



# Instructions for Use and Owner's Manual



**International Biophysics Corporation**

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Austin. TX 78744

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[AffloVest.com](http://AffloVest.com)

Dear Customer,

Congratulations on your purchase of an AffloVest from International Biophysics! We are excited to bring you a new level of freedom while complying with the therapeutic requirements of your health professional. Thank you for placing your trust with us. To ensure that you derive maximum benefit from the AffloVest and to ensure your safety, please familiarize yourself with the information in this AffloVest User Manual.

The AffloVest User Manual contains important SAFETY and TECHNICAL DATA. Please keep this manual in a safe place for easy reference.

With proper care and maintenance, the AffloVest will reward you with a long, trouble-free service life. We greatly value the satisfaction of our Customers and hope you are completely satisfied with your AffloVest by International Biophysics Corporation. For assistance setting up or using the AffloVest, or to report unexpected operation or events please contact International Biophysics Corporation, or the local DME that supplied you with the AffloVest.

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## EXPLANATION OF SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Caution		Stand-by
	Type BF Equipment - All parts considered applied parts		Play/Pause
	Direct Current		High Intensity
	Manufacturer		Medium Intensity
	Reference Number		Low Intensity
	Lot Number		Do not machine wash
	Serial Number		Do not bleach
	Refer to Instructions for Use		Do not tumble dry
	Keep dry		Do not iron
	Waste electrical and electronic equipment; do not dispose in household waste. Dispose of equipment in accordance with all relevant local, state and federal regulations.		Do not wet clean
	Authorized European Union Representative: QNET BV Kanstraat 19 NL5076 NP Haaren The Netherlands		The AffloVest® conforms to the European Medical Device Directive 93/42/EEC

## TECHNICAL DATA

Nominal Voltage:	12VDC
Nominal Power Consumption:	Approx. 30W max
Battery Charger:	See the Battery Charger User Manual, included in package.
A/C Power Supply:	See the A/C Power Supply User Manual, included in package. The provided power supply is specified as part of the AffloVest system
Lithium-ion Battery:	MODEL: 8027 OUTPUT: 14.4VDC, 2.5A typ. Li-ion CHARGING VOLTAGE: 16.8VDC, 3.5A max
12V Car Power Inverter (optional accessory)	MODEL: 8046 See the User Manual, included in package.
Manufacturer:	International Biophysics Corporation 2101 E. St. Elmo Road, Building 2, Suite 275 Austin, TX 78744 USA <a href="http://www.afflovest.com">www.afflovest.com</a> 888-711-1145
Sizes:	XXS (Extra Extra Small) XS (Extra Small) S (Small) M (Medium) L (Large) XL (Extra Large) XXL (Extra Extra Large)

## TRANSPORTATION, OPERATION AND STORAGE CONDITIONS

### **IMPORTANT**

Please observe the following during transportation, storage and operation of the AffloVest product.

#### Storage and Transport Conditions Between Uses

In between uses, please observe the following:

- Keep the AffloVest dry
- Protect the AffloVest from direct sunlight
- Remove the battery from the AffloVest during transport/storage
- Keep in the AffloVest between -20° C (without relative humidity control) and 50° C (93% relative humidity, non-condensing)

#### Operating Conditions

While using the AffloVest, please observe the following:

- Keep the AffloVest dry
- Protect the AffloVest from direct sunlight
- Keep the AffloVest between 5° C - 35° C, 15 - 93% relative humidity (non-condensing) and 700 - 1060 hPa.

## SAFETY FEATURES

The AffloVest was designed with maximum safety in mind, therefore it contains the following safety features:

- Motors operate at safe, low voltages.
- Controller contains a fuse in the event of electrical problems.
- The Controller operates on a timer to ensure shut-off.

## USER INFORMATION



### IMPORTANT

The AffloVest should be worn over clothing or with a fabric shield to prevent cross-contamination in a clinic or hospital setting where more than one patient uses the unit. The AffloVest should be cleaned appropriately between patient use, see the Cleaning Section.

