



## PRODUCT INSERT

### INFORMATION FOR PATIENTS & MEDICAL PROFESSIONALS

AW-1.01171 Rev B 0715

#### INDICATIONS FOR USE

- Breg Flex is intended for use to assist in tracking the progress of the physical therapy program that has been prescribed by your health care professional.

#### The Breg Flex System

- Breg Flex Sensor
- Charger
- Attachment Strap
- Micro USB Cable

#### Mobile Device Compatibility

The Breg Flex sensor is compatible with the mobile devices listed below. For a list of compatible operating systems (OS) , log onto bregflex.com or contact Breg Flex Support at (888) 290-8481or (800) 321-0607.

#### Apple® Corporation

- iPhone®4S
- iPhone®5 / 5C / 5S
- iPhone®6 / 6plus
- iPod touch® (5th Gen)
- iPad®(3rd Gen)
- iPad Mini™
- iPad Air®

Apple, iPhone, iPod, iPod touch, iPad and iPad Air are Registered Trademarks of Apple® Corporation. iPad Mini is a Trademark of Apple® Corporation.



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Scan QR Code  
for video



bregflex.com

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## WARNINGS



#### Use only as prescribed

This product is to be used only in the manner prescribed by your Health Care Practitioner or Physical Therapist for the specific exercise and frequency of treatment.



#### General safety

Keep the micro USB cable and application strap away from the neck to avoid risk of strangulation.

No modification of this equipment is allowed.

Keep micro USB cable out of pathways to avoid a risk of tripping.

Choking hazard, do not place sensor in mouth.



#### Electrical safety

Like all electrical products, you must follow precautions to avoid electrocution, fire, burns, or other injuries. Use only the charger provided with the Breg Flex system to meet the requirements of EN 60601-1.



#### Keep electrical connections dry and free of debris

The electrical connections at the power outlet and from the micro USB cable to the Breg Flex Sensor must be kept dry. Do not handle the charger or micro USB cable with wet hands. Always keep the charger and sensor in a place where the connections will not fall into water (e.g., a tub, sink, etc.). If the electrical connections fall into water, do not touch any wet part of the product. Unplug only at dry electrical connections.



#### Protect the micro USB cable and charger

Keep the micro USB cable and charger away from heated surfaces. Set up and use this equipment in a low traffic location away from children and pets. Never operate this product if it has a damaged micro USB cable, charger, or plug, which could result in electric shock. If the micro USB cable, charger, or plug is damaged, unplug and contact Breg Customer Care at (888) 290-8481or (800) 321-0607.



#### Electromagnetic interference

This Breg Flex Sensor may cause electromagnetic or other interference with other electrical devices. Should this occur, discontinue using the Breg Flex App and contact the Breg Flex Support Group at (888) 290-8481 for further assistance.



#### Avoid flammables and oxidizers

Do not use in places with flammable vapors or gasses (e.g. flammable anesthetics), high oxygen concentrations, or other oxidizers (e.g. nitrous oxide).



#### Discontinue use

If significant pain or discomfort are present, please discontinue use immediately and contact your health care professional.



#### Not intended to be used

Do not use outside of the program prescribed by your health care professional.

Do not use after your physical therapy program is complete.



#### Do not submerge Breg Flex Sensor

#### LED Indicator Light

|                                          | Blink twice/1 sec | Blink once/1 sec       | Steady Glow   |
|------------------------------------------|-------------------|------------------------|---------------|
| Sensor with Micro USB Cable Connected    | Charging          | — —                    | Fully charged |
| Sensor without Micro USB Cable Connected | — —               | Pairing with Bluetooth | Sensor paired |

- Sensor will automatically turn off after 10 minutes of inactivity
- Recharge sensor prior to each treatment period

#### Troubleshooting Guide:

##### Charging:

- Sensor LED should blink twice every 1 second to indicate it is charging. If the sensor is not charging, ensure power outlet is working and power connections are fully engaged.

##### Pairing:

- Sensor LED should blink once every 1 second to indicate it is pairing. If the sensor is not pairing with your device, try each of the following steps.
  - Ensure the Bluetooth setting on your mobile device is activated.
  - If sensor is not responding, try moving it around to receive a blinking LED signal. If sensor does not respond from movement, plug sensor into charger to ensure sensor is fully charged.
  - If your device Bluetooth setting is on and sensor is still not responding restart your mobile device.

