Instructions for Use

Fist Assist®

www.fistassistdevices.com

Fist Assist Model FA-1

www.fistassistdevices.com

www.fistassistusa.com

Contents

⚠ Warnings

***Note**:* Failure to observe one or more of the following warnings could compromise safety or result in ineffective therapy.

***Note**:* Review this Instructions for Use (IFU) prior to use. If there are additional questions after reading this IFU, or you suspect the device may not be operating properly, discontinue its use and contact Fist Assist Devices, LLC

- The Fist Assist Model FA-1 device is only to be used by adults only who are capable of applying and removing the device without assistance.

Warning or Safety sign	Consideration of hazards
	Possible hazard the warning/safety sign is intended to avoid and likely consequences that could occur if the advice is not followed
Do Not Dissassemble the Fist Assist Model FA-1 Device.	An improperly re-assembled device might provide no therapy or insufficient therapy

 Fist Assist Devices, LLC recommends that all users who will be operating the Fist Assist Model FA-1, review this Instructions For Use (IFU) prior to use. If there are additional questions after reading this IFU, contact Fist Assist Devices, LLC.	Improper use of the device might provide no therapy or insufficient therapy
 Fist Assist Devices, LLC recommends that all users who will be operating the Fist Assist Model FA-1, review this Instructions For Use (IFU) prior to use. If there are additional questions after reading this IFU, contact Fist Assist Devices, LLC.	Improper use of the device might cause discomfort
 During setup, ensure that the batteries are installed with the proper polarity as indicated in the battery compartment.	Improper installation of the batteries will cause the device to provide no therapy
 The Fist Assist Model FA-1 should not be used adjacent to other equipment. If adjacent use is necessary, the user is to insure proper operation with the adjacent equipment before use.	The unit might make the adjacent equipment malfunction
 Portable and mobile RF communications equipment can	The device might malfunction provide no therapy or insufficient therapy

negatively affect the performance of the Fist Assist Model FA-1	The device might malfunction and operate in such a way as to cause discomfort
 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Model FA-1. Otherwise, degradation of the performance of this equipment could result.	The device might malfunction provide no therapy or insufficient therapy
	The device might malfunction and operate in such a way as to cause discomfort
 Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.	The device might malfunction provide no therapy or insufficient therapy
 Replace the batteries if the low battery indicator is activated (orange colored LED illumination).	The device might provide no therapy or insufficient therapy if the batteries are depleted
 If performance changes are detected during use- stop using the device, remove it from arm, contact customer service at Fistassistdevices.com. There is no risk to non-use during period of device return.	A suspect device might provide no therapy or insufficient therapy
	A suspect device might malfunction and operate in such a way as to cause discomfort

 Do not autoclave, use automated cleaning methods, or immerse the Control Module or Wrap in liquid as damage may occur. If the device's Control Module is exposed to liquids, turn off the unit, remove the batteries, dry the unit thoroughly, and test the device to evaluate for proper operation before reapplying to the arm for use.	A damaged device might provide no therapy or insufficient therapy
 After periods of storage or transport at temperature extremes (within those specified), the device should be allowed to return to normal operating temperature (within those specified) for a duration of 2 hours (when the ambient temperature is 20°C)	A device stored or transported outside of its specified operating environmental conditions might require up to 2 hours to return to operating conditions. A suspect device might provide no therapy or insufficient therapy
 Keep the device dry and away from heaters, steam, children and pets.	The unit might become damaged and provide no therapy or insufficient therapy
 Do not attempt to service the device while it is attached to patient	The user might increase their risk of inadvertent electrical contact
 Rechargeable batteries of type HR6 or any other are NOT APPROVED FOR USE	The device might provide no therapy or insufficient therapy. The device might not perform properly.
 The Device must not be exposed to water or extreme heat	A damaged device might provide no therapy or insufficient therapy

Warning

Do not disassemble the Fist Assist Model FA-1. Refer all servicing to qualified service personnel at FIST ASSIST DEVICES, LLC. No modification of the Fist Assist Model FA-1 device is allowed.

