Department of Health & Social Care

NHS

The PAQ is endorsed by NHS Business Services Authority (NHSBSA), NHS Supply Chain (NHSSC), Health Care Supply Association (HCSA), Association of British Healthcare Industries (ABHI), and Association of Healthcare Technology Providers for Imaging, Radiotherapy & Care (AXREM).

PRE-ACQUISITION QUESTIONNAIRE (PAQ Form)

The purpose of this Form is to provide information to a NHS organisation about a Medical Device(s) which the NHS organisation shall then use to inform its pre-acquisition planning and approval of proposals to procure such Medical Device(s) – whether by purchase, exchange, rental, lease, loan, donation or other agreement.
(Note: The term 'Device' as used here includes equipment, systems and accessories. In the case of systems the requirements below apply both to the individual constituent Devices and to the configured system as a whole. Accessories within the scope of this Form need to be identified under 1(d).)

Please ensure that all relevant sections have been completed and that all supplementary information requested has been provided, (shaded boxes ☐ indicate that supplementary information is required); questions for which the only available response is 'YES' indicate that this response is a requirement, if the question applies.

PART I - PRODUCT INFORMATION

to be completed by the device Manufacturer or Authorised Representative

PRODUCT DETAILS:

UDI Device Identifier: (GS1-GTIN)		See attachment
Device Description: (GMDN Code / Group if available)		See attachment
Type:	Make:	n/a
	Model:	n/a
Manufacturer:		MMJ Labs, LLC dba Pain Care Labs
Supplier:		**Rebecca Woodland**
EU Authorised Representative:		**Compliance Solutions (Lifesciences) Ltd**

1 a) When was this Model first placed upon the market ? **May 2009**

b) Is this Model still in production ? NO ☐ YES ☒ if NO, when did production cease ?

c) Does this Form cover a range of Model variants ? NO ☐ YES ☒ if YES, list of Models attached to this Form ? YES ☒

d) Does this Form cover Accessories ? NO ☐ YES ☒ if YES, list of Accessories attached to this Form ? YES ☒

e) Has a Device brochure and specification been attached to this Form ? YES ☒

REGULATORY COMPLIANCE:

2 a) Is the Device CE-marked, for its intended use, to all currently applicable EC Directives ? NO ☐ YES ☒

b) - if YES, have the EC Declaration/s of Conformity been attached to this Form ? YES ☒

c) Which EC Directive/s apply ?

Medical Devices Directive ☒ Classification? 1 ← (1, 1-m, 1-s / IIa / IIb / III)

Active Implantable Devices Directive ☐

In-Vitro Diagnostics Medical Device Directive ☐ Category? ← (general / self-test / List-A / List-B)

Other/s ☐

- which Directive/s?

c) Has this included Notified Body conformity assessment ? NO ☒ YES ☐

- Notified Body identification number & name:

d) Is the manufacturer currently certified to any management / quality system Standards ? NO ☐ YES ☒

- which Standard/s ? **ISO 13485:2016 MDSAP** ← (eg: EN-ISO-9001, 13485, 14001, etc.)

- Certification Body: SAI Global

3 If not CE-marked, (or if 'off-label' use is proposed for a CE-marked Device), then -

a) Is this a Medical Device for 'Clinical Investigation' ? NO ☒ YES ☐

- if YES, quote the MHRA 'no objection' reference

- if YES, has a copy of the MHRA's notice of 'no objection' been attached to this Form ? YES ☐

b) Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation' ? NO ☒ YES ☐

- if YES, has a copy of notification to MHRA been attached ? YES ☐

c) Is this a 'custom-made' Medical Device ? NO ☒ YES ☐

- if YES, name the prescribing Medical Practitioner:

d) - if NO to 2(a), and to 3(a) (b) and (c), then provide justification of the Device's status (e.g.: MHRA-approved humanitarian grounds)-

PRODUCT COMMITMENT:

4 a) To what date is manufacturer support for this Model guaranteed ? **12/31/2022**
- does this include availability of parts and supply of consumables / accessories ? YES ☒
- does this include product support, as detailed below, (training, maintenance, repair, etc.) ? YES ☒

b) What is the Device warranty period? **12 months** Have warranty details been attached to this Form ? YES ☒

c) What is the recommended working lifetime for this Device? **n/a** ← ('not applicable' for disposable Devices)

d) Have details for end-of-life waste management of the Device been attached to this Form ? YES ☒

e) Does the manufacturer / supplier have a robust system for notification of Device alerts / upgrades to a named hospital representative ? YES ☒

PRODUCT SUPPORT:

5 a) Can an additional User Manual be provided (electronic format) ? YES ☒

b) Can a Technical Manual be provided (electronic format) ? NO ☐ YES ☒

c) Is identical loan equipment normally available in the event of equipment failure ? NO ☒ YES ☐

(Any conditions or costs associated with 5(b) or 5(c) should be included in the response to 7(b))

Commissioning & Deployment

6 a) Has a protocol for post-delivery inspection and acceptance testing of Device function and safety been attached to this Form ? YES ☒

b) Does the Device have particular installation requirements and / or require ancillary services or other prerequisite arrangements ? NO ☒ YES ☐

- if YES, then have details of all installation requirements been attached to this Form ? YES ☐

Technical Support

7 a) Is this a disposable non-serviceable device ? (- if YES, proceed to Section 8) YES ☒

b) Does the manufacturer or an authorised servicing agent provide a maintenance / repair and technical support service ? NO ☒ YES ☐

- if YES, then have details of all service contract options been detailed, fully costed and attached to this Form ? YES ☐
- where is the servicing facility located ?
- are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform ? YES ☐
- are qualification / competency records of servicing staff available upon request ? YES ☐

c) Is the servicing organisation currently certified to any management system Standards ? NO ☒ YES ☐

- which Standard/s ? ← (eg: EN-ISO-9001, 13485, 17025, etc.)
- Certification Body:

d) Do the contract alternatives offered in 7(b) include an option for in-house equipment servicing by hospital staff ? NO ☒ YES ☐

- if YES, have details of the availability of spare / replacement parts to support equipment servicing been attached to this Form ? YES ☐
- if YES, have details of information / test equipment / tooling / software required for equipment servicing been attached to this Form ? YES ☐

Decontamination

8 a) What level of Device decontamination is required ? - (for multi-component systems identify all applicable levels)

☐ none ☐ cleaning ☒ disinfection ☐ sterilisation

- if answer is not 'none', have validated decontamination instructions been attached to this Form? YES ☒
- for sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ? YES ☐

b) Does the device require processing / reprocessing before / between uses ? NO ☐ YES ☒

- if YES, have all decontamination process requirements for special equipment, tools and materials been detailed in attached information ? YES ☒
- if YES, have any special post-processing Device storage requirements been detailed in the attached information ? YES ☒
- is there a limit to the number of Device reprocessing cycles ? NO ☒ YES ☐ if YES, what is the limit ?
- are Devices uniquely identifiable ? NO ☐ YES ☒ ↑ state if 'Single-Use'
- is this an implantable Device ? NO ☒ YES ☐

Data Security

9 a) Does the Device store or transmit patient information that will require information governance measures ? NO ☒ YES ☐

- if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this Form ? YES ☐

b) Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems ? NO ☒ YES ☐

- if YES, then have details of Device IT software / hardware compatibility requirements been attached to this Form ? YES ☐
- if YES, then have details of provisions made for Device IT cybersecurity been attached to this Form ? YES ☐

Particular Requirements

10 a) Does the Device present particular hazards that require special safety management measures ? NO ☒ YES ☐

(eg: ionising / non-ionising radiation; contamination / infection; hazardous materials; hazardous mechanical / electrical energy; etc.)

