

GelSponge Iontophoresis Electrodes and Phoresor[®] Dose controllers are components of the IOMED Phoresor Iontophoretic Drug Delivery System. These components are designed to operate safely when used together.

Caution

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

Indications

- IOMED's iontophoretic drug delivery electrodes are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injection.
- They are also indicated for administration of dermal anesthesia using Iontocaine[®] (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

Contraindications

- The Phoresor Iontophoretic Drug Delivery System is contraindicated for use on patients with:
 - cardiac pacemakers or other sensitive implanted devices.
 - known sensitivity to drug to be administered.
- It is contraindicated for use over damaged or denuded skin or other recent scar tissue.
- It is contraindicated to apply drug delivery electrode and dispersive pad across the temporal regions or for treatment of the orbital region.

- ⚠ **Read the Phoresor System Instruction Guide for additional important information.**
- ⊗ **Single Use Only**
- ⬇ **Store at ambient temperature 15°-30°C (59°-86°F)**
- ⬇ **DO NOT expose to temperatures above 50°C (122°F)**

Each Treatment Kit Contains:

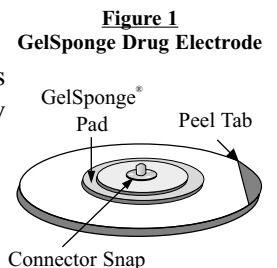
- 1 Drug Delivery Electrode
- 1 Dispersive Pad (electrode)
- 1 Alcohol Prep

Latex Free

Product	Size	Order Number	Quantity (Kits Per Carton)	Approx. Fill Volume	Active Area
IOGEL	Small	5000021	12 ea.	1.5cc	7.2cm ²
	Medium	5000022	12 ea.	2.5cc	11.1cm ²
	Large	5000023	12 ea.	3.5cc	16.3cm ²
TransQFlex	Medium	5000033	12 ea.	2.5cc	11.2cm ²
TransQE	Small	5000009	12 ea.	1.5-2.0cc	10.1cm ²
	Medium	5000008	12 ea.	2.5-3.0cc	13.4cm ²
TransQ	1GS	5000017	10 ea.	1.5cc	7.6cm ²
	2GS	5000018	10 ea.	3.0cc	13.4cm ²

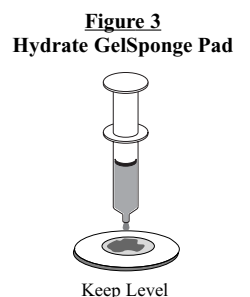
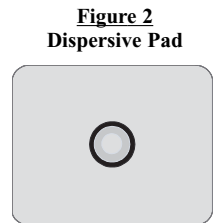
A. PREPARING PATIENT

- 1. Advise patient that iontophoresis has the potential to cause skin irritation and/or burns.**
Precaution: Direct current can cause transient erythema under either electrode; it generally resolves within a few hours to a few days. Use caution when treating patients with sensitive skin or who may have difficulty healing.
 - Erythema under the dispersive electrode usually exhibits a uniform redness.
 - Erythema under the drug electrode can exhibit a uniform or mottled redness.
- 2. Advise patient to remove any jewelry that can come in contact with either electrode.**
Note: Jewelry in contact with electrodes during treatment may cause burns.
- 3. Advise patient to immediately report any pain during treatment.**
Note: If the patient complains of pain, pause treatment, inspect area under the electrodes and take any necessary corrective action (e.g. reposition electrode to ensure full skin contact, decreasing current, etc.) before resuming treatment or discontinue treatment.



B. PREPARING ELECTRODES

- 1. Tear open sealed pouch and remove contents:**
 - Drug Delivery Electrode (Figure 1)
 - Dispersive Pad (Figure 2)
 - Alcohol Prep
- 2. Remove EZ Fill Window[™] from drug delivery electrode and place the electrode with the pad side up on a flat surface (Figure 3).**
- 3. Saturate the GelSponge pad thoroughly with the medication, eliminating any dry spots (Figure 3).**
Note: To ensure proper electrode hydration and performance:
 - **DO NOT** fill drug electrode on patient.
 - **DO NOT** over- or under-fill drug electrode.
 - **DO NOT** use medications in suspension form (i.e. not water soluble).
 - **DO NOT** use electrodes that appear altered or damaged.



