

ActivaDose[®] II

Iontophoresis Delivery Unit



CAUTION: Federal law (USA) restricts this device to use by or on the order of a physician.



Read Before Use

I. INDICATIONS

The ActivaDose® II Iontophoresis Delivery Unit is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injection in situations when it is advisable to avoid the pain that may accompany needle insertion and drug injection, when it is advisable to minimize the infiltration of carrier fluids, or to avoid the damage caused by needle insertion when tissue is traumatized.

II. CONTRAINDICATIONS

The ActivaDose® II Iontophoresis Delivery Unit is contraindicated for use on patients with electrically sensitive support systems (e.g., pacemakers) and patients with known allergy or sensitivity to the drugs to be administered. It is contraindicated for use over damaged or denuded skin or other recent scar tissue, across the right and left temporal regions and for treatment of the orbital region.

III. WARNINGS AND PRECAUTIONS

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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.

A. Never attempt to reuse single-use electrodes. Discard after use.

B. Iontophoresis can cause skin irritation and burns. Patients should be advised of this potential. It is important to note the following:

1. Continuous direct current used in iontophoresis can cause transient (uniform or mottled) erythema under either electrode which will generally resolve within a few hours to a few days.
2. Advise patient to report any undue burning, pain, or discomfort during treatment. Pause the treatment, inspect the area under the electrodes and make any necessary corrective actions before resuming the treatment.
3. Patients should remove any jewelry that may come in contact with either electrode. Failure to do so may cause burns.
4. Do not exceed maximum levels of current or dose (total delivered charge):
Maximum current: 4.0 milliamps (mA).
Maximum dose: Refer to directions for use supplied with electrodes.
5. Failure to observe the following precautions may result in excessive skin irritation or burns:
Do not tape, bind or compress electrodes during treatment.
Do not use electrodes that have been altered or appear damaged.
Do not apply electrodes over damaged skin.
Do not reuse single-use electrodes.
6. Do not use the ActivaDose® II Iontophoresis Delivery Unit and electrodes on patients with electrically sensitive support systems (e.g., pacemakers). Doing so may cause the support system to malfunction.
7. Exercise caution in handling the ActivaDose® II Iontophoresis Delivery Unit. Do not allow it to be dropped or immersed in fluids. Do not connect unit to external devices. Doing so may cause a malfunction or patient injury.

8. Do not apply electrodes over or across the right and left temporal regions, or use the ActivaDose® II Iontophoresis Delivery Unit and electrodes for treatment of the orbital region. Doing so may cause transient visual disturbances.
9. Patients with known sensitivity to electrical current should be treated with lower current settings than those recommended for general use. If a treatment results in prolonged skin irritation or burns, consult a physician and do not give additional treatments.
10. Patients should be asked about their history of drug allergies or sensitivities. The ActivaDose® II Iontophoresis Delivery Unit and electrodes should not be used on any patient who demonstrates a known allergy or sensitivity to the drug being administered. Consult the drug package insert for additional contraindications and warnings.
11. The "REJECT" safety feature of the ActivaDose® II Iontophoresis Delivery Unit terminates the delivery of the electric current to the electrodes whenever an interruption in the electrical circuit occurs. This is indicated by the flashing "REJ" light, beeps and a flashing "ELECTRODE REJECT" on the display. A mild shocking sensation may be experienced by the patient whenever an electrode reject occurs. Do not disconnect the lead wires from the electrodes, or the electrodes from the patient while the current is ON since this will cause the reject feature to function. The patient should avoid unnecessary movement during the treatment to ensure that an inadvertent disconnection of an electrode or lead wire does not occur.
12. Refer to the directions for use supplied with the iontophoresis electrodes for important additional information.
13. The ActivaDose® II Delivery Unit is recommended for use with the NCM branded Trivarion™ Iontophoresis and Norco® Buffered Iontophoresis electrodes.

IV. THEORY OF OPERATION

Iontophoresis can be used to transport soluble drug ions across intact skin. The technology is based on the principle that an electric potential will cause ions in solution to migrate according to their electrical charges. The quantity and distribution of a drug delivered by iontophoresis is dependent upon the charge of the ion, the size of the ion (molecular weight), the strength of the electrical current being applied, electrode composition, the duration of current flow and numerous other factors.

