ONE SYSTEM USER MANUAL

PRIMAEVA MEDICAL, INC

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Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

Caution: Applicable to RF Generator software Miratone User Interface (PFUI) Version 42

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TABLE OF CONTENTS

Miratone System User Manual **1**

1. Introduction **4**

1.1 Overview 4

2. Indicated Use **5**

3. Contraindications **5**

4. Warnings and Precautions **6**

4.1 General 6

4.2 RF Generator 6

4.3 Cooler 7

5 RF GENERATOR **9**

5.3 Overview 9

5.4 Cleaning 9

5.5 General Description 9

6 Software / Graphical User Interface **12**

6.1 Overview 12

6.2 Installation 12

7 RF Generator Setup **13**

7.1 Overview 13

Berube-0001099

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CX-0946.2

7.2 Setup 13
8 RF Generator Operation 14
8.1 Overview 14
8.2 Power on 14
8.3 Operation 14
9 Cooling system 26
9.1 Overview 26
9.2 Cleaning 26
9.3 General Description 27
10 Cooling System Setup and Operation 29
10.1 Overview 29
10.2 Setup and Operation 29
11 Data File 31
12 FAQ / Troubleshooting 32
13 Maintenance 34
14 Specifications 34
15 Electromagnetic Interference 35
15.1 Electromagnetic Emissions 36
15.2 Electromagnetic Immunity 36
16 Labeling Symbol 38

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1. INTRODUCTION

1.1 OVERVIEW

TABLE 1.1: APPROVED COMPONENT LIST

Miratone System Components
RF Generator
Treatment Applicator
Electrode Cartridge
Cooling System Applicator
Cooler Controller
USB-to-RS232 Cable (1)
Power cable (2)
User Manual (This Book)
Miratone System Instructions For Use
Graphical User Interface (GUI) Installation CD
Computer with USB connector

The Primaeva Medical Miratone System consists of a Treatment Applicator, an Electrode Cartridge, an RF Generator with a user interface, and a Cooling System.

The RF Generator is a multi-channel bipolar system. It delivers RF Energy to the Electrode Cartridge, which consists of 10 electrodes (5 pairs) that are extended into the target tissue during a treatment. A Cooling System comprised of a Cooler Controller and a Cooling System Applicator is applied to the tissue surface to reduce thermal effects in the outer layer. A computer with a USB connector acts as the user interface for the RF Generator. The system is capable of measuring certain key parameters such as energy

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delivered, tissue temperature, resistance, etc., that provide information on the treatment delivered. These parameters are displayed on the user interface. The software also has the ability to store these parameters in a file for further analysis.

This user manual describes in detail the operations and the setup of the RF Generator, the Cooling System and the graphical user interface. Use this manual in conjunction with the Primaeva Medical Miratone System Instructions for Use. The Miratone System should only be operated with the components listed above.

2. Indicated Use

The Primaeva Medical Miratone System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles.

3. Contraindications

The Miratone System is contraindicated for use in patients with the following conditions:

- An implantable pacemaker, an Automatic Cardioverter/Defibrillator (AICD), or any other implantable electric device as these devices may be adversely affected by radiofrequency (RF) field or current
- Active skin infection(s)
- Collagen vascular disease
- A known bleeding disorder
- A history of keloid formation
- A history of hypertrophic scarring
- Accutane use in the previous 12 months

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4. Warnings and Precautions

The following warnings and precautions shall be read and understood before the operation of the device.

4.1 General

a. USE ONLY APPROVED COMPONENTS LISTED IN SECTION 1.1.

b. Before using the Miratone system, the physician must be familiar with the device, method of use, indications for use, contraindications, warnings, and precautions. It is recommended that physicians receive preceptor training from an experienced user and be required to receive in-service training from Primaeva personnel in the correct use of the equipment and clinical techniques. The suitability of the Miratone procedure for all patients should be individually assessed by the physician on the basis of medical history, indication suitability, and contraindications.

4.2 RF Generator

a. Do not operate the device in the presence of sources of high electromagnetic energy, e.g. electrosurgical equipment.

b. Ensure that the generator is connected to a properly grounded receptacle using a hospital grade power cord and that the appropriate input voltage is supplied.

c. The hospital grade AC mains power cord supplied with the RF Generator must be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must not be used.

d. Ensure that the generator is placed in a stable and secure position.

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e. If the generator suffers impact due to mishandling during transportation and does not function, contact a Primaeva Medical, Inc. representative. DO NOT ATTEMPT TO CORRECT THE SITUATION.

f. Do not use the system if there are signs of physical damage to the generator or any other component. Contact a Primaeva Medical, Inc. representative for a replacement.

g. Use only approved components specified in Table 1.1.

h. Familiarize yourself with the labels and symbols printed on the generator.

i. Understand and recognize the system's activation tones and lights. Do not obstruct or disable their functioning.

j. Ensure that the instrument cables are not tangled or wrapped around other electrical equipment. This avoids unnecessary electrical interference.

k. Interference produced by the system may adversely influence the operation of other electronic equipment.

l. Do not use this system in the presence of flammable anesthetics or other flammable substances such as skin preparation agents or oxidizing agents.

m. Allow flammable agents used for cleaning or disinfecting to evaporate before use of the equipment.

n. Do not operate the instrument in an oxygen enriched environment or in the presence of nitrous oxide (N_2O).

4.3 COOLER

a. Do not operate the device in the presence of sources of high electromagnetic energy, e.g. electrosurgical equipment.

b. Ensure that the Cooler Controller is connected to a properly grounded receptacle using a hospital grade power cord and that the appropriate input voltage is supplied.

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c. The hospital grade AC mains power cord supplied with the Cooler Controller must be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must not be used.

d. Ensure that the Cooler Controller is placed in a stable and secure position.

e. If the Cooler Controller suffers impact due to mishandling during transportation and does not function, contact a Primaeva Medical, Inc. representative. DO NOT ATTEMPT TO CORRECT THE SITUATION.

f. Do not use the system if there are signs of physical damage to the generator or any other component. Contact a Primaeva Medical, Inc. representative for a replacement.

g. Use only approved components specified in Table 1.1.

h. The Cooling Applicator has ventilation slots. DO NOT BLOCK THE VENTILATION SLOTS DURING USE.

i. Familiarize yourself with the labels and symbols printed on the Cooler Controller.

j. THE COOLER CONTROLLER DOES NOT HAVE ALARMS. If the two temperatures displayed on the Cooler Controller are not with 3 degrees of each other turn off the Cooler Controller and contact a Primaeva Medical Inc. representative.

k. Ensure that the applicator cables are not tangled or wrapped around other electrical equipment. This avoids unnecessary electrical interference.

l. Interference produced by the system may adversely influence the operation of other electronic equipment.

m. Do not use this system in the presence of flammable anesthetics or other flammable substances such as skin preparation agents or oxidizing agents.

n. Allow flammable agents used for cleaning or disinfecting to evaporate before use of the equipment.

