I-Bresis

Charging Station (1360) - Instructions For Use

READ THE I-BRESIS™ CONTROLLER AND PATCH INSTRUCTIONS FOR USE FOR ADDITIONAL IMPORTANT INFORMATION.
GLOSSARY OF SYMBOLS

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

- Consult Instructions
- Keep Dry
- Keep Away from Sunlight
- Class II Equipment
- Storage: 5°C - 40°C (41°F - 104°F)
- DO NOT expose to temperatures above 50°C (122°F)

For Prescription Only
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Dangerous Voltage

Precautionary Instructions

Medical Equipment Classified by Underwriters Laboratories Inc., with respect to electric shock, fire and mechanical hazards only in accordance with UL-60601-1, and CAN/CSA C22.2 No. 601.1-M90.
**Warnings**

- Keep out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and alarms) may not operate properly when this equipment is in use.
- Electrodes should be removed before using equipment that generates high frequency or high energy electromagnetic radiation such as welding equipment, surgical electrocautery units, shortwave and microwave therapy. Operation in close proximity (<3m) to this equipment may startle the user by causing output instability or improper operation of the stimulator. Simultaneous connection to the patient may result in burns and possible damage to the stimulator.
- 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.
- Do not operate these units 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.
- This unit generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following: reorient or relocate the receiving device, increase the separation between the equipment, connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected or consult the DJO LLC Repair Department for help.
- The system is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. Such use could result in fire or explosion.
- No modification of this equipment is allowed.

**Precautions**

- Use only accessories that are specially designed for this unit and recommended by DJO LLC. The use of other accessories or cables may result in increased emissions or decreased immunity of this unit.
- Avoid exposure to water. Do not allow the charging station to be immersed in fluids.
DESCRIPTION AND INTENDED USE
The I-Bresis™ Charging Station is designed to charge and store I-Bresis™ Controllers.

The I-Bresis™ Charging Station is intended to be used in a hospital or clinic setting. It is not designed for home use.

The I-Bresis™ Charging Station is not an Applied Part. It is not intended to come into contact with patients.

OPERATION
The I-Bresis™ Charging Station charges up to four I-Bresis™ Controllers, maintains them in a fully charged state and provides a convenient place for storage.

- Make sure that the power cord is connected to the Charging Station. Place the Charging Station on a level surface and connect the power cord to an appropriate wall outlet.
- Make sure that the device is positioned so that it is easy to disconnect the power cord from the device or from the wall outlet in the event that power needs to be turned off.
- Insert one to four I-Bresis™ Controllers into the charging bays.

CAUTION: Make sure that the Controllers are dry. Water dripping into the Charging Station may cause the Charging Station to malfunction.

General
When a Controller is inserted into one of the charging bays, the Charging Station will automatically detect the battery level of the Controller and will begin to charge it.
Charging Station Lights
The two windows on each of the charging bays indicate the following:

<table>
<thead>
<tr>
<th>Light</th>
<th>Status</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Green</strong></td>
<td>Charge Complete;</td>
<td>None Required</td>
</tr>
<tr>
<td></td>
<td>The Controller is fully charged and ready for use.</td>
<td></td>
</tr>
<tr>
<td><strong>Orange</strong></td>
<td>Charging;</td>
<td>None Required</td>
</tr>
<tr>
<td></td>
<td>The Controller is charging normally.</td>
<td></td>
</tr>
<tr>
<td><strong>Red</strong></td>
<td>Charging Fault;</td>
<td>Return Controller to DJO LLC for replacement.*</td>
</tr>
<tr>
<td>Continuous or Flashing</td>
<td>Controller battery not charging properly.</td>
<td></td>
</tr>
</tbody>
</table>

*On rare occasions, the problem may be due to a defective Charger. If you have another Controller, please charge it to determine if the Charger is functioning correctly or not. If the same problem occurs with multiple Controllers, then the Charger may be defective.*

Turning Off Charging Station
To turn off the Charging Station, disconnect the power cord from the device or from the wall socket.
The Charging Station is designed to store up to four Controllers when they are not in use.

Information on I-Bresis™ Controller Batteries
Each I-Bresis™ Controller contains one 3.7 Volt DC rechargeable lithium-polymer battery. The 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 mAH 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 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.
<table>
<thead>
<tr>
<th><strong>Charging Station Specifications</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Voltage Requirement</strong></td>
<td>100 – 240 VAC @ 50 – 60 Hz</td>
</tr>
<tr>
<td><strong>Current Requirement</strong></td>
<td>0.125 A maximum</td>
</tr>
<tr>
<td><strong>Environmental Conditions</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>5°C - 40°C (41°F - 104°F)</td>
</tr>
<tr>
<td></td>
<td>DO NOT expose to temperatures above 50°C (122°F)</td>
</tr>
<tr>
<td><strong>Operating</strong></td>
<td>15°C - 30°C (59°F - 86°F)</td>
</tr>
<tr>
<td><strong>Ingress of Water</strong></td>
<td>Not protected against ingress of water, IPX0</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>8.5 cm H x 15 cm W x 12.5 cm L</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>421g</td>
</tr>
<tr>
<td><strong>Class II</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Continuous Operation</strong></td>
<td></td>
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</tbody>
</table>
REPAIR AND MAINTENANCE

- There are no user serviceable parts inside the Charging Station. If the station or power cord appears to be damaged or 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.

EXPECTED LIFE AND DISPOSAL

- The Charging Station is expected to provide at least seven years of normal use.
- The Charging Station is electronic equipment and may include substances that can damage the environment. DO NOT dispose of the Charging Station as municipal waste.
- Contact DJO for information regarding disposal of the Charging Station.

ORDERING

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1360</td>
<td>I-Bresis™ Charging Station</td>
</tr>
<tr>
<td>1361</td>
<td>I-Bresis™ Controller</td>
</tr>
<tr>
<td>5000060</td>
<td>I-Bresis™ Patch</td>
</tr>
</tbody>
</table>
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 IIA 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.)