V. ACTIVADOSE® II IONTOPHORESIS DELIVERY UNIT SAFETY AND CONVENIENCE FEATURES

- A. **Description:** The ActivaDose® II Iontophoresis Delivery Unit is a solid state, microprocessor controlled device utilized to administer soluble salts or other drugs. The microprocessor performs several safety tests continually from the time of power on and other safety tests depending upon the mode of operation.
- B. **Display Help:** During normal operation the display provides guidance. Various prompts help in performing the next step. In only a few seconds, the dose and current can be set and a treatment can be started.
- C. **Turning the Dose Controller ON and OFF:** The dose controller can be turned ON by depressing the On/Dose/Start knob **OR** turning it clockwise. The unit can be turned OFF by depressing the On/Dose/Start knob.
NOTE: If a treatment is being performed and the unit is turned off, it will automatically ramp down prior to shut-off.

- D. **Pause Feature:** If a pause in treatment is desired, pressing the CURRENT knob will automatically ramp down the current and place the unit in pause mode. The current can also be turned down manually to activate pause mode. To restart the treatment, set the current to the desired level and turn the On/Dose/Start knob clockwise. The unit will automatically recalculate the treatment time, ramp up and continue the treatment.
- E. **Automatic Time Calculation:** Only the desired dose and current need to be entered for a treatment. All time calculations are performed automatically, even if dose and current settings are changed or the unit is paused.
- F. **Automatic Current Ramp Up:** After selecting the desired dose and setting the current, treatment can be started. The unit automatically ramps up the current output at a rate comfortable for most patients. The current may be adjusted for patient comfort any time during treatment, including during current ramp up.
- G. **Automatic or Manual Current Ramp Down:** After the preset dose is reached, the current automatically ramps down to 0.0 mA and the unit beeps, terminating the treatment. Also, automatic current ramp down takes place if a **"LOW BATTERY REJECT"** occurs during treatment. Current may be turned off manually any time, including during ramp up, to terminate treatment.
- H. **Resistance Limit:** Occasionally, when treating high resistance skin areas, such as the plantar surface of the foot, the unit may beep and flash **"LIMIT"** on the display. However, the unit will continue treatment if possible. As resistance drops during treatment, the unit will automatically ramp up the current to the desired level, or as high as possible if the desired level cannot be reached.
- I. **Dose and Current Limit:** The unit will beep and the dose display will flash **"LIMIT"** if an attempt is made to turn the dose knob beyond the upper limit of 80.0 mA-min. (milliamps-minutes). Also, the unit will beep and the current display will flash **"LIMIT"** if an attempt is made to turn the current knob beyond the maximum of 4.0 mA. Refer to directions for use supplied with electrodes for maximum recommended dose and current.
- J. **Electrode Reject:** Circuit problems (e.g., loose electrodes, dry skin, improperly connected electrodes, inappropriate drugs, etc.) can cause an **"ELECTRODE REJECT."** The unit beeps, the **"REJ"** light flashes and the display shows **"ELECTRODE REJECT."** The current output is turned off automatically. See Section X, **"Troubleshooting,"** to correct the problem.

VI. SETTING UP THE ACTIVADOSE® II IONTOPHORESIS DELIVERY UNIT

A. Install 9V Battery: Do not use rechargeable type batteries.

1. Prior to a treatment, if battery power is too weak for proper circuit operation, the current output of the unit will remain disabled and the **"BAT"** indicator will light. If a treatment is attempted, the alarm will sound and the display will flash **"LOW BATTERY."**
2. The battery compartment is at the rear of the unit. To open, gently press the door inward and slide it open. Polarity symbols (+) and (-) are marked on the inside of the compartment. If the battery is installed incorrectly, with the polarity reversed, the unit will not operate. Be sure the door is fully closed after installing the battery.

NOTE: Always insert battery FLAT into the battery compartment. Use battery strap to remove. DO NOT remove or insert battery at an angle or attempt to pry battery from the compartment, as this will damage battery contacts.

- B. Lead Wires:**
Connect the appropriate lead wires to the ActivaDose® II Iontophoresis Delivery Unit (see Figure 1).



