Ionto 4

Iontophoretic Stimulator

02/28/24
Instructions for Use

P/N 5601

For more information, contact:

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Comments or Questions?
We appreciate receiving any suggestions, comments, or questions that would help us to improve this manual. Please forward comments to the address above.

Contents

IMPORTANT: Read and understand the entire Operator's Manual PRIOR TO treating a patient!

Special attention should be paid to the Warnings, Precautions, and Contraindications sections.

Danger – Explosion Hazard: Do not use the Ionto4® in the presence of flammable anesthetics or other flammable products. When using alcohol or other flammable skin cleaning agents, make sure the flammable liquid and vapors have evaporated and dispersed before beginning the iontophoretic treatment.

Danger – Shock Hazard: Contact with other sources of electricity may pose a risk of electric shock. Do not connect this instrument to any source of electricity other than that outlined in this manual.

Indications

Ionto4® is intended to deliver ions of soluble salts or other drugs into the body using direct current.

Contraindications

The Ionto4® is contraindicated for use on patients who:

1. Are electrically sensitive; or
2. Have electrically sensitive support systems (e.g. pacemakers); or
3. Exhibit allergic reactions to the drugs being administered

Electrodes should not be placed over recent scar tissue, denuded or damaged skin, across the left and/or right temporal regions, or over the thoracic or orbital region.

Warnings and Cautions

Warning: Do not use the Ionto4® on patients who are electrically sensitive, (e.g. uncontrolled cardias arrhythmias, myocardial damage, patients with pacemakers, etc.).

Warning: Not defibrillation proof. Disconnect from patient prior to defibrillation.

Warning: The conductive parts of Electrodes and associated connectors for applied parts, including the Return Electrode, should not contact other conductive parts including earth.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Ionto4®, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: To prevent damage, remove batteries if instrument is likely to remain unused for a prolonged period of time.

Warning: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

Caution: Iontophoresis can cause skin irritation or burns. Patients should be advised of the possibility of skin burns before treatment.

Caution: Do not use this device in the presence of (HF) electrosurgical instruments.

Caution: This device is to be operated only by trained personnel under the direction of a physician.

Caution: Do not use the Ionto4® if the patient is allergic to the medications being administered.

Caution: Carefully route patient cables to reduce the possibility of patient entanglement or strangulation.

Caution: Portable and mobile RF communication devices can affect this instrument.

Precautions

1. Ionto4® is for use only in a professional healthcare environment.
2. Do not allow the Ionto4® to be dropped or immersed in fluids.
3. Do not use battery chemistries other than NiMH, such as alkaline. Doing so may result in poor performance and/or permanent damage to the instrument.
4. Use of low-quality NiMH batteries and/or those with a capacity below 2000mAh may result in poor instrument performance and/or significantly reduced battery life.
5. Do not exceed recommended Application Current setting for any electrode. Doing so may cause burns.
6. Do not use electrodes other than those supplied by or expressly approved by WR Medical Electronics Co. These electrodes have been specifically designed for use with the Ionto4® and the use of unapproved electrodes could result in poor instrument performance and/or patient burns.
7. Do not use altered or damaged Electrodes
8. Use only a buffered return electrode intended for iontophoretic use.
9. Do not use electrodes for more than one treatment. Discard after each use.
10. Consult proper protocols for electrode use with specific drugs.
11. Ensure that the treatment area is clean, dry and free of lotions or other substances.

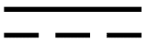
12. Treatment will normally cause transient erythema under the electrodes. This appears as redness and should disappear in one to eight hours under the Return Electrode and within one to twenty-four hours under the Delivery Electrode. Other reactions may be caused by drug allergies.
13. Do not apply electrodes over the thoracic area.
14. Do not apply electrodes over the left and/or right temporal regions.
15. Do not apply electrodes in the orbital region.
16. Do not apply electrodes over sensitive or damaged skin.
17. If the patient complains of discomfort or pain, do not continue treatment. Stop and verify the correct electrodes are being used and have complete contact with the patient.
18. The instrument should be situated so that its location or position does not interfere with its proper ventilation. Allow 10 cm (4") clearance from the front, rear, sides, and top of the instrument. Never cover the instrument with any cloth or other object that might interfere with proper ventilation.
19. Care should be taken so that objects do not fall into and liquids are not spilled into or onto the instrument, connectors, battery compartment, or other openings. Do not subject this instrument to excessive smoke, dust, mechanical vibration or shock.
20. The instrument should be situated away from equipment or devices that generate strong magnetic fields.
21. The instrument contains no internal user-serviceable parts and should only be serviced by qualified service personnel. Users should not attempt to service the instrument beyond that described in the Operating Manual unless directed by WR Medical Electronics Co. Service Personnel.
22. The instrument should be serviced when:
    a. Objects have fallen or liquid has been spilled into the instrument; or
    b. The instrument has been exposed to rain or moisture; or
    c. The instrument does not appear to operate normally or exhibits a marked change in performance; or
    d. The instrument has been dropped, or the enclosure damaged; or
    e. The instrument displays a message informing the operator to contact WR Medical Electronics Co.

Sterilization

Not required.

Safety and Information Symbols

Follow Instructions for Use



Direct Current (DC Power)

Type BF (Patient-Applied Part)

Dangerous Voltage

Class II Equipment

On/Off (Power)

General Warning – Must read for safe operation

Terms and Definitions

Application Current	The Application Current forces medication ions to flow from the Delivery Electrode into the tissue below. The Application Current returns to the instrument through the Return Electrode.
Applicator Cable	The Applicator Cable is used to connect the Electrode Leads to the Delivery and Return Electrodes.
Current	A flow of electric charge
Delivery Electrode	The active electrode which contains the drug to be delivered to the patient, such as the WR Medical Electronics Meridian® Capsule.
Direct Current	An electric current flowing in one direction only and substantially constant in value. Often abbreviated as DC.
Dose	The Treatment Dose is the total dose in mA-minutes specified by the protocol. The Treatment Dose is calculated by multiplying the Application Current (in mA) by the Application Time (in minutes). Treatment is ended when the Accumulated Dose equals the Treatment Dose.
Drug	A drug, medication, or non-drug solution
mA	Abbreviation for milliamps (one thousandth of an Ampere) The Ampere is an electrical value that qualifies the rate of flow of charge passing into the patient (electric current).
mA-minutes	The Dose units of measure is specified in milliamp-minutes.
Multi-Site Application	The concurrent treatment of multiple sites on a single patient using one instrument output per site.
NiMH	Nickle-Metal Hydride – A type of rechargeable battery

