

# Numby® 900

## IONTOPHORETIC DRUG DELIVERY SYSTEM INSTRUCTION GUIDE

### Ordering

Order No.	Model	Description
5070001	PM900	Numby 900 Iontophoretic Drug Delivery System
5020012	AN-3	Twin Lead - Use only with Numby Stuff® anesthesia electrodes

\*IONTOCAINE® (brand of lidocaine hydrochloride 2% and epinephrine 1:100,000 Topical Solution) is manufactured for IOMED by Abbott Laboratories, North Chicago, IL 60064, USA. Complete prescribing information available upon request.



Comments? Questions?  
Call 1-800-621-3347

**IOMED, Inc.** 3385 West 1820 South • Salt Lake City, UT • 84104 USA • 1.800.621.3347 • FAX 1.801.975.7366

US Pat. Nos. 4,141,359; 4,416,274; 5,087,242; 4,747,819; 4,744,787; 5,135,477; 5,236,412; 5,281,287; 5,328,544; 5,374,241; 5,415,628.

Other patents pending. IOMED, Phoresor, We Deliver Solutions, IONTOCAINE, and Numby Stuff are trademarks of IOMED, Inc.

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# Numby® 900

## IONTOPHORETIC DRUG DELIVERY SYSTEM INSTRUCTION GUIDE

Read and understand all instructions before using. Keep these instructions for future use.

Comments? Questions? Call 1-800-621-3347



## I. INDICATIONS

The NUMBY® 900 Iontophoretic Drug Delivery System is indicated for production of local dermal anesthesia using IONTOCAINE® (brand of lidocaine hydrochloride 2% and epinephrine 1:100,000 Topical Solution)\*

## II. CONTRAINDICATIONS

The NUMBY 900 Iontophoretic Drug Delivery System 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 (U.S.A.) restricts this device to use by or on the order of a physician.**

- A. The NUMBY 900 and IOMED electrodes are designed to operate safely when used together.
- B. Never attempt to reuse disposable electrodes. Discard after use.
- C. Iontophoresis can cause skin irritation and burns. Patients should be advised of this potential prior to treatment. 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. Patients should be advised to report any undue burning or pain at once during treatment.

- 3. **DO NOT** exceed maximum possible total delivered charge (dose): 40 mA-minutes. Refer to directions for use supplied with electrodes.
- 4. 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.
- 5. **DO NOT** use the NUMBY 900 and electrodes on patients with electrically sensitive support systems (e.g., pacemakers). Doing so may cause the support system to malfunction.

- 6. Exercise caution in handling the NUMBY 900. 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.
- 7. **DO NOT** apply electrodes over or across the right and left temporal regions, or use the NUMBY 900 and electrodes for treatment of the orbital region. Doing so may cause transient visual disturbances.
- 8. Patients with known sensitivity to electrical current should be treated with lower current settings than those recommended for general use. If treatment results in prolonged skin irritation or burns, do not give additional treatments and consult a physician.
- 9. Patients should be asked about their history of drug

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allergies or sensitivities. The NUMBY 900 and electrodes should not be used on any patient who demonstrates a known allergy or sensitivity to the drugs being administered. Consult the drugs package insert for additional contraindications and warnings.

10. The "REJECT" safety feature of the NUMBY 900 indicates an interruption in the electrical circuit has occurred. Treatment is temporarily suspended and the "REJECT" condition is indicated by the flashing "REJ" light and beeps. 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.

11. Refer to the directions for use supplied with IOMED electrodes for important additional information.

#### 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. NUMBY 900 SAFETY AND CONVENIENCE FEATURES

- A. Description:** The NUMBY 900 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. Automatic Dose Calculation:** Only the desired current needs to be selected for a treatment. The total drug dose delivered calculation is performed automatically by using a preset dose of 40 mA-minutes.
- C. Automatic Time Calculation:** Only the desired current needs to be selected for a treatment. All time calculations are performed automatically, even if the current selection is changed.
- D. Automatic Current Ramp Up:** After selecting the desired current the treatment will begin in approximately 2 seconds. 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 a treatment, including during current ramp up.

- E. Automatic or Manual Current Ramp Down:** After the preset dose of 40 mA-minutes 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.
- F. 10 Minute Automatic Shut Off:** The unit shuts off automatically after 10 minutes if a "REJECT" occurs and no other action has been taken.
- G. Resistance Limit:** Occasionally, when treating high resistance skin areas, such as the plantar surface of the foot, the unit will

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continue to beep and to flash on the selected current level display until the desired current level has been reached. As resistance drops during treatment, the unit will automatically ramp up the current to the desired level. If the desired level can not be reached within 30 additional seconds, the unit will "REJECT."

**H. Electrode Reject:** Circuit problems (e.g., loose electrodes, dry skin, improperly connected electrodes, inappropriate drugs, etc.) can cause an "ELECTRODE REJECT." The unit beeps and the "REJ" light flashes. The current output is turned off automatically. See Section IX, "Troubleshooting," to correct the problem.

## VI. SETTING UP THE NUMBY 900

**A. Install Battery:** NOTE: Duracell® batteries (9 volt, model MN1604) are recommended for best performance. Use alkaline batteries only. Other batteries may not provide optimum performance. **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, the "BAT" indicator will light and the unit will beep every 10 seconds until the battery is replaced or the unit is turned off.
2. The battery compartment is on the back of the unit. To open, gently press the door inward where indicated and slide it open. Press the battery clip onto the battery terminals. Place the battery into the compartment and replace the door.