According to the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage Therapy, the decision to use the unit for Airway Clearance Therapy requires careful consideration and a doctor's assessment of the individual patient's case if the following conditions exist:

- Intracranial pressure (ICP) greater than 20 mm Hg
- Recent spinal surgery or acute spinal injury
- Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- Large pleural effusions or empyema
- Pulmonary embolism
- Acute illness
- Pregnancy or nursing mothers
- Electronic implants
- Rib fractures, with or without flail chest
- Surgical wound or healing tissue or recent skin grafts or flaps on the thorax
- Uncontrolled hypertension
- Distended abdomen
- Recent esophageal surgery
- Active or recent gross hemoptysis
- Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal
- Subcutaneous emphysema
- Recent epidural spinal infusion or spinal anesthesia
- Burns, open wounds, and skin infections on the thorax
- Recent placement of transvenous or subcutaneous pacemaker
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Osteoporosis or osteomyelitis of the ribs
- Coagulopathy
- Complaint of chest wall pain

## INDICATIONS FOR USE/METHOD/APPLICATION

### INDICATIONS FOR USE

The AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment.

### METHOD

The AffloVest generates vibration and oscillation of the user's chest wall through integrated motor modules, installed into various parts of the vest. The patient controls the rate and frequency at which these motors oscillate the thoracic region with the use of a controller attached to the vest that can increase or decrease intensity to address the volume of mucus present in the air pathways, in compliance with a physician's prescription and orders.

### APPLICATION

Your doctor may prescribe the Afflovest if you have one of the following conditions\*:

- Bronchiectasis
- Cystic Fibrosis
- Late Effects of poliomyelitis
- Other deficiencies of circulating enzymes
- Anterior horn cell diseases
- Multiple sclerosis
- Quadriplegia
- Muscular dystrophy
- Myotonic disorders
- Myopathies
- Disorders of the diaphragm

\* Not all conditions allow for insurance reimbursement; contact your provider for details.

## UNPACKING AND USING THE AFFLOVEST FOR THE FIRST TIME

### IMPORTANT

Please follow the STEPS in order to ensure proper set-up.

Battery must be fully charged before use (this is covered in the STEPS below).

### PACKAGE CONTENTS



AffloVest



Rechargeable Battery (Li-Ion)



AC Power Supply



Controller



Battery Charger



Carrying Case

## STEP 1 – UNPACKING THE AFFLOVEST

Carefully unpack the AffloVest and its accessories.

You must fully charge the battery before proceeding to STEP 3.

## STEP 2 - CHARGING THE BATTERY

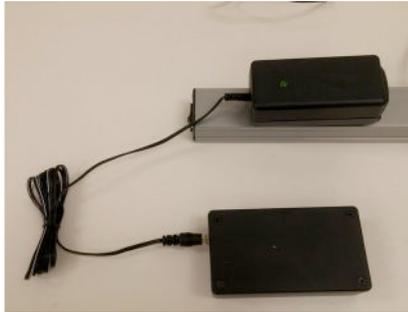
### **IMPORTANT**

Use only the supplied rechargeable battery and the supplied battery charger to ensure safe and reliable operation of the AffloVest.

- The battery must be fully charged before using the AffloVest for the first time.
- To charge the battery, connect it to the battery charger unit.
  - » *When charging, the Red LED on the battery charger will illuminate.*
  - » *When fully charged, the Red LED on the battery charger changes to Green.*
  - » *When the battery charger LED changes from Red to Green unplug the battery charger and proceed to the next STEP.*



**Battery Charging - Red LED**



**Battery fully charged - Green LED**

## STEP 3 – CONNECTING THE CONTROLLER TO THE AFFLOVEST

- Insert the hand-held controller into its pocket on the left side of the AffloVest.
- Carefully align and plug the controller connector into the cable coming from the AffloVest. Verify the arrows match before connecting.
- Make sure the controller cable connectors are fully inserted into one another.



## STEP 4 – CONNECTING THE BATTERY OR A/C POWER SUPPLY TO THE AFFLOVEST

- Place battery in pouch with battery label facing inwards towards the blue flap
- Place battery in pouch with plug in location shown
- Attach strap over battery and snap to pouch, securing as shown
- Securely press wire connector into battery plug
- Fold battery pouch closed and secure with buckle
- The AC Power Supply may be used to power the AffloVest instead of the battery. Connect the AC Power Supply to the AffloVest by plugging the AC Power Supply into a wall outlet. Connect the AC Power Supply to the power cable coming from the vest.



