![Figure 1-1 Wet-Field Coagulator PN 221340](image)

1.1.2 Intended Use

The Wet-Field Coagulator is intended for use during ocular surgery to coagulate tissue or arrest bleeding using a high frequency electric current.
1.1.3 Indications

Patients undergoing invasive ophthalmic surgical procedures, including episcleral, intrascleral, or intraocular procedures. Some examples of these procedures include:
- Conjunctival Tacking
- Episcleral Vascular Ablation
- Scleral Dissection Bleeding
- Sclerotomy Induced Bleeding
- Glaucoma Filtration Procedures
- Trabeculectomy Flap Tracing
- Epiretinal Membrane Hemostasis
- Controlled Drainage Retinotomy
- Chorioretinal Adhesions at margins of the macula hole.
- Ciliary Process Hemostasis
- Intraocular Bleeding, Including Choroidal Hemorrhage
- Retinal Marking.

Refer to Wet-Field eraser instrument literature for a complete description of all sub-specialty applications.

1.1.4 Contraindications

None known.

1.1.5 Compliance to Standards

EN 60601-1, EN 60601-2-2, & EN 60601-1-2

1.2 Principles of Bipolar Coagulation

Bipolar coagulation by Medtronic Ophthalmics utilizes a radio frequency diathermy technology, employing a variety of coagulator electrode types.

1.2.1 Diathermy Forceps

Diathermy forceps utilize insulated blades. The coagulation region lies between the blade points.

1.2.2 Wet-Field® Hemostatic Eraser® Instruments

Wet-Field Hemostatic Eraser Instruments use a small, coaxial pair of electrodes as part of single probe shaft design, and require no pinching or squeezing. Hemostasis is accomplished by a gentle wiping action or pinpoint application.
Both Wet-Field® Forceps and Hemostatic Eraser® Instruments are connected to the electrically isolated front panel output jacks through a flexible, two conductor, electrical cable. Bipolar diathermy is a hemostatic system in which the current flows along the path of least resistance between the two coaxial poles of the Wet-Field Hemostatic Eraser Instrument or between the tips of the forceps. The RF oscillation of water molecules found, within blood cells, generates heat within vasculature, causing coagulation.

Bipolar diathermy allows hemostasis of most vessels encountered in ophthalmic surgical procedures. Vessels which are too small to manually ligate are prime targets for diathermy application.

1.2.3 Advantages of Bipolar Diathermy

Bipolar diathermy has four significant advantages over other methods:

1. Limited depth or spread of coagulation.
   When using the forceps, current flow is concentrated between the closely spaced electrode tips and there is little depth or spread of coagulation. Of course, should the electrodes touch each other without tissue between them, they will short circuit and coagulation will not occur (blade spacers are available to set tip distance).

2. Coagulation can be done with saline.
   Bipolar diathermy is best accomplished using saline irrigation which minimizes tissue heating, shrinkage, drying, and the sticking of coagulum to the electrodes. There is a tendency for the forceps tips to become coated when used in a dry field or under a layer of blood; coagulation under saline irrigation minimizes these concerns.

3. A ground plate is not required.
   Neither Wet-Field Forceps or Hemostatic Eraser Instruments require a ground plate for current return as with older, monopolar diathermy methods. Because current flow is provided between the bipolar forceps blades or eraser poles, ground plates are unnecessary. For this reason, a broad selection of intraocular specialty products are particularly effective.

4. A well defined coagulation path is achieved.
   The Wet-Field Hemostatic Eraser Instruments confine hemostasis to the annular region between the poles. A gentle wiping action of the Wet-Field Hemostatic Eraser Instrument results in a well defined, coagulated path; “erasing” episcleral vasculature.
SECTION 2

Warnings and Cautions

2.1 Introduction

The Wet-Field® Coagulator is used in invasive ophthalmic surgical procedures. Hazards exist from improper usage with excessive cautery power. Damage to the system or improper operation may create other hazards, including electrocution. Adhering to good protocol should meet most requirements for the patient’s safety.

This section lists WARNINGS (which indicate a threat of injury or death) and CAUTIONS (which indicate conditions that may cause damage) that are associated with electrosurgical devices and procedures.

