## "SdedareLabs"

04.24.2023

IFU-002 Rev 02 Buzzy® Personal Instructions for Use

BKM1' BKM5' BKM3' BKL1' BKL5' BKL3 Buzzy® Personal (Striped, Black, and LadyBuzz) For Buzzy® Mini Personal (Striped, Black, and LadyBuzz) and

#### PainCareLabs.com

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

broximal to the procedure area to reduce pain or distress from: operator. Buzzy® Personal is applied for up to 2 minutes directly or a single user or in home healthcare environments by a lay Personal) is a personal consumer product intended to be used by Buzzy® Personal (Model Names: Buzzy® Mini Personal, Buzzy® XL



| Indications For Use                   |
|---------------------------------------|
| Warnings, Contraindications, Cautions |
| Buzzy® Personal Includes              |
| Directions For Use                    |
| Ice Packs                             |
| For Injections                        |
| Buzzy® Placement                      |
| Finger Sticks, Splinters              |
| Stomach Injections                    |
| Burning, Itching                      |
| IVs & Phlebotomy, For children        |
| Maintenance, Ordering, Guarantee      |
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#### 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

Dublin 7, D07 P4AX, Ireland EC REP The Black Church, St. Mary's Place CS Lifesciences Europe Limited



6682.208.778

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return instructions.

distributor in the country where the device was purchased for Buyer must contact Customer Service or the authorized Warranty is void if used by clinicians in a healthcare setting. may also have other rights which vary from state to state. versions. This warranty gives you specific legal rights, and you the right to upgrade or replace parts with the latest product replace your product or retund your purchase and reserves backs lasts 6 months from date of purchase. The company will product for 6 months. The warranty for soft goods and Ice may appear or arise from normal use in the motor unit of the The Company covers every type of malfunction or defect that

## Warranty:

stimulation, replace batteries.

frequently. If device stops working or has weak mechanical fluctuations, batteries may need to be replaced more at least 6 months. With heavy use or extreme temperature With proper care, your Buzzy® Personal motor unit will last for

## I roubleshooting:

Buzzy® contains a durable therapeutic vibration motor unit device. Ice packs and straps are personal consumer products intended to be used by a single user

#### 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 • 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 wings in a cool, dry place. • Ice Packs must be frozen solid for best effect. - Do not use dry ice to freeze Ice 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.

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

#### DO NOT SERVICE WHILE IN USE

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

#### :aagueseng

accessories, and replacement parts.

ot FAQ's, other pain management tips, how-to videos, Please visit our website PainCareLabs.com for a complete list

## How To Order/Additional Information:

sterilization for use.

autoclave or immerse. This device does not require or chlorhexidine, or a hospital-grade sanitizing wipe. Do not solution. To disinfect, wipe all exposed surfaces with alcohol exposed surfaces with a soft cloth dampened with a mild soap orientation shown inside the device. Gently wipe clean all screwdriver and open back panel, placing batteries in the To replace AAA batteries, unscrew using a Phillips-head switch moves freely. Make sure external screw(s) are secure. visible evidence of damage such as cracks. Ensure that the be used by a single user. Check the entire device for any Buzzy® Personal is a personal consumer product intended to

### Maintenance:

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## Buzzy® Personal Includes:

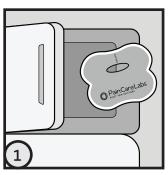
All Buzzy® Personal kits include a vibration unit with 2 AAA batteries (installed) and instructions. All accessories are latex free and reusable.

Buzzy® Mini Personal includes an M-Stim® vibration unit with button switch & energy saving automatic 3-minute shut-off, two reusable Ice Packs. Press and hold button firmly until vibration activates.

Buzzy® Personal includes an M-Stim® vibration unit with toggle switch, two reusable Ice Packs, and a hands-free strap.

- 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 are not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment."
- 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:**



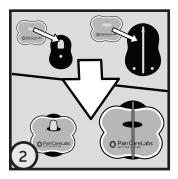
## Fold & place Ice Packs in freezer.

Remove just prior to use. (Do not freeze vibration unit). Gel inside ice may deteriorate if not stored properly and will dehydrate over time or in dry climates. Ice Packs will refreeze solid in approximately 30-60 minutes. Ice Packs do not contain Ethylene Glycol ("anti-freeze").

Ice Packs will stay frozen for approximately 10 minutes at room temperature and 5 minutes against skin. Buzzy® Ice Packs are reversible. Face the blue or smooth side of the Ice Pack toward the skin for more numbing power. If sensitive to cold, face the white or soft side of the Ice Pack against the skin.

Why Frozen? For best effect, the Ice Packs must be frozen solid to transmit vibration at the effective frequency and strength. Intense cold causes the brain to inhibit pain everywhere.

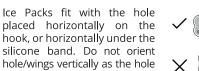
**Tip:** For icing larger areas, prepare additional Ice Packs (sold separately).



Attach Ice Packs to back of Buzzy® Personal.

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Activate vibration switch or press button firmly.







Opinional O

will rip/band may snap.

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## Buzzy® Placement:



Buzzy® Personal controls pain on contact.

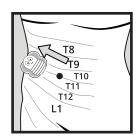
Place directly on injury or "between the brain and the pain" of needle procedures.

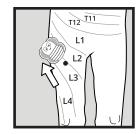
# Dot

## For Injections:

Activate vibration toggle switch. Place Buzzy® Personal directly on the injection site for 30-120 seconds. Leave on longer for larger volumes or more painful injections. During injection, move Buzzy® Personal 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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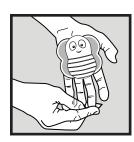


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Place the dot (located at the bigger rounded end) as close as possible to the site of the procedure, with Buzzy's switch end farthest away. During the injection, move Buzzy® 2-3 cm toward the spine along nerve pathways/zones (dermatomes) as shown. **Note:** To transport, place Ice Packs between two commercial cold packs or Cold2Go Bag (sold separately) to maintain frozen temperature.

#### 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.



For additional placement information, please visit: PainCareLabs.com/Buzzy



## For finger sticks or splinter removal:

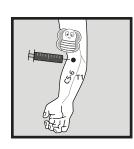
Press Buzzy® onto the palm with the bottom end toward the finger. Activate vibration. Leave in place throughout cleaning and during the procedure.

## For stinging or itching sensations:

Place Buzzy® directly on the site. Activate vibration. Rub or press in place until the area feels better.

### For stomach injections:

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



### For IVs or phlebotomy:

Do not put directly on the site of access to avoid vasoconstriction.

Activate vibration toggle switch. Hold or tuck Buzzy® Personal 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® Personal to secure Buzzy® Personal to arm. For instances where pain is anticipated to be ongoing (e.g., infusion of painful medication), Buzzy® may be left in place to block the pain. In most cases, when the IV access is completed, the clinician will remove the tourniquet and device. Hold the vibration unit to prevent the unit from falling.

#### For Children:

Let children hold Buzzy® 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® Personal for them.

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