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IFU-002 Rev 01 Buzzy® Personal Instructions for Use

BKMJ, BKM2, BKM3, BKT1, BKT2, BKT3 Buzzy® Personal (Striped, Black, and LadyBuzz) and PadyBuzz)

PainCareLabs.com

- Temporary relief of itching, splinter and bee sting removal
 - Orthopedic injections or local procedures
 - painful

 Dental injections or procedures
- Acute pain from needles, injections, or dialysis cannulation
 Cosmetic injections or local procedures expected to be

brocedures for:

Buzzy® is a personal consumer product intended to be used by a single user or in home healthcare environments by a lay operator. Buzzy® is applied for up to 2 minutes proximal to the procedure to reduce pain or distress from



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

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MM Labs, LLC dba Pain Care Labs (MM) Labs, LLC dba Pain Care Labs, U.S.A. 195 Arizona Ave NE LW8 • Atlanta, GA 30307, U.S.A. PainCareLabs.com • info@PainCareLabs.com

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 6 months. The warranty for soft goods and ice packs lasts 6 months from date of purchase. The company will the right to upgrade or refund your purchase and reserves the right to upgrade or refund your purchase and reserves wersions. This warranty gives you specific legal rights, and you way also have other rights which vary from state to state. Warranty is void if used by clinicians in a healthcare setting.

Warranty:

atteries.

With proper care, your Buzzy® motor unit will last for at least 6 months. 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

Lroubleshooting:

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:

Controls pain associated with injections (venipuncture, IV starts, cosmetic procedures) and the temporary relief of minor injuries (muscle or tendon aches, splinters, and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension.

Warnings:

For intended use only • Direct or prolonged application of ice could vasoconstrict or alter lab values.

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.

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

DO NOT SERVICE WHILE IN USE

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

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accessories, and replacement parts.

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

How To Order/Additional Information:

sterilization for use.

Buzzy® is a personal consumer product intended to be used by a single user. 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 a Phillips-head screwdriver and open back panel, placing batteries in the crewdriver 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 autoclave or immerse. This device does not require

Maintenance:

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Buzzy® Personal Includes:

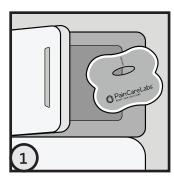
All Buzzy® kits include a vibration unit with 2 AAA batteries (installed) and instructions. All accessories are latex free and reusable.

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

Buzzy® Mini Personal includes a vibration unit with button switch and energy saving automatic 3-minute shut-off, two reusable Ice Packs, and a hands free strap. Press and hold button firmly until vibration activates.

- 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.
- "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."
- 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.
- Pain Care Labs, 195 Arizona Ave. LW08 NE Atlanta GA 30307 877-805-2899 (Pain Care Labs Responsible Party in USA.)

Directions For Use:

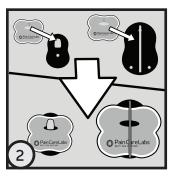


Fold & place Ice Packs in freezer.

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"). (For optimal battery life, do not freeze vibration unit).

Ice Packs will stay frozen for approximately 15 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 soft side of the Ice Pack against the skin.

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



Attach Ice Packs to back of Buzzy®.

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Activate vibration switch or press button firmly. Leave in place 30-120 seconds.

Why Frozen?

For best effect, the Ice Packs must be frozen solid to transmit vibration at the effective frequency and strength. For injections, ice provides up to 60% of the numbing, because intense cold causes the brain to inhibit pain everywhere.

Buzzy® Placement:



Buzzy[®] controls pain on contact.

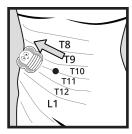
Place directly on injury or "between the brain and the pain" for procedures.



For Injections:

Place Buzzy® with ice directly on the injection site. Activate vibration. Leave in place at least 30 seconds. Larger volumes or more painful injections may require up to 120 seconds. During injection, move Buzzy® 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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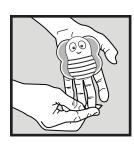


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Place the dot (located at the bigger rounded end) as close as possible to the site of the procedure, with Buzzy's switch end farthest away. During the injection, move Buzzy® 2-3 cm toward the spine along nerve pathways/zones (dermatomes) as shown. Tip: To transport, place in Cold2Go bag, or between 2 commercial cold packs (sold separately). An insulated environment will help 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:

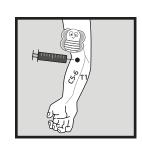
Press Buzzy® onto the palm with the bottom end toward the finger. Activate vibration. Leave in place throughout cleaning and during the procedure.

For burning or itching:

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®) on a horizontal line between the belly button.



For IVs or phlebotomy:

Do not put directly on the site of access.

Activate, then hold or tuck Buzzy® under the tourniquet 3-5 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® 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® for them.

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