Polarity	The particular state either positive or negative with reference to electrification.
Ramp Down Phase	The final Treatment Phase where the stimulation outputs are ramped down from the configured output current down to 0.00mA, followed by a shutdown of the stimulation circuits. This also occurs when the Pause key is pressed during a treatment. The rate at which the output current ramps down can be found in the Technical Description.
Ramp Up Phase	The initial Treatment Phase where the stimulation outputs enable and the output current ramps up from 0.00mA to the configured output current. This also occurs when resuming treatment from a paused state. The rate at which the output current ramps up can be found in the Technical Description.
Resistance	The opposition offered by a body or substance to the passage through it of a steady electric current.
Return Electrode	Electrode which returns the Application Current to Ionto4® and contains a buffering agent, such as the WR Medical Electronics Co. Gel-Trode®. It is placed several centimeters away from the Delivery Electrode over healthy skin.
Single Phase Treatment	An iontophoretic treatment that administers medication ions with only a single polarity (e.g. only “+” or “-”) to the treatment site.
Single Site Application	A term that applies to iontophoretic treatments where one site (e.g. the right elbow) is treated. It requires only one Delivery Electrode and one return electrode.
Solution	A liquid preparation of one or more soluble chemical substances.
Stimulation Phase	The main Treatment Phase for delivering a drug or non-drug solution and takes place between the Ramp Up and Ramp Down phases. The full output current is being delivered during this phase and a countdown timer is visible to indicate the remaining treatment time to deliver the full dose.
Treatment Phase	The Ionto4® treatment consists of three phases. A treatment beings with a Ramp Up phase, followed by the Stimulation phase, and finally the Ramp Down phase.
Voltage	Electric potential or potential difference expressed in Volts.

Theory of Operation

Iontophoresis can deliver clinically significant amounts of medication to cutaneous and subcutaneous tissues without the use of needles. The Ionto4® - Model 5600, is a multi-channel iontophoretic drug delivery system that uses direct current to enhance the transcutaneous administration of ionizable substances. When such a substance dissolves in water, it separates into positive and negative ions. If electric current passes through the ionized solution, the substance ions carry the electric current from the positive electrode to the negative electrode.

For iontophoresis, an ionized solution is held against the skin with two specially designed electrodes, the *Delivery Electrode* and the *Return Electrode*. The positive ions in one electrode and the negative ions in the other can carry a DC electric *Current*, if sufficient DC voltage is developed, across the two electrodes. Since the skin's surface has a much higher resistance than the bodily fluids below it, most of the DC electric *Current* passes through the skin into the tissue below. Since like charges repel each other, positive substance ions pass through the skin at the positively charged electrode. Once the ions are inside the body, more mobile ions (e.g. Na+ and Cl) may accept the electrical charge from the substance ions and carry the *Current* to the other electrode. Thus, substance ions can accumulate in the tissues immediately below the *Delivery Electrode*. The *Delivery Electrode* is saturated with a solution that includes the active substance (e.g. a drug or non-drug solution) while the return electrode contains a buffering agent.

Many drugs are composed of an active ion (positive or negative) combined with a second ion (whose polarity is opposite the active ion) which together make a compound that is water-soluble. For instance, Lidocaine Hydrochloride, when dissolved in water, separates into the Lidocaine ion (positive) and the Chloride ion (negative). Only the positive Lidocaine ion has a therapeutic effect. Driving the Lidocaine ion through the skin into the tissue below has a therapeutic effect, however, driving the chloride ion would have little or none[1]. A separate *Return Electrode,* containing a buffering agent, assumes the opposite polarity to the *Delivery Electrode* to complete the circuit. Thus, the electrical polarity of the *Delivery Electrode* determines whether the positive charged ions or negatively charged ions pass into the tissue below.

The Ionto4® is uniquely designed to allow up to four sites on the same patient to be treated simultaneously with a single instrument. This is possible because of the electrically isolated nature of each output, allowing each site to be independently controlled and monitored. While each output is unique and can be individually enabled or disabled, treatment parameters such as Current, Dose, and Polarity are the same for all channels to ensure consistent treatment across all sites.

[1] This example is provided solely for the purpose of explaining the iontophoresis process. WR Medical Electronics Co. makes no claims as to the indications for Lidocaine Hydrochloride. Indications for specific drugs or non-drug solutions and their compatibility with iontophoretic delivery can only be determined by a qualified physician.

Hardware Overview

Front Panel

The front panel has a control key section and a Liquid Crystal Display (LCD). Activation of keys results in an audible sound (“beep”).

Figure 1 - Ionto4

LCD

The Liquid Crystal Display (LCD) shows the instruments settings, status, and displays messages to the operator. (See Figure 1 Above)

Control Keys

Arranged in labeled functional groups, the individual front panel control keys have the following functions. (See Figure 1 on Page 11)

On/Off key. Controls instrument power. Press once to turn the instrument On, press and hold for two seconds to turn the instrument off.

Menu key. Press to cycle through the configuration pages on the instrument display. During treatment this key has no function.

Up key. Moves selection cursor up in a list when no parameters are selected. When a parameter has been selected the parameter value is increased. During treatment this key has no function.

Down key. Moves selection cursor down in a list when no parameters are selected. When a parameter has been selected the parameter value is decreased. During treatment this key has no function.

Start/Select key.
Treatment Parameters Screen: Begins treatment.
Configuration Screens: Selects a list item for adjustment when pressed once. A second press stores the updated parameter value.
Ramping Up/Down: Pauses treatment by ramping the output Current down to zero.
Treatment Progress Screen: Pauses treatment by ramping the output Current down to zero.
Paused: Restarts treatment.