2.1.1 WARNINGS

Wet-Field Coagulator Specific

• This device is intended for use by qualified surgeons and operating room personnel familiar with radio frequency electrosurgery who have been properly trained in the surgical techniques that are to be employed. Surgeons should seek relevant pre-clinical education including literature review before attempting new surgical procedures.

• It is the responsibility of the surgical team to select the appropriate devices for each intended use.

• Begin procedures at the lowest possible electrosurgical power setting. Slowly increase power until the desired coagulation effect is achieved. This practice reduces the potential for the following problems: a) Capacitive coupling, b) Damage to insulation, c) Increased risk of patient burns at high voltages. Do not exceed settings which are in excess of that needed to achieve diathermy.

• The Wet-Field Coagulator and associated instruments may cause electromagnetic interference with other operating room devices.

• The Wet-Field Coagulator operates from power sources of 50/ 60 Hz at 100-240 VAC volts with T 2.0A L fuses. Protective earth grounding through the grounding connection in the power cords is essential for safe operation. Without the protective earth ground connection, all parts of the system could be shock hazards, including buttons and controls that may appear to be insulated.

• The Wet-Field Coagulator provides no explosion or fire protection from arcing components. Do not energize the unit or associated instruments in the presence of flammable materials, liquids or explosive gases such as anesthetics, nitrous oxide or oxygen enriched environments, including oxygen concentration under surgical drapes. Review safety procedures prior to using this device.
• Monitoring electrodes should be placed as far away from the site of
coaulation as possible.
• Alternate site injuries may occur at an EMG needle electrodes moni-
toring site.
• Always keep the tip of the device away from fingers and loose
clothing. Prevent lacerations of user and cross contamination
through compromised glove.
• Avoid prolonged activation. Multiple short activations allow the
normal surrounding tissue to remain cool.
• Be aware that bipolar coagulation is not immediate, but progres-
• Connect the device to the BIPOLEAR receptacle of the electrosurgical
generator only. Improper connection may result in inadvertent acti-
vation or other potentially hazardous conditions.
• DO NOT apply a patient return electrode for bipolar-only proce-
dures.
• This device may interfere with the operation of cardiac pacemakers,
deep brain stimulators, neurostimulators, ICD’s or other active
implants.
• DO NOT discharge directly into any part of an active implanted
device, including cardiac pacemakers, deep brain stimulators,
neurostimulators, or ICD’s. Injury to the patient could occur if cau-
tery is performed within 7-10 cm of any part of an active implanted
system.
• DO NOT immerse the electrosurgical device in a fluid. Immersion
of this device in fluids could result in electrical shorting and non-
functioning of this device or possible damage to the coagulator.
• DO NOT place the electrosurgical device on the patient when not
in use. Place the device in an isolation holster or on a dry, clean,
highly visible, non-conductive surface to prevent accidental
electrosurgical injury.
• Ensure that the Bipolar Cable plugs are inserted completely and fit
snugly in the coagulator.
• Local burning of patient, physician, or other personnel may result
from current paths through conductive elements like metal instru-
m ents and endoscopes. Contacting conductive elements with the
active cautery area may cause undesired tissue heating and burns.
• Temporarily unused cautery electrodes should be stored away from
the patient.
• The cautery cable should be placed in such a way as to avoid con-
tact with the patient or other leads.
• The control module, foot control, and handpieces are electrical/elec-
tronic devices. Thus, there is danger of electrical shock. Rea-
sonable care should be made in making electrical connections and
handling electrically powered devices. Do not use damaged electro-
cal equipment or frayed electrical cords. During repair or mainte-
nance, turn off Wet-Field® Coagulator and disconnect power.
• The patient should not come in contact with grounded metal parts
when cautery is used.
• To avoid alternate site lesions, only activate the electrosurgical generator when the surgical field and distal end of the device are under adequate visualization.
• To avoid electrical and fire hazard, use only recommended fuses. Fuses must match by type, voltage rating, and current rating.
• Use extreme care when handling the device. Mishandling or dropping the device may damage it and render it inoperable.
• When not operating the device, eliminate potential foot control activation.