*A/C Power Supply - Connected to wall outlet*



*A/C Power Supply - Connected to AffloVest*

## STEP 5 – CONNECTING THE AFFLOVEST USING THE 12V CAR INVERTER (OPTIONAL ACCESSORY)

The 12V Car Inverter is an optional accessory which can be used with a 12V Cigarette Lighter outlet, found in automobiles, RV's and boats.

Connect the Car Inverter using the provided cord into a 12V cigarette lighter capable of providing at least 60W.

Once the car inverter is connected to the cigarette lighter, the AffloVest battery charger can be used to charge the AffloVest battery, or power the AffloVest using the A/C power supply that came with your afflovest plugged into the inverter. (For pricing, contact International Biophysics Customer Service or your HME/DME)



*12V Car Inverter*

## YOUR AFFLOVEST IS NOW READY FOR USE!



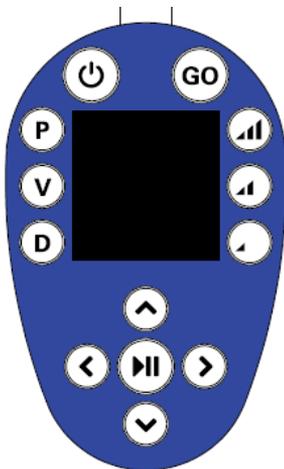
- Unplug the battery charger from outlet when not in use.
- If the battery has not been used for over 30 days, please recharge prior to using.

## FITTING THE AFFLOVEST

- Unbuckle the chest buckles on the AffloVest and set the buckles to maximum size.
- Put on the AffloVest and fasten all 3 buckles. Firmly pull the buckle straps so that the vest fits snugly on the body, but does not restrict a deep, full breath. Adjust the straps until there is only an approximate 1" to 5" gap between the two sides of the AffloVest.
- Adjust the shoulder snaps to place the front upper AffloVest motors on the upper chest just below the collar bone.



## CONTROLLER LAYOUT



(Stand-By)

Press and hold to turn Controller ON and OFF

GO

Press to start pre-programmed GO sequences

P V D

Percussion, Vibration, Drainage modes



High intensity



Medium intensity



Low intensity



(Play/Pause)

Press to start treatment from Main Menu. Press to select Program/Usage Menus



(Up/Down)

Press to navigate through menu items



(Left/Right)

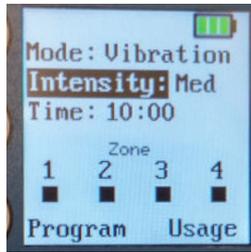
Press to change current highlighted selection

## RUNNING A TREATMENT CYCLE

When the AffloVest is properly setup, press and hold the Standby (  ) button on the controller. After a brief start-up period, the controller will navigate to the main treatment menu.



**Figure 1. Welcome Screen**



**Figure 2. Main Treatment Menu**

Treatment may be started at any time by hitting the  button (Play/Pause) from the main treatment menu. Pressing the following buttons will update the treatment whether the vest is running or not.

- "P" - Percussion mode, all motors operate in a pulsed fashion.
- "V" - Vibration mode, all motors operate continuously.
- "D" - Drainage mode, motors operate in a pre-programmed sequential fashion.
- "GO" - Automatically starts the GO mode, the system will perform the following treatments sequentially (by default):
  - » *Percussion mode, 10 minutes duration at Medium intensity (followed by a 10 second pause)*
  - » *Vibration mode, 10 minutes duration at Medium intensity (followed by a 10 second pause)*
  - » *Drainage mode, 10 minutes duration at Medium intensity*

The AffloVest will start in the Medium intensity mode by default. Pressing the following buttons will update the treatment whether the vest is running or not:

-  - HIGH intensity
-  - MEDIUM intensity
-  - LOW Intensity

While treatment is running, the AffloVest may be paused by pressing the  button (Play/Pause). This shall suspend treatment until the  button is pressed again.