- identified hazards:

- if YES, then have details of the nature of identified hazards been attached to this Form ? YES ☐

b) Does the Device require particular performance quality assurance measures ? (eg: calibration, qualification, PoCT controls, etc.) NO ☒ YES ☐

- QA measures:

- if YES, then have details of quality assurance requirements been attached to this Form ? YES ☐

IMPLEMENTATION SUPPORT:

11 a) Is competency-based user training available from the manufacturer or an authorised provider ? NO ☒ YES ☐

- if YES, have details of user training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES ☐

b) Is competency-based technical (equipment servicing) training available from the manufacturer or an authorised provider ? NO ☒ YES ☐

- if YES, have details of technical training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES ☐

c) Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider ? NO ☒ YES ☐

- if YES, have details of decontamination training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES ☐

d) Are qualification / competency records of training providers available upon request ? YES ☒

e) If other additional support facilities are available, (eg: helpdesk, literature, website resources, etc.), have details of these been attached ? YES ☒

DECLARATION:

Please ensure that all necessary supplementary information, (as indicated by shaded boxes ☐ in the Form above) accompanies this Form.

1.c)	List of all Model variants covered by this Form	ATTACHED ☒	NOT APPLICABLE ☐
1.d)	List of all Accessories covered by this Form	ATTACHED ☒	NOT APPLICABLE ☐
1.e)	Device brochure / specification	ATTACHED ☒	
2.b)	EC Declaration/s of Conformity	ATTACHED ☒	
3.a)	MHRA's notice of 'no objection' for Medical Device 'Clinical Investigation'	ATTACHED ☐	NOT APPLICABLE ☒
3.b)	Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performance Evaluation'	ATTACHED ☐	NOT APPLICABLE ☒
4.b)	Warranty details	ATTACHED ☒	
4.d)	Details for end-of-life waste management of the Device	ATTACHED ☒	
6.a)	Protocol for post-delivery Device inspection / acceptance testing	ATTACHED ☒	
6.b)	Details of installation requirements	ATTACHED ☐	NOT APPLICABLE ☒
7.b)	Service support contract options for maintenance / repair	ATTACHED ☐	NOT APPLICABLE ☒
7.d)	Availability of spare / replacement parts	ATTACHED ☐	NOT APPLICABLE ☒
	Information / test equipment / tooling / software required for Device servicing	ATTACHED ☐	NOT APPLICABLE ☒
8.a)	Validated decontamination instructions / protocols	ATTACHED ☐	NOT APPLICABLE ☒
8.b)	Requirements for special reprocessing equipment, tools and materials	ATTACHED ☐	NOT APPLICABLE ☒
	Details of special post-processing Device storage requirements	ATTACHED ☐	NOT APPLICABLE ☒
9.a)	Details of patient information capture / encryption / storage / transmission / deletion	ATTACHED ☐	NOT APPLICABLE ☒
9.b)	Details of Device IT software / hardware compatibility requirements	ATTACHED ☐	NOT APPLICABLE ☒
	Details of provisions made for Device IT cybersecurity	ATTACHED ☐	NOT APPLICABLE ☒
10.a)	Details of particular hazards that require special safety management	ATTACHED ☐	NOT APPLICABLE ☒
10.b)	Details of particular performance quality assurance measures required	ATTACHED ☐	NOT APPLICABLE ☒
11.a)	Details of user training offered	ATTACHED ☒	
11.b)	Details of technical training offered	ATTACHED ☐	NOT APPLICABLE ☒
11.c)	Details of decontamination training offered	ATTACHED ☐	NOT APPLICABLE ☒
11.e)	Details of any additional support facilities offered	ATTACHED ☐	NOT APPLICABLE ☒

We agree that the NHS organisation will be entitled to rely upon the contents of this Form and its attachments, and that subsequent non-compliance with the statements contained herein will entitle the NHS organisation to seek redress.

