



 **Type B Applied Part**

Environmental conditions:

Transport and storage between uses: -25 to 70 °C. 0-95% RH. 700-1060 hPa

Operating conditions:

5-40 °C. 15-95% RH 700-1060 hPa. 2000m altitude

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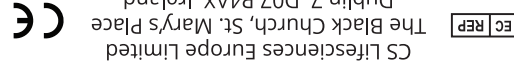
Buzzy® Healthcare (Model Names: Buzzy® Mini Healthcare, Buzzy® XL Healthcare) is a reusable pain relief product intended for multiple patients.

Thoroughly clean and disinfect Buzzy® and its accessories between patients following your facility's infection control protocol for reprocessing non-critical equipment. Buzzy® Healthcare is applied for up to 2 minutes directly or proximal to the procedure to reduce pain or distress from:

- Acute pain from needles, injections, or dialysis cannulation
- Vascular access, cannulation, lab draws, or blood donation
- Cosmetic injections
- Dental injections
- Temporary relief of itching, splinter and bee sting removal

For Buzzy® Mini Healthcare (Striped and LadyBuzzy) and Buzzy® XL Healthcare (Striped, Black, LadyBuzzy, BKHM1, BKHM3, BTH1, BTH2, BTH3, BTH4, BKD1, BKD2, BKD3 IFU-001 Rev 01 Buzzy Healthcare Instructions for Use 11.01.2023

PainCareLabs.com



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The Company covers every type of malfunction or defect that may appear or arise from normal use in the motor unit of the product for 1 year. The warranty for soft goods and ice packs lasts 1 year from date of purchase. The company will replace your product or refund your purchase and reserves the right to upgrade or replace parts with the latest product versions. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

Warranty:

With proper care, your Buzzy® motor unit will last for at least 1 year. With heavy use or extreme temperature fluctuations, batteries may need to be replaced more frequently. If device stops working or has weak mechanical stimulation, replace batteries.

Troubleshooting:

Indications For Use:

Buzzy® is intended to control pain associated with needle procedures (e.g., injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections) and the temporary relief of minor injuries (muscle or tendon aches, splinters, and bee stings).

Warnings:

For intended use only • Direct or prolonged application of ice could vasoconstrict. • Repeated application of ice could reduce blood flow or damage tissue.

Contraindications:

Do not use in the presence of unexplained calf pain. Consult a physician. • This device should not be used over swollen or inflamed areas or skin eruptions. • Do not place directly on a thermal burn • Do not use ice pack with underlying sensitivities to ice or cold (e.g. Sickle Cell Disease, Reynaud's Disease).

Cautions:

Store Ice Packs in a cool, dry place. • Ice Packs must be frozen solid for best effect. - Do not use dry ice to freeze packs unless supervised by a healthcare professional • Do not puncture Ice Pack chambers. • Discard if leaking. • Do not ingest gel. • Keep out of reach of children or pets. • Do not use with neuropathy, CRPS, or sensitivities to ice.

US Patented British Patent No. 2455695
RM-1910, 1248-064-5002-00, 1248-064-5001-00

DO NOT SERVICE WHILE IN USE

Please visit our website PainCareLabs.com for a complete list of FAQs, other pain management tips, how-to videos, accessories, and replacement parts.

How To Order/Additional Information:

Buyer must contact Customer Service or the authorized distributor in the country where the device was purchased for return instructions.

Returning Device For Service:

Buyer must contact Customer Service or the authorized distributor in the country where the device was purchased for return instructions. Does not require sterilization for use. Motor Unit Maintenance Between Patients: Check the entire device for any visible evidence of damage such as cracks. Ensure that the switch moves freely. Make sure external screw(s) are secure. To replace AAA batteries, unscrew using Phillips-head screwdriver and open back panel, placing batteries in the orientation shown inside the device. Gently wipe clean all exposed surfaces with a soft cloth dampened with a mild soap solution. To disinfect, wipe all exposed surfaces with alcohol or chlorhexidine, or a hospital-grade sanitizing wipe. Do not autoclave or immerse. This device does not require sterilization for use.

Maintenance:

Buzzy® Healthcare Includes:

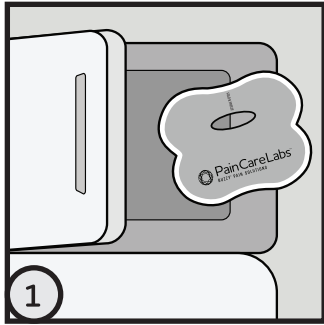
All Buzzy® Healthcare Kits include a durable therapeutic vibration motor unit with 2 AAA batteries (installed) and instructions. All accessories are latex free and reusable. • Buzzy® Healthcare Mini includes a two speed M-Stim® vibration unit with button switch & energy saving 3-minute automatic shut off, four reusable Ice Packs, and one hands-free strap. • Buzzy® Healthcare XL includes an M-stim® vibration unit with toggle switch for manual shutoff, four reusable Ice Packs, two hands-free straps.

Guarantee:

If not completely satisfied, return within 30 days to place of purchase for a full refund, or contact us at the address below.

1. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
2. "Please note that changes or modifications of this product is not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment."
3. NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: • Reorient or relocate the receiving antenna. • Increase the separation between the equipment and receiver. • Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. • Consult the dealer or an experienced radio/TV technician for help.
4. Pain Care Labs, 195 Arizona Ave. • LW08 NE Atlanta GA 30307 • 877-805-2899 (Pain Care Labs Responsible Party in USA.)