##### While in Use:

- If sensor and your mobile device become unpaired during your therapy, check your app for instructions on continuing.
- If your app is not responding to either your range of motion, sets or repetitions ensure the sensor light is in a solid state, not blinking.
- If sensor LED is not coming on during movement or when charging, please call Breg Flex support at (888) 290-8481or (800) 321-0607.

#### CLEANING, MAINTENANCE & SERVICE: HOME CLEANING PROTOCOL

##### Sensor:

- Clean external surface with a mild cleaner applied to a clean cloth.
- Do not spray cleaner into micro USB port.
- Do not submerge sensor unit in water or cleaning solution.
- Use a small comb or toothpick to remove any fiber build up in hook fastener.

The Breg Flex Sensor contains no user-serviceable parts.  
Contact Breg Customer Care for service or replacements.  
(888) 290-8481or (800) 321-0607

##### Micro USB Cable / Charger:

- Clean external surfaces with a mild cleaner applied to a clean cloth.
- Inspect micro USB cable before use to ensure insulation is unbroken.
- Do not spray cleaner into USB port.
- Do not submerge charger or micro USB cable in water or cleaning solution.

##### Application Strap:

- Hand wash strap in luke warm water with a mild detergent.
- Lay flat to air dry only.
- Use a small comb or toothpick to remove any fiber build up in hook fastener.

#### Federal Commications Commission (FCC) Statement (USA):

This device complies with FCC part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference and
- This device must accept any interference recieved, including interference that may cause undesired operation

**Note:** Breg is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Changes or modifications not approved by Breg , Inc. could void the user's authority to operate the equipment. This device meets the FCC requirements for RF exposure in public or uncontrolled environments.

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarentee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the recieving antenna

-Increase the seperation between the equipment and the reciever

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

-Consult the Breg Customer Service Representative or an experienced radio/TV technician for help

#### DISPOSAL

Dispose of product according to local regulations.

#### WARRANTY

Breg, Inc. warrants that this product is free from defects in workmanship, materials, and fitness for use for 180 days from initial purchase under normal use for which it was intended and under direct supervision of a licensed healthcare practitioner.

Breg, Inc.'s obligation under this warranty is limited to the replacement or repair of any defective part or parts of this product. All expressed or implied warranties, including the warranty of merchantability and fitness for a particular purpose, are limited to the actual warranty period set forth above. No other warranty, express or implied, is given and no affirmation of or by seller, by words or action, will constitute a warranty.

#### Physical and Electrical Specifications

Unit Rated: 5Vdc, 1000mA

##### Power supply is specified as part of ME Equipment

|                                                              |                                              |
|--------------------------------------------------------------|----------------------------------------------|
| Manufacturer: Qualtek USA<br>Rated Input: 100-240V~, 50-60Hz | Model: QFAW-05-05<br>Output: 5Vdc, max. 1.0A |
|--------------------------------------------------------------|----------------------------------------------|

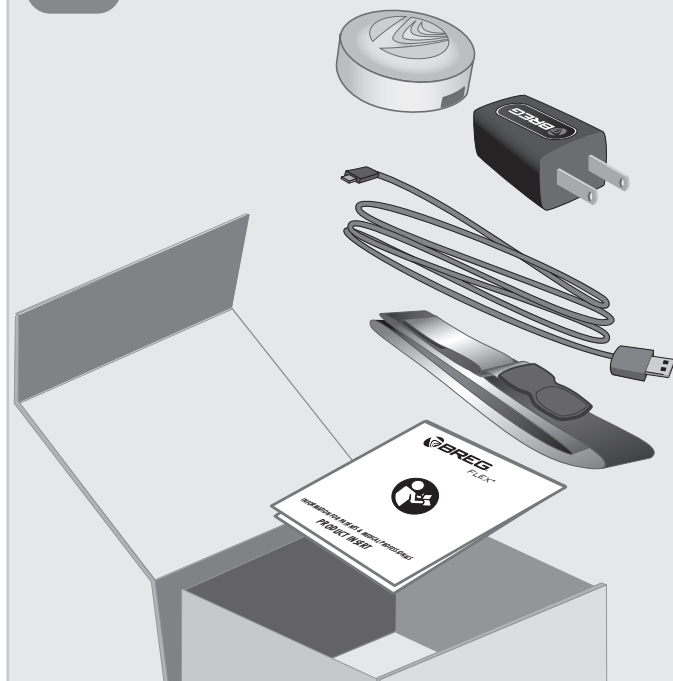
##### Environmental Requirements:

|                             |                                                                            |
|-----------------------------|----------------------------------------------------------------------------|
| Transport & Storage:        | −25°C (−13°F) no humidity control to 70°C (158°F ) up to 93%RH             |
| Operating:                  | 5°C to 40°C (41°F to 100°F )15-93%RH - 700 hPa to 1060 hPa                 |
| Standards Compliance:       | Designed to conform to applicable requirements of: IEC60601-1, 3rd Edition |
| Electrical Classifications: | Class II, Continuous Operation - Not suitable with flammable anesthetics   |

# BREG FLEX™ PRODUCT INSERT INFORMATION FOR PATIENT USE

1

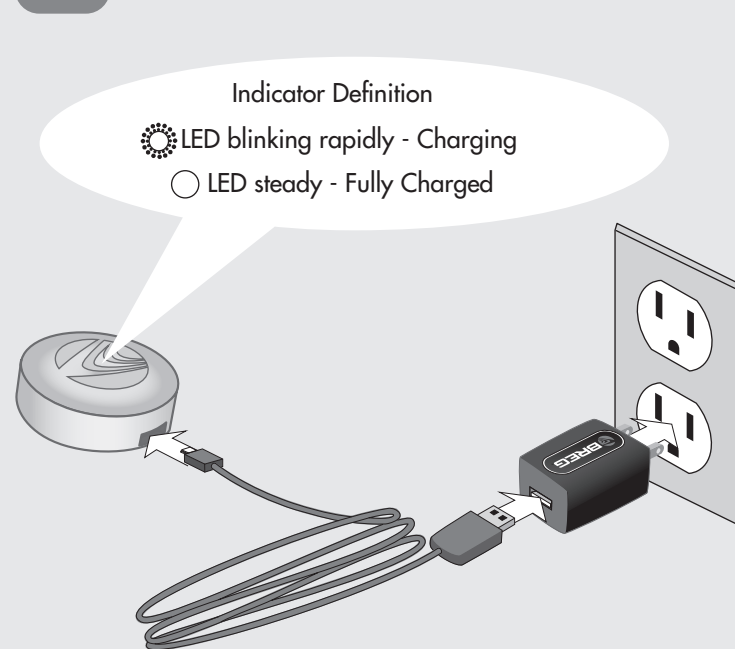
What's in the package



Breg Flex Sensor  
Charger  
Micro USB Cable  
Attachment Strap  
Instructions for Use

2

Charge the sensor

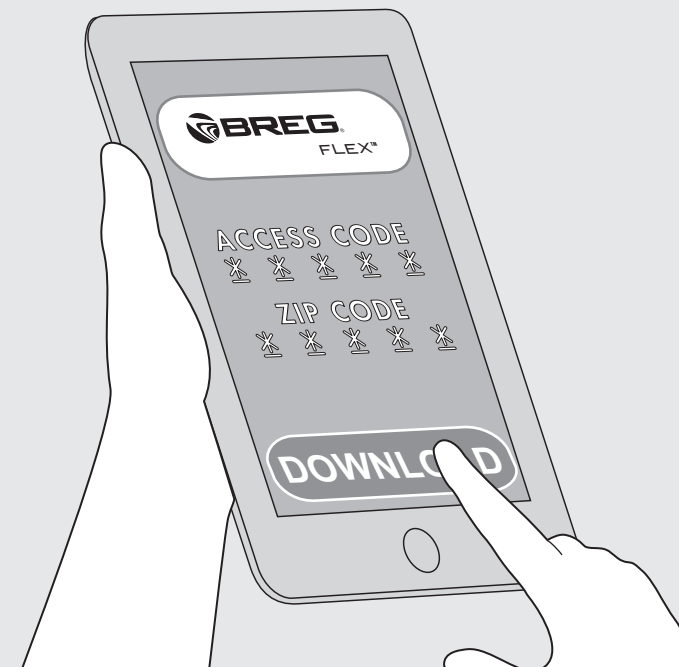


## WARNING!

Use only the power source and cable provided.  
Use of other cables and / or power source  
may cause damage to the sensor.