Pause key.
Treatment Parameters Screen: No function.
Configuration Screens: No function.
Ramping Up/Down: Pauses treatment by ramping the output Current down to zero.
Treatment Progress Screen: Pauses treatment by ramping the output Current down to zero.
Paused: Restarts treatment.

Top Panel

The top panel has four *Applicator Cable* connectors labeled 1, 2, 3, and 4. (See Figure 2 Below)

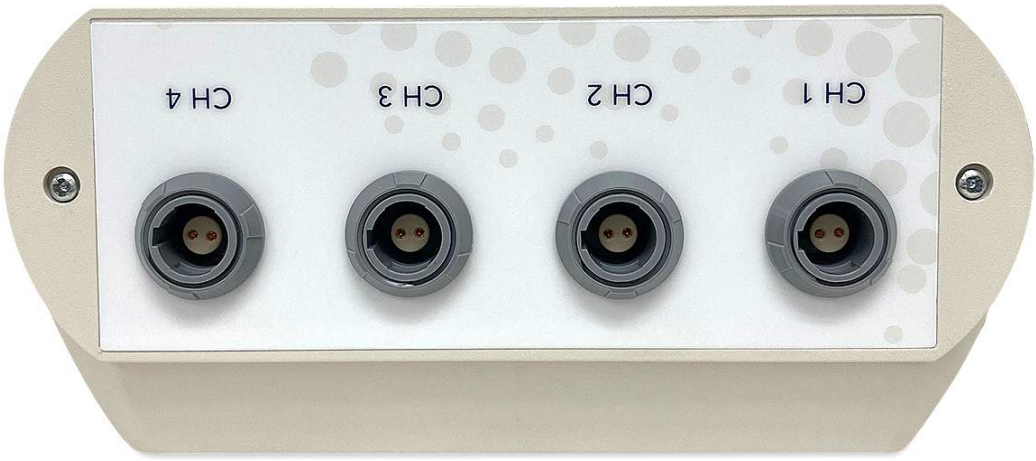


Figure 2 - Top Panel

Fastener Screws

Two screws hold the Ionto4® instrument together. (See Figure 3 Below)

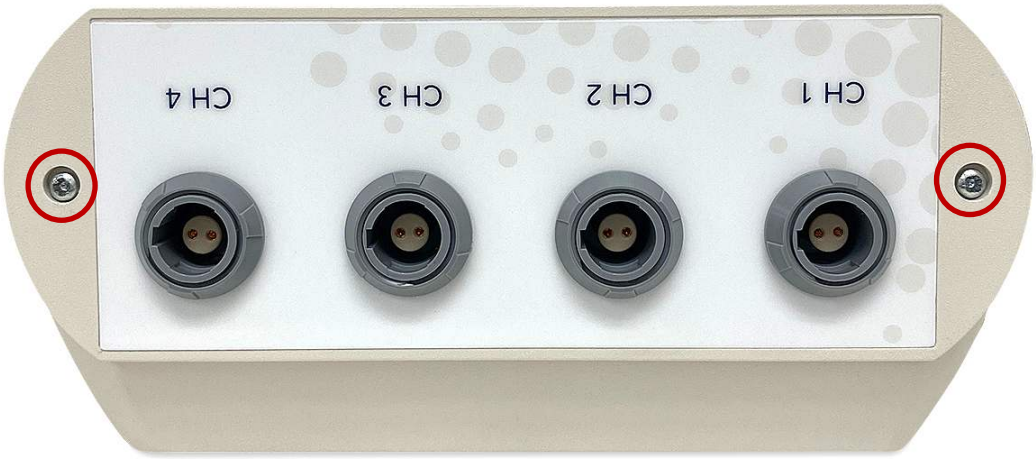


Figure 3 - Fastener Screws

Do not remove the screws and open the instrument! Dangerous voltages are present inside the Ionto4®. Refer all servicing to qualified service personnel.

Rear Panel

The battery compartment and product label are found on the rear panel of the Ionto4®. (See Figure 4 Below)

Figure 4 - Rear Panel

Battery Compartment

The battery compartment opens by simultaneously depressing the release tab and lifting the battery door. (See Figure 5 Below) The battery *Polarity* for each battery position is labeled in the case below each battery position. Always replace all four batteries at once, following the battery *Polarity* markings.

Figure 5 – Battery Compartment Tab

Product Label

The product label contains regulatory information, power supply requirements, and device manufacturer contact information. (See Figure 6 Below)

Figure 6 – Product label

Connections

Applicator Cables

Overview

The *Applicator Cable* has two connectors, one at each end. The instrument side has a round, keyed connector that inserts into one of the four Ionto4® output connectors (See Figure 7 Below). The electrode side has a flat, rounded connector consisting of three touch-proof sockets (See Figure 8 Below). The black socket is labeled “Return” and is connected to the *Return Electrode* lead wire. The two red sockets are labeled “Drug”, either of which can be used to connect to the *Delivery Electrode* lead wire. While either of these sockets may be used, only one should be connected at a time.

Figure 7 - Applicator Cable Instrument Connector

Figure 8 - Applicator Cable Electrode Connector

Connecting the Applicator Cable to the Ionto4

One end of the *Applicator Cable* has a round, keyed connector that inserts into the instrument. To attach the *Applicator Cable*, follow these steps (See Figure 9 Below):

1. Look at the flat end of the round connector on the *Applicator Cable*. Notice that it has a raised “key” which prevents incorrect insertion (Circled In Red Below).

2. Look at the flat end of the mating connector labeled CH 1 on the instrument’s Top Panel. Notice it has a notch that matches the key on the *Applicator Cable* connector.

3. With the instrument Off, align the notch with the key and push the two connectors together. A slight audible “snap” happens when they lock together. Minimal force is required to insert the *Applicator Cable* connector into the instrument. If resistance is encountered stop and verify connector orientation.