VII. PREPARING ELECTRODES AND PATIENT FOR TREATMENT

NOTE: Please refer to the directions for use supplied with electrodes for detailed instructions. Do not tape, bind or compress either electrode against the skin during treatment. Doing so may cause excessive skin irritation or burns.

- A. Examine the skin sites for both electrodes. The skin must be free of damage, i.e., avoid broken skin, skin with ingrown hairs, acne, razor nicks, wounds that have not healed, recent scar tissue, etc.
- B. Prepare the drug electrode according to the directions for use supplied with the electrodes. **Always refer to the directions for use supplied with electrodes for correct fill volumes. Caution: Do not over- or under-fill electrodes.**
- C. Prepare the skin sites for both electrodes by briskly rubbing the areas with an alcohol wipe to remove dry skin, oils and other contaminants. Allow the skin to dry thoroughly. Remove any jewelry that may come in contact with either electrode.
- D. Apply the drug electrode over the treatment site according to the directions for use supplied with the electrodes.
- E. Apply the dispersive pad over a major muscle at least 4" to 6" (10 to 15 cm) away from the drug electrode according to the electrode's directions for use. Avoid placing the dispersive pad over a bony prominence with minimal tissue thickness; excessive skin irritations or burns may result.
- F. Attach the lead wire clips to the electrodes. Refer to the directions for use supplied with the electrodes for specific guidelines concerning polarity.

VIII. OPERATING THE ACTIVADOSE® II IONTOPHORESIS DELIVERY UNIT

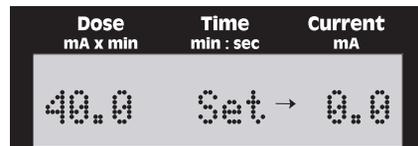
Normally, a typical treatment requires only three steps:

- A. **Select Dose**
- B. **Set Current**
- C. **Start Treatment**

A. Select Dose:

Depress the ON / DOSE / START knob or turn clockwise to turn on the unit. The unit performs a "System Check." The unit is preset at 40.0 mA-min (milliamps-minutes) dose. If desired, dose can be changed. Refer to the directions for use supplied with electrodes for specific information concerning recommended dosages.

EXAMPLE: For a 40 mA-minute dose, the display shows:



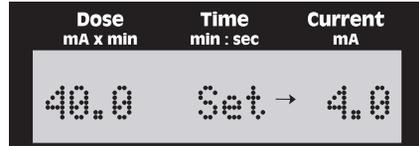
NOTES:

1. Maximum possible dose is 80 mA-min. The unit beeps and the display flashes "LIMIT" if an attempt is made to exceed 80 mA-min.
2. After a two-second delay, current can be set.

B. Set Current:

Read electrode instructions for recommended current. Turn the CURRENT knob clockwise to set the current. Maximum possible is 4.0 mA.

EXAMPLE: To deliver 4.0 mA of current, the display shows:



IMPORTANT

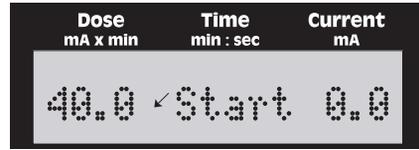
Current lower than 4.0 mA is recommended for:

1. Patients known to be sensitive to direct current.
2. Sensitive anatomic sites (e.g., fingers, carpal tunnel area, palms, face, feet).
3. Patients with thin or fragile skin.

C. Start Treatment:

Turn on the **ON / DOSE / START** knob clockwise one “click” to start treatment.

Current automatically ramps up gradually to desired set point and display shows:



NOTES:

1. “DOSE” shows dose delivered as mA-minutes accumulate.
2. “TIME” shows time remaining in minutes and seconds until treatment is complete. Time calculation is automatic.
3. “CURRENT” shows actual current being delivered in mA-minutes.
4. Automatic current ramp includes built in “comfort pauses.”



IMPORTANT:

If a patient experiences significant discomfort at a current setting of 4.0 mA, the current may be decreased anytime during the treatment by turning the CURRENT knob counterclockwise. Treatment time is automatically increased to achieve the preset dose. For example, if the current is reduced to 4.0 mA to 2.0 mA, the treatment time will automatically double to deliver the preset dose.