Wet-Field Bipolar Forceps Specific
• These devices are intended for use with the Wet-Field® Coagulator and Cables. Use with higher powered coagulators could result in undesirable arcing and charring of tissue.
• Forceps must be cleaned and sterilized prior to first use and before each reuse. Refer to the cleaning and sterilization instructions provided with the device.
• Forceps should be inspected before and after each use for damage such as tip misalignment, tip damage, insulation damage, or cracks or nicks in the base of the instrument. Using forceps that are damaged or worn can increase the risk of injury to both the patient and operating room personnel. Discard and replace any damaged instrument.
• When operating the device, it is important that the vessels or tissues to be coagulated be placed between the tips of the forceps before depressing the foot switch.
• Care should be taken to prevent shorting of forceps tips, which can occur by touching the metal tips together with nothing between the two poles. When shorting occurs, no hemostasis is possible.
• DO NOT modify the device. Performance could be diminished or injury may result if the device is modified in any way.
• To prevent injury, use extreme care during handling and cleaning of instruments with sharp points or edges.

Wet-Field Hemostatic Eraser Specific
• These devices are intended for use with the Wet-Field Coagulator and Cables. Use with higher powered coagulators could result in undesirable arcing and charring of tissue.
• These devices are provided STERILE and are intended for SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE THESE DEVICES. MEDTRONIC OPHTHALMICS Assumes no liability for devices that have been resterilized by health care facilities.
• DO NOT use if package is opened or damaged. Broken sterile seal offers no protection against cross contamination.
• DO NOT modify the device. Performance could be diminished or injury may result if the device is modified in any way.
• These devices should be handled with extreme care to prevent damage.
• If active aspiration is being used, care must be taken to limit the vacuum to safe levels for the procedure being performed.
• Prior to using reflux action, ensure that the silicone chamber is fully primed with fluid to avoid the possibility of introducing air bubbles into the posterior segment.
• Discard disposable devices following local regulations for proper disposal of contaminated materials.

2.1.2 CAUTIONS

Wet-Field Coagulator Specific
• Check the reusable cautery cables periodically for damage; such as cracking, peeling, or blistering. Replace immediately if damage occurs. Use only cables of the same type as supplied with the Wet-Field Coagulator. Use of other types of cable may adversely effect cautery performance, or compromise reliable console power output. The effectiveness of the Hemostatic console and hand instruments are dependent upon the integrity of cable components.
• This unit should not be modified in any way by the user. Unauthorized modifications to the unit may cause it to malfunction, fail in use, or void the warranty terms.
• Use only hospital-grade power cords and the connectors supplied with the Wet-Field Coagulator. Be sure power cords and connectors are in good condition. Never apply a voltage to the equipment that is outside the range specified for its connectors (100-240 VAC, 50/60 Hz).
• To prevent overheating, keep ventilation holes free from obstruction.
• Protective covers must not be removed except by qualified personnel. Do not operate the Wet-Field Coagulator without the protective console cover.
SECTION 3
Checkout and Set-Up

3.1 Overview

The Wet-Field® Coagulator is subjected to rigorous tests and quality control inspections before shipping and little trouble should be encountered in checkout.

If required by hospital procedures, have the Wet-Field Coagulator approved by the Bioengineering Department before installation in the operating room.

3.2 Power Data

The power output levels when tested, should give results similar to the graphs in Figures 3-1, 3-2, and 3-3.

Note: All test loads are a non-inductive type.

3.2.1 Power Output vs. Load Resistance

Figure 3-1 shows the expected results of testing the power output levels (in watts) at half power and at the maximum power setting for each of the various loads 10Ω-1000Ω).

Figure 3-1 Power Output vs. Load Resistance
3.2.2 Power Output vs. Load Resistance and Control Settings

Figure 3-2 shows the power output levels for each control setting at the various load resistances.

3.2.3 Open Circuit Power

Figure 3-3 shows the maximum open circuit RMS voltage for each control setting.
3.3 Setup Procedure

The following procedure is recommended in order to properly integrate the Wet-Field® Coagulator into the operating room.

1. Connect the AC power cord from the connector at the rear of the unit, into the appropriate AC power outlet (see Figure 3-4).
2. Insert each of the plugs from the bipolar probe cable (see Figure 3-5) into the power output jacks on the front panel of the unit. The plugs must be inserted completely and fit snugly (see Figure 3-6).
3. Attach the appropriate Wet-Field Forceps or Hemostatic Eraser® Instrument to the bipolar cable.
4. Connect the foot switch by inserting the right angle connector into the receptacle located on the rear panel (see Figure 3-7).