Precautions

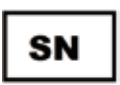
Note: *Precaution statements are used to highlight information relating to special care that should be exercised to ensure the safe and effective use of the Fist Assist Model FA-1.*

- The device shall be applied to the arm gently and fit snugly.
- The device should only be used over full clothing and never on direct skin.
- The biocompatibility of the materials has not been verified by the FDA and contact of the cuffs/accessories to direct skin may lead to skin irritation, skin sensitization and/or cytotoxicity.

- Limit arm movements to ensure best therapy (sit and keep arm still during use).
- Make sure the device is applied as instructed.
- Safety in non-adult users has not been established.
- Do not intentionally get the device wet. If liquid does drip onto the device, dry the Control Module and Wrap immediately.
- There are no known major adverse events associated with Fist Assist Model FA-1.
- If you suspect an allergic reaction, please stop using the device and contact Fist Assist, LLC.

List of Symbols and Abbreviations

	Manufacturer and date of manufacture
	Refer to the Instructions for Use
	Lot number
	Fist Assist Model FA-1 is a Type BF applied part (per IEC 60601-1)
	Temperature limits
	Relative humidity limits
	Keep dry
	MR Unsafe
	General Warning

	Push button that toggles the device between ON and STANDBY (where STANDBY is the OFF mode)
	Batch code of the device
	Serial number of the device

Indications for Use

The Fist Assist Model FA-1 is an arm air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas

Risks and Benefits

The risks and benefits of using the Fist Assist Model FA-1 are similar to having a massage. If the FA-1 device feels uncomfortable, you should stop the session.

Similar to a massage, the benefits include the temporary relief of minor muscle aches and pains. It also temporarily increases circulation in the area being massaged.

System Overview

Description

The Fist Assist Model FA-1 is a wearable, non-sterile, battery operated, intermittent pneumatic compression device. It is composed of two major components that are permanently attached to one another:

1. Control Module- contains the electronics with miniature pump
2. Wrap- made of elastic cloth that holds the Control Module and internal air bladder and uses hook tape for attachment to any part of the Wrap exterior.

The Control Module and Wrap are integral and permanently attached. It is powered by (2) AA batteries (not included with the device packaging).

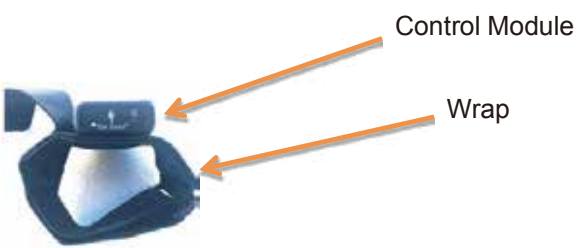
The device is placed on the arm by looping the strap through the elongated ring and bringing the strap back over and toward the Control Module. The strap is tightened so it is just snug to the arm and not too tight. The hook fastener at the end of the strap will then adhere to the exterior Wrap fabric to hold the device on the arm.

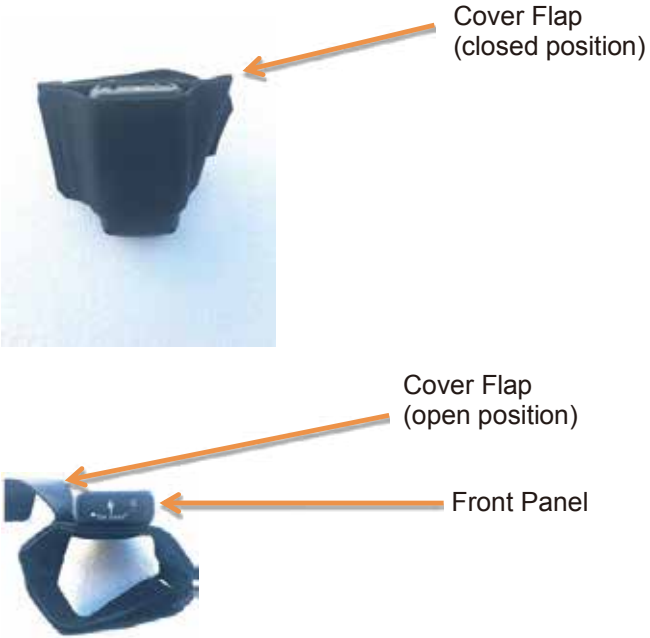
The Fist Assist Model FA-1 has a single operation mode. When powered on by depressing the single

push button switch, it goes through pressure cycles wherein the air bladder inflates to 60 mmHg and is held at that pressure for 20 seconds; the air bladder is then deflated and a minimal pressure is held for 55 seconds until the next inflation to 60 mmHg begins again. The cycle repeats continuously until the power is turned off using the single push button switch. The device will turn off automatically after 1 hour of continuous use.