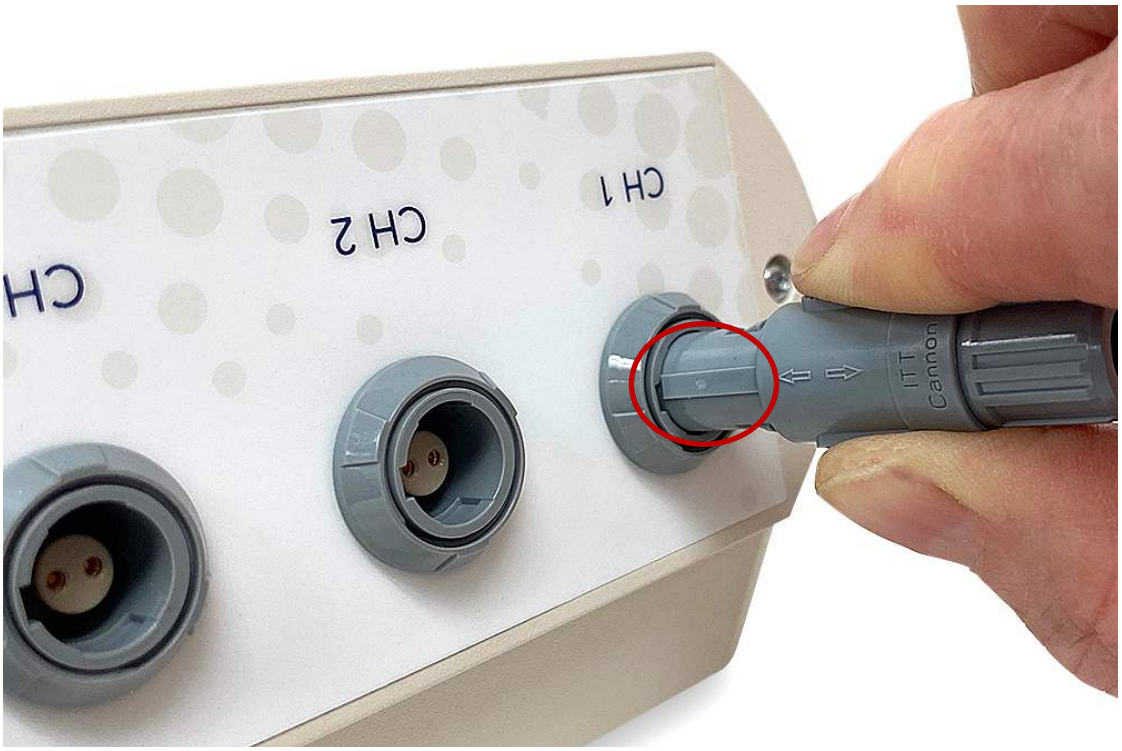


Figure 9 - Connecting Applicator Cable

DO NOT force the *Applicator Cable* Connector into the instrument! This will result in permanent damage to the instrument.

Disconnecting the Applicator Cable from the Ionto4

To remove the *Applicator Cable* from the Ionto4®, follow these steps:

1. Grasp the instrument in your left hand and the ribbed portion of the *Applicator Cable* connector with your right. (See Figure 10 Below)

2. Gently pull the connector out from the instrument. The connector may resist slightly at first, then disengage.

DO NOT pull on the *Applicator Cable* itself! Because the *Applicator Cable* connector locks into the instrument, doing so may cause permanent damage to the instrument and *Applicator Cable*.

DO NOT connect or disconnect the *Applicator Cable* during stimulation!

Figure 10 - Disconnecting Applicator Cable from the Ionto4

Electrodes

Overview

The Ionto4® uses two electrodes, a *Delivery Electrode* and a *Return Electrode*. The *Delivery Electrode* is filled with the *Solution* to be delivered to the patient while the *Return Electrode* provides a return path for the electric *Current* to the Ionto4®. Examples of electrodes manufactured by WR Medical Electronics Co. include the Meridian® Capsule *Delivery Electrode* (See Figure 11 Below) and the Gel-Trode® *Return Electrode*. (See Figure 12 Below) Sufficient electrode surface area is critical during Iontophoresis and undersized electrodes, or those intended for purposes other than Iontophoresis, may result in patient burns due to excessive current density.

Current density is measured in mA/cm^2. Current density should not exceed $0.33mA/cm^2$ for a *Delivery Electrode* and $0.5mA/cm^2$ for a *Return Electrode*. WR Medical Electronics Co. recommends a Return Electrode size of 4 in^2.

WARNING: DO NOT use electrodes other than those specified in this manual! Use of electrodes other than those specified in this manual or otherwise explicitly approved by WR Medical Electronics Co. may result in poor performance and/or patient burns.

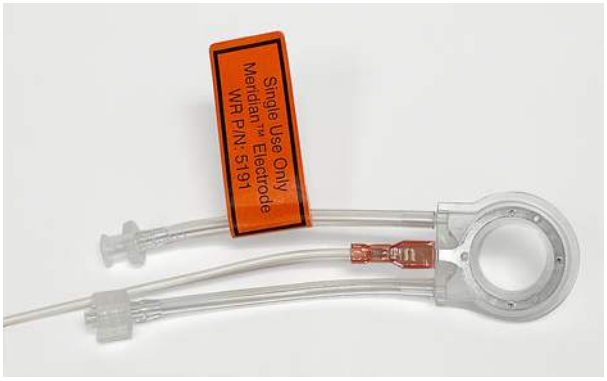


Figure 11 – Meridian Capsule

Figure 12 – Gel-Trode

Electrode Connection Using a Meridian® Capsule

To connect the *Delivery Electrode*, insert the red connector that extends from the Meridian® Capsule into either of the sockets labeled “Drug” on the *Applicator Cable*. (See Figure 13 Below)

Figure 13 - Applicator Cable Electrode Connections

Example Return Electrode Connection Using a Gel-Trode®

To connect the *Return Electrode* Lead Wire, insert its black connector into the black socket on the applicator cable labeled "Return". (See Figure 13 Above)

With the thumb and forefinger, pinch the *Return Electrode* Lead Wire's black clip until open and place on the Gel-Trode® snap and then release the clip. Tug slightly on the lead to ensure it is firmly connected. (See Figures 14 & 15 Below)

Figure 14 – Clipping Lead Wire to Gel-Trode

Figure 15 – Proper Gel-Trode Attachment

Operating the Ionto4

Introduction

Before using the instrument for the first time, follow the steps in this section to learn its operation. Insert the batteries and attach the *Applicator Cables* before following these steps. The instrument includes four Test Loads that simulates the electrode connections to the patient.
Note: Keep these Test Loads to help isolate future instrument problems if they occur.