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o. Do not operate the instrument in an oxygen enriched environment or in the presence of nitrous oxide (N_2O).

5 RF GENERATOR

5.3 OVERVIEW

Check the System for damage. If there is any sign of damage to the system, contact a Primaeva Medical, Inc. representative to arrange for a replacement. Do not open the enclosure under any circumstances. Primaeva Medical, Inc. must approve all returns and replacements.

5.4 CLEANING

A 70% isopropyl alcohol solution or damp cloth may be used to clean the RF generator cover, side and front panels and the AC mains power cable. Allow isopropyl alcohol solution to evaporate before using. Do not allow fluids to enter the RF generator chassis. **Do not spray or pour liquids directly on the RF Generator.**

The RF Generator is not sterilizable.

5.5 GENERAL DESCRIPTION

5.5.1 FRONT PANEL

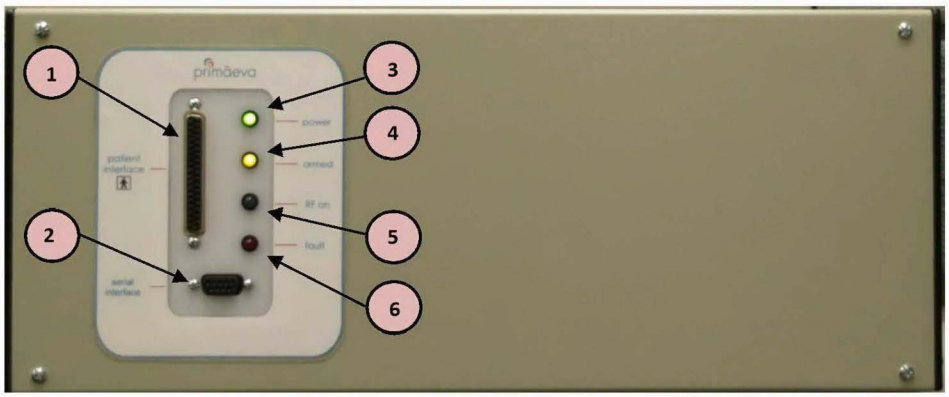

FIGURE 5.1: FRONT PANEL OF RF GENERATOR

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5.5.1.1 INDICATORS

	Indication	Sound Indication
Green LED	**Power** Green Light – Power On [Item 3 in Figure 5.1]	During power-up - 2 beeps; a short beep followed by a long beep
Yellow LED	**Armed** Yellow Light – Armed [Item 4 in Figure 5.1]	**N/A**
Blue LED	**RF on** Blue Light – RF energy delivered [Item 5 in Figure 5.1]	1 beep for each second energy is applied
Red LED	**Fault** Red Light – Fault in system. Check user's manual for instructions on fault correction. [Item 6 in Figure 5.1]	2 beeps a second continuously until the mains power is cycled off and on

5.5.1.2 CONNECTORS

	RF Applicator 37 pin D-Sub female connector Connection for the Treatment Applicator. [Item 1 in Figure 5.1]

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	Serial Port (RS-232) 9 pin D-Sub female connector Connection for the USB-to-RS-232 Adapter Note: The other end of the USB-to-RS-232 cable is connected to the computer. [Item 2 in Figure 5.1]

5.5.2 Rear Panel

Figure 5.2: Rear Panel of RF Generator

5.5.2.1 Receptacles

	Power Supply AC Power connector Note: Check **Specifications-Section 14** for the appropriate input power specifications. [Item 2 in Figure 5.2]

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5.5.2.2 SWITCHES

POWER	**Power On/Off Switch** Switches the supply power for the RF Generator On/Off. [Item 1 in Figure 5.2]

6 SOFTWARE / GRAPHICAL USER INTERFACE

6.1 OVERVIEW

This section provides information on the accessories, installation and operation of the software that is provided along with the Miratone System.

6.2 INSTALLATION

6.2.1 Review Section 14 – Specifications for the minimum requirements for the software.

6.3.2 Remove the software CD from the cover and insert into the disk drive of the computer.

6.3.2 Run the file Setup.exe and follow the instructions.

6.3.3 When the installation is complete, connect the RF Generator to the computer and restart the system.

6.3.4 On identifying the new hardware, the Windows operating system will request the hardware driver location. Select the CD drive to install the necessary drivers.

6.3.5 The User Interface is now ready to use. Go to Start > All Programs > Miratone System. Click on the file *Miratone System.*

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7 RF Generator Setup

7.1 Overview

This section provides information on the setup of the Miratone System RF Generator.

7.2 Setup

1. Set the RF Generator on a stable location.
2. Verify that the Power Switch on the rear panel of the RF Generator is in its Off position. Do not turn it On until all checks are complete.
3. Connect the Power Cable to the AC Power connector on the rear of the RF Generator.
4. Connect the Power Cable of the RF Generator to a properly grounded receptacle of the main power supply.
5. Connect the Treatment Applicator securely to the RF Applicator receptacle on the front of the RF Generator.
6. If the Electrode Cartridge is attached to the Treatment Applicator make sure that the electrodes are in the retracted position to avoid accidental needle-sticks or electrode damage during handling.
7. Ensure that the USB-to-RS-232 cable for the computer interface is connected securely to the computer interface port on the front of the RF Generator.
8. Connect the other end of the USB-to-RS-232 cable to the USB port on the computer.

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8 RF Generator Operation

8.1 Overview

This section provides information on the operation of the Miratone System.

8.2 Power on

1. Verify the connections on the RF Generator per Section 7.
2. Open the GUI software application on the computer.
3. Turn on the RF Generator using the Power switch at the rear panel.
4. Verify all the indicators on the front panel turn on briefly. This indicates that all LEDs are functioning. The Power and Armed indicator LEDs will remain turned on.
5. Concurrently with the LEDs turning on verify 2 beeps are heard (a short beep followed by a long beep) from the RF Generator. This indicates that the system has powered on successfully.
6. Verify the **Serial link OK** id displayed on the GUI.
7. An error message will be displayed on the GUI if the RF Generator fails to power up correctly. If this occurs contact a Primaeva Medical customer support representative.
8. Read the Miratone System Instructions for Use prior to initiating treatment.