While paused, press and hold the  button to reset the treatment time to the previous setting.

## INDICATORS

The Main Menu for the AffloVest contains the following indicators to provide the user with useful information:

- Battery Indicator - Displays an approximate battery life. When the battery indicator begins flashing, remove the battery and charge fully.
- Zone Indicator - Displays which motor zones are currently active during treatment.

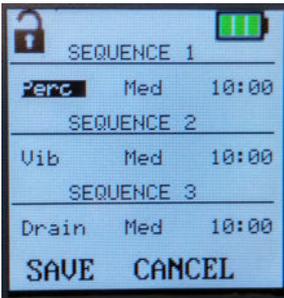
## MENU NAVIGATION

Press the “UP” and “DOWN” buttons to navigate through menus on the controller. To change the value, press the “RIGHT” and “LEFT” buttons while the value is highlighted.

To navigate to the Program Menu or Usage Menu, navigate to the desired menu selection. Press the **▶||** button to navigate to that menu.

## PROGRAM MENU

Navigating to the Program Menu allows the user to modify the default GO treatment settings.



**Figure 3. Program Menu**

Modify the settings as desired within the following allowable ranges:

- Treatment Type: Percussion, Vibration, Drainage
- Treatment Time: 5 - 15 Minutes
- Treatment Intensity: Low, Medium, High

Select “Save” and press the **▶||** button to save the settings. To exit without saving select “Cancel” and press the **▶||** button.

The next time the “GO” button is pressed from the Main Menu the new treatment settings will be run.

## USAGE MENU

Navigating to the Usage Menu allows the user to view run-time information.



*Figure 4. Usage Menu with Run-Time Information*

Press the **▶||** button to return to the Main Menu.

## TURNING OFF THE AFFLOVEST

To turn off the AffloVest controller, press and hold the Standby (  ) button for at least two (2) seconds. The system will enter a standby mode.

Alternatively, to turn off the AffloVest controller, remove the power by either disconnecting the battery or A/C power supply.

## CLEANING THE AFFLOVEST

Clean the AffloVest in the following situations:

- When the AffloVest becomes visibly soiled
- Between patient uses in multi-patient care environments, we recommend cleaning the AffloVest.
- In a single-user environment; it is recommended that the AffloVest be cleaned monthly.

To clean the AffloVest, please utilize a broad-spectrum disinfecting wipe rated to kill at least 99.9% of bacteria and viruses and follow the manufacturer's instructions for use. Using appropriate protective equipment, including disposable latex-free gloves, follow the instructions below to clean the AffloVest using the disinfecting wipes. Follow the disinfecting wipe label with regards to concentration, contact time, rinsing and drying after cleaning.

1. Ensure the AffloVest is unplugged from all power sources.
2. Unbuckle battery and controller flaps
  - a. *Disconnect and remove battery from AffloVest pouch*
  - b. *Disconnect and remove controller from AffloVest pouch*
3. Unbuckle front buckles and shoulder snaps and lay AffloVest flat so that the inside of AffloVest is exposed
  - a. *Wipe the outer edges of the AffloVest, starting in the collar area, tracing the outer edges all the way around the AffloVest and repeat.*
  - b. *Wipe all exposed fabric thoroughly, pressing into creased areas, and repeat.*
4. Turn AffloVest over and lay it flat
  - a. *Starting at the top, wipe the exposed AffloVest fabric thoroughly, pressing into creased areas, and repeat.*
  - b. *Wipe male and female snaps.*
  - c. *Wipe buckles and straps on each side.*
    - i. Make sure to wipe inside female connector of buckle.
    - ii. Make sure to wipe ridges on male connector of buckles.
  - d. *Wipe battery flap and the inside and outside of battery pouch.*
  - e. *Wipe battery cable protruding from AffloVest.*
  - f. *Wipe controller flap and the inside and outside of controller pouch.*
  - g. *Wipe controller cable protruding from AffloVest.*
5. Wipe battery thoroughly.
6. Wipe controller thoroughly.
7. Wipe all accessories thoroughly including all cables.
8. Wipe carry case thoroughly (inside and outside).