Time-Out

While not administering a treatment (e.g. While on the treatment parameters screen) the instrument will time out and shut down five minutes after the last key press has occurred.

Powering the Instrument On

Press and release the Power key located on the front of the instrument. Under normal operation the LCD will display the WR Medical Electronics Co. logo, then automatically proceed to the treatment parameters screen.

Powering the Instrument Off

To power off the Ionto4®, press and hold the Power key for approximately three seconds. The instrument will shut down and power itself off. In the rare event that the instrument has become unresponsive, pressing and holding the Power key for at least six seconds will trigger a hard power-off.

CAUTION: Powering the instrument off while a treatment is active will immediately disable the stimulation outputs which may cause patient discomfort. If a treatment is active, the preferred method for powering the instrument down is to press the Pause key, wait for the LCD to display 0.00mA output for all channels, then power off the instrument.

Starting a Treatment

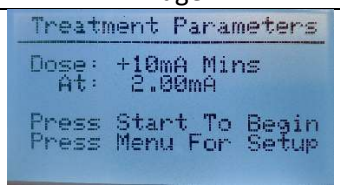
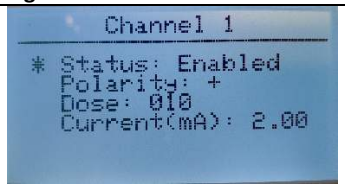
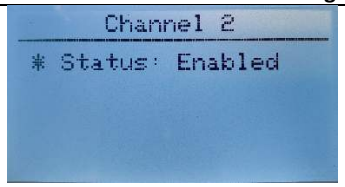
A treatment may only be started from the treatment parameters screen (See Figure 16 Below). This screen displays the total treatment *Dose* in *milliamp-minutes* as well as the *Current* at which the treatment will be delivered. To begin a treatment, press the Start/Select key. This will cause the instrument to begin the automated treatment program.

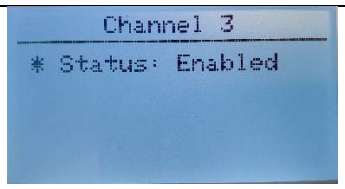
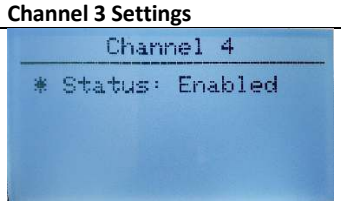
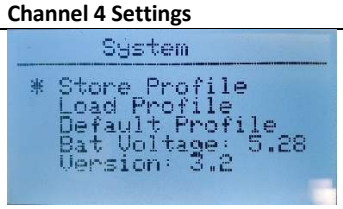
Configuring a Custom Treatment

The Ionto4® allows a treatment to be customized. To enter the configuration menus, press the menu key. Each press of this key will advance the display through a series of five configuration screens, then return to the Treatment Parameters screen. The following global parameters can be modified and will be the same for all enabled output channels:

- Treatment *Polarity* (Positive or Negative)
- *Dose* (Total dose to be delivered in milliamp-minutes)
- *Current* (the output current used to deliver the prescribed dose)

Additionally, the four output channels can be independently enabled or disabled allowing for any configuration where at least one of the four channels are enabled. Attempting to run a treatment with all four channels disabled will display a notification on the LCD alerting the operator to enable at least one channel.

Screen	Available Actions	Image
Treatment Parameters Screen.	* View Current Treatment Parameters. * Begin a treatment. * Enter Configuration Menus.	 **Figure 16 - Treatment Parameters**
Channel 1 and Dose Configuration Screen	* Enable/Disable Channel 1 Output. * Set Global Treatment *Polarity*. * Set Global Treatment *Dose*. * Set Global Treatment *Current*.	 **Channel 1 and Treatment Setting**
Channel 2 Configuration Screen	* Enable/Disable Channel 2 Output.	 **Channel 2 Settings**

Channel 3 Configuration Screen	* Enable/Disable Channel 3 Output.	 **Channel 3 Settings**
Channel 4 Configuration Screen	* Enable/Disable Channel 4 Output.	 **Channel 4 Settings**
System Settings Screen	* Store the current treatment configuration * Recall the previously stored treatment configuration. * Recall the factory default treatment configuration.	 **System Settings**

Modifying a Treatment Parameter

The Up and Down keys are used to navigate up and down within a menu as well as to modify a treatment parameter value once it has been selected. To select a parameter, navigate the cursor using the up and down keys, to the desired parameter. Next, press the Start/Select key to select that parameter. Once selected, the up and down keys are used to modify the value. Once the desired value has been reached, press the Start/Select key again to store the change.

Storing a Treatment Profile

The Ionto4® can store one user-defined treatment profile for later recall. Storing a profile will record the current state of the instrument. To store a profile, follow these steps:

1. Set all Ionto4® treatment parameters as desired.
2. Use the Menu key to navigate to the “System” screen.
3. Move the cursor to the “Store Profile” line using the Up and Down keys.
4. Press the Start/Select key to select “Store Profile”
5. Press the Up or Down key to complete storing the profile to instrument memory.

Recalling the User-Stored Profile

To recall a profile stored by the operator perform the following steps:

1. Use the Menu key to navigate to the “System” screen.
2. Move the cursor to the “Load Profile” line using the Up and Down keys
3. Press the Start/Select key to select “Load Profile”
4. Press the Up or Down key to complete recalling the profile from instrument memory.