8.3 Operation

The Miratone System software interface enables the control of the RF Generator, displays key measured parameters and also stores these parameters for further analysis.

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Electrode Temperature Controlled:

The treatment is controlled by maintaining the electrodes at a set temperature during the treatment. This requires the **Power**, **Energy**, Temperature (**Temp**), **Duty Cycle**, and Treatment Time (**Time**) parameters be set on the GUI. See the Miratone System Instructions for Use for the appropriate settings.

The electrodes are initially at body temperature and are ramped up to the target temperature during treatment. The temperature is controlled through a Proportional, Integral, Derivative (PID) algorithm. The maximum power available is set by **Power**. The **Power** setting is therefore required to determine the maximum power that the RF Generator can deliver in order to reach the target temperature.

The following step-by-step instructions explain the operations of the interface and directions to control the RF Generator:

1. Click on the file Miratone Medical GUI.
2. A dialog box opens which identifies the available communication ports. The Selection box already contains the port number that is to be selected. This communication port is used to interface with the RF Generator. Press Continue to proceed to the next step.

Note: The numbers for the communication ports might vary depending on the USB port used. Press Continue on the preselected communication port and proceed. This change does not affect the treatment.

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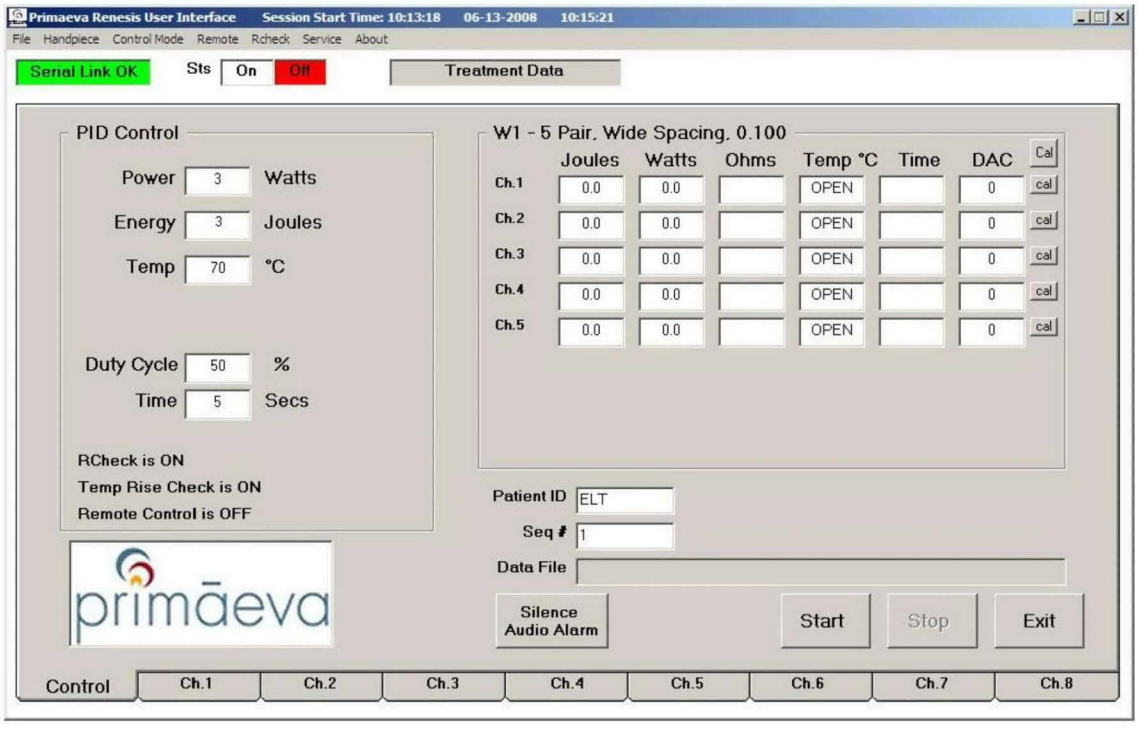
3. Now the Control Window opens



Understanding this Control Window is critical to the treatment as all the parameters necessary for the RF Generator are communicated via this interface.

4. Menus

A series of pull-down menus are available at the top of the interface.

The **File** menu allows for exiting the program.

The **Handpiece** menu is used for selecting the Electrode Cartridge configuration. C1, W1, S1 or Custom. Custom allows any channels 1-8 to be enabled.

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The **Control Mode** menu is used for selecting the mode desired. Only the PID control mode is available.

The **Remote** menu is used to enable or disable the start/stop button of the Treatment Applicator.

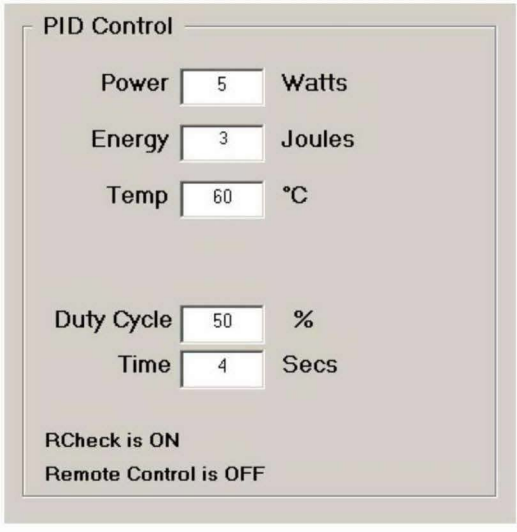
The **Rcheck** menu is used to turn Rcheck on or off and to view the Rcheck status.

The **Service** menu is used to enter the Service mode.

The **About** menu displays the Generator and GUI software version.

5. Control and Measurement Parameters

The screen can be viewed as two groups, the Control Parameters and the Measured Parameters. The left side of the display consists of all the parameters that are set prior to starting the procedure and the right side consists of the parameters that are measured during the treatment.



