

I-Bresis[™]

Controller (1361) - Instructions For Use

**READ THE I-BRESIS[™] PATCH AND CHARGING STATION
INSTRUCTIONS FOR USE FOR ADDITIONAL IMPORTANT
INFORMATION.**

GLOSSARY OF SYMBOLS

This device may contain one or all of the following symbols:



Consult Instructions



Council Directive 2002/96/EC concerning Waste Electrical and Electronic Equipment (WEEE).

Indicates a requirement not to dispose of WEEE as municipal waste. Contact your local distributor for information regarding disposal of the unit and accessories.



Type BF Equipment



“On” / “Off” (Push-Push)



For Prescription Only



Precautionary Instructions



Underwriters Laboratories Inc., indicates product meets US and Canadian product safety standards. This device complies with UL 60601-1 and CSA C22.2 No. 601-1-M90



Keep Dry



Keep Away from Sunlight

10°  35°C
Storage: 10° - 35° C
(50°-95° F)

THEORY OF OPERATION

Iontophoresis transports charged water-soluble drugs and other ionic substances across intact skin. Iontophoresis technology is based on the principle that an electric potential causes charged water-soluble ions in solution to migrate according to their electrical charges. The distribution of a charged ionic drug delivered by iontophoresis is dependent upon the charge of the ion, the size of the ion (molecular weight), the strength and duration of the electrical current applied, the composition of the Patch and numerous other factors.

DESCRIPTION

The I-Bresis™ System delivers charged water-soluble drugs and other ionic substances across intact skin and consists of three components: a Charging Station, rechargeable Controller(s) and disposable Patch(es).

The I-Bresis™ System is designed to provide the following three treatment options:

I-Bresis™ Treatment

The Controller delivers current at 3 mA to the Patch for three minutes for a Skin Conductivity Enhancement (SCE), followed by the patient wearing the Patch for approximately one to two hours, resulting in a 40-80 mA-min treatment respectively.

Standard Treatment

The Controller delivers current at 2, 3 or 4 mA to the Patch for 10-20

minutes, resulting in a 40 mA-min treatment. For an 80 mA-minute treatment, repeat the treatment.

Patch Treatment

The Patch delivers low-level current over 2-4 hours, resulting in an approximate 40-80 mA-min treatment respectively.

INDICATIONS

The I-Bresis™ System is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injection.

CONTRAINDICATIONS

- Cardiac pacemakers - Do not use on patients with pacemakers or other implanted devices.
- Drug sensitivity – Do not use on patients with known sensitivity to the drug to be administered.
- Pregnancy – Do not use on pregnant women. The safety of the system used during pregnancy has not been established.
- Scarring – Do not use on damaged skin, denuded skin or other recent scar tissue.
- Skin sensitivity – Do not use on patients with known sensitivity to electrical current or to the solution being administered.
- Head treatment – Do not treat across either the temporal region or the orbital region.



Warnings

- Keep out of the reach of children and pets.
- Do not apply electrodes such that the current pathway crosses the heart or brain, as safety has not been established.
- Advise the patient to remove electrodes if any undue sensation of pain or burning occurs during the treatment and to report discomfort to clinic.
- To establish good contact between the electrodes and skin, excessive hair may be clipped, but **DO NOT SHAVE**. Shaving may cause skin breaks that are not readily seen and can increase the risk of adverse skin reactions.
- Do not apply over broken or compromised skin (e.g., sunburns, cuts, or acne) due to increased risk of skin reaction.
- Small pinhead size blisters may result in response to the drug. Contact physician if problem persists longer than 24 hours.
- On rare occasions, iontophoresis therapy can result in transient skin reactions such as rash, inflammation, irritation or burns. These skin reactions may be the result of individual sensitivity to the ionic solution used, the condition of the skin at the onset of treatment, reaction to the materials in the electrodes, or a poor connection between the electrode and the patient's skin. Advise the patient of this possibility before starting treatment. If a visible skin reaction does occur, instruct the patient to discontinue the treatment and consult the prescribing physician.
- Care must be taken when operating this equipment adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- The system is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Do not wear electrode or controller during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and causing skin burns in the area of the patch.



