BPMpathway Instructions for USE (IFU)

Model: BPMpathway

The serial number for the BPMpro sensor contained in the BPMpathway Sensor Kit is on the packaging and held electronically in the device.

Intended use

BPMpathway is a system for remote reporting of patient's movement data. It is intended to be used by joint injury patients and their treating health professionals in pre- and rehabilitation. BPMpathway consists of a single BPMpro sensor and BPMpathway software for patients and health professionals. The BPMpro sensor reports the range of joint motion of patients while it is attached to the limb, over clothing, with a strap. The BPMpro sensor transmits the motion data to a tablet/computer, which runs a companion data visualisation program to display and record the range of motion of patient tests during the clinician-defined programme of tests and exercises. The software reports the results back to the health professionals through a wireless connection. The BPMpathway software is downloaded and run on a suitable tablet PC. A further description of the correct use and functionalities of BPMpathway is available in the Patient User Guide and Professional User Guide.

Downloading the BPMpathway application & User Guides:

Patient users with Android and Apple tablets:

- Using the app store for your tablet, click on the store icon.
- Search for apps called BPMpathway.
- Download and install the application as required.
- Download the user guide from www.bpmpathway.com/downloads.

Patient users with Windows laptops/tablets and professional users:

- Go to www.bpmpathway.com/downloads.
- Select the download for your device, download and install.
- Download the user guide from www.bpmpathway.com/downloads.

Locate the orange BPMpathway icon and click to run the app.

Using the application

Environment

Sensor operating temperature 5°C to 35°C.

Sensor charging

- Before first use, charge the BPMpro sensor using the supplied charger lead by plugging the lead into the sensor, then into a large USB charger unit.
- While charging, the sensor LED flashes orange.
- When fully charged, the sensor LED flashes slowly blinks green.
- When the sensor battery is low, the sensor LED flashes red. To continue with the test, it is critical to charge the sensor. If the sensor is not charged, the test cannot be performed.

Warning

Do not use the BPMpro sensor while it is charging. When the BPMpro sensor is fully charged and the LED is green, remove from charge.

Activate the sensor

- Shake the BPMpro sensor to wake it.
- The sensor LED flashes blue.

Perform the test

BPMpathway can be used by medical professionals and patients and is designed to be used in consulting room and home environments.

- Start the app on your laptop/tablet.
- The activated sensor auto-connects to the app.
- Using the strap provided, attach the sensor to the limb to be assessed. Note: The sensor is not intended to be used directly on the skin.
- Position the sensor as explained by the clinician and/or in the app.
- Follow the instructions in the app to perform the test.
- During the test you can mark the position where you feel pain for the professional to review.

After the test

- Remove the BPMpro sensor from the body/limb.
- Close the app.
- Repeat as directed by the clinician.

Indications

Pre- and rehabilitation of post joint injury or surgery.

Contraindications

There are no known contraindications of BPMpathway when used as instructed.

Servicing

BPMpathway contains no user serviceable parts. If the sensor becomes dirty wipe with a damp cloth. Do not immerse in water.

Calibration

BPMpathway is supplied pre-calibrated.

Certification

CE	Dir 93/42/EEC ; Dir 2002/95/EC
FC	ICES-003 Issue 6 2016-01 Interference-Causing Equipment Standard Digital Apparatus.
	R 202-L S D026 T D 15-0014 202
IP33	Protected from tools and wires greater than 2.5 millimetres. Protected from water spray at less than 60 degrees from vertical.

Disposal

At the end of its serviceable life the BPMpro sensor should not be treated as household waste. The sensor should be returned to the supplier for suitable disposal or handed over to a suitable recycling facility for electrical and electronic equipment.

nt of physical damage

When inspection of a BPMpro sensor identifies physical damage to the case, contact your hospital/clinician.

Storage & handling

Sensor storage temperatures 5°C to 40°C.
Do not immerse in water, tested to IP33 light water spray only.

Technical description

BPMpathway contains a wireless BPMpro sensor, which is designed to be used by clinicians and patients in the consulting room or home environment. The BPMpro service period / maintenance period is 2 years from the date of manufacture. Natural latex is not used in the manufacture of BPMpathway. BPMpathway has an integrated wireless Tx/Rx with <20mW transmitted power, on a frequency band of 2400-2483.5 MHz with the carrier modulated using Gaussian Frequency Shift Keying (GFSK).

Support

If you have any problems, contact your hospital/clinican or send an email to support@bpmpathway.com detailling your problem.

Manufactured in the EU by:

270 Vision Limited, registered office: The Pavilion, Botleigh Grange Business Park, Hedge End, SO30 2AF, United Kingdom.

Any serious incident that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is located.