Control Parameters

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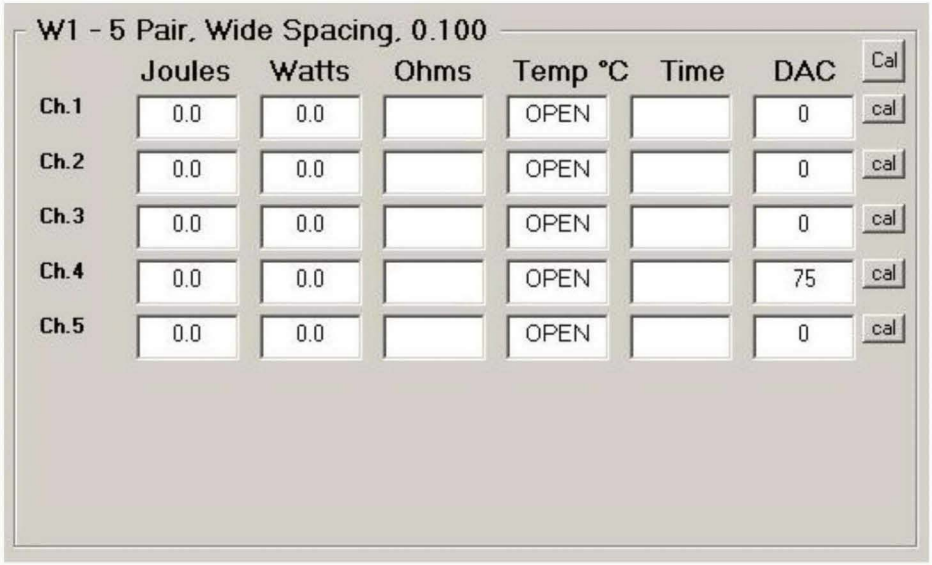
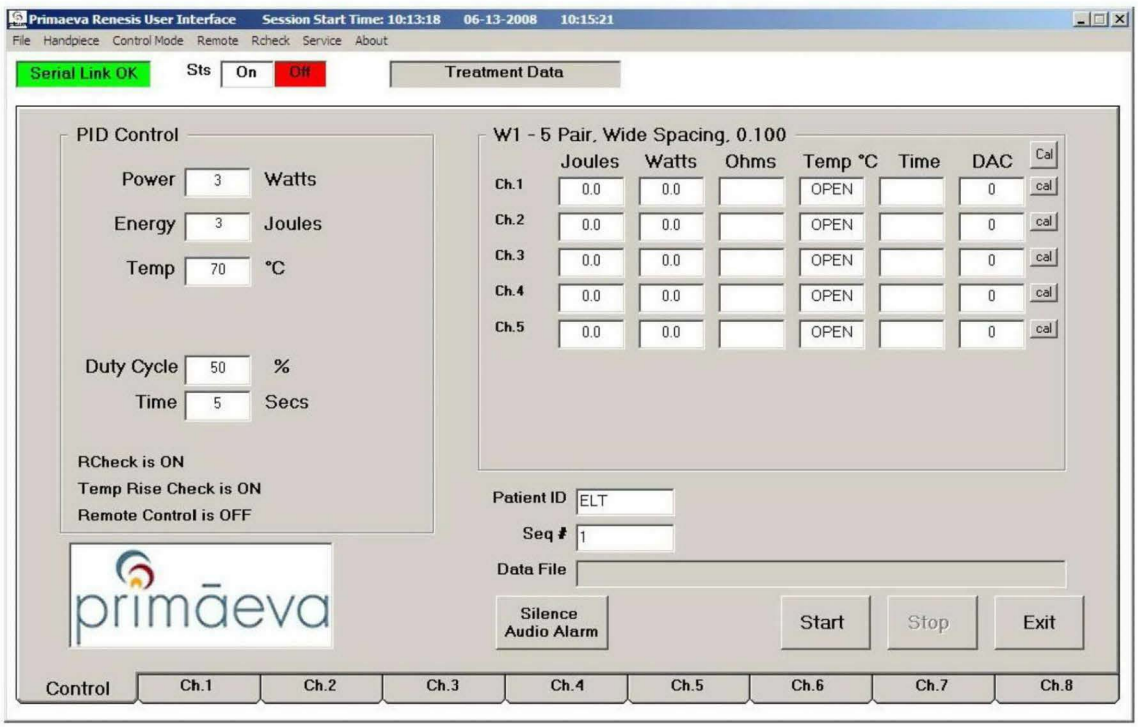


Measured Parameters

6. Verify proper Communication Link



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Serial Link OK	Display reads *Serial Link OK* if there is a successful communication between the software and the RF Generator. It would now be ok to set the control parameters.
No Serial Link	Display reads *No Serial Link* if there is a loss in the communication between the software and the RF Generator. In this case, verify the connections to the RF Generator. Also, cycle the power to the system. If the error persists, contact a Primaeva Medical, Inc. Representative for customer support.

7. Select the Electrode Cartridge

   7.1 From the **Handpiece** pull-down menu described in step 4 above select the Electrode Cartridge to be used, C1, W1, or S1.

8. Set the Treatment Parameters

   8.1 **Power**

      8.1.1 **Power** is a power limit for each channel during a treatment. It will limit the power delivered to the set value. This should be set to 3 Watts.

   8.2 **Energy**

      8.2.1 **Energy** is an energy limit for each channel that will be delivered for a treatment. Once the energy limit is reached for an individual channel RF energy is turned off for the remainder of the treatment. This should be set to 3.5 Joules.

   8.3 **Temp**

      8.3.1 **Temp** is the electrode temperature that will be achieved during a treatment. When the temperature has been

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reached the algorithm will maintain that temperature for the duration of the treatment.

8.4 **Time**

8.4.1 **Time** sets the total treatment time. It includes the time required to achieve the target temperature.

9. Enter Patient ID and Sequence Number

Before a treatment can be started a Patient ID and starting Sequence number must be entered. The sequence number will increment after each treatment. A data file name will also be created for each treatment.

The filename is descriptive of the treatment parameters that were selected before the Start button is clicked.

<File Path>\ (Patient ID)(Seq#)(Duty Cycle)(Control Mode Setting)(Power Limit)(End Point) (Date) (Time)

The filename above is:

C:\Data\ELT001-DC50 CMpid-60C-P5.0W EP04S 051308 085848.csv

C:\Data - Directory where data file is created

DC 50 - Duty Cycle of 50 %

CMpid60C- The PID Control Mode is selected and the target temperature is set to 60°C

P5.0W – Power limit of 5.0 Watts

EP04S - End Point of 4 seconds

051308 - Date of treatment [mm-dd-yy]

085840 - Time of treatment [hh-min-sec]

10. Alarms

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The RF Generator can detect several alarm conditions. Audio and visual alarms are displayed and sounded either on the RF Generator or the computer running the GUI. Alarms displayed and sounded by the RG Generator are Power On Self Test (POST) alarms and can not be silenced.

