"sde_SainCareLabs"

For Buzzy® Mini Personal (Striped, Black, and LadyBuzz) and LBU-002 Rev 00 Buzzy Personal Instructions for Use IFU-002 Rev 00 Buzzy Personal Instructions for Use

BuzzyHelps.com

 ${\tt Buzzy}^{\circledast}$ is a personal consumer use product intended to be used by a single user. For use in home healthcare environment by lay operator.

Bring to the doctor or use at home for splinters, shots, stings, and more.



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★ Type BF 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 Authorized European Representative MPC International S.A. 26, Boulevard Royal • L-2449 Luxembourg Tel. +352 22 99 99 5546 | www.mpc.cc

2.2 Sutherland Place • Atlanta, GA 30307, U.S buszyhelps.com • info@paincarelabs.com 877.805.2899

322 Sutherland Place • Atlanta, GA 30307, U.S.A.

Previous medical history and intrinsic physiologic differences may make Buzzy® less effective for some people. If not completely satisfied, return within 30 days to place of purchase for a full refund, or contact us at the address below.

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Please visit our website buzzyhelps.com for a complete list of FAQ's, other pain management tips, how-to videos, accessories, replacement parts, and more!

How To Order/Additional Information:

second to activate or turn off.

With proper care, your Buzzy® should 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, replace batteries. Press switch firmly for 1/2

Iroubleshooting:

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

DO NOT SERVICE WHILE IN USE

accessories.

Please contact your local authorities to determine the proper method of disposal of potentially biohazardous parts and

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period of time.

Unscrew the back using a Phillips-head screwdriver to remove back panel. Buzzy® is powered by 2 alkaline AAA batteries. Remove batteries if Buzzy® is not being used for extended

Batteries:

Buzzy® is a personal consumer product intended to be used by a single user. Buzzy® may be cleaned with alcohol based sanitation wipes. Do not autoclave. Do not immerse in liquid. Soiled wings should be disposed of and replaced.

Cleaning:

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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. • Wings must be frozen solid for best effect. • Do not use dry ice to freeze wings 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.

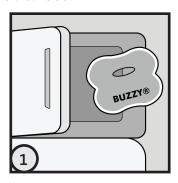
Model Differences:

Buzzy® Mini: Comes with Buzzy® vibration unit with button switch and energy saving automatic 3-minute shut-off, two reusable ice wings and instructions. Press and hold button firmly until vibration activates.

Buzzy® XL: Comes with Buzzy® vibration unit with toggle switch, two reusable ice wings, a hands free strap, and instructions. Keep the tape on the switch during transport to avoid accidental activation. Activate with the on/off toggle switch. o

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

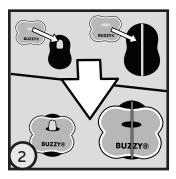
Directions For Use:



Place wings in freezer.

(Do not freeze vibration unit). Leave in until frozen solid (~30-60 minutes). Remove wings from freezer just prior to use. Wings stay frozen for ~10 minutes at room temp.

Note: To transport, place between 2 commercial cold packs (sold separately) in an insulated environment to maintain frozen temperature.



Attach wings to back of Buzzy®.

Flip switch or press button firmly to activate.

Why Frozen?

Our unique formula freezes solid to transmit vibration; commercial gels absorb the specific vibration frequency needed for pain. Ice provides 60% of the numbing, because intense cold causes the brain to inhibit pain everywhere.



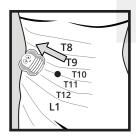


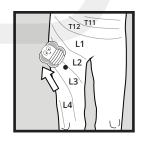
Buzzy® controls pain on contact.

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

For Injections:

Place Buzzy® directly on the injection site for 30-120 seconds. Leave on longer for larger volumes or more painful injections. Move 2-3 cm proximal during injection and press in place. Closer to the injection is better.



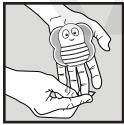


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TIP: Place Buzzy®'s bigger rounded end as close as possible to the site of the procedure, with Buzzy®'s switch end furthest away. During the injection, move Buzzy® 2-3 cm toward the spine along nerve paths (dermatomes) as shown.

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.





For burning or itching:

throughout cleaning

during the procedure.

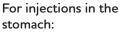
Press Buzzy® onto the palm with the bottom end toward

the finger. Leave in place

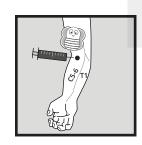
For finger sticks or

splinter removal:

For insect bites or medications that cause burning or itching, put Buzzy[®] directly on the site. Rub or press in place until the area feels better.



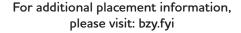
Place the injection on a horizontal line between the belly button and Buzzy®.



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 site and access without delay. Optional: Pass tourniquet through the slot of Buzzy® XL to secure Buzzy® to arm.



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.