## CLEANING AND CARE WARNINGS

### IMPORTANT



Do not machine wash

---



Do not bleach

---



Do not tumble dry

---



Do not iron

---



Do not wet clean

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## BATTERY WARNING INFORMATION

### IMPORTANT

- The battery must never be thrown into a fire or incinerated.
- The battery must not be immersed in liquids, such as water, sea water, or beverages. Contact with liquids must be avoided.
- The battery is not a toy and must be kept away from young children and babies.
- The battery must not be placed in a microwave or subjected to pressure. It may combust, resulting in smoke and fire.
- The battery must not be dropped onto a hard surface.
- Never dismantle the battery, as this may cause internal short-circuits, resulting in gas emissions, fire and explosion, or other problems.
- The electrolytes and electrolyte vapors contained within the case of lithium-ion batteries may be harmful to humans. **DO NOT ATTEMPT TO OPEN THE BATTERY CASE.** If the battery case breaks or is compromised, avoid direct contact with the electrolytes within. If electrolytes come in contact with the skin, eyes or other parts of the body, immediately flush or rinse with fresh water and seek medical attention as soon as possible.
- Store battery on a non-combustible, heat resistant and non-conductive surface.
- Do not expose the battery to direct sunlight.

## SAFETY INFORMATION

### **IMPORTANT**

The AffloVest is certified with the standard EN 60601 and corresponds to the Medical Devices Directive 93/42EEC:

THE MANUFACTURER, INTERNATIONAL BIOPHYSICS CORPORATION, SHALL ACCEPT NO LIABILITY WHATSOEVER FOR ANY DAMAGE AND/OR CONSEQUENTIAL DAMAGE RESULTING FROM NON-COMPLIANCE WITH THE FOLLOWING SAFETY INFORMATION.

- Repairs to the AffloVest or its electrical components may only be carried out by International Biophysics Corporation authorized electricians or service dealers. Unauthorized repairs will void the AffloVest warranty and may place the user at considerable risk or damage the AffloVest.
- There are no parts of the AffloVest which are intended to be serviced or maintained while the AffloVest is in use with the patient. Do not service or perform maintenance while the AffloVest is in use.
- The patient is intended to be an operator for the AffloVest. All functions of the AffloVest may be safely used by the patient.
- The expected service life of the AffloVest, including all accessories, is five (5) years.

THE MANUFACTURER, INTERNATIONAL BIOPHYSICS CORPORATION, SHALL NOT BE LIABLE FOR ANY DAMAGE AS A RESULT OF: 1) THE AFFLOVEST BEING USED FOR ANYTHING OTHER THAN ITS INTENDED PURPOSE, 2) INCORRECT USE, OR 3) IMPROPER REPAIR RESULTING FROM HAVING THE AFFLOVEST REPAIRED BY ANYONE THAT IS NOT AN INTERNATIONAL BIOPHYSICS CORPORATION AUTHORIZED REPAIR FACILITY OR TECHNICIAN.

- **WARNING:** No modification of this equipment is allowed.
- To protect the AffloVest from potential damage, avoid leaving in direct sunlight for extended periods of time and keep the AffloVest clean of debris such as lint or dust. In addition, avoid leaving the AffloVest in areas where it may be damaged by pets, pests or children.
- To avoid a potential strangulation hazard for small children, properly store the AC power supply in between uses.
- To avoid potential skin irritation, it is recommended to wear the AffloVest over comfortable clothing.

- The AffloVest may only be used with the included accessories. Do not use unapproved accessories with the AffloVest.
- The battery may only be charged with the supplied battery charger in accordance with the charger instructions. The use of any other power supply units or chargers may lead to fire and electric shock and will void the AffloVest Warranty.
- Always unplug the AffloVest when not in use.
- Unplug the AC power supply if the AffloVest malfunctions while powered by AC current.
- Always unplug the AffloVest from wall outlet, and remove the battery and the hand-held controller before cleaning with any type of liquid disinfectant or cleaning solution.
- Never disconnect the power plug from an electrical outlet with wet hands.
- Never pull the AffloVest power cords or cable over sharp edges or allow them to kink or bind.
- Never carry or lift the AffloVest by any of its electrical cables or components.
- Children and disabled persons should not use the AffloVest without supervision.
- Do not use the AffloVest in damp environments, such as in the bathroom or at a swimming pool. Do not puncture the AffloVest with sharp objects, such as pins or needles.