3

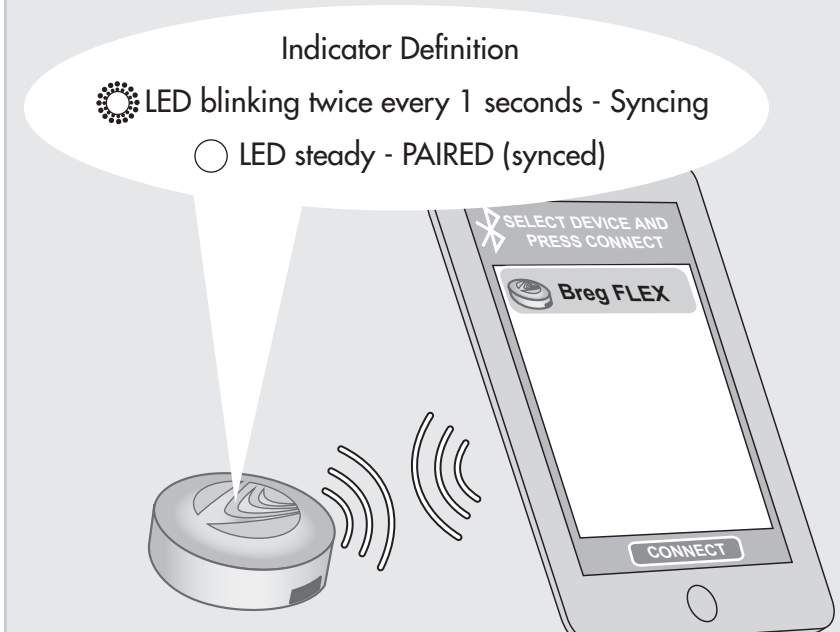
Download the App  
to your mobile device



You will receive an email or printout from your  
medical professional that will contain a link to  
download the app and a unique 5-digit code to  
allow you to access your prescribed exercises.

4

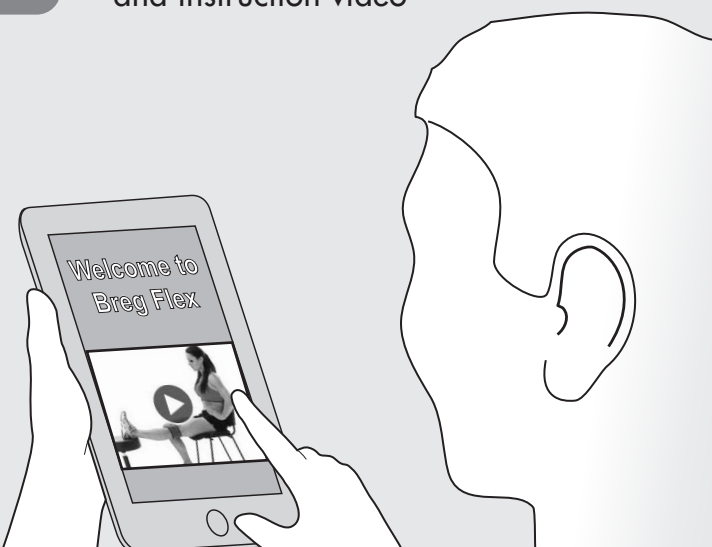
Activate Bluetooth and PAIR (sync) the sensor  
with your smart phone or tablet



On the mobile device, go to tools and ensure that the  
Bluetooth function is turned on and the sensor is  
available for pairing (syncing).