![Figure 3-4 Rear View, Wet-Field Coagulator](image)
Figure 3-5  Bipolar Probe Cable
Reusable (PN 221202)
Disposable (PN 22135010)

Figure 3-6  Bipolar Cable Connections

Figure 3-7  Foot Switch Connection
PN 232345
3.3.1 Clinical Power Levels

Begin procedures at the lowest possible electrosurgical power setting. Slowly increase power until the desired coagulation effect is achieved. Specific tissues technique, pressure, degree of bloodflow and application duration will dictate the necessary power setting to achieve the desired hemostatic result. Typical power ranges for some specific procedures are given in Table 3-1.

<table>
<thead>
<tr>
<th>Application</th>
<th>Power Selector Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coaptation of Conjunctiva</td>
<td>20-30</td>
</tr>
<tr>
<td>Episcleral Hemostasis</td>
<td>10-30</td>
</tr>
<tr>
<td>Intraocular Hemostasis</td>
<td>10-20</td>
</tr>
<tr>
<td>Glaucoma Filtration</td>
<td>20-30</td>
</tr>
<tr>
<td>Trabeculectomy Dissection</td>
<td>20-30</td>
</tr>
<tr>
<td>Choroidal Hemorrhage</td>
<td>30+</td>
</tr>
<tr>
<td>Peacekeeper™ Thin Film Technology</td>
<td>40+</td>
</tr>
</tbody>
</table>
SECTION 4
Operation

4.1 Operating Instructions

To operate the unit, follow the instructions below.

1. Insert each of the plugs from the bipolar probe cable into the power output jacks on the front panel of the unit. The plugs must be inserted completely and fit snugly.
2. Attach the appropriate Wet-Field® Forceps or Hemostatic Eraser® Instrument to the bipolar probe cable.
3. Turn the MAINS switch ON.
4. Rotate the Power Selector switch to the lowest power setting. Due to variables such as vessel diameter, diathermy probe selection, scleral dryness, or application duration, only the approximate settings in Table 3-1 can be recommended by Medtronic Ophthalmics. Final power levels may be above or below these settings, and should be governed by the clinical effect desired by the surgeon for the specific clinical application.
5. Begin low, and adjust the power level to achieve the desired coagulation.
6. Depress the foot switch to activate the instrument. Sound level may be adjusted to suit the surgeon.
7. Place the Coagulator and its foot switch in a convenient location for the surgeon.

4.2 Diathermy

Before performing Diathermy, be sure that the accessory equipment is sterilized and cooled properly. Be sure that the foot pedal is connected (see “Setup Procedure”) and that the power level is adjusted.
SECTION 5
Coagulator Probes and Accessories

5.1 Coagulator Probes

Medtronic Ophthalmics supplies a wide range of Wet-Field® Hemostatic Eraser® Instruments and Forceps for use with the Wet-Field Coagulator. (see Figure 5-1/5-2 for a sample.) A number of these diathermy probes are listed in the tables that follow. Further information and applications are provided in separate product data sheets.
5.1.1 Wet-Field® Hemostatic Eraser® Bipolar Instruments

Wet-Field Hemostatic Eraser Instruments are convenient, disposable, single-use bipolar probes that are supplied in sterile packages. They can be connected to the power unit via a sterile, disposable cable or via a sterilizeable, reusable cable (see Table 5-1).