## ENVIRONMENTAL PROTECTION



Electrical and electronic products must be disposed of separately from any household waste at the end of their service. To ensure that these products are recycled effectively, deposit them at municipal collection points for recyclable materials where they will be accepted free of charge.

Correct disposal of products will help protect the environment and avoid harmful effects to human beings and the environment that may arise from incorrectly handling devices at the end of their service life. Please contact local authorities to determine the proper method of disposal.

## **TRAVELING WITH LITHIUM-ION BATTERIES**

Lithium-ion batteries can be considered hazardous by the FAA. Familiarize yourself with any travel guidelines before you travel. Contact your carrier or visit their website for guidance.

## **PREVENTIVE INSPECTION, CALIBRATION, AND MAINTENANCE**

On a periodic basis, the AffloVest should be cleaned as described in the Cleaning section. After cleaning, it is recommended to inspect the AffloVest for any damage to the product, wiring, battery, accessories and the controller. This may be performed by the user or by authorized service personnel. If any damage is noted, please contact the manufacturer for assistance.

The AffloVest is designed to operate without any periodic calibration or maintenance required. Only the manufacturer may replace parts or perform repair on the AffloVest.

## TROUBLESHOOTING



### IMPORTANT

Before attempting any troubleshooting, ensure that the battery is fully charged. To check the battery charge level, connect the battery to the Battery Charger and plug the charger into a wall outlet. Wait 30 seconds. If the indicator on the Battery Charger is GREEN, the battery is fully charged. If the indicator is RED, allow the battery to charge until the indicator turns GREEN.

SYMPTOM	POSSIBLE CAUSE	TROUBLESHOOTING STEPS
AffloVest controller will not power on when connected to battery	Battery discharged <b>OR</b> Battery not connected properly <b>OR</b> Possible damaged controller <b>OR</b> Possible damaged battery	Ensure battery is fully charged  Verify that the battery is connected to the AffloVest correctly  Attempt to operate the AffloVest when connected to the AC Power Supply  Contact your dealer for further assistance.
AffloVest controller will not power on when connected to AC Power Supply	AC Power Supply not connected to power <b>OR</b> AC Power Supply not connected properly <b>OR</b> Possible damaged controller <b>OR</b> Possible damaged AC Power Supply	Ensure AC Power Supply is connected to a working outlet  Verify that the AC Power Supply is connected to the AffloVest correctly  Attempt to operate the AffloVest when connected to a fully charged battery  Contact your dealer for further assistance.
The selected program function has suddenly switched off.	The therapy cycle has finished and a new therapy cycle must be started. <b>OR</b> Battery discharged.	Start a new therapy cycle.  Charge battery or switch to the AC Power Supply.

## ELECTROMAGNETIC GUIDELINES FOR CLINICAL APPLICATIONS

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

EMITTED INTERFERENCE MEASUREMENT	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
RF emissions as per CISPR 11	Class B	The AffloVest is suitable for use in all establishments, including domestic, and those directly connected to the public power supply network that supplies buildings used for domestic purposes.
Harmonic component emissions as per IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions as per IEC 61000-3-2	Compliant	