**B. Twin Lead Connectors:** Attach the appropriate twin lead connector into the connector port at the top of the NUMBY 900. Different models of IOMED electrodes require the use of specific twin lead connectors. Refer to the back of this manual for information on the specific connector required for the IOMED electrode being used.

## 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, pimples, 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.
  1. For local dermal anesthesia: use only IONTOCAINE (brand of lidocaine hydrochloride 2% and epinephrine 1:100,000 Topical Solution). **Always refer to directions**

for use supplied with electrodes for correct fill volumes.

**Caution: DO NOT over-fill 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.
- 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 4-6 inches 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 irritation or burns may result.
- F.** Attach the twin lead connector clips to the electrodes. Refer to the directions for use supplied with the electrodes for specific guidelines concerning polarity.

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## VIII. OPERATING THE NUMBY 900

### A. Starting a treatment:

1. Turn the unit on by depressing the ON/SELECT button. The lowest current level, 2.0 mA, is automatically selected.
2. After a 2 second delay the NUMBY 900 will automatically ramp the current up to begin the treatment.

**NOTE:** The preset dose is 40 mA-minutes.

### B. Setting Current: Push the ON/SELECT button until the desired current level LED is lit. The maximum possible current is 4.0 mA.

**NOTE:** The LED for the selected current level will blink continuously until desired current level is achieved. The LED will then be illuminated constantly.

**IMPORTANT:** Current lower than 4.0 mA is recommended for:

- Patients known to be sensitive to direct current.
- Sensitive anatomic sites (e.g., palms, fingers, face, carpal tunnel area, feet).

- Patients with thin or fragile skin.

### NOTES:

1. If the current level needs readjustment, push the ON/SELECT button until the desired current level LED is lit.
2. After a 2 second delay, the current will automatically ramp to the new level.

### IMPORTANT:

1. If a patient experiences significant discomfort at a current setting of 4.0 mA, the current may be decreased anytime by pushing the ON/SELECT button until the lower desired current level LED is lit.
2. Treatment time is automatically adjusted to achieve the preset dose of 40 mA-minutes. For example, if the current is reduced from 4.0 mA to 2.0 mA, the treatment time will automatically adjust to deliver the preset dose.

### NOTES:

1. The NUMBY 900 continuously keeps track of the total dose (mA-minutes) delivered until the treatment is completed at 40 mA-minutes or the unit is turned off.
2. If the unit "REJECTS" during a treatment the unit will retain the dose delivered information. The treatment can be resumed by pushing the ON/SELECT button.

### C. Stopping Treatment Manually: The treatment can be stopped manually by depressing and holding the OFF button until the NUMBY 900 beeps. The current level LED will flash as the unit ramps down and until the NUMBY 900 beeps again and current level LED turns off.

**DO NOT** disconnect the lead wires or remove the electrodes until all LEDs are turned off.

**NOTE:** When the NUMBY 900 is turned off all information regarding the total dose (mA-minutes) delivered will be erased from the NUMBY 900 memory.

### D. Stopping Treatment Automatically: After the preset dose of 40 mA-minutes is delivered, the current automatically ramps down to 0.0 mA.

### NOTES:

1. The LED for the selected current level will blink continuously until 0.0 mA is reached.
2. After 0.0 mA is reached the unit will beep and automatically turn off.

### E. After Treatment: Disconnect the lead wire clips and remove the electrodes from the patient. Discard both the drug electrode and the dispersive pad. The electrodes cannot be reused.

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## IX. TROUBLESHOOTING

### “REJ” indicator lit

**NOTE:** Unit will sound 3 consecutive beeps twice and the “REJ” light will flash continuously for 10 minutes. Identify problem and correct from the following list:

- Loose electrical connection at one or both electrodes
- One or both electrodes have pulled away from the skin
- Drug electrode not properly hydrated
- Medication inappropriate for iontophoresis
- Skin resistance at an electrode site is too high for selected current level, for example, on a plantar surface of the foot

**Press ON/SELECT button to restart treatment at current level previously selected**

- The unit automatically ramps current up to selected level and adjusts the time to deliver the preset dose of 40 mA-minutes

### “BAT” indicator lights when unit is turned on

- Battery voltage is low
- If battery voltage is very low, unit will not allow treatment to begin
- Replace battery  
(Refer to Section VI. A of this NUMBY 900 Instruction Guide)

### “BAT” indicator lights during treatment

- Battery voltage is decreasing during treatment but treatment may continue
- After treatment is finished, replace battery  
(Refer to Section VI. A of this NUMBY 900 Instruction Guide)

### “BAT” and “REJ” indicator lights during treatment

- Battery voltage is too low for treatment to continue
- Unit will not allow treatment to be restarted

- Unit ramps down current before preset dose of 40 mA-minutes is delivered
- Replace battery  
(Refer to Section VI. A of this NUMBY 900 Instruction Guide)

### All LEDs are lit

- Battery voltage is too low for proper operation
- Unit is malfunctioning
- Replace battery  
(Refer to Section VI. A of this NUMBY 900 Instruction Guide)
- Have unit serviced  
(see Section X of this NUMBY 900 Instruction Guide)

## X. SERVICE

After following the troubleshooting procedures above, if a problem still exists, call IOMED Customer Service toll free at 1.800.621.3347. If your NUMBY 900 requires servicing Customer Service will assist you in returning the unit.

When returning the unit along with twin lead connector please include your name, address, phone number, a description of the problem and a copy of the IOMED Customer Product Report issued to you by Customer Service.

### Return the unit with postage and insurance prepaid to:

IOMED, Inc.  
Repair Department  
3385 West 1820 South  
Salt Lake City, Utah 84104 USA

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