If a POST alarm occurs, the RED fault LED on the front of the RF generator will be illuminated and a dialog box will be displayed on the GUI. If a POST alarm occurs turn off the RF Generator and contact a Primaeva Medical, Inc. Customer Service representative.

If an alarm condition occurs during operation an audio alarm will be sounded by the computer running the GUI and a visual indication will be displayed on the GUI. Audio alarms can be silenced by pressing the **Silence Audio Alarm** button on the GUI. Pressing the **Silence Audio Alarm** button shall silence audio until the next time the alarm occurs. Audio volume may be adjusted by the volume control on the computer.

A List of the alarm conditions are listed below.

Alarm Condition	Alarm indication	Silence
Electrode resistance below 100 Ohms during a treatment.	**Ohms** display turns red	Yes
Energy limit exceeded the selected value for a treatment	**Joules** display turns red	Yes
Temperature did not rise above 40C and 5C from the starting temperature in 0.5 seconds.	**Temp** display turns red	Yes

11. Understanding the Measured Parameters

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The RF Generator has 5 channels for delivering power. Each channel delivers power to a pair of electrodes to deliver therapy. The measured parameters (Joules, Watts, Ohms etc.) for each channel are located on the Measured Parameters side of the GUI.

Joules:

Indicates the total amount of Energy delivered at that particular channel from the start of treatment.

Watts:

Indicates the instantaneous amount of Power that is being delivered at a particular channel.

Ohms:

The Miratone system is a bipolar device. This parameter indicates the resistance of a particular channel.

Electrode Temperature:

Measures the real-time tissue temperature at the electrode for each pair. These temperature values are collected directly from the thermocouples in the Electrode Cartridge and are constantly updated as soon as the GUI is started. These values would show the ambient room temperature when the device is left in the air.

If the Electrode Cartridge is not connected to the Treatment Applicator and the Treatment Applicator is not connected to the generator the value would read *OPEN*. In the case that the channel reads *OPEN* when the Electrode Cartridge is connected, try disconnecting and reconnecting it securely. If it still does not show the ambient temperature,

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it could be possible that the thermocouple is not functioning. Do not use this Electrode Cartridge. Open another Electrode Cartridge and check temperature readings after attaching it to the generator.

Treatment Time:

This shows the time for which the treatment has been delivered.

DAC Out:

This parameter is included for troubleshooting purposes. A Primaeva Medical, Inc. customer service representative would request the status of these values in the case of an improper functioning system.

On/Off Status:

This indicates the current status of the Miratone System. When the system is delivering RF energy, the On text will be bold and the corresponding text box will be displayed with a green background. The Off text will be faded and the corresponding text box will be displayed with a white background.

When the system is not delivering RF energy, the On text will be faded and the corresponding text box will be displayed with a white background. The Off text will be bold and the corresponding text box will be displayed with a red background.

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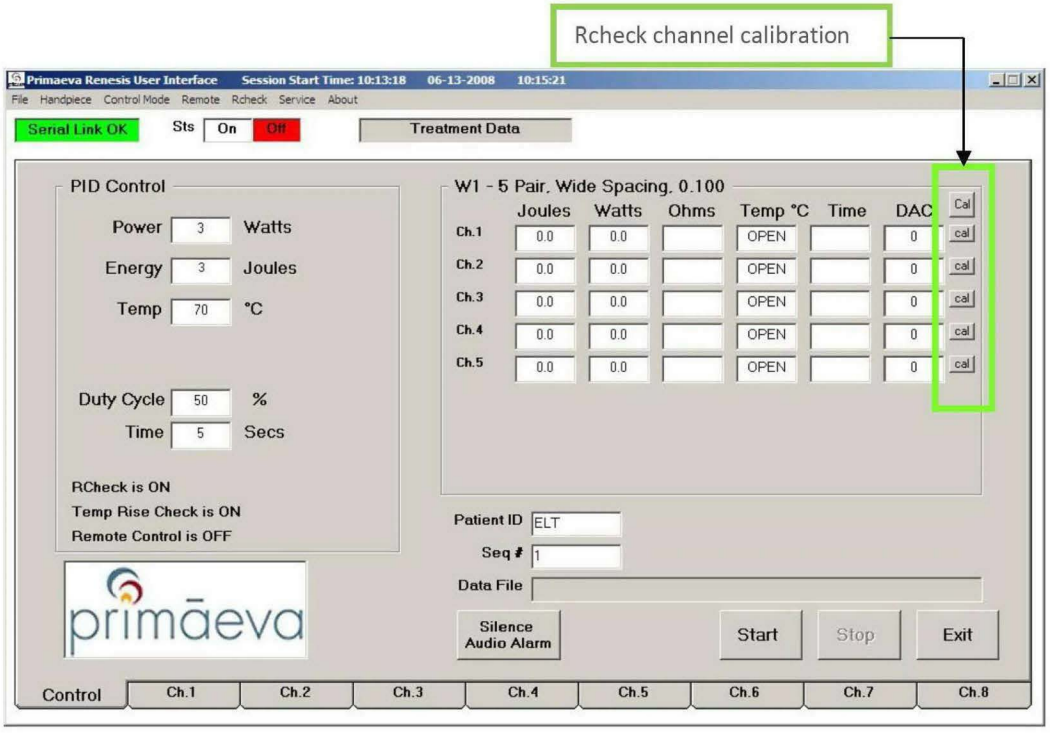
12. Calibrate the channels



The purpose of the calibration function is to be able initiate the Rcheck function to measure the resistance of the tissue prior to applying the treatment. Using this function can provide information on the location of the electrode tip, as every tissue layer has a unique value of resistance.

There is a calibration button for each channel and the top most button which initiates an Rcheck for all enabled channels.

Connect the Treatment Applicator as per the instructions detailed in **Setup - Section 7.2**. Position it at the desired region and extend the electrodes. The cal button can now be activated to deliver power at a single channel. The

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resistance values will be displayed in the **Ohms** section of the user interface.

A Rcheck calibration is not a necessary step before the start of every treatment. It is performed automatically when the start button is pressed to start a treatment.

If the Rcheck value is not within a predetermined range (default is 250 ohms to 3000 ohms) RF energy for that particular channel will not be delivered during a treatment.