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

<b>INTERFERENCE IMMUNITY TESTS</b>	<b>IEC 60601-TEST LEVEL</b>	<b>COMPLIANCE LEVEL</b>	<b>ELECTROMAGNETIC ENVIRONMENT GUIDELINES</b>
Electrostatic discharge (ESD) as per IEC 61000-4-2	±6 kV Contact Discharge ±8 kV Air Discharge	±6 kV Contact Discharge ±8 kV Air Discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%
Fast Electrical Transients/Bursts as per IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input/Output Lines	±2 kV for Power Supply Lines ±1 kV for Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment
Surge Voltages (Surge) as per IEC 61000-4-5	±1 kV Normal-Mode Voltage ±2 kV Common-Mode Voltage	±1 kV Normal-Mode Voltage ±2 kV Common-Mode Voltage	Mains power quality should be that of a typical commercial or hospital environment
EVoltage Dips, Short-Term Interruptions and Fluctuations in Supply Voltage as per IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 0% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip Ut) for 5 s	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 0% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip Ut) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AffloVest requires continued operation during interruptions in the power supply, it is recommended that the AffloVest be powered from an uninterruptible power supply or battery
Power Frequency (50 Hz) Magnetic Field as per IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a location in a commercial or hospital environment

NOTE: Ut is the mains AC voltage prior to application of the test level.

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

INTERFERENCE IMMUNITY TESTS	IEC 60601-TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Conducted RF interference as per IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	Portable and mobile RF communications equipment should be used no closer to any part of the AffloVest, including the cables, than the recommended distance calculated from the equation applicable to the transmit frequency.
Radiated RF interference as per IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	<p>Recommended distance:  <math>d = 1.2 \text{ m P}</math></p> <p><math>d=1.2 \text{ m P}</math> for 80 MHz to 800 MHz <math>d=2.3 \text{ m P}</math> for 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended distance in meters (m). The field strength of fixed RF transmitters, as determined by an electromagnetic site survey(a) should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following symbol.</p>

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and persons.

(a) The field strength from fixed transmitters, such as base stations for radio telephones and mobile terrestrial radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in terms of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AffloVest is used exceeds the applicable compliance level specified above, the AffloVest should be observed to verify normal operation. If abnormal performance features are observed, additional measures may be necessary, such as re-orienting or relocating the AffloVest.

(b) The field strength should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz.

Recommended distances between portable and mobile RF telecommunications equipment and the AffloVest.

The AffloVest is intended for use in an electromagnetic environment, in which RF interference is controlled. The customer or user of the AffloVest can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the AffloVest as recommended below - dependent on the maximum output power of the communications equipment.

Nominal Transmitter Output (W)	Distance Dependent on Transmit Frequency (m)		
	150 kHz to 80 MHz d = 1.2 m P	80 MHz to 800 MHz d = 1.2 m P	800 MHz to 2.5 GHz d = 2.3 m P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The recommended distance d in meters (m) for transmitters with a maximum nominal output not specified in the table above can be calculated using the equation applicable to the transmitter frequency (in the specific column in the table), where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

*NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.*

*NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and persons.*

## AFFLOVEST® LIMITED WARRANTY

International Biophysics Corporation (“IBC”) warrants to the original end-user purchaser (“Purchaser”) and not to any other purchaser or subsequent owner, that the AffloVest® and associated accessories, controller and batteries purchased from IBC or its authorized distributor or dealer are free from defects in design, material and workmanship under normal use and operation, for the Applicable Warranty Period (see table below), subject to the below limitations.

UNDER THIS LIMITED WARRANTY, IBC’S OBLIGATION IS LIMITED TO THE REPAIR OR REPLACEMENT (AT IBC’S OPTION) OF DEFECTIVE ITEMS ONLY. Reimbursement for the cost of return are not included. IBC may, in its sole discretion, refund the purchase price of the warranted item in lieu of repair or replacement, but IBC will never be obligated to do so. This Limited Warranty excludes any damage, failure or malfunction caused by or related to:

- Abuse, misuse, negligence or accident
- Failure to comply with instructions contained in the Operator’s Manual
- Operation of the battery pack outside of voltage and current ratings specified in the Operating Manual
- Alteration, tampering, or modification by someone other than an authorized IBC representative
- Unauthorized repairs or alterations or opening of the inside of device
- Extreme or unusual environmental conditions (including but not limited to extreme heat or cold or water damage)
- Lack of regular, preventative maintenance and cleaning
- Damage in return shipment to IBC
- Other acts beyond the reasonable control of IBC