Components

The following section provides information on the different components of the device.





Front panel view of the Control Module

Set Up, Proper Operation, and Use

⚠ **WARNING**! BEFORE OPERATING THIS DEVICE: read all warnings at the beginning of this information for use. If you do not understand these operating instructions, contact Fist Assist Devices at 1-833-434-5283 with questions.

Step 1: Unpack the Device

Remove the contents from the shipping box and verify the following items are included as shown below: The Wrap and Control Module.

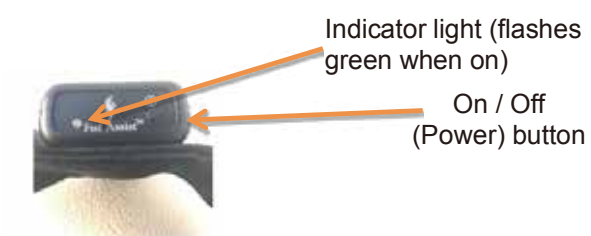
After unpacking the contents, inspect the shipment for any signs of damage or loss. If any damages are discovered, notify the carrier and the supplier, and retain all shipping cartons for examination.

Step 2: Install the Batteries

Open the cover flap. Remove the battery door by lightly pressing on the finger grooves and sliding the door off. Be sure to install alkaline AA batteries with the correct polarity using the + and – signs found inside the Control Module. Re-attach the battery door by sliding it back onto the Control Module until a click is heard. Re-apply the cover flap.

Step 3: Check for Proper Operation

Momentarily depress (for 2 seconds) and release the button on the front panel. Check for pump sound / vibration and that the front indicator blinks green. Turn the device off by momentarily depressing the button again and ensure that the pump stops and the indicator light is off.



Step 4: Use of the Device

a. Apply the device to a clothed arm by sliding the Wrap over the hand and onto the arm with the front panel facing upward so it can be seen and operated by the user. The device should only be used over full clothing and never on direct skin.

b. The Control Module is to be centered over a line that extends from the thumb and up along the arm.

c. Locate the Wrap to just below the elbow or just below the shoulder.

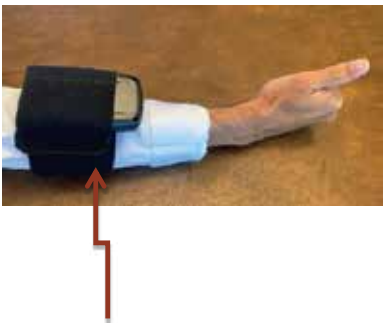
d. Use the hook tape on the end of the strap to adjust the Wrap to be snug (not tight) on the arm.

e. Use the button on the front panel to start and stop device operation as shown in Step 3, above.

f. The device will shut OFF after one (1) hour of continuous therapy. Press the power button to turn the device back ON and continue therapy in accordance with your instructions. Typical daily usage is two (2) hours.

g. After removing the device always check for any irritation. In case of any irritation, discontinue use and contact Fist Assist.

The following photos are to illustrate proper positioning of the device only.



Control Module centered in line with thumb

Positioning the Device

Applied just below the elbow

Note alignment of the Control Module with the thumb

Applied just below the shoulder

Note alignment of the Control Module with the thumb

Indicator LED

The indicator LED flashes approximately once every 2 seconds to indicate that the device is “ON”.

- GREEN flashing LED indicates that the battery has adequate charge remaining for therapy.

- ORANGE flashing LED indicates the battery charge is low and batteries require replacement soon.