13. Start Treatment

Set the desired treatment parameters. After fully reviewing the Miratone System Instructions for Use and positioning the Treatment Applicator at the required position and extending the electrodes into the skin, press the start button to deliver energy.

A beep will be emitted from the RF Generator for each second power is applied and the **RF on** indicator on the front of the RF Generator will be illuminated. The Measured Parameter section will also start to populate and the treatment time will be measured. At the end of treatment time, the system will automatically stop.

14. Temperature Check

In the first ½ seconds after a treatment begins the electrode temperature for each channel is checked. If the electrode temperature at the first ½ second of the treatment is below 40C and the temperature rise from the start of treatment is less than 5C the energy for that particular channel will be turned off for the remainder of the treatment.

15. New Treatment Area

To proceed to a new treatment area, retract the electrodes as directed in the Miratone System Instructions for Use for

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the Treatment Applicator and carefully remove the device. Reposition the device at the desired location. It is not necessary to calibrate the system again. The previously set Control Parameters will be maintained unless changed.

9 COOLING SYSTEM

9.1 OVERVIEW

As explained in Section 1.1, the Primaeva Medical Miratone System consists of a bipolar electrode array that delivers RF energy to the target tissue. In order to further control the thermal effects of the energy delivery on the tissue, a cooling system has been designed. This cooling system consists of a hand-held applicator (Cooling System Applicator) and a controller module (Cooler Controller). The Cooler Controller has provisions on its front panel to set a target temperature at which the Cooling System Applicator will maintain the tissue surface. Once this temperature has been set, the system will acquire temperature readings from the surface plate and drive the cooling system in order to achieve the target temperatures.

9.2 CLEANING

The Cooling Applicator must be cleaned following the instructions below prior to use.

A 70% isopropyl alcohol solution or damp cloth may be used to clean the Cooling System Applicator, and the Cooler Controller cover, side and front panels and the AC mains power cable. Allow isopropyl alcohol solution to evaporate before using the cooling system. Do not allow fluids to enter the Cooling System Applicator of the Cooler Controller chassis. **Do not spray or pour liquids directly on the either the Cooling System Applicator or the Cooler Controller.**

The Cooling System Applicator is not sterilizable.

The Cooler Controller is not sterilizable.

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9.3 General Description

9.3.1 Front Panel

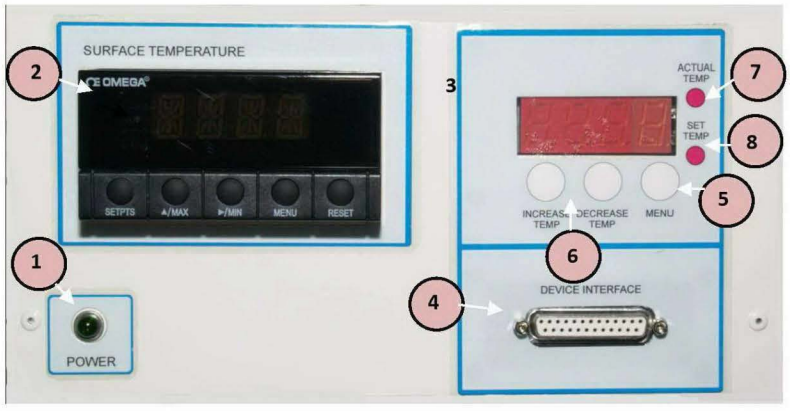

Figure 9.1: Front Panel – Cooler Controller

Connect the hand-held Cooling System Applicator to the Controller Interface port (Item 4 as shown in Figure 9.1).

9.3.1.1 Indicators

Green LED	**Power** Green Light – Power On [Item 1 in Figure 9.1]
Red LED	**Actual Temperature** Red Light – Display indicates measured temperature [Item 7 in Figure 9.1]
Red LED	**Set Temperature** Red Light – Display indicates the set target temperature [Item 8 in Figure 9.1]

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9.3.1.2 CONNECTORS

	Device Interface 25 pin D-Sub female connector Connection for the Cooling System Applicator. [Item 4 in Figure 9.1]

9.4.2 REAR PANEL

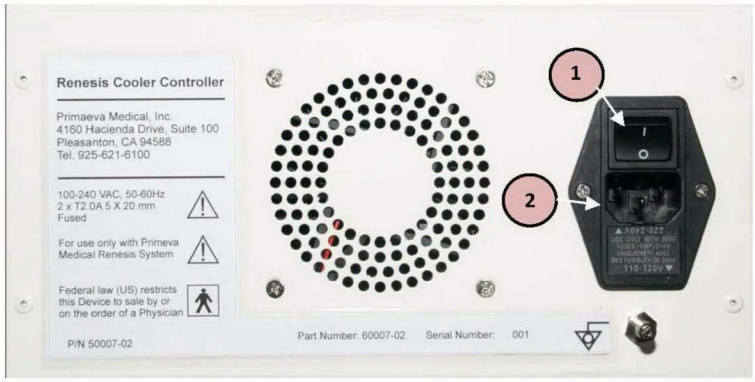

FIGURE 9.2: REAR PANEL – COOLER CONTROLLER

Connect the power cable (provided) to the connector on the rear panel (Item 2 as shown in Figure 9.2).

9.4.2.1 CONNECTORS

	Power Supply AC Power connector Note: Check **Specifications-Section 11** for the appropriate input power specifications. [Item 2 in Figure 9.2]

Berube-0001125

Ex. 2150-028

CX-0946.28

9.4.2.2 SWITCHES

POWER	**Power On/Off Switch** Switches the supply power for the Cooler Controller On/Off. [Item 1 in Figure 9.2]

10 COOLING SYSTEM SETUP AND OPERATION

10.1 OVERVIEW

This section provides information on the setup of the Cooling Controller System.

10.2 SETUP AND OPERATION

1. Ensure that the Cooler is connected to a properly grounded receptacle using a hospital grade power cord and that the appropriate input voltage is supplied.
2. The hospital grade AC mains power cord supplied with the Cooler must be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must not be used
3. Turn on power on the Cooler Controller (Item 2 in Figure 9.2).
4. Turn on power on the rest of the Miratone System.
5. Connect the Cooling System Applicator to the Cooler Controller via a DB-25 connector (Item 4 in Figure 9.1).
6. The Menu button toggles between the set temperature and the measured temperature (Item 5 in Figure 9.1).