TIP:

For manual ramp up: Set dose, then set current below the maximum desired. Example: Set current at 0.1 mA. Start treatment. Gradually increase current to desired level, according to patient comfort, by turning CURRENT knob clockwise. Each “click” increases current 0.1 mA.

D. Pause or Stop Treatment Manually:

During treatment or current ramp up, turn the CURRENT knob counterclockwise to reduce current output to 0.0 mA, or press the CURRENT knob for automatic ramp down. The display will flash "PAUSE", and the dose delivered prior to the pause is retained in memory.

EXAMPLE: After decreasing current to 0.0 mA display shows:



NOTES:

1. During a pause, electrodes may be disconnected, replaced or removed. Dose and/or current may also be adjusted.
2. To restart the treatment, turn the CURRENT knob clockwise to the desired current level.
3. Turn the ON/DOSE/START knob clockwise to start. The unit will automatically recalculate the treatment time, ramp up and continue treatment.



E. Stop Treatment Automatically:

After the preset dose is reached, the current automatically ramps down to 0.0 mA.

After a 40 mA-minute treatment is complete the unit beeps and the display shows:



NOTES:

1. After Automatic current ramps down, turn the current knob to silence the beep, or depress the ON/DOSE/START knob to turn OFF.
2. Turn CURRENT knob counterclockwise to 0.0 mA anytime to stop treatment, or depress the ON/DOSE/START knob.

F. After Treatment:

Remove electrodes: Disconnect the lead wire clips and remove the electrodes from the patient. Discard both the drug electrode and the dispersive pad. They cannot be reused.

IX. SPECIFICATIONS

Electrical Shock	 Type BF Applied Part.
Environmental Conditions	Transport and store 50°F to 131°F (10°C to 55°C). Operate 41°F to 104°F (5°C to 40°C). Humidity less than 90%. Atmospheric pressure from sea level to 9,842 feet (3,000m)
Ingress of Water	Not protected against ingress of water.
Flammability	Do not use around flammable gases, liquids or materials.
Mode of Operation	Continuous.
Dimensions	6.1" x 3.5" x 1.9" (15.5 x 8.9 x 4.8cm)
Weight	.4 lbs. (.18kg)
Cleaning	Clean the case and lead clip wires as needed with an alcohol moistened cloth. Do not immerse in fluids.
Disposal	Dispose of according to local, state and federal regulations. Remove battery before disposal.
Controls	Two (dose and current)
Dose Range	0 to 80 mA-min.
Maximum Voltage	80V DC
Maximum Current	4.0 mA
Current Ramp Up	Automatic (0 to 4.0 mA) Built-in option for manual override
Current Ramp Down	Automatic at end of treatment; Paused or turned off by depressing knob. Built-in option for manual override
Battery	Use only 9V DC Alkaline. Ensure battery door is in place before starting treatment. Remove battery from unit when not in use.
Display	Dose, Time Remaining, and Current (displayed simultaneously with interactive set-up)
Pause Feature	YES (w/recalculation when restarted)
Visual Indicators	Low battery and open circuit
Audible Alerts	Low battery, open circuit, and end-of treatment
Auto Shut-Off	Will automatically shut off after one (1) minute, if not in use.