Warnings

- Consult directions for the use of the drug before delivery. Some drugs require a specific polarization for use. Observe the indications, contraindications, warnings and precautions related to this issue.
- Do not use electrodes that have been previously used as these electrodes have been designed for single use only.
- Inspect the electrodes before use. Discard any electrode that shows signs of alteration or damage, as these electrodes may not be safe for use.
- The electrodes can be worn during normal activity. However, excessive motion where the electrodes have been placed can cause poor contact between the skin and the electrode or uneven distribution of current, resulting in greater risk of skin irritation.
- A transient erythematous reaction, characterized by a uniform red pattern, can sometimes occur directly under one or both electrodes. The redness usually disappears within 12 hours of treatment. Advise the patient of this possibility before starting treatment.
- Use only saline ampule supplied for the return pad. For positive polarity (+), use only drugs with Chloride (Cl-) counter ions. Use of tap water or any other solution may cause tattooing or staining.
- Handle the system with care. Do not immerse the system in fluids or allow it to be connected with other electrical devices. Do not drop, abuse, or in any way exceed normal use. Do not sterilize.
- Do not operate this system in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

CONTROLLER OPERATION

The I-Bresis™ Controller is a solid state, microprocessor-controlled device that delivers low-level electrical current. When used in conjunction with the Patch, the Controller provides visual and audible indications of treatment status.



WARNING:

- DO NOT allow it to be immersed or come in contact with fluids.
- DO NOT connect the unit to external devices except the I-Bresis™ Patch or the I-Bresis™ Charging Station. Doing so may cause a malfunction or patient injury.

Button Functions -

There are three buttons on top of the Controller. The buttons have the following functions:

ON/OFF -

Turns the power on and off. After power-on, the unit defaults to I-Bresis™ mode. If power is turned off during a treatment, the current is ramped to zero (to avoid excessive electrical sensation) before the unit powers off. This aborts the treatment and mA- minute dose information is lost.

START/PAUSE -

Starts the selected treatment or pauses treatment. If pressed during a treatment, the current will ramp down and the treatment will be

paused. Pressing this button while paused will resume the treatment.

STANDARD MODE -

Selects a standard treatment of 2, 3 or 4 mA. The selection can be made during setup, pause or treatment. If made during treatment, the current will ramp-up or ramp-down to the newly selected current setting.

Lights -

There are five lights on the face of the Controller that indicate the following:

I-Bresis™ Treatment - One Green Light

I-Bresis™ Treatment selected.

Standard Mode - One of Three Green Lights

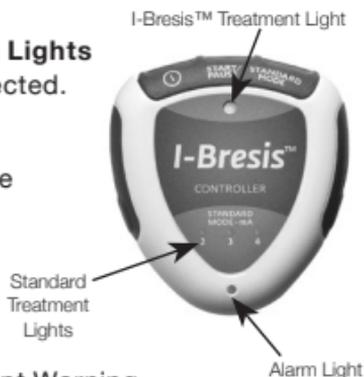
Standard Treatment of 2, 3 or 4 mA selected.

Interpretation of Four Green Lights

- Flashing Slowly (1 Hz): Setup or Pause
- Flashing Rapidly (4 Hz): Ramp-up, Ramp-down or Current Interrupt
- Continuous: Steady State Current

Alarm Light - One Multicolor Light

- Red Flashing Rapidly: Current Interrupt Warning
- Yellow Continuous: Low Battery



Warnings or Cautions

Light Warning or Caution	Cause	Corrective Action
Yellow light constant with beep sequence every 30 seconds	Low Battery: Controller not recently recharged.	Press OFF to terminate the treatment. Place the Controller in a Charging Station until fully charged.
Red light and selected green light flashing rapidly with beep sequence every 30 seconds	Current Interrupt: May be caused by a loose connection, insufficiently hydrated drug pads or poor contact between the Patch and the skin.	Press PAUSE to pause the treatment. Check for loose connections, properly hydrated drug pads and good contact between the Patch and the skin. After correcting the problem, press START to continue the treatment.