Name:			
Position:			
Company:			
Address:			
Website:			
Email:		Telephone:	
Signature:		Date:	

PAQ Form (Part-I) – Declaration Reference No.: Buzzy

PART II – TRANSACTION DETAILS

for completion by the device Supplier
(eg: Manufacturer, Authorised Representative or other)

Previous sections in PART I provided general product information; this PART II addendum provides details specific to particular transaction/s for supply of the product:-

PRODUCT INFORMATION:

This statement is to be read in conjunction with product information provided in **PAQ FORM (Part-I)** Declaration Reference No.: Buzzy

Dated: 09/09/2021

TRANSACTIONAL:

14 a) On what basis will the product be supplied, (including Devices for clinical investigation / research) ?

purchase ? ☒ exchange ? ☐ rental / lease ? ☐ loan ? ☐ donation ? ☐

b) For supply by loan or donation, other than Devices for clinical investigation / research -

Is the Supplier on the Department of Health & Social Care (DHSC) Master Indemnity Agreement (MIA) Register ? NO ☒ YES ☐

(Note: unregistered Suppliers are advised to register for the MIA Overarching Agreement with the DHSC)

- if YES, has a Department of Health & Social Care (DHSC) MIA Call-Off Agreement Form been attached ? YES ☐

DHSC MIA registration number:

- if NO, has an Indemnity Insurance Certificate (for local indemnity agreement with the customer) been attached ? YES ☐

c) For supply by loan or donation of Devices for clinical investigation / research -

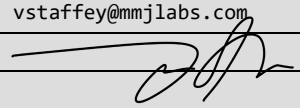
Has confirmation of Health Research Authority (HRA) approval, including indemnity arrangements, been attached ? YES ☐

d) Is the particular item to be supplied a pre-used product ? NO ☒ YES ☐

- if YES, has usage and full service history been attached to this Form ? YES ☐

15 a) Are there any outstanding Field Safety Corrective Actions / Field Safety Notices relating to this product? NO ☒ YES ☐

- if YES, are issued Notices / Alerts attached to this Form ? YES ☐

Name:	Valerie Staffey		
Position:	Global Director of Regulatory		
Company:	MMJ Labs, LLC dba Pain Care Laba		
Address:	195 Arizona Ave LW08		
Email:	vstaffey@mmjlabs.com	Telephone:	18778052899
Signature:		Date:	09/09/2021

Product Trade Name	Product Family	Intended Purpose	GMDN Code	GS1 Barcode / UDI
Buzzy® Mini Personal Striped	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003008,
Buzzy® Mini Personal Plain Black	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003022,
Buzzy® Mini Personal LadyBuzz®	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003350,
Buzzy® Mini Healthcare Striped	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003404,
Buzzy® Mini Healthcare Plain Black	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003428,
Buzzy® Mini Healthcare LadyBuzz®	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003442,
Buzzy® XL Personal Striped	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003411,
Buzzy® XL Personal Plain Black	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003473,
Buzzy® XL Personal LadyBuzz®	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003459,
Buzzy® XL Healthcare Striped	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003503,
Buzzy® XL Healthcare Plain Black	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003435,
Buzzy® XL Healthcare LadyBuzz®	Buzzy®	Therapeutic massager in combination with cold pack to relieve minor aches and pains	36560, 37240	856921003497,
Universal Soft Ice Wings	Buzzy®	Cold pads for pain relief	37240	856921003558,
Universal Healthcare Ice Wings	Buzzy®	Cold pads for pain relief	37240	856921003329,

Warranty Details:

Buzzy Mini Personal – 6 months from date of purchase

Buzzy Mini Healthcare – 12 months from date of purchase

Buzzy XL Personal – 6 months from date of purchase

Buzzy XL Healthcare – 12 months from date of purchase

Ice Wings – 12 months from date of purchase

This declaration is issued under the sole responsibility of MMJ Labs, LLC dba Pain Care Labs.