Audio Indicator

An audio indicator within the Control Module has two functions:

1. It will emit a single short “beep” when the power button is pressed to either turn the device on or off.
2. The Control Module will emit 3 short beeps when the system shuts down.

Storage and Cleaning

Storage

Keep the device in a safe, dry location using the box that it came in. Make sure the device is off by ensuring that the indicator light is no longer blinking.

If it is anticipated that the device will not be used for several months or longer, remove the batteries from the Control Module. Also ensure the storage location is safe from any liquids that may drip inside the Control Module and damage its internal components.

Cleaning

The Fist Assist Model FA-1 is supplied non-sterile. It is suggested to clean the device once per week. Use only a cloth, dampened with water (no soaps or detergents) to wipe the outside surfaces of the Control Module and Wrap. Allow to dry in air before use. Do not autoclave, and do not use automated cleaning methods, or immerse the Control Module or Wrap in liquid as damage may occur. Never spray cleaning agents or other fluids directly onto the Control Module. The Control Module should be surface cleaned only - do NOT immerse.

If the device's Control Module is exposed to liquids, turn off the unit, remove the batteries, dry the unit thoroughly, and test the device to evaluate for proper operation before reapplying to the arm for use.

Technical Specifications

List of Technical Specifications

The following table lists the technical specifications for the Fist Assist Model FA-1 device:

Item	Specification
Dimensions of Control Module	9.9 CM x 5.6 CM x 2.4 CM (Length x Width x Depth)
Weight including Wrap and batteries	160 g (0.35 lbs.)
Battery	AA alkaline 1.5V (IEC type LR6) (2 Required)
Principle Technology	Pressure Sensor Type: Semiconductor strain gauge pressure transducer
Operational Environmental Limits	Temperature = 5 °C to 40 °C Humidity = 15% to 93% relative humidity, non-condensing Atmospheric pressure = 700 hPa to 1060 hPa

Item	Specification
Transport / Storage Environmental Limits	-25°C to +5°C, and +5°C to +35°C at a relative humidity up to 90% non-condensing >35°C to 70°C at a water vapor pressure up to 50hPa after the device has been removed from its packaging and subsequently between uses
Rated Applied Pressure Range	10 to 60 mmHg
Rated Pressure Accuracy	±5 mmHg or 10% whichever is greater
Protection Against Electric Shock	Type BF applied parts (Per IEC 60601-1)
Protection Against Ingress of Solids and Liquids	IP22 which means the device is protected against ingress of hazardous parts larger than 12.5 mm and, vertically dripping water when the enclosure is tilted at an angle of 15° from its normal position

Item	Specification
Mode of Operation	Continuous
Fire Hazard	Not suitable for use in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
Battery Life	The device will operate for approximately 30 hours on a fresh set of batteries
Low battery indicator	The device will operate for approximately 10 hours after the low battery indicator illuminates
Service Life	The service life of the device is approximately 1000 hours
Applied Part Type	BF

Battery Service Life

Two “AA” 1.5V alkaline-type batteries used in the device yield a typical service life of 30 hours.

Operation Modes

The Fist Assist Model FA-1 has a single operation mode. When powered on it goes through a pressure cycle wherein the air bladder inflates to 60 mmHg and is held at that pressure for 20 seconds. The air bladder is then deflated to 10 mmHg or less and that pressure is held for 55 seconds. This cycle is continued until the power button is pressed. Bladder pressure as a function of time is shown below.

Electromagnetic Compatibility

Classification and Standards

The Fist Assist Model FA-1 meets the electrical safety requirements of:

- IEC 60601-1/EN 60601-1,/AAMI-ANSI ES 60601-1/IEC/EN 60601-1-2

Manufacturer's Declaration Table

The information contained in this section (such as separation distances) is specifically written with regard to the Fist Assist Model FA-1

General Notes

In the event this device interferes with other devices or that other devices interfere with operation of this device, take the following steps:

- Move the devices farther away from each other.
- Move the cord from the other devices as far apart as possible.