Automatic Time Calculation -

All time calculations are performed automatically, even if the current setting is changed.

Automatic Current Ramp Up -

When the start button is pushed, the Controller automatically ramps up the current output to the desired setting. While the current is ramping, the green light will flash rapidly. When the current reaches the setting selected, the green light will be on constantly.

Automatic Current Ramp Down -

After reaching the preset dose, the current automatically decreases, returning to 0 mA, indicating the treatment is complete. Also, automatic current ramp down takes place if the ON/OFF button is pressed (i.e. Treatment Abort) or if the PAUSE button is pressed.

Automatic Fast Current Shut Off -

If there is a Low Battery Alarm or Current Interruption Alarm, the current will be immediately set to 0 mA.

PATCH DESCRIPTION

The I-Bresis™ Patch is a disposable, single-use Patch with an internal battery and current-limiting circuitry. It can deliver both negatively and positively charged water-soluble drugs. The Patch-Only Treatment can be used with and without the Controller. The Controller is used with the Patch to deliver a I-Bresis™ or Standard Treatment. A Patch Treatment does not require the use of the Controller.

Drug Polarity Labeling -

The polarity of the drug pads are labeled on the Patch.

Patch Drug Pads -

The Patch has two drug pads. Each drug pad has a ~1.5 mL fill volume. Use negatively charged water-soluble drugs on the negative (-) drug pad and positively charged water-soluble drugs on the positive (+) drug pad.

Battery Pack and Controller Connector -

The Battery Pack that contains two 3-Volt batteries is also the connecting location for the Controller.

PREPARING THE PATIENT

Advise the patient that iontophoresis has the potential to result in skin irritation and/or burns.

- Direct current may result in transient erythema under the pads. The erythema generally resolves itself within a few hours to a few days.
 - Use caution when treating patients with sensitive skin or those who may have difficulty healing.
1. Advise the patient that iontophoresis causes mild tingling, prickling and/or a warm sensation. This is normal and should be anticipated by the patient.
 2. Advise the patient to report immediately any pain during treatment. If the patient complains of pain, pause the treatment, inspect the area under the Patch and make any necessary adjustments (e.g. reposition the Patch to ensure full skin contact, decrease current, etc.) before resuming the treatment, or discontinue the treatment.
 3. Advise the patient to remove any jewelry that may come in contact with the Patch.

PREPARING THE PATCH

1. Tear open the sealed treatment kit and remove the Patch.
2. Place the Patch on a flat surface with the absorbent pads facing up.
3. Clean the treatment site thoroughly with alcohol prep by rubbing for six to eight seconds to remove dry skin, oils and other contaminants. Allow the treatment site to dry completely.



CAUTION: Failure to clean skin thoroughly may cause excessive skin irritation or burns.

NOTE: The Patch will not adhere sufficiently to skin with lotion, oil or dirt.

NOTE: Clip hair if necessary to improve skin contact. DO NOT shave.

4. Place ~1.5 mL of a charged water-soluble drug on appropriate polarity pad (active pad). On the other pad (return pad), apply ~1.5 mL of supplied saline ampule. Use negatively charged water-soluble drugs on the negative (-) drug pad and positively charged water-soluble drugs on the positive (+) drug pad to actively deliver the drug. For (+) polarity, use only drugs with Chloride (Cl⁻) counter ions.

NOTE: Fill volume is approximately ~1.5mL. Drug pads should be saturated but not overfilled. If the drug pads are overfilled beyond the saturation point, the pads will leak and directly affect the adhesion of the patch to the treatment site.



CAUTION: Failure to evenly distribute drug or saline onto active or return pads can cause excessive skin irritation or burns.

DO NOT fill Patch while it is on the patient.

DO NOT over or under fill drug pads.

DO NOT use drugs that are not water-soluble.

DO NOT use drug suspensions.

DO NOT use a Patch that appears altered or damaged.

DO NOT apply Patch to dirty, oily or lotioned skin.