We, the manufacturer hereby declare that the below-mentioned medical device complies with the relevant provisions of the European Communities' Council Regulation 2017/745/EC in accordance with Annex I, General Safety and Performance Requirements and Annex IX. This declaration is supported by the Quality Management System being in compliance with 2017/745/EC.

All supporting documentation is retained at the premises of the manufacturer.

Manufacturer	MMJ Labs, LLC dba Pain Care Labs 195 Arizona Ave LW0 30307 Atlanta, USA
Product Name	VibraCool® Ice Packs, Universal Healthcare Ice Wings, Universal Soft Ice Wings
Product Trade Name	VibraCool® Ice Packs, Buzzy® Universal Healthcare Ice Wings, Buzzy® Universal Soft Ice Wings
Product Code	Reference schedule
Product Family	VibraCool® and Buzzy®
Intended Purpose	Cold pads for pain relief
SRN (Single Registration Number)	US-MF-000010505
Basic UDI-DI	New info form barcode
GMDN Code	37240
Risk Classification	Class 1 (active, non-measuring, non-sterile) Annex VIII of regulation 2017/745, Rule 13
Sterilization Method	Non-sterile
Conformity Assessment	Article 52, section 7 of the Medical Device Regulation 2017/745/EC Technical Documentation: Annex II and Annex III of regulation 2017/745
Excluded Sections	None
Common Specifications	None
	• EN 1041:2008 (Harmonized Version) • EN ISO 10993-1:2009/AC:2010 (Harmonized Version) • BS EN ISO 10993-1:2020 • ISO 10993-1: 2018

Standards	• EN ISO 10993-5:2009 (Harmonized Version) • EN ISO 10993-10:2013 • EN ISO 15223-1:2012 (Harmonized Version) • ISO 15223-1:2016 • ISO 15223-2:2010 • EN ISO 14971:2012 (Harmonized Version) • ISO 14971:2019 • ASTM F1980-16 • MEDDEV 2.7.1
Authorised Representative	CS Lifesciences Europe Limited The Black Church St. Mary's Place Dublin 7 D07 P4AX Ireland Email: eurep@cslifesciences.com
Notified Body for CE Mark	Not Applicable
EC Certificate for CE Mark	Not Applicable
Quality System Certificate	Not Applicable

Approved on behalf of MMJ Labs, LLC dba Pain Care Labs

Valerie Staffey **Global Director of Regulatory**	
Date, town, and country of signing	**August 26, 2021, Atlanta, United States of America**

Schedule: Product Codes/ Catalogue Numbers

Product Code/Catalogue Number	Description and Size
VC-ICE	VIBRACOOL® ICE PACKS
REP-MBG25	UNIVERSAL HEALTHCARE ICE WINGS 25 PACK
REP-MS100	UNIVERSAL SOFT ICE WINGS 100 PACK

This declaration is issued under the sole responsibility of MMJ Labs, LLC dba Pain Care Labs.

We, the manufacturer hereby declare that the below-mentioned medical device complies with the relevant provisions of the European Communities' Council Regulation 2017/745/EC in accordance with Annex I, General Safety and Performance Requirements and Annex IX. This declaration is supported by the Quality Management System being in compliance with 2017/745/EC.

All supporting documentation is retained at the premises of the manufacturer.

Manufacturer	MMJ Labs, LLC dba Pain Care Labs 195 Arizona Ave LW0 30307 Atlanta, USA
Product Name	Buzzy® and VibraCool®
Product Trade Name	Buzzy® and VibraCool®
Product Code	Reference schedule
Product Family	Buzzy® and VibraCool®
Intended Purpose	Therapeutic Massager combined with Cold Pack used to relieve minor aches and pains.
SRN (Single Registration Number)	US-MF-000010505
Basic UDI-DI	New info form barcode
GMDN Code	36560 37240
Risk Classification	Class 1 (active, non-measuring, non-sterile) Annex VIII of regulation 2017/745, Rule 13
Sterilization Method	Non-sterile
Conformity Assessment	Article 52, section 7 of the Medical Device Regulation 2017/745/EC Technical Documentation: Annex II and Annex III of regulation 2017/745
Excluded Sections	None
Common Specifications	None
	• EN 1041:2008 (Harmonized Version) • EN ISO 10993-1:2009/AC:2010 (Harmonized Version) • BS EN ISO 10993-1:2020 • ISO 10993-1: 2018