Recalling the Factory Default Profile

To return the Ionto4® to its factory default configuration perform the following steps:

1. Use the Menu key to navigate to the “System” screen.
2. Move the cursor to the “Default Profile” line using the Up and Down keys
3. Press the Start/Select key to select “Default Profile”

4. Press the Up or Down key to complete recalling the default profile from instrument memory.

Pausing an Active Treatment

A running treatment can be paused at any time using the Pause key. This will work during any of the three treatment phases (*Ramp-Up*, *Stimulation*, and *Ramp-Down*). Pressing this key during treatment will cause the instrument to immediately begin ramping all enabled channels down to an output of zero, then display the word

"Paused." The instrument will remain in this state until either 1) the treatment is resumed, or 2) the instrument is powered off. Note that the treatment timer is halted while the instrument is paused.

Resuming a Paused Treatment

To resume a paused treatment, press the Start/Select key. This will cause the outputs to ramp back up to their prescribed level and restart the treatment timer where it left off when the instrument was paused.

Treatment Guidelines

Overview

This Section addresses the technical details associated with iontophoresis. For specific *Drugs*, combinations of *Drugs*, non-drug compounds, application parameters, or other information on how to use iontophoresis clinically, refer to published protocols.

Because of the unique design of the Ionto4®, up to four sites can be treated simultaneously. Each site of a multi-site treatment is setup as if it were independent and has its own *Applicator Cable*, *Delivery Electrode*, *Return Electrode*, and *Return Electrode* Lead Wire. The *Applicator Cables* from each site are connected to one of the four Ionto4® output channels and the instrument must be configured so each channel connected to a site is enabled in the configuration menus, while unconnected channels are disabled.

Delivery Electrodes – Multi-Site Application

Multi-Site treatments follow the same application procedure as the single-site procedure; however, each site uses a dedicated *Applicator Cable*, *Delivery Electrode*, *Return Electrode* Lead Wire, and *Return Electrode*. Refer to the treatment protocol for site selection(s).

Drug Selection and Solution Mixture

Be sure to use only the polar (water soluble) form of the *Drug(s).* Some *Drugs* are available in both polar (water soluble) and non-polar (non-water soluble) compounds. Iontophoresis cannot force non-polar *Drugs* through the skin. Try to use *Drugs* without extraneous ions (e.g. preservatives) as these ions compete with the desired ions during iontophoresis and may be forced through the skin also.

Drug mixtures are often unstable (e.g. they may react with air and lose potency). The *Solutions* should be made fresh for every treatment. Discard any unused *Solution* after the treatment ends.

Batteries

Battery Requirements

The Ionto4® is powered by four AA-size, 1.2V Nickle-Metal Hydride (NiMH) rechargeable batteries. Use of high-quality NiMH batteries with a capacity >2000mAh is critical for proper operation of the instrument. If you are unsure when purchasing batteries, contact WR Medical Electronics Co. for suggestions.

Please note that when using brand new batteries, they should be fully charged prior to first use.

DO NOT use battery chemistries other than NiMH! Use of non-NiMH batteries will result in poor instrument performance and may cause permanent damage to the instrument.

DO NOT USE ALKALINE BATTERIES.

Battery Replacement

Replace all four AA size NiMH batteries at the first opportunity after the instrument indicates the batteries are low. When this notification occurs the batteries may have sufficient power to complete the next treatment however, depending on the treatment parameters, this cannot be guaranteed. When replacing batteries, always replace all four simultaneously and be sure to use four fully charged, identical NiMH Rechargeable batteries. While alkaline and NiMH rechargeable batteries are both available in the AA size, the instrument will not operate correctly if anything other than NiMH rechargeable batteries are used.

How to Install Batteries

1. Remove the Battery Access Door as described in the Battery Compartment section. (See Figure 17 Below)

2. Insert four fully charged NiMH batteries according to the *Polarities* marked inside the battery compartment. (See Figure 18 Below)

3. If one or more batteries are inserted incorrectly, the Ionto4® will not operate correctly. Be sure to check the battery orientation prior to reinstalling the Battery Access Door.

4. When replacing batteries, always replace all four simultaneously and be sure to use **only** fully charged, identical NiMH rechargeable batteries.

Figure 17 – Battery Compartment

Figure 18 – Installed Batteries

Troubleshooting Guide

General

Instrument problems fall into one of three categories (listed in order of decreasing likelihood):

1. Failure to understand and follow operating instructions (e.g. reading and understanding the Operating Manual's instructions). Please take the time to read the **Operating Manual**.

2. Problems unrelated to the instrument (e.g. incorrect electrode connection).

3. Electronics failure.

When a problem occurs, first look through the problem/remedy list on the following page. If the problem matches one on the list, try the suggested checks and tests. For assistance, contact WR Medical Electronics Co. Service Department by calling 651-604-8483 or by e-mailing HelpDesk@wrmed.com.

Return Information

If your instrument must be returned to WR Medical Electronics Co. for service or calibration, contact the WR Medical Electronics Co. Service Department and obtain a return authorization number. To ship, use either the original packing box or a strong box with soft packing material. Damage due to poor packaging is not covered under warranty. For faster service, use prepaid air freight. Include the following information with the shipment:

- A list of failure symptoms.
- Your name and address.
- Your purchase order number for non-warranty repairs.
- A telephone number and email address we can use to consult with the instrument's user.
- Return shipping address and return shipping instructions.

Address the outside of the box with your return address, the return authorization number, and WR Medical Electronics Co. address:

WR Medical Electronics Co.
1700 Gervais Avenue Maplewood, MN 55109 USA
Attention: SERVICE DEPARTMENT

Ensure the shipment and keep the name of the freight handler and freight waybill number to trace the shipment if necessary.

Common Troubleshooting Issues

Failure to follow operating instructions. Most instrument problems can be answered by reading and following the instructions in this Operating Manual.