Use of tap water or non-chloride drug solution on positive polarity may cause tattooing or staining.

5. Make sure that the treatment site has intact skin.



CAUTION: Failure to follow these guidelines may result in skin irritation or burns.



WARNING: DO NOT apply the Patch over damaged or denuded skin or other recent scar tissue, skin with ingrown hair, pimples, sunburned skin, razor nicks or skin with wounds that have not healed.

6. Remove the adhesive release liner from the hydrated Patch.
7. Apply the hydrated Patch so that the drug pad is over the treatment site and secure it by pressing the adhesive border. Avoid pressing directly over the pads. Pressing directly on the pads can cause leakage that will compromise adhesion to the patient.

NOTE: DO NOT tape or bind the Patch during treatment. Do not apply hot or cold therapy over Patch during treatment.

ADMINISTERING TREATMENT

The I-Bresis™ System is designed to provide the following three treatment options:

I-Bresis™ Treatment

The Controller delivers current at 3 mA to the Patch for three minutes for a Skin Conductivity Enhancement (SCE), followed by the patient wearing the Patch for approximately one to two hours, resulting in a 40-80 mA-minute treatment respectively.

Standard Treatment

The Controller delivers current at 2, 3 or 4 mA to the Patch for 10-20 minutes, resulting in a 40 mA-minute treatment. For an 80 mA-minute treatment, repeat the treatment.

Patch-Only Treatment (For use without Controller)

The Patch delivers low level current over 2-4 hours, resulting in an approximate 40-80 mA-minute treatment respectively.

I-Bresis™ MODE TREATMENT

NOTE: While using the Controller, should an in-process iontophoresis treatment need to be stopped or paused, DO NOT suddenly remove the Controller from the Patch without first switching off the Controller. To stop a treatment while the Controller is administering iontophoresis, press the ON/OFF button and wait a few moments for the Controller to turn off.

1. Examine the Controller before use to assure that the two prongs that insert into the Patch are free of grime and debris. Dirty contacts could cause erratic behavior during treatment. If needed, the prongs may be cleaned with an alcohol wipe.
2. Push the ON button on the Controller. The Green I-Bresis™ Light will blink slowly.
3. Attach the Controller to the Patch. The Patch connector (located at the center of the Patch) plugs into the slot on the back of the Controller. Ensure that the Patch connector is fully and securely engaged into the Controller- a click will be heard upon full engagement.
4. Position the patient so that there is no pressure on the Patch during treatment.
5. Press the START button to begin treatment. The Green I-Bresis™ Light will blink more rapidly, then glow steadily.

- After three minutes, the Controller will sound a beep and the lights will turn off automatically. This indicates that the Skin Conductivity Enhancement (SCE) is completed.
- Remove the Controller from the Patch. The Patch will now continue to deliver the remainder of the iontophoresis treatment to the patient.
- The average time to complete the dose is indicated in the following table. To prevent excessive dosing, the Patch automatically switches off iontophoresis after the maximum dose has been administered.

I-Bresis™ Mod	40 mA-minutes	60 mA-minutes	80 mA-minutes
Wear Time	1 hour	1.5 hours	2 hours

- Instruct the patient to remove and discard the Patch after a minimum of one to two hours for a 40 to 80 mA-minute dose respectively.
- Discard the Patch after treatment has been completed. The Patch cannot be reused.

STANDARD MODE TREATMENT

NOTE: While using the Controller, should an in-process iontophoresis treatment need to be stopped or paused, DO NOT suddenly remove the Controller from the Patch without first switching off the Controller. To stop or pause a treatment while the Controller is administering iontophoresis, press the ON/OFF button and wait a few moments for the Controller to turn off.

- Press the ON/OFF button on the Controller. The Green I-Bresis™ Light will blink slowly.