Berube-0001126

Ex. 2150-029

CX-0946.29

7. Use the Increase Temperature and Decrease Temperature buttons to set the Cooler Controller to a temperature desired on the Cooling System Applicator (Item 6 in Figure 9.1). The minimum set temperature is 15°C and the maximum is 40°C
8. The display on the left (Item 2 in Figure 9.1) indicates an additional surface temperature measurement taken near the side of the contact plate on the Cooling System Applicator. The main measured surface temperature measurement is taken at the center of the contact plate. By observing both temperatures proper operation of the cooling system can be verified. If the two displayed temperatures are not within 3 degrees turn off the Cooling Controller, discontinue treatments and contact a Primaeva Medical representative.
9. Apply the sterile barrier to the cooler applicator tissue contact surface per the Instructions for Use.
10. The treatment is delivered by positioning, the Cooling System Applicator directly above the target tissue where the extended electrodes of the Electrode Cartridge are located and applying simultaneous heating to the target tissue and cooling to the surface tissue.
11. Repeat the process for other treatment areas.
12. When the treatment is complete, disconnect the Cooling System Applicator from the Cooler Controller.
13. Turn off power to all the system components.

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Ex. 2150-030

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11 DATA FILE

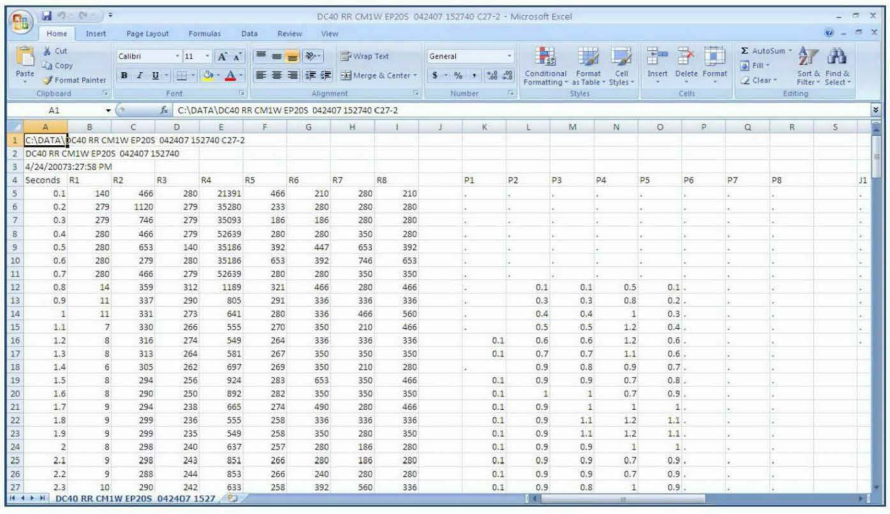
The Data File is created after the treatment to record the control parameters that were used and the resulting measured parameters during a treatment. The file name was created in Paragraph 10 of Section 8.3. To view the Data File, follow the instructions below.

Data is stored in .csv format

To open the treatment data set go to the directory where the file is saved (C:/Data)

Double click on the data file to be viewed.

The data sheet will look similar to the example below:



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	C:\DATA\DC40 RR CM1W EP20S 042407 152740 C27-2																		
2	DC40 RR CM1W EP20S 042407 152740																		
3	4/24/20073:27:58 PM																		
4	Seconds	R1	R2	R3	R4	R5	R6	R7	R8		P1	P2	P3	P4	P5	P6	P7	P8	J1
5	0.1	140	466	280	21391	466	210	280	210		.	.	.	.	.	.	.	.	.
6	0.2	279	1120	279	35280	233	280	280	280		.	.	.	.	.	.	.	.	.
7	0.3	279	746	279	35093	186	186	280	280		.	.	.	.	.	.	.	.	.
8	0.4	280	466	279	52639	280	280	350	280		.	.	.	.	.	.	.	.	.
9	0.5	280	653	140	35186	392	447	653	392		.	.	.	.	.	.	.	.	.
10	0.6	280	279	280	35186	653	392	746	653		.	.	.	.	.	.	.	.	.
11	0.7	280	466	279	52639	280	280	350	350		.	.	.	.	.	.	.	.	.
12	0.8	14	359	312	1189	321	466	280	466		.	0.1	0.1	0.5	0.1	.	.	.	.
13	0.9	11	337	290	805	291	336	336	336		.	0.3	0.3	0.8	0.2	.	.	.	.
14	1	11	331	273	641	280	336	466	560		.	0.4	0.4	1	0.3	.	.	.	.
15	1.1	7	330	266	555	270	350	210	466		.	0.5	0.5	1.2	0.4	.	.	.	.
16	1.2	8	316	274	549	264	336	336	336		0.1	0.6	0.6	1.2	0.6	.	.	.	.
17	1.3	8	313	264	581	267	350	350	350		0.1	0.7	0.7	1.1	0.6	.	.	.	
18	1.4	6	305	262	697	269	350	210	280		.	0.9	0.8	0.9	0.7	.	.	.	
19	1.5	8	294	256	924	283	653	350	466		0.1	0.9	0.9	0.7	0.8	.	.	.	
20	1.6	8	290	250	892	282	350	350	350		0.1	1	1	0.7	0.9	.	.	.	
21	1.7	9	294	238	665	274	490	280	466		0.1	0.9	1	1	1	.	.	.	
22	1.8	9	299	236	555	258	336	336	336		0.1	0.9	1.1	1.2	1.1	.	.	.	
23	1.9	9	299	235	549	258	350	280	350		0.1	0.9	1.1	1.2	1.1	.	.	.	
24	2	8	298	240	637	257	280	186	280		0.1	0.9	0.9	1	1	.	.	.	
25	2.1	9	298	243	851	266	280	186	280		0.1	0.9	0.9	0.7	0.9	.	.	.	
26	2.2	9	288	244	853	266	240	280	280		0.1	0.9	0.9	0.7	0.9	.	.	.	
27	2.3	10	290	242	633	258	392	560	336		0.1	0.9	0.8	1	0.9	.	.	.	

The top most row indicates the path and filename of the current data set. This would be the same as the filename that was specified in paragraph 10 of section 8.3.

The second row contains the control parameters that were used to create the data set. The format for this is very similar to the file name, with the only addition information being the GUI version.

The following rows and columns detail a time-wise variation of the measured parameters. Impedance (R), Power (P), Energy (J), Temperature (T), and DAC are listed for each channel of the system.