This Limited Warranty extends only to the Purchaser identified above and is not transferable except upon IBC’s prior written consent. IBC’s warranty obligations hereunder are conditioned upon Purchaser’s compliance with the warranty procedures set forth below. If any warranted item fails to conform to the Limited Warranty set forth herein, Purchaser must give prompt timely written notice to IBC, including a detailed description of the alleged fault or defect, at which time IBC or its authorized distributor will issue a Return Material Authorization (“RMA”) number. All warranted items claimed to be defective must be properly packaged and shipped on a prepaid basis to IBC or its authorized distributor at Purchaser’s expense. The exterior of the shipping container must clearly display the RMA number which properly identifies the returned item, which must include the invoice or other proof of purchase and identity of the Purchaser. Items returned without a proper RMA number and proof of purchase shall be refused and returned to Purchaser at Purchaser’s expense. All returned items are subject to warranty confirmation by IBC. IBC will pay for standard shipping back to any Purchaser located in the United States for repair or replacement of items properly covered under this Limited Warranty. All other shipping charges, freight charges, customs fees, taxes or tariffs concerning the shipping to IBC or the return of the repaired or replaced defective item to the Purchaser are the exclusive responsibility of the Purchaser and to be paid by the Purchaser.

When repairing or replacing warranted items, IBC may use functionally equivalent components or parts, as long as they are new, equivalent to new or refurbished. Any components or parts removed by IBC in the repair or replacement of any warranted item shall become IBC’s property.

To the extent permitted by applicable law, the warranty coverage will not be extended or renewed by virtue of IBC’s compliance with this Limited Warranty. Any components or parts which are repaired or replaced will be warranted for the unexpired term of the Limited Warranty.

ANY IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, ARE LIMITED TO THE TERM OF THE APPLICABLE EXPRESS WARRANTY PROVIDED HEREUNDER. IBC IS NOT RESPONSIBLE FOR INJURY, PROPERTY DAMAGE OR OTHER INDIRECT,

SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OF THE AFFLOVEST®, NOTWITHSTANDING THE FACT THAT SAID INJURY, PROPERTY DAMAGE OR OTHER DAMAGES AROSE DIRECTLY OR INDIRECTLY FROM AN ACTUAL OR ALLEGED DEFECT IN MATERIAL AND/OR WORKMANSHIP.

SOME JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS AND EXCLUSIONS MAY NOT APPLY TO YOU.

This Limited Warranty gives you specific legal rights and may also have other rights, which vary from jurisdiction to jurisdiction.

AffloVest® is a registered trademark of IBC. This Limited Warranty is the exclusive responsibility of IBC and is given in lieu of all other warranties or assurances. Claims hereunder may be presented only to IBC or its authorized distributor. This Limited Warranty may not be expanded or modified by anyone (including but not limited to any authorized distributor) except in writing by an authorized officer of IBC.

The rights and obligations of the parties pursuant to this Limited Warranty and any dispute arising hereunder shall be governed by and interpreted in accordance with the internal laws of the State of Texas, USA. The parties agree and consent that the state or federal courts in Travis County, Texas, USA shall have exclusive jurisdiction with respect to any dispute arising out of or relating to this Limited Warranty, whether sounding in contract, tort or otherwise. If any provision of this Limited Warranty is held to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that this Limited Warranty will otherwise remain in full force and effect and enforceable. EACH PARTY EXPRESSLY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

Description	Applicable Warranty Period United States Purchasers	Applicable Warranty Period Non-U.S. Purchasers
AffloVest (XXS, XS, S, M, L, XL, XXL)	Lifetime of the Purchaser	Five (5) years
A/C Power Supply (used to power the AffloVest from electrical outlet)	Five (5) years	One (1) year
Battery Charger (used to charge the AffloVest battery from electrical outlet)		
Rechargeable Lithium-Ion Battery		
Hand-held Controller		
AffloVest "Go Anywhere" Case	One (1) year	One (1) year

"United States Purchasers" are those original end-user Purchasers who first took possession of the warranted item in the United States of America, its possessions or territories for use of that item in the United States. "Non-U.S. Purchasers" are all other Purchasers. "Lifetime" refers to the life of the original end-user patient using the AffloVest. A warranty period measured in years begins on the date of original purchase.

## **International Biophysics Corporation**

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