Standards	• EN ISO 10993-5:2009 (Harmonized Version) • EN ISO 10993-10:2013 • EN ISO 15223-1:2012 (Harmonized Version) • ISO 15223-1:2016 • ISO 15223-2:2010 • EN ISO 14971:2012 (Harmonized Version) • ISO 14971:2019 • ASTM F1980-16 • MEDDEV 2.7.1
Authorised Representative	CS Lifesciences Europe Limited The Black Church St. Mary's Place Dublin 7 D07 P4AX Ireland Email: eurep@cslifesciences.com
Notified Body for CE Mark	Not Applicable
EC Certificate for CE Mark	Not Applicable
Quality System Certificate	Not Applicable

Approved on behalf of MMJ Labs, LLC dba Pain Care Labs

Valerie Staffey **Global Director of Regulatory**	
Date, town, and country of signing	**August 26th, 2021, Atlanta, United States of America**

Schedule: Product Codes/ Catalogue Numbers

Product Code/Catalogue Number	Description and Size
BKM1	Buzzy® Mini Personal Striped
BKM2	Buzzy® Mini Personal Plain Black
BKM3	Buzzy® Mini Personal LadyBuzz®
BKHM1	Buzzy® Mini Healthcare Striped
BKHM2	Buzzy® Mini Healthcare Plain Black
BKHM3	Buzzy® Mini Healthcare LadyBuzz®
BKT1	Buzzy® XL Personal Striped
BKT2	Buzzy® XL Personal Plain Black
BKT3	Buzzy® XL Personal LadyBuzz®
BTH1	Buzzy® XL Healthcare Striped

BTH2	Buzzy® XL Healthcare Plain Black
BTH3	Buzzy® XL Healthcare LadyBuzz®
VC-Plantar	VIBRACOOL® FOR PLANTAR FASCIITIS
VC-2	VIBRACOOL® FLEX
VC-E	VIBRACOOL® WRIST/ELBOW
VC-K	VIBRACOOL® KNEE/Ankle

100% Biodegradable Packaging
Made from at least 30% post consumer waste

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

Indications For Use:

Controls pain and itch associated with minor aches and pains (e.g. injections, venipuncture, IV starts, lab draws, blood donation, cosmetic procedures) and the temporary relief of minor joint and muscle pain and stiffness (muscle or tendon aches, splinters and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension and increase muscle strength and flexibility with physical therapy.

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, four reusable ice wings and 1 Comfort Strap, and instructions. Press and hold button firmly until vibration activates.

Buzzy® XL: Comes with Buzzy® vibration unit with toggle switch, four reusable ice wings and 2 Comfort Straps, and instructions. Keep the tape on the switch during transport to avoid accidental activation. Activate with the on/off toggle switch. ON OFF

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. 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.)

Troubleshooting:

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 second to activate or turn off.

How To Order/Additional Information:

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!

Guarantee:

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.

MMJ Labs, LLC dba Pain Care Labs
322 Sutherland Place • Atlanta, GA 30307, U.S.A.
buzzyhelps.com • info@paincarelabs.com
877.805.2899

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

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

DO NOT SERVICE WHILE IN USE

Disposal:

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

Batteries:

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 period of time.

Cleaning:

Buzzy® is a reusable medical device that should be thoroughly cleaned and reprocessed following your facility's infection control protocol for non-critical equipment. All accessories must be cleaned and disinfected with your facility's disinfecting wipes or method used to reprocess non-critical equipment such as stethoscopes or patient monitors. Do not autoclave. Do not immerse in liquid.