Note: For information on “needle free” filling techniques, contact your authorized IOMED

representative or IOMED Customer Service.

4. Select the drug delivery electrode and dispersive pad sites that have intact skin.

Note: **DO NOT** apply electrodes to damaged skin; skin with ingrown hairs, pimples or razor nicks or to wounds that have not healed.

Warning: Failure to follow these guidelines can cause skin irritation or burns.

Note: The recommended site for the dispersive pad is over a major muscle.

Precaution: **DO NOT** apply drug delivery electrode and dispersive pad over or across the temporal regions or use the Phoresor System for treatment of the orbital region.

5. Prep both sites by thoroughly rubbing with alcohol prep for 6 to 8 seconds to remove dry skin, oils and other contaminants (Figure 4).

Precaution: Failure to clean skin thoroughly can cause excessive skin irritation or burns.

6. Allow both sites to dry completely.

7. Remove the backing from the dispersive pad and apply over a major muscle ensuring the entire surface area of the dispersive pad is in good contact with the skin (Figure 5).

Precaution: **DO NOT** tape, bind or compress drug delivery electrode or dispersive pad during treatment.

Note: Avoid placing the dispersive pad over a bony prominence with minimal tissue thickness.

8. Remove the backing from the drug delivery electrode, apply the hydrated electrode on the selected treatment site and secure it by pressing on the adhesive border (Figure 6).

Precaution: **DO NOT** tape, bind or compress drug delivery electrode or dispersive pad during treatment.

Note: Avoid pressing directly on the GelSponge pad; excessive pressure can cause medication leakage.

- If the electrode leaks, dry area around the site before beginning treatment.

Figure 4
Clean Electrode Sites

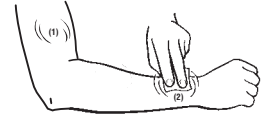


Figure 5
Apply Dispersive Pad



C. ADMINISTERING TREATMENT

1. Connect lead wires from the dose controller to drug delivery electrode and dispersive pad using the proper polarity for the drug being delivered (Figure 7 & Table 1).

Table 1

DRUG/POLARITY	DRUG ELECTRODE	DISPERSIVE PAD
NEGATIVE	BLACK (NEG)	RED (POS)
POSITIVE	RED (POS)	BLACK (NEG)
Iontocaine®	RED (POS)	BLACK (NEG)

Note: Attach lead wires securely and advise patient to avoid any excessive movement during treatment.

- Excessive movement can cause lead wires to disconnect, resulting in disruption in electrical current. This will result in an alarm, accompanied by a flashing “REJECT” light and the patient can experience a mild shocking sensation.

Note: Keep lead wires clean.

- Corrosion or dirt accumulation can cause poor contact and “REJECT.”

Precaution: Position patient so that no pressure is put on the drug delivery electrode or dispersive pad.

2. Set the dose controller to deliver recommended total dose.

Precaution: Refer to Phoresor System Instruction Guide for important information about setting current and/or dose.

- If the patient is sensitive to current, use lower current settings than those recommended for general use.

- **DO NOT** give additional treatments and consult a physician if there is prolonged skin irritation or a burn.

- **DO NOT** exceed 80mA-Minutes or 4.0 mAmps *negative* polarity.

- **DO NOT** exceed 40mA-Minutes or 4.0 mAmps *positive* polarity.

3. Ensure that nothing is binding or compressing drug delivery electrode and/or dispersive pad during treatment.

4. Start the treatment.

5. At the completion of treatment, remove and discard both the single-use electrode and dispersive pad.

Precaution: **DO NOT** reuse disposable drug delivery electrode and dispersive pad.

Figure 6
Apply Drug Electrode



Figure 7
Connect Lead Clips To Electrode Snaps