<table>
<thead>
<tr>
<th>Instrument Part No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td># 221250 18 Gauge, Straight with 45° Bevel Tip.</td>
<td>A lightweight, flat tip probe with which hemostasis is accomplished by a gentle, wiping action.</td>
</tr>
<tr>
<td># 221251 18 Gauge, 45° Angled Shaft with Tip.</td>
<td>An 18 gauge unit with a 45° angled shaft for those preferring an extended reach with deeper set eyes.</td>
</tr>
<tr>
<td># 221260 20 Gauge, Straight</td>
<td>Very effective in treating surface retinal bledders, the underside of the epiretinal membranes and the margins of macula holes.</td>
</tr>
<tr>
<td># 221260135 20 Gauge, 135° Curve.</td>
<td>Hemostatic Eraser with 135° curve.</td>
</tr>
<tr>
<td># 221260150 20 Gauge, Curve.</td>
<td>Hemostatic Eraser with 150° curve.</td>
</tr>
<tr>
<td># 221261 20 Gauge, Passive Aspirator</td>
<td>For passively aspirating blood from the area of vitreous or retinal bleeders and coagulating with the same instrument.</td>
</tr>
<tr>
<td># 221262 20 Gauge, active Aspirator with reflux mode.</td>
<td>For actively aspirating and refluxing fluid from the area of vitreous or retinal bledders and coagulating with the same instrument.</td>
</tr>
<tr>
<td># 221262135 20 Gauge, 135° Curve.</td>
<td>Active Aspirator Eraser with 135° curve.</td>
</tr>
<tr>
<td># 221262150 20 Gauge, 150° Curve.</td>
<td>Active Aspirator Eraser with 150° curve.</td>
</tr>
<tr>
<td># 221263 20 Gauge, Peacekeeper® Eraser Instrument with 18 mm Extrusion Cannula.</td>
<td>A unique product that combines an adjustable extrusion silicone tube brush manipulator with passive and active aspiration, reflux, and pinpoint hemostasis modalities.</td>
</tr>
<tr>
<td>Instrument Part No.</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td># 221265</td>
<td>20-23 Gauge, Tapered Fine Point.</td>
</tr>
<tr>
<td></td>
<td>For use in controlled drainage retinotomies.</td>
</tr>
<tr>
<td># 221265135</td>
<td>20-23 Gauge, 135° Curve, Tapered.</td>
</tr>
<tr>
<td></td>
<td>Fine Point Eraser with 135° curve.</td>
</tr>
<tr>
<td># 221265150</td>
<td>20-23 Gauge, 150° Curve, Tapered.</td>
</tr>
<tr>
<td></td>
<td>Fine Point Eraser with 150° curve.</td>
</tr>
<tr>
<td># 221266</td>
<td>20-23 Gauge, Tapered Blunt Point.</td>
</tr>
<tr>
<td></td>
<td>For effective hemostasis of deep scleral flaps and wound sites where viewing angle is impaired.</td>
</tr>
<tr>
<td># 22126690</td>
<td>20-23 Gauge, 90° Curve, Tapered.</td>
</tr>
<tr>
<td></td>
<td>Blunt Point Eraser with 90° curve.</td>
</tr>
<tr>
<td># 221266135</td>
<td>20-23 Gauge, 135° Curve, Tapered.</td>
</tr>
<tr>
<td></td>
<td>Blunt Point Eraser with 135° curve.</td>
</tr>
<tr>
<td># 221266150</td>
<td>20-23 Gauge, 150° Curve, Tapered.</td>
</tr>
<tr>
<td></td>
<td>Blunt Point Eraser with 150° curve.</td>
</tr>
<tr>
<td># 221267</td>
<td>25 Gauge, Fine Point, Straight Hemostat.</td>
</tr>
<tr>
<td></td>
<td>For general hemostasis, &amp; controlled drainage retinotomies.</td>
</tr>
<tr>
<td># 221267135</td>
<td>25 Gauge, Fine Point, 135° Curve, Hemostat.</td>
</tr>
<tr>
<td></td>
<td>For general hemostasis, &amp; controlled drainage retinotomies.</td>
</tr>
<tr>
<td># 221267150</td>
<td>25 Gauge, Fine Point, 150° Curve, Hemostat.</td>
</tr>
<tr>
<td></td>
<td>For general hemostasis, &amp; controlled drainage retinotomies.</td>
</tr>
</tbody>
</table>
5.1.2 Wet-Field® Forceps

Table 5-2 lists the part numbers and descriptions for many of the Wet-Field forceps which are offered by Medtronic Ophthalmics.