X. TROUBLESHOOTING

Display Shows	Possible Cause	Corrective Action
Unit does not turn on. Screen is black with no back-lighting.	<ul style="list-style-type: none"> No power source. 	<ul style="list-style-type: none"> Replace battery.
“ ELECTRODE REJECT ” and “ REJ ” indicator lights	<ul style="list-style-type: none"> Loose electrical connection at one or both electrodes. One or both electrodes have pulled away from the skin. Insufficient medication in drug electrode. Drug electrode not properly hydrated. Medication inappropriate for iontophoresis. 	<ul style="list-style-type: none"> Turn CURRENT knob counter-clockwise to “PAUSE” treatment and silence beep. Correct problem. Turn CURRENT knob to reset current. Restart treatment.
Dose “ LIMIT ”	<ul style="list-style-type: none"> Maximum dose of 80.0 mA-min has been reached. 	<ul style="list-style-type: none"> Refer to electrode directions for dosage recommendations. <p>CAUTION: Do not exceed recommended dosage.</p>
Current “ LIMIT ”	<ul style="list-style-type: none"> Maximum current of 4.0 mA has been reached. 	<ul style="list-style-type: none"> Refer to electrode directions for use and Section VIII-B for recommendations on current settings.
“ RESISTANCE LIMIT ”	<ul style="list-style-type: none"> Skin resistance at an electrode site is too high for preset current level, for example, the plantar surface of the foot. 	<ul style="list-style-type: none"> None. The unit automatically ramps current up to preset level, or as high as possible, and adjusts time to delivered desired dose.
“ PAUSE ”	<ul style="list-style-type: none"> Treatment has been paused by decreasing current to 0.0 mA, or by depressing the CURRENT knob. 	<ul style="list-style-type: none"> During a pause, electrodes may be disconnected, moved or replaced. Correct situation that caused treatment to be paused. Turn CURRENT knob to reset current. Restart treatment.
BAT indicator lights during treatment.	<ul style="list-style-type: none"> Battery voltage is decreasing during treatment but treatment may continue. 	<ul style="list-style-type: none"> After treatment is finished, replace battery.
“ LOW BATTERY ” and “ BAT ” indicator lights when unit is turned on.	<ul style="list-style-type: none"> Battery voltage is too low for proper operation. If battery voltage is very low only BAT indicator lights. Unit will not allow treatment to begin. 	<ul style="list-style-type: none"> Replace battery.
“ LOW BATT REJECT ” and during treatment “ BAT ” indicator lights.	<ul style="list-style-type: none"> Battery voltage is too low for treatment to continue. Unit will not allow treatment to be restarted. Unit ramps down current before preset dose is delivered. 	<ul style="list-style-type: none"> Replace battery.

XI. RETURNS

If following the troubleshooting guidelines listed in section “X” does not help to resolve a problem found with the unit, please reach out to **Customer Service** by calling **800-821-9319**, or send an e-mail to: **custserv@ncmedical.com**

LIMITED WARRANTY AND DISCLAIMER

ActivaDose® II Iontophoresis Delivery Unit with Lead Wires

I. DISCLAIMER

While in the opinion of North Coast Medical, Inc. (NCM) the use of the ActivaDose® II Iontophoresis Delivery Unit with Lead Wires has met with success in delivering certain medications into tissues, NCM makes no warranties (i) to the Purchaser as to the effectiveness of the Product in the treatment of any disease or physiologic dysfunction, or (ii) to Prescribing Physicians that its use will be effective in the treatment of those patients to whom it is applied.

II. WARRANTY

- A. NCM represents and warrants to the Purchaser that the Product (excluding accessories such as batteries, electrodes, cables and the component parts thereof) as distributed or manufactured by NCM, will be free of defects in materials and workmanship for a period of one (1) year, the “Warranty Period” from the date of purchase.
- B. Accessories, including, but not limited to, cables, batteries or electrodes assemblies are excluded from this warranty since they are designed to be used over a short period of time.

III. LIMITATION OF LIABILITY

- A. NCM’s sole obligation in the case of any breach of its representation and warranty set forth in Paragraph II., above shall be, without cost to the Purchaser, to repair or, at NCM’s option, replace the Product at any time during the warranty period. In the event of a defect in materials or workmanship, to recover under the warranty, the Purchaser must return the Product, freight and insurance paid by the Purchaser, within thirty (30) days.

To return the product, contact NCM Customer Service.

This warranty shall not apply if the Product has been subjected to misuse, negligence or accident.

- B. EXCEPT AS PROVIDED IN PARAGRAPH II. A., THE PRODUCT IS BEING SOLD ON AN “AS IS” BASIS. THE ENTIRE RISK OF THE QUALITY AND PERFORMANCE OF THE PRODUCT IS WITH THE PURCHASER AND NCM GIVES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURCHASE, EITHER EXPRESS OR IMPLIED.
- C. NCM shall not be liable for direct, indirect, special, incidental, or consequential damages, lost profits, or medical expenses caused by any defect, failure, malfunction or otherwise of the Product, regardless of the form in which any legal or equitable action may be brought against NCM (e.g., contract, negligence or otherwise) and the warranty provided in Paragraph II. A., hereof, shall constitute the Purchaser’s sole remedy. (This warranty gives you specific legal rights and you may have additional rights which may vary from state to state.)





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