PainCareLabs™

BuzzyHelps.com

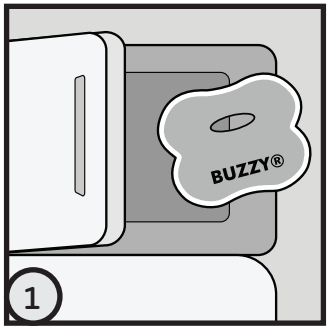
For Buzzy® Mini Healthcare (Striped, Black, and LadyBuzz) and Buzzy® XL Healthcare (Striped, Black, and LadyBuzz)
BKHM1, BKHM2, BKHM3, BTH1, BTH2, BTH3
IFU-001 Rev 00 Buzzy Healthcare Instructions for Use
09.08.2021

Developed by a physician, Buzzy® is a reusable device for minor aches and pains.

Buzzy® Healthcare is for use in a professional healthcare facility by trained operator. Reusable pain relief product intended for multiple users. Thoroughly clean and disinfect Buzzy® and its accessories between patients following your facility's infection control protocol for reprocessing non-critical equipment.

Buzzy® « DRUG FREE PAIN RELIEF »

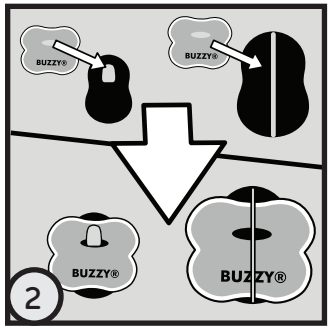
Directions For Use:



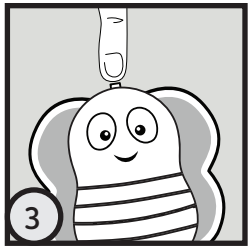
Place wings in freezer.

(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.



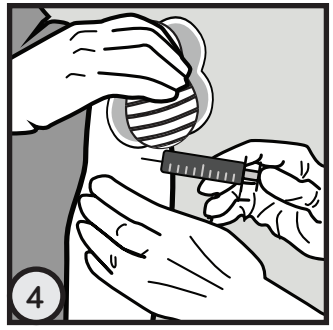
Attach wings to back of Buzzy®.



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 up to 60% of the numbing, because intense cold causes the brain to inhibit pain everywhere.

Buzzy® Placement:

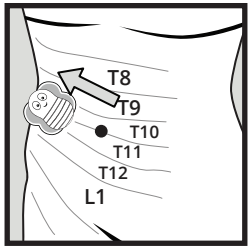


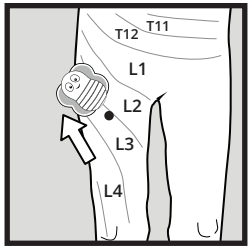
Buzzy® controls pain on contact.

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

For Injections:

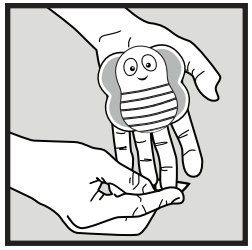
Place Buzzy® directly on the injection site for 30-120 seconds. Leave on longer for larger volumes or more painful injections. Move 2-3 cm proximal during injection and press in place. Closer to the injection is better.





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.

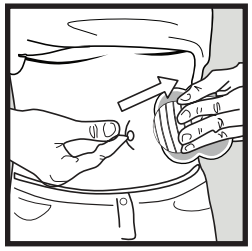


For finger sticks or splinter removal:

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

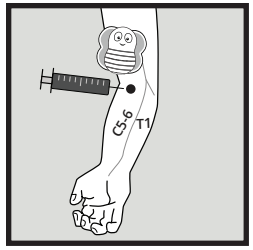
For burning or itching:

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.



For injections in the stomach:

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 additional placement information, please visit: bzy.fyi

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.