Symptom	Possible Cause and Remedy
The instrument will not turn On.	1. Batteries have not been installed. Open Battery Compartment and insert four fully charged AA size NiMH batteries following the *Polarity* markings inside the case. 2. One or more batteries have been inserted backwards by *Polarity*. Open Battery Compartment and check the batter orientation by *Polarity*. 3. The batteries are depleted. Open Battery Compartment and remove the depleted batteries. Insert four identical, fully charged AA size NiMH batteries following the *Polarity* markings inside the case. 4. An electronics malfunction, Contact the WR Medical Electronics Co. Service Department.
The instrument turns on, beeps, and a notification on the display reads “Low Battery Please Replace Soon” for 15 seconds then continues on to normal operation.	1. Batteries are nearly depleted. Batteries should be replaced with a complete set of four fully charged AA size NiMH batteries as soon as possible. Ignoring this notification may result in poor instrument performance. 2. An electronics malfunction. Contact the WR Medical Electronics Co. Service Department.
The instrument turns on, beeps, and a notification on the display reads “Battery Level Critically Low! Replace Immediately” for 30 seconds then turns off.	1. The batteries are depleted. Open Battery Compartment and remove the depleted batteries. Insert four identical, fully charged AA size NiMH batteries following the *Polarity* markings inside the case. 2. An electronics malfunction. Contact the WR Medical Electronics Co. Service Department.

A notification on the display reads “Open Circuit” and a channel number(s).	1. The instrument has detected an open circuit. Check all connections from the instrument to the electrodes on the patient. Is the *Applicator Cable* connected to the instrument? Is the *Return Electrode* Lead Wire properly connected to the black receptacle labeled “Return” on the *Applicator Cable* and to a *Return Electrode* on the patient’s skin? Is the *Delivery Electrode* Lead Wire connected to one of the two red receptacles labeled *Drug* and to a *Delivery Electrode* on the patient’s skin? Is each *Delivery Electrode* completely filled/saturated with the appropriate *Solution*? 2. If the open circuit occurs during the initial *Ramp-Up Phase* an Open Circuit message will be displayed for ten seconds, then the instrument will return to the Treatment Parameters screen so the open circuit can be corrected. Verify all electrical and patient connections. This is the most common reason for the and Open Circuit notification and can usually be remedied by improving contact between the electrode(s) and the patient’s skin. 3. If the open circuit occurs during a treatment, after the *Ramp-Up Phase* has completed, the Open Circuit message will be displayed, indicating the affected channel, for up to fifteen seconds. From here one of two things will happen: • If, within the fifteen seconds, the open circuit condition is corrected, the affected channel will automatically ramp up to prescribed output and the treatment will continue. • If the open circuit is not corrected within the fifteen seconds, the instrument will disable the affected channel for the remainder of the treatment and the display will return to the Treatment Progress screen. The word “OPEN” will be displayed instead of the output current for the affected channel, indicating that it has been disabled. The treatment will otherwise continue as normal. 4. To test the instrument and *Applicator Cable*, turn the instrument Off. Then insert the Test Load between either of the two “Drug” ports and the “Return” port of the affected channel’s *Applicator Cable*. Next, turn the instrument On and configure the device so

	only the affected channel is enabled then repeat the application. • If the OPEN condition occurs again, the problem may be caused by an electronic malfunction inside the instrument or a defective *Applicator Cable*. To test the *Applicator Cable*, swap the affected cable with another and re-test. If the problem follows the cable, then the *Applicator Cable* is likely defective. If the problem remains on the affected channel, then there may be an electronics malfunction inside the unit. Contact the WR Medical Electronics Co. Service Department for further assistance. • If the OPEN condition does not occur, the problem is with a Lead Wire, *Delivery Electrode*, *Return Electrode*, *Solution*, or application to the patient. Was tap water or distilled water used to fill the *Delivery Electrode*? Was a non-water-soluble *Drug* used in the *Drug Solution*? Did you clean the skin? Does the patient have dry or excessively thick skin (e.g. on the heel)? Dry or excessively thick skin may have sufficient *Resistance* to prevent current flow and cause an OPEN or High Impedance (HI-Z) condition. 5. An electronics malfunction. Contact the WR Medical Electronics Co. Service Department.
A notification on the display reads “All channels are disabled! Please enable at least one channel” for fifteen seconds then returns to the treatment parameters screen.	1. Operator has attempted to begin a treatment while all four output channels were set to the “Disabled” state. Return to the configuration menus and enable at least one channel, then restart treatment. 2. An electronic malfunction. Contact the WR Medical Electronics Co. Service Department.
During ramp-up and the treatment phases one or more channels show the word “OFF” instead of the channel output current value.	1. The instrument has been configured in a state where one or more channels have been disabled. If this is incorrect, pause treatment, wait for the output *Currents* to reach zero, then power the instrument off and on again. Set the affected channel to “Enabled” and restart treatment. 2. An electronics malfunction. Contact the WR Medical Electronics Co. Service Department.

A notification on the display reads: "Current Out of Range. Channel X YYYY. Please Restart"	1. Contact the WR Medical Electronics Co. Service Department.
A notification on the display reads: "Voltage Out of Range Channel X YYY.YY Contact Support"	1. Contact the WR Medical Electronics Co. Service Department.
A notification on the display reads "Over-Current Detected Please Restart"	1. An electronic malfunction. Contact the WR Medical Electronics Co. Service Department.
During treatment one or more channels display the word "Hi-Z" instead of the channel output current value on the Treatment Parameters screen.	1. The instrument is unable to deliver the desired output current due to an extremely high *Resistance* at the treatment site. Dry or excessively thick skin (e.g. on the heel) may have sufficient *Resistance* to impede *Current* flow, limiting the maximum *Current* that can be delivered. The affected channel is disabled; however, the treatment will continue as normal on the unaffected channels. 2. Pause treatment, waiting for the output *Currents* to reach zero, then power the instrument off and on again. Verify the *Return Electrode* is well adhered to the patient, the *Delivery Electrode* is making sufficient contact with the patient, and the is filled/saturated with *Solution*. 3. Adjust placement of the *Delivery Electrode(s)* and/or *Return Electrode(s)* slightly to a location with lower skin *Resistance* (e.g. off a callus). 4. An electronics malfunction. Contact the WR Medical Electronics Co. Service Department.
The instrument powers on, beeps for three seconds, and a notification on the display reads "Device Malfunction Please Contact WR Medical" for thirty seconds then powers off.	1. Contact the WR Medical Electronics Co. Service Department.