Berube-0001128

Ex. 2150-031

CX-0946.31

The data set is now ready for analysis. It is recommended that a backup of the original data set be created before modifying the original data file.

12 FAQ / TROUBLESHOOTING

The following is a list of frequent issues that you might encounter if certain steps are overlooked during the setup process. If for any reason the suggestions below do not solve the issue, call a Primaeva Medical, Inc. customer service representative for further assistance. Do **NOT** attempt to open the RF Generator.

Q) Power LED does not turn on when the On Switch on the rear panel is turned on.

A) Verify the connections between the RF Generator and AC Mains.

Q) Choice of Communication Port: Which one to choose?

A) The selection of the communication port is automatic. It is usually the second port that is shown to be open in the Serial Communication Window.

Q) The Fault indicator light remains illuminated after powering up the RF Generator.

A) Cycle the RF Generator switch off and on. If the Fault light still remains illuminated contact a Primaeva Medical, Inc. for customer support.

Q) The GUI display reports: No Serial Link (intermittent or continuous display)

A) Verify the connections between the RF Generator and the computer. Try cycling the power to the RF Generator. If there is still no Serial Link contact Primaeva Medical, Inc. for customer support.

Berube-0001129

Ex. 2150-032

CX-0946.32

Q) The Fault indicator light comes on during treatment and RF delivery is interrupted.

A) The RF Generator includes a fault detection that stops RF delivery if the impedance is too low. Cycle the power to the RF Generator and try repeating the treatment. If the Fault light comes on again during treatment, cycle the RF Generator power and reposition the Treatment Applicator electrodes before starting the treatment again. If the Fault light still comes on again during treatment, cycle the Generator power, replace the Treatment Applicator with a new device and try repeating the treatment. Should the Fault light come on again contact Primaeva Medical, Inc. for customer support.

Q) Cannot read the data file / Formatting is incorrect

A) The steps in **Section 11** describe in detail the steps that need to be followed in formatting the data file as required. The data file is originally a text document and therefore needs to be formatted appropriately before importing. If there was any mistake in the formatting, close the file and repeat the steps described above.

Q) Recovering previous data sets after modifications.

A) If any changes are made to the original data set they cannot be undone. However, after importing the data set text document into the spreadsheet software, a new version of the spreadsheet file can be saved with another filename. If there is a need to recover the original data set, the text document can be imported again into the spreadsheet software.

Q) There is no RF output from the RF Generator.

A) Check the connection of the AC mains power cord on the back of the RF Generator and check the connection of the Treatment Applicator to the RF Generator. Cycle the power to the RF Generator and start a new file on the GUI. After trying again to deliver RF output should the RF Generator still fail to deliver RF output contact Primaeva Medical, Inc. for customer support.

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Ex. 2150-033

CX-0946.33

13 MAINTENANCE

Maintenance: No routine maintenance is required. There are no user serviceable parts for the Miratone System. Contact a Primaeva Customer Service Representative for all maintenance of the RF Generator, the Cooler Controller or the Cooling System Applicator.

14 SPECIFICATIONS

The interface for the RF generator needs to be installed on a computer. The specifications for this computer are:

Memory	: 0.5 GB of RAM, minimum
Processor	: 1.73 GHz Intel Pentium M or better
Operating System	: Microsoft XP with Service Pack 2
Free space on hard disk	: 500 MB, minimum

Power Requirements

RF Generator	: 120 VAC, 60 Hz, 500 mA
Cooler Controller	: 120 VAC, 60 Hz, < 2.0 A

RF Output

RF frequency	: 460kHz +/- 5kHz
Maximum Power	: 25 watts (5 per channel) into 100 to 2000 Ω
Duty Cycle	: Adjustable 10-50 ms on for every 100 ms

Electrical Safety

Class 1, Type "BF" Applied Part

Measurement Accuracy

Power	: +/- 20% of reading
Impedance	: +/- 20%
Temperature RF Generator	: +/- 3 °C

Berube-0001131

Ex. 2150-034

CX-0946.34

Temperature Cooling Controller : +/- 1 °C

Enclosure Material

Generator : Aluminum

Cooler Controller : Aluminum

Operating Environment Conditions

RF Generator : 15°C to 25°C
: 75% relative humidity (non-condensing)

Cooler Controller : 15°C to 25°C
: 80% relative humidity (non-condensing)

Storage Environment Conditions (RF Generator and Cooler Controller)

RF Generator : -20°C to 60°C
: 95% relative humidity (non-condensing)

Cooler Controller : -30°C to 55°C
: 80% relative humidity (non-condensing)

15 ELECTROMAGNETIC INTERFERENCE

Warning:

- The Miratone System RF Generator requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the Miratone System RF Generator
- The use of accessories, transducers and cables other than those specified by Primaeva Medical, Inc. may result in increased emissions or decreased immunity of the equipment.
- This equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

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Ex. 2150-035

CX-0946.35

15.1 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Miratone System is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Miratone System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
The Miratone System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

15.2 Electromagnetic Immunity

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000 -4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast	± 2 kV for power	± 2 kV for power	Mains power quality

Berube-0001133

Ex. 2150-036

CX-0946.36

transient/burst IEC 61000 0-4-4	supply lines ± 1 kV for input/output lines	supply lines ± 1 kV for input/output lines	should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) For 0.5 cycle 40 % U_T (>95 % dip in U_T) For 5 cycles 70 % U_T (>95 % dip in U_T) For 25 cycles <5 % U_T (>95 % dip in U_T) For 5 sec	< 5 % U_T (>95 % dip in U_T) For 0.5 cycle 40 % U_T (>95 % dip in U_T) For 5 cycles 70 % U_T (>95 % dip in U_T) For 25 cycles <5 % U_T (>95 % dip in U_T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Miratone System requires continuous operation during power mains interruptions, it is recommended that the Miratone System be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level			

Berube-0001134

Ex. 2150-037

CX-0946.37

16 LABELING SYMBOL

Description	Symbol
Attention: consult accompanying documents	
Dangerous Voltage	
Expiration Date	
Fuses	T 500 mA L 250V
Sterilized with Gamma Radiation	STERILE R
Reorder Number	REF
Lot Number	LOT
Serial Number	S/N
Potential Equalization Terminal	
Single Use Only	
Type "BF" Symbol	
Manufactured Date	
Manufacturer	

Berube-0001135

Ex. 2150-038

CX-0946.38

Explosion Hazard Symbol	
Non-Ionizing Radiation	

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Ex. 2150-039

CX-0946.39