2. Push the Standard Mode button on the Controller. The 2 mA indicator light will blink slowly. Each additional depression of the button will scroll to the next setting- 3 mA or 4 mA.
3. Attach the Controller to the Patch. The Patch connector (located at the center of the Patch) plugs into the slot on the back of the Controller. Ensure that the Patch connector is fully and securely engaged into the Controller- a click will be heard upon full engagement.
4. Position the patient so that there is no pressure on the Patch during treatment.
5. Press the START button to begin treatment. The Green mA Light will blink more rapidly, then glow steadily.
6. To change the iontophoresis current setting while the Controller is administering a treatment, press the Standard Mode button to re-select the desired setting. Within a few moments, the Controller will automatically adjust to the new setting.
7. In 10-20 minutes (see following table) the Controller will sound a beep and the lights will turn off, indicating the 40 mA-minute treatment has been completed.

Standard Mode	40 mA-min	80 mA-min
2mA	20 minutes	Repeat steps 1-2 and 5-7
3mA	13 minutes	Repeat steps 1-2 and 5-7
4mA	10 minutes	Repeat steps 1-2 and 5-7

8. Remove the Controller from the Patch.
9. Remove and discard the Patch after the treatment has been completed. The Patch cannot be reused.

Controller Specifications

Electrical Shock	Internally Powered Type BF
Battery	Rechargeable Lithium-ion, 3.7 VDC Nominal, 230 mA- Hr
Environmental Conditions	Storage: 10° - 35° C (50° - 95° F) Operating: 15° - 30° C (59° - 86° F)
Ingress of Water	Not protected against ingress of water, IPX0
Flammability	Do not use around flammable gasses, liquids or materials
Treatment	I-Bresis™ and Standard
Dimensions	5.5 cm H x 4.5 cm W x 1.5 cm L
Weight	23 g
Disposal	Dispose according to local, state and federal regulations.
Dose Range	0 to 40 mA-minute (I-Bresis™ Patch has an 80 mA-minute dose capacity)
Controller Capacity	Approximately 200 mA-minutes when fully charged.
Maximum Voltage	70V DC
Maximum Current	4 mA
Current Ramp Up	0.1 mA/sec (start of treatment, restart after pause)

Current Ramp Down 0.5 mA/sec (end of treatment, pause, power-off)

Fast Current Ramp Down Instantaneous (Low Battery Warning, Current Interrupt Alarm)

Buttons ON/OFF, START/PAUSE and STANDARD

Treatment Lights or Green Flashing: I-Bresis™, 2, 3 or 4 mA ramping-up
ramping-down Green Continuous: I-Bresis™, 2, 3 or 4 mA steady state

Battery Light Yellow Continuous: Low Battery Warning

Interrupt Light Red Flashing: Current Interruption Alarm

Charging

The single internal 3.7 VDC rechargeable lithium-ion battery cell is connected to a Protection Circuit Module (PCM) that provides additional protection for over-charging and over-discharging. However, the battery will enter an over-discharge state via self-discharge if it is not used for a long time. This results in battery degradation (e.g. the mA-Hr capacity of the battery will decrease). To prevent over-discharging, return the Controller to the Charging Station after each use. If the Controller cannot be stored in the Charging Station for a considerable period of time (e.g. 6 months), fully charge the Controller before long-term storage.

Lithium-ion batteries, unlike Ni-Cad batteries, do not suffer from “Memory Effect” (the lithium-ion battery does not require a periodic full discharge and recharge to “refresh” the battery). The Controller can be stored and recharged in the Charging Station after each use. Elevated temperature will result in degraded battery performance and reduced battery service life. Therefore, never place the Controller near heating sources or in direct sunlight for long periods. DO NOT open the Controller case to access the battery or for any other reason.

When returning any products, please include your name, address, phone number and a description of the problem.

Return to:

DJO Global

1430 Decision Street
Vista, CA 92081

Repair and Maintenance

There are no user serviceable parts inside the Controller. If the Controller appears to be non-functional, contact your Authorized DJO, LLC Distributor, or contact DJO, LLC directly.

Clean the case as needed with a damp cloth. Do not immerse in fluids.