<table>
<thead>
<tr>
<th>Instrument Part No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td># 221204 Standard</td>
<td>Fine forceps with angled tips for pinpoint coagulation and increased visibility.</td>
</tr>
<tr>
<td># 221206 Straight McPherson Iris</td>
<td>Fine point straight microsurgical forceps.</td>
</tr>
<tr>
<td># 221207 Curved McPherson Iris</td>
<td>Fine point microsurgical forceps for those McPherson Iris preferring an angled configuration.</td>
</tr>
<tr>
<td># 221208 Adson</td>
<td>A standard for facial plastic surgery.</td>
</tr>
<tr>
<td># 221209 Coaptation</td>
<td>Used for sutureless closure of the conjunctiva. Tines have a complex angle for maximum visibility.</td>
</tr>
<tr>
<td># 221211 Tenzel</td>
<td>Similar to the standard Wet-Field forceps, but include a stop spacer to prevent the tips from touching.</td>
</tr>
</tbody>
</table>

Note: All bipolar forceps have insulated blades and highly polished tines to prevent tissue sticking and coagulum build up.
5.2 Accessories

Listed in Table 5-3 are accessories for the Wet-Field® Coagulator which are available from Medtronic Ophthalmics.

Table 5-3  Bipolar Diathermy Cables

<table>
<thead>
<tr>
<th>Cable Part No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td># 221202</td>
<td>Reusable Coagulator Cable Steam or ETO Sterilization</td>
</tr>
<tr>
<td># 22135010</td>
<td>Disposable, Single Use Coagulator Cable, 10/box</td>
</tr>
<tr>
<td># 22135050</td>
<td>Disposable, Single Use Coagulator Cable, 50/box</td>
</tr>
<tr>
<td># 221350NS</td>
<td>Disposable, Single Use Coagulator Cable, Non-Sterile 100/box</td>
</tr>
</tbody>
</table>
SECTION 6

Preventive Maintenance

6.1 Overview

Regular maintenance should be performed on the Wet-Field® Coagulator to insure reliable and safe operation.

6.1.1 Console Maintenance

The Wet-Field system should be occasionally checked for exterior damage. Only qualified Medtronic Ophthalmics service personnel should replace damaged parts. Unplug the unit. Remove dust on the outside of the console with a soft brush or cloth that has been slightly dampened with a mild solution of detergent and water or a cold sterilization agent. Do not allow any liquid to penetrate the console.

6.1.2 Forceps Tips

Forceps tips can become coated with coagulum which will interfere with the flow of current. Tips should be cleaned immediately and regularly with Merocel® PVA sterile wipes to avoid tissue and coagulum buildup.

6.1.3 Eraser Instruments

Medtronic Ophthalmics Wet-Field Hemostatic Eraser® Instruments are single use products and are to be discarded after use. They will not tolerate autoclave sterilization.

6.1.4 Bipolar Sockets

Bipolar sockets on the front panel should be inspected for oxidation or contamination. Periodic gentle cleaning of the contacts with an abrasive cloth will avoid the possibility of intermittent coagulator operation.
6.1.5 Foot Switch

- The foot switch should be located with adequate slack in the cable to avoid damage to the cable or connector from inadvertent pulling.
- **DO NOT** immerse the foot switch.
- Clean the outside of the foot switch by wiping with a mild detergent and water or a standard disinfectant.

6.1.6 Cable

The electrode cable should be disconnected from the front panel by holding the plugs in one hand and the coagulator in the other. Do not disconnect the cable to the coagulator by pulling on the cable, as this may result in damage due to bending, or dislodging the connecting hardware.
SECTION 7

Troubleshooting Guide

7.1 Overview

The Wet-Field® Coagulator is a very reliable device and should provide years of trouble free service. Malfunctions can usually be diagnosed by referring to the Troubleshooting Guide in this section. Should a malfunction persist, contact the Medtronic Ophthalmics Technical Service Group BEFORE returning the unit to Medtronic Ophthalmics or to the dealer for repair. Return of any unit requires an assigned return goods authorization (RGA) number from Medtronic Ophthalmics Customer Service.

