

How to Use **Buzzy® Pro**

B7P



IFU-005 Rev 01 06-30-2023

Table of Contents

Device Description:	······································	1
Buzzy® Pro Includes:	······································	1
Indications For Use:		2
Warnings:		2
Contraindications:		2
Cautions:		3
Maintenance:		3
Buzzy® Pro Preparation	n For Use: 4	4
How to use Buzzy® Pro	o for Dialysis:	4
How to use Buzzy® Pro	for Extremity	
Injections:		5
How to use Buzzy® Pro	For IV Access,	
Blood Donation, etc	:::	6
How to use Buzzy® Pro	for	
Cosmetic Injections	:6	6
Troubleshooting:		8
Environmental condition	ons:8	8
How To Order/Addition	nal Information: 10	C
Warranty:	10	C
Returning the device for	or service: 10	C
Guarantee:	1 ⁻	1

PainCareLabs.com • info@paincarelabs.com +1.877.805.2899

Device Description:

Buzzy® Pro is a reusable device to control needle pain or sharp procedural pain by direct application of focal mechanical vibration with or without cold. Buzzy® Pro is applied for up to 2 minutes directly or proximal to the procedure area 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 stinger removal

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

Buzzy® Pro Includes:

- All Buzzy® Pro kits include a motor unit with 2 AAA batteries (installed) and instructions. All accessories are latex free and reusable. An indentation "dot" marks the site of maximum vibration.
- Five 1-chamber Ice Packs.
- Two sample hands-free starter straps
- 2mm Allen Wrench for battery replacement

Note: To transport, place Ice Packs between two commercial cold packs (sold separately) to maintain frozen temperature.

Indications For Use:

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:

This device should not be used over broken skin or skin eruptions. • Do not use in the presence of unexplained calf pain. Consult a physician. • 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, CRPS).

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.

Maintenance:

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 a 2mm Allen wrench (included) 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 hospitalgrade sanitizing wipe. Do not autoclave or immerse. This device does not require sterilization for use.

Buzzy® Pro Preparation For Use:

Store Ice Packs in freezer or freeze for approximately one hour until solid. Remove just prior to use.

Ice Packs:

Ice Packs will stay frozen for approximately 15 minutes at room temperature and 5 minutes against skin. For best effect, the Ice Packs must be frozen solid to transmit vibration at the effective frequency and strength.

Buzzy® Pro 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 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.

How to use Buzzy® Pro for Dialysis:

- 1. Thread hands-free strap or tourniquet through the ice pack and Buzzy® Pro so that the ice pack is on the concave side of the device.
- 2. Attach the device and the

- ice directly over the site, with the switch toward the patient's head.
- 3. Activate vibration toggle switch. Leave in place 30-120 seconds.

During cannulation, move Buzzy Pro proximally so the dot on the side opposite the switch is 2-3 cm proximal to the cannulation site. Clean site per cannulation protocol, remove after painful part of procedure is completed.



How to use Buzzy® Pro for Extremity Injections:

- Thread hands-free strap or regular tourniquet through the ice pack and Buzzy® Pro so that the ice pack is on the concave side of the device.
- 2. Hold or attach the device and the ice with tourniquet directly on the site to be injected.
- 3. Activate vibration toggle switch.
- 4. Leave in place 30-120 seconds.
- 5. During injection, move Buzzy® Pro proximally 2-3 cm proximal (closer to the







regular

- head) to the injection site in the same dermatome as the injection.
- 6. Dermatomes in the lower extremity come from the lower spine and curve anteriorly around the leg and thigh.
- 7. Clean injection site per protocol.

How to use Buzzy® Pro For IV Access, Blood Donation, etc.:

- 1. Thread hands-free strap or regular tourniquet through the ice pack and Buzzy® Pro so that the ice pack is on the concave side of the device. Buzzy Pro may also be used effectively without ice for venipuncture, lab draws, or other superficial venous procedures.
- 2. Do not put directly on the site of access. Attach Buzzy Pro so the dot is 2-3 cm proximal to the access site with the switch toward the patient's head and the lower side with the



- concave dot toward the procedure. 3. Activate vibration toggle switch.
- 4. Clean site per cannulation protocol.

How to use Buzzy® Pro for Cosmetic Injections:

1. Thread hands-free strap or regular tourniquet through the ice pack and

- Buzzy® Pro so that the ice pack is on the CONVEX side of the device.
- 2. Activate vibration toggle switch.
- 3. With the tourniquet holding the ice in place, press directly on the site of the procedure for 30 - 60 seconds.
- 4. For less painful procedures, or after area is pre-numbed, hold Buzzy Pro so the dot is 2-3 cm proximal to the procedure site with concave dot toward the procedure. For areas where multiple

nerves overlap (e.g. S2,3,4) placing on a bony prominence may give greater pain relief.

5. Clean site per protocol.

For Scalp/Neck Injections:

Allow patient to press directly on neck, near the base or on location of muscle to be injected. After area is pre-numbed, guide patient's hand or have an assistant press Buzzy Pro against the skull anywhere in a 5 cm proximity of the injections on the same half of the head. Vibration transmits strongly through solids, so injections on or near the skull do not require the same proximity as for soft tissue. DO NOT attempt to wrap hands-free strap around neck.

For Oral/Dental Injections:
Position the device
against the maxilla or
mandible, lateral to
the injection site with
the dot closer to the
injection and the switch



injection and the switch oriented to the ear (where nerves come out).

Troubleshooting:

With proper care, your Buzzy® Pro motor unit will last for at least 3 years. 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.

DO NOT SERVICE WHILE IN USE

Environmental conditions:

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

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

US Patented; British Patent No. 2455695

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

 this device may not cause harmful interference, and
 this device must accept any interference received, including interference that may cause undesired operation.
- Please note that changes or modifications of this product that 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 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 Atlanta GA 30307 • 877-805-2899 (Pain Care Labs Responsible Party in USA.)

How To Order/Additional Information:

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

Warranty:

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 3 years. The warranty for soft goods and ice packs lasts 1 year from date of purchase. Heat packs are warrantied for 5 boil-cool-reuse cycles. 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.

Returning the device for service:

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

Guarantee:

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

MMJ Labs, LLC dba Pain Care Labs 195 Arizona Ave LW08 • Atlanta, GA 30307, U.S.A.

PainCareLabs.com • info@paincarelabs.com +1.877.805.2899

EC REP

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

10

11