5

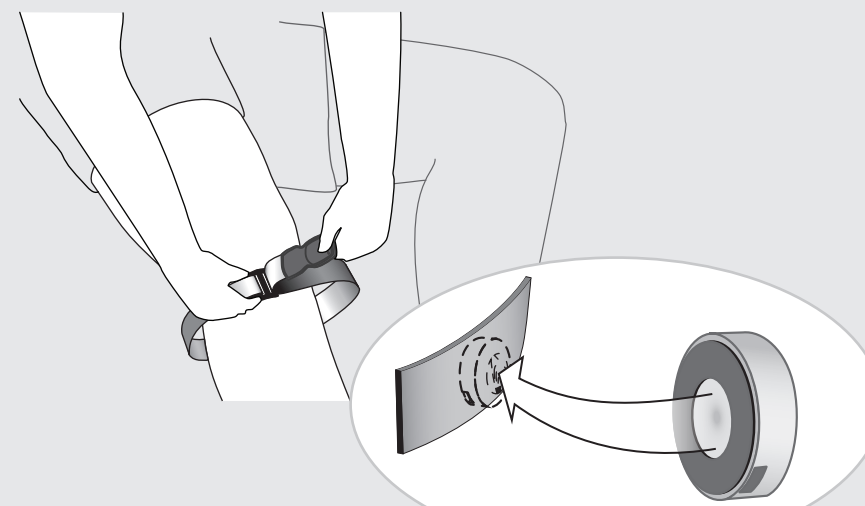
Watch set up  
and instruction video



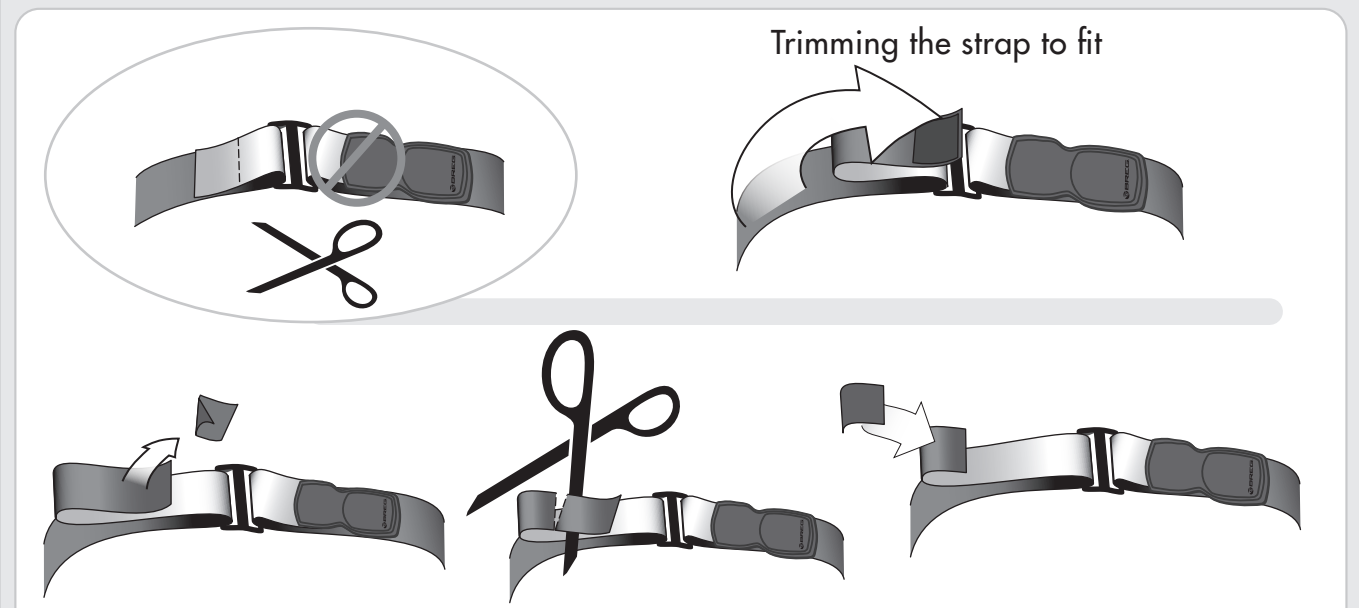
Each instructional video will contain information on  
calibration and application of the sensor,  
based on the program that has been selected  
by your medical professional.

6

Application and use  
of the sensor and strap



Use of the strap and sensor will vary based on the program  
that has been prescribed by your medical professional.  
If the strap/sensor is to be used in the exercise,  
the proper application of the strap will be shown in the video.



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