Ordering

Order Number	Description
1360	I-Bresis™ Charging Station
1361	I-Bresis™ Controller
5000060	I-Bresis™ Patch

Limited Warranty

I. Warning

While, in the opinion of DJO, LLC (“DJO, LLC”), the use of the I-Bresis™ System (the “Product”) has met with some success, DJO, LLC makes no warranties to the purchaser as to the effectiveness of the product.

II. Warranty

A. DJO, LLC warrants to the initial Purchaser (“Purchaser”) (and to no other person) that the Product (with the exclusion of accessories) and the component parts thereof, distributed or manufactured by DJO, LLC, shall be free from defects in the workmanship and materials for three years from the initial date of purchase from DJO, LLC (the “Warranty Period”).

B. The patches are excluded from the Warranty and sold “AS IS” because their structure is such that they may be easily damaged before or during use.

III. Limitation of Liabilities and Disclaimer of Warranties

A. DJO, LLC’s sole obligation in the case of any breach of its warranties set forth in Paragraph IIA above, shall be, at DJO, LLC’s option, to repair or replace the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send DJO, LLC written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period, and within 30 days of discovery of the defect. Upon DJO, LLC’s written request and authorization, Purchaser shall return the Product to DJO, LLC, freight and insurance prepaid, for inspection.

Notice and return shipment shall be sent to DJO LLC at 1430 Decision St. Vista, CA 92081, USA, or to an DJO, LLC Authorized Service Center. To locate the appropriate service center outside of North America, or to request shipment approval, contact DJO, LLC directly. DJO, LLC will not be responsible for damage due to improper packaging or shipment. If DJO, LLC determines in its sole reasonable discretion that the Product contains defective workmanship or materials, DJO, LLC will refund to the Purchaser, the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, freight and insurance prepaid, as soon as reasonably possible following receipt of the Product by DJO, LLC. If DJO, LLC determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, DJO, LLC will return the Product to the Purchaser, freight and insurance billed to the Purchaser.

B. This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of DJO, LLC or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

C. EXCEPT AS PROVIDED IN PARAGRAPH IIA, THE PRODUCT IS BEING SOLD ON AN "AS IS" BASIS, ALL ACCESSORIES ARE SOLD "AS IS", AND THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE PRODUCT IS WITH PURCHASER. THE WARRANTY PROVIDED IN PARAGRAPH IIA IS INTENDED SOLELY FOR THE BENEFIT OF THE INITIAL PURCHASER AND DJO, LLC DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED

WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE; PROVIDED, HOWEVER, THAT NOTWITHSTANDING THE FOREGOING SENTENCE, IN THE EVENT AN IMPLIED WARRANTY IS DETERMINED TO EXIST, THE PERIOD FOR PERFORMANCE BY DJO, LLC THEREUNDER SHALL BE LIMITED TO THE LIFETIME OF THE INITIAL PURCHASER. NO EMPLOYEE, REPRESENTATIVE OR AGENT OF DJO, LLC HAS ANY AUTHORITY TO BIND DJO, LLC TO ANY AFFIRMATION, REPRESENTATION OR WARRANTY EXCEPT AS STATED IN THIS WRITTEN WARRANTY POLICY.

(This Warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.)

D. DJO, LLC SHALL NOT BE LIABLE TO ANY PERSON FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR MEDICAL EXPENSES CAUSED BY ANY DEFECT, FAILURE, MALFUNCTION OR OTHERWISE OF THE PRODUCT, REGARDLESS OF THE FORM IN WHICH ANY LEGAL OR EQUITABLE ACTION MAY BE BROUGHT AGAINST DJO, LLC (E.G. CONTRACT, NEGLIGENCE OR OTHERWISE) THE REMEDY PROVIDED IN PARAGRAPH IIIA ABOVE SHALL CONSTITUTE PURCHASER'S SOLE REMEDY. IN NO EVENT SHALL DJO, LLC'S LIABILITY UNDER ANY CAUSE OF ACTION RELATING TO THE PRODUCT EXCEED THE PURCHASE PRICE OF THE PRODUCT.

(This Warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to the Purchaser.)



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MOTION IS ⁺MEDICINE®

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