Tests listed in the Table 7-1 may be performed by the user or by the Bioengineering Department.
**Table 7-1  Troubleshooting Guide**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Probable Cause</th>
<th>Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit Does Not Operate</td>
<td>A. Power Cord not properly inserted into AC power outlet.</td>
<td>Be sure that the power cord is fully plugged into a functioning outlet.</td>
</tr>
<tr>
<td></td>
<td>B. Power Switch not turned on.</td>
<td>Check position of power switch and that PWR lamp is illuminated.</td>
</tr>
<tr>
<td></td>
<td>C. Foot Switch not connected or defective.</td>
<td>Check foot switch connection and continuity.</td>
</tr>
<tr>
<td></td>
<td>D. Defective electronic component or connection.</td>
<td>Contact Medtronic Ophthalmics Technical Service group.</td>
</tr>
<tr>
<td>Erratic Power Output</td>
<td>A. Loose or dirty connections between cable and jacks.</td>
<td>Gently clean plug contacts with an abrasive cloth.</td>
</tr>
<tr>
<td></td>
<td>B. Intermittent break in coagulator cable.</td>
<td>Replace coagulator connecting cable.</td>
</tr>
<tr>
<td></td>
<td>C. Intermittent break in foot switch cable.</td>
<td>Replace foot switch and cable.</td>
</tr>
<tr>
<td></td>
<td>D. Moisture at connections.</td>
<td>Unplug cable from unit and accessory Hemostatic instruments. Wipe dry and reconnect.</td>
</tr>
</tbody>
</table>
SECTION 8

Specifications

8.1 Overview

This section provides the operational and physical specifications of the Wet-Field® Coagulator.

**Table 8-1** Operational Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Requirements:</td>
<td>100-240 VAC, 65W, 50/60 Hz</td>
</tr>
<tr>
<td>Output Waveform:</td>
<td>455 kilohertz (kHz) square wave variable burst length.</td>
</tr>
<tr>
<td>Nominal Frequency:</td>
<td>455 kilohertz (kHz)</td>
</tr>
<tr>
<td>Output Current mA range:</td>
<td>10 - 130 millampere (mA rms) into a 500 ohm load continuously variable.</td>
</tr>
<tr>
<td>Output Power-Watts:</td>
<td>.05-8.5 watts into a 500 ohm load continuously variable.</td>
</tr>
<tr>
<td>Test Load:</td>
<td>500 ohm, non-inductive, Neurosurgical forceps input (using electrosurgical analyzer).</td>
</tr>
</tbody>
</table>

**Table 8-2** Physical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight:</td>
<td>3 lb. 9 oz. (1.6 kg)</td>
</tr>
<tr>
<td>Size:</td>
<td>Height 4 inches (1.02 cm)</td>
</tr>
<tr>
<td></td>
<td>Width 6 1/4 inches (15.9 cm)</td>
</tr>
<tr>
<td></td>
<td>Length 9 1/2 inches (24.1 cm)</td>
</tr>
</tbody>
</table>
SECTION 9
Warranty and Repair

LIMITED WARRANTY
A. This LIMITED WARRANTY provides assurance for the customer who purchases a Wet-Field® Coagulator (hereinafter the “Product”) that should the Product fail to function to Medtronic Ophthalmics’ published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment), Medtronic Ophthalmics will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Ophthalmics or from its affiliate or its authorized distributor or representative.

B. To qualify for this LIMITED WARRANTY, the following conditions must be met:
   (1) The Product must be used on or before its “Use By” or “Use Before” date, if applicable.
   (2) The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
   (3) Medtronic Ophthalmics must be notified in writing within thirty (30) days following discovery of a defect.
   (4) The Product must be returned to Medtronic Ophthalmics within thirty (30) days of Medtronic Ophthalmics receiving notice as provided for in (3) above.
   (5) Upon examination of the Product by Medtronic Ophthalmics, Medtronic Ophthalmics shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Ophthalmics or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

C. This LIMITED WARRANTY is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic Ophthalmics be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.
D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

CAUTION
Applicable law may restrict the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner.

RETURNS AND/OR REPAIRS
Contact Medtronic Ophthalmics Customer Service at (800-874-5797) to obtain a Return Goods Authorization number (RGA#) prior to shipping the Product to Medtronic Ophthalmics. Please have the original invoice number or purchase order number available to assist in verifying warranty information. The RGA# should be prominently displayed on the box and included on all paperwork enclosed with the return and/or repair. All Product returned to Medtronic Ophthalmics should be safely packed in protective wrapping.

Customer must supply the Purchase Order number; the correct shipping and billing address; and either a completed Repair Order Form or a statement of the problem or reason for return.