Medical equipment needs special precautions regarding EMC and must be installed and put into service according to the information provided in this IFU. Portable and mobile RF communications equipment (cell phones, wireless networks, etc.) can affect medical equipment. The following tables will help the user understand the EMC environment including how far away wireless devices should be kept to best ensure correct operation of the Fist Assist Model FA-1. Guidance & Manufacturer's Declaration -Electromagnetic Emissions

The Fist Assist Model FA-1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	

Guidance & Manufacturer's Declaration-Electromagnetic Immunity

During immunity testing, the Fist Assist Model FA-1 maintained its ability to function within specification.

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m
Power Frequency Magnetic Field Immunity Test IEC 61000-4-8	30 A/m	30 A/m

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device

[b] Over the frequency range 150 kHz to 80 MHz, field strengths less than 3 V/m.

Recommended Separation Distances

Between portable and mobile RF communications equipment and the Fist Assist Model FA-1

The Fist Assist Model FA-1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The customer or the user of the Fist Assist Model FA-1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fist Assist Model FA-1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Troubleshooting

Problem	Solution
What if the device double beeps?	The device is sensing a pressure issue and must be reset. Replace with new batteries or reset by removing the batteries from the battery compart, then reinsert in the proper orientation.
How do I turn it on?	Hold the start button for 2 seconds then release.
How do I turn it off?	Press and release the center button.
How do I change batteries?	Battery compartment is on the back of the Control Module. Make sure batteries are fresh alkaline batteries and in the proper orientation.
How can I do a hard reset the device?	Reset by removing the batteries from the battery compart, then reinsert in the proper orientation.
When do I change the batteries?	When device color light turns to yellow, this indicates that it is time to replace the batteries.

If it gets damaged or is not working, how do I return it?	Please contact your authorized dealer from which you purchased the device for refund or replacement.

Contacting Fist Assist Devices, LLC

Manufacturer Contact and Ordering Information

All products can be ordered through your Fist Assist Devices, LLC sales or customer service representative, or an authorized dealer. For assistance in setting up, using, or maintaining the Fist Assist Model FA-1 or to report unexpected operation or events, please contact Fist Assist at the contact information is shown below.

 Manufactured for

Fist Assist Devices, LLC

www.fistassistdevices.com

P/N: _____ Rev NEW

U.S. Patent Nos. 8,231,558 and 8,905,953

Technical Support

If the Fist Assist device fails to perform as specified, replace the batteries with fresh AA alkaline types while ensuring proper polarity per the label in the battery compartment and proceed to Step 2 Install the Batteries. If the problem is not resolved and the cause cannot be determined, do not use or attempt to repair it. Instead, contact the authorized dealer from which you purchased the device.

Disposal

For disposing this device, the user must contact its local authorities to determine the proper method of disposal of potentially biohazardous materials such as the Wrap component and batteries.

Warranty

In the first 30 days after purchase, Fist Assist Devices will refund any working device returned to our Distributer network at the patient's request. After 30 days and up to 1 year after purchase, only non-functional/non-working devices will be accepted on return. Non-functional devices can be returned via our return policy, will be inspected and if found to be non-functional will be replaced. Any device found to be damaged by the user (water damage, falls,

case damages) will not be refunded or replaced.

EXCEPT AS PROVIDED IN THE SPECIFIC WARRANTIES SET OUT HEREIN, ALL DEVICES ARE PROVIDED ON AN "AS IS" BASIS. NEITHER FIST ASSIST DEVICES, LLC, NOR ANY OF ITS AFFILIATES, EMPLOYEES, OFFICERS, DIRECTORS, AGENTS, OR LICENSORS WARRANTS THAT THE FIST ASSIST DEVICES WILL BE DEFECT FREE, NOR DO THEY WARRANT THAT CERTAIN RESULTS MAY BE OBTAINED BY THE USE OF ANY FIST ASSIST DEVICE IN CONNECTION WITH THE DELIVERY OF PROFESSIONAL MEDICAL SERVICES BECAUSE, WITHOUT LIMITATION, STORAGE AND HANDLING OF THIS DEVICE BY THE USER, AS WELL AS OTHER FACTORS RELATING TO THE USER'S DIAGNOSIS, TREATMENT, SURGICAL THERAPY, AND OTHER MATTERS ARE BEYOND THE CONTROL OF FIST ASSIST DEVICES, LLC. FIST ASSIST DEVICES, LLC, AND ITS AFFILIATES, EMPLOYEES, OFFICERS, DIRECTORS, AGENTS, AND LICENSORS MAKE NO WARRANTY, GUARANTEE, OR REPRESENTATION, EITHER EXPRESS OR IMPLIED, REGARDING THE MERCHANTABILITY, TITLE, OR FITNESS FOR A PARTICULAR PURPOSE OF THE FIST ASSIST DEVICES.