Maintenance

Cleaning

Clean the exterior of the instrument and applicators with a cloth dampened with a mild water- detergent mixture. Do not submerge or otherwise expose the instrument to significant quantities of water or other liquids.

Calibration

The instrument should be calibrated to factory specifications every two years unless erratic operation warrants an earlier examination. Dangerous voltages are present inside the instrument, refer all servicing to qualified service personnel. WR Medical Electronics Co. has a Service Department that can perform these services.

Calibration Verification

To verify correct output, have a properly trained technician place a 1K load across the red and black ports of the lead (a load with the correct connectors is provided with the Ionto4®) and measure the voltage across the load. 1V +/- 4% should be output for each mA output. Also confirm that an open error occurs when load is removed.

Preventative Maintenance

To ensure the instrument is operating correctly the Calibration Verification procedure should be performed on all four channels at least once every six months.

Disposal

When the device has reached the end of its service life it must be properly disposed of. The device must be taken to an appropriate electronics recycler for proper disposal. Batteries must be disposed of separately in accordance with local laws and regulations.

Replacement Parts and Supplies

General

WR Medical Electronics Co. maintains replacement parts and supplies for your instrument. Instrument parts are available directly from WR Medical Electronics Co. while supplies such as Gel-Trodes® or Meridian® Capsules can be ordered from local distributors or directly from WR Medical Electronics Co. if there is not a local distributor in your area. When contacting WR Medical Electronics Co., ask for the Neurological Sales Department.
Contact WR Medical Electronics Co. by phone at 651-604-8483 or by e-mailing HelpDesk@wrmed.com. The Service Department hours are Monday through Friday, 8 AM – 4:30 PM CST.

Electrodes, including the Meridian® Capsule and Gel-Trode®, are SINGLE USE ONLY. Discard after use.

Part Numbers

5191	Meridian® Capsule – Package of 20
5292	Meridian® Capsule with Expanding Foam Inserts – Package of 20
5599	Ionto4® Black Return Electrode Lead
5587	Gel-Trode® Return Electrode – Package of 20
5602	Applicator Cable
460-W0-10039	Ionto4® Test Load

Replacement Parts

WR Medical Electronics Co. Service Department has replacement parts for your instrument. Contact the Service Department for replacement parts.

Ionto4 Limited One-Year Warranty

Components of the Ionto4®, manufactured by WR Medical Electronics Co., Inc, excluding special cases listed below, are warranted against defects in materials and workmanship for a period of not less than one full year after delivery to the original purchaser.

Exclusions

- Disposable items are expressly excluded from this warranty, except when received damaged in the initial, new product shipment from WR Medical Electronics Co. or your WR Medical representative.
- Cables are warranted for 90 days from delivery.
- Loaner instruments are not provided under this warranty.
- Damage due to accident, abuse, negligence, acts of God, or other misuse are not covered by this warranty. This warranty shall not apply if the product has been repaired or altered by anyone other than an authorized representative of WR Medical Electronics Co., unless said repairs or alterations are performed under direct instruction of WR Medical authorized personnel.
- Except as expressly set forth herein, this warranty creates no other rights or obligations. WR Medical Electronics Co. makes no representations or warranties regarding these products, including express or implied warranties of merchantability and of fitness for a particular purpose. In no event shall WR Medical Electronics Co. be liable for any lost profits or for special, indirect or consequential damages.

SALES SPECIFICATION SHEET- **Ionto4**

WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109
www.wrmed.com | 651-604-8400

PHYSICAL DIMENSIONS

Height:	2.82 in. (7.15 cm.)
Width:	5.910 in. (15 cm.)
Length:	7.880 in. (20 cm.)
Weight:	1.1 lbs (500 gm.)

POWER SOURCE

Batteries:	Four, AA size, 1.2V NiMH batteries with a capacity greater than 2000mAh

ENVIRONMENT

	OPERATING	TRANSPORT AND STORAGE
Temperature:	20˚C to 25.6˚C	0˚C to +40˚C
Relative Humidity:	30 – 80% (non-condensing)	0 – 80% (non-condensing)
Atmospheric Pressure:	80kPa – 106kPa	30kPa – 106kPa

DEVICE SPECIFICATIONS

Application Current Range:	0.16mA – 4.00mA in 0.02 mA steps
Application Current Accuracy:	±3% of setting
Treatment Dose Range:	1 – 150 mA-minutes in 1 mA-minute steps
Treatment Dose Accuracy:	±3% of setting
Open Circuit Voltage:	120 VDC ± 5%
Current Ramp Up Rate:	0.25 mA/second
Current Ramp Down Rate:	0.6 mA/second
Output Polarity:	The Delivery Electrode can assume positive (+) polarity or negative (-) polarity
Output Channels:	4

REGULATORY

FDA 510K:	K863166
FDA Device Class:	II

ETL CLASSIFIED
Intertek

System Classification (IEC601-1 / EN 60601-1)

Degree of protection against moisture ingress	IPX0 - Ordinary
Degree of protection in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Not protected (unsuitable)
Mode of operation	Continuous
Ionto4® Type of protection against electric shock: Type BF	
Defibrillation Proof	Not Defibrillation Proof

EMC Compliance

Tested EMC Standards:

No.	Test / Standard	Port (enclosure, AC, DC, I/O)	Emissions Class and Group / immunity test level
1	CISPR 11, Radiated Emissions	Enclosure	Class B; Group 1
2	IEC 61000-4-2	Enclosure	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
3	IEC 61000-4-2	Patient Coupling Port	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
4	IEC 61000-4-3 Radiated RF Immunity	Enclosure	3V/m, 80-2700MHz, 80% 1kHz AM
5	IEC 61000-4-3 Proximity fields from RF wireless equipment	Enclosure	Section 8.10 of the IEC 60601-1-2 standard
6	IEC 61000-4-6	Patient Coupling Port	3V, 0.15-80MHz, 80% 1kHz AM 6V in ISM Band within 0.15-80MHz, 80% 1kHz AM