Directions For Use:

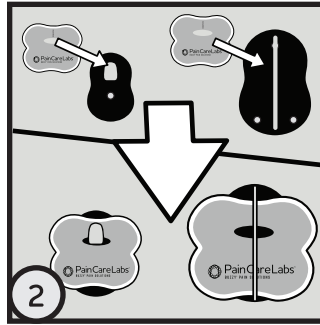


Place wings in freezer.

Store Ice Packs in freezer or freeze for approximately one hour until solid. Remove just prior to use. Ice Packs will stay frozen for approximately 15 minutes at room temperature and 5 minutes against skin. (Do not freeze vibration unit). Ice Packs will refreeze solid in approximately 30-60 minutes. Wings fit with the hole placed horizontally on the hook, or

horizontally under the silicone band. **Do not orient hole/wings vertically as the hole will rip/band may snap.** Buzzy® Healthcare Ice Packs are the same intensity on both sides. If single patient ice packs (sold separately) are used, face the blue or smooth side of the Single Patient Ice Pack toward the skin for more numbing power. If the patient is sensitive to cold, face the soft side of the Ice Pack against the skin. **Tip:** For icing larger areas, prepare additional Ice Packs (sold separately). Ice Packs do not contain Ethylene Glycol ("anti-freeze"). Gel inside ice may deteriorate if not stored properly and will dehydrate over time or in dry climates. **Note:** To transport, place between two commercial cold packs or Cold2Go Bag (sold separately) to maintain frozen temperature.

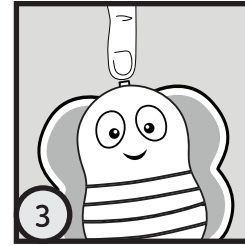
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Attach wings to back of Buzzy® Healthcare.

Why Frozen?

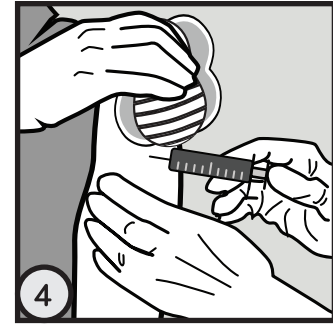
For best effect, the Ice Packs must be frozen solid to transmit vibration at the effective frequency and strength. Commercial gels absorb the specific frequency needed for pain. Ice provides up to 60% of the numbing because cold causes the brain to inhibit pain everywhere.



Flip switch or press button firmly to activate. 

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Buzzy® Placement:



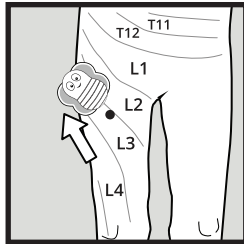
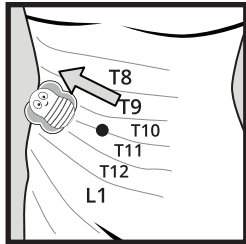
Buzzy® Healthcare controls pain on contact.

Place directly on injury or "between the brain and the pain" of needle procedures.

For Injections:

Place Buzzy® Healthcare directly on the injection site for 30-120 seconds. Leave on longer for larger volumes or more painful injections. Activate vibration toggle switch. Leave in place 30-120 seconds. During the injection, move Buzzy® Healthcare proximally so the dot is 2-3 cm proximal (closer to the head) to the injection site in the same dermatome as the injection.

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Place Buzzy®'s bigger rounded end as close as possible to the site of the procedure, with Buzzy®'s switch end furthest away. During the injection, move Buzzy® 2-3 cm toward the spine along nerve paths (dermatomes) as shown.

Why Does Placement Matter?

Vibration and cold are transmitted together to the same place in the spine as pain. To block pain, Buzzy® needs to be on the same nerve paths as the source of the pain.

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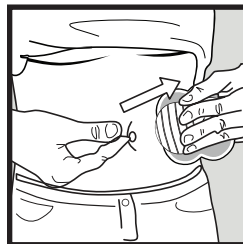


For finger sticks or splinter removal:

Press Buzzy® Healthcare onto the palm with the bottom end toward the finger. Activate vibration toggle switch. Leave in place throughout cleaning and during the procedure.

For dental procedures:

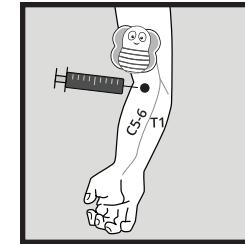
Press Buzzy® against the mandible or maxilla of the injection side, close to the ear. Activate vibration toggle switch.



For injections in the stomach:

Place the Buzzy® Healthcare on the surface of the abdomen on a horizontal line from the belly button to the side of the body. Activate vibration toggle switch. Place the injection (proximal to the Buzzy®) on a horizontal line between the belly button.

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For IVs or phlebotomy:

Do not put directly on the site of access.

Activate vibration toggle switch. Hold or tuck Buzzy® Healthcare under the tourniquet 2-3 cm above (proximal to) the access site. Clean the site and access without delay.

Optional: Pass tourniquet through the slot of Buzzy® Healthcare to secure Buzzy® Healthcare to arm.

For additional placement information, please visit: bzy.fyi

For children:

Let children hold Buzzy® Healthcare in advance for familiarity and let them choose whether or not to use the ice pack. For vaccinating children sitting up, a parent can put an arm around the child's shoulders and hold Buzzy® Healthcare for them.

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