NOTWITHSTANDING ANY TERM OR PROVISION CONTAINED HEREIN, IN NO EVENT SHALL FIST ASSIST DEVICES, LLC, BE LIABLE TO ANY PURCHASER OR USER OF THE FIST ASSIST

DEVICE, OR TO ANY OTHER PERSON OR ENTITY, FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, EXEMPLARY, OR PUNITIVE DAMAGES, OR OTHER SIMILAR TYPE OF DAMAGES, ARISING OUT OF OR IN ANY WAY RELATED TO THE PURCHASE, USE OR PERFORMANCE OF THE FIST ASSIST DEVICE OR FIST ASSIST DEVICES, LLC,'S ALLEGED BREACH OF ANY WARRANTY OR AGREEMENT, REGARDLESS OF WHETHER FIST ASSIST DEVICES, LLC, KNEW OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE.

Return Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling.

Determination of a product defect or mislabeling will be made by Fist Assist Devices, LLC, and the determination will be final. Products will not be accepted for replacement if they have been in the possession of the customer for more than 30 days unless the product is non-functional in accordance with the warranty policy.

Limitations of Liability

Fist Assist Devices, LLC assumes no liability if the device is misused, and Fist Assist Devices, LLC neither assumes, nor authorizes any other person to assume for it, any other or additional LIABILITY or RESPONSIBILITY in connection with the sale or use of any Fist Assist Devices, LLC device.

UNDER NO CIRCUMSTANCES WHATSOEVER SHALL FIST ASSIST DEVICES, LLC, BE LIABLE TO ANY PURCHASER, USER, OR ANY OTHER PERSON OR ENTITY FOR DAMAGES OF ANY KIND ARISING OUT OF OR IN ANY WAY RELATED TO THIS SALE OF A FIST ASSIST DEVICES, LLC DEVICE OR THE PERFORMANCE THEREOF OR FIST ASSIST DEVICES, LLC,'S ALLEGED BREACH OF ANY ALLEGED OBLIGATION IN ANY AMOUNT OF MONEY WHICH SHALL EXCEED THE AMOUNT PAID BY THE PURCHASER TO FIST ASSIST DEVICES, LLC, FOR THE FIST ASSIST DEVICES, LLC DEVICE.

THE LIMITATIONS ON LIABILITY SET FORTH ABOVE SHALL APPLY TO ALL CAUSES OF ACTION, INCLUDING, WITHOUT LIMITATION, BREACH OF CONTRACT, BREACH OF WARRANTY, STRICT LIABILITY, NEGLIGENT MISREPRESENTATION AND OTHER TORTS, AND LIABILITY BASED UPON THE PROVISIONS OF ANY OTHER ALLEGED AGREEMENT AND ANY NATIONAL, STATE, OR LOCAL LAW OR ORDINANCE. THE LIMITATIONS ON LIABILITY REPRESENT A FUNDAMENTAL TERM OF

SALE AND USE OF ANY FIST ASSIST DEVICES, LLC DEVICE, AND FIST ASSIST DEVICES, LLC, WOULD NOT HAVE SOLD ANY DEVICE WITHOUT THEIR INCLUSION.

NO ACTION, REGARDLESS OF FORM, ARISING OUT OF THE PURCHASE OR USE OF ANY FIST ASSIST DEVICES, LLC DEVICE MAY BE BROUGHT BY ANY PURCHASER OR USER AGAINST FIST ASSIST DEVICES, LLC, MORE THAN ONE YEAR AFTER THE CAUSE OF ACTION HAS ARISEN.