



BPMpathway

Professional User Guide



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Introduction

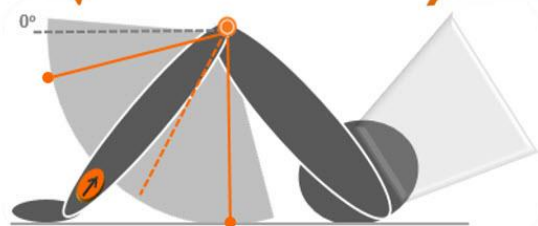


What is BPMpathway?

Before a patient leaves hospital or during the pre-operative period, BPMpathway helps the clinician to create them a personalised rehabilitation programme designed to give them the best possible post-operative support programme to meet their individual needs. The patient is issued with a sensor, which has a unique system identifier that means their software will only download settings and transmit data relating to that particular sensor. This ensures that no PHI is transmitted outside of the hospital.

Using the sensor and the patient-centric software, the patient's daily test programme is a combination of tests to assess range of motion and physiotherapy exercises to help with rehabilitation. They will probably be asked to do their routine three times each day. The easy-to-use system is designed to encourage patient engagement by clearly explaining what they have to do at each stage of their recovery and displaying their progress via easy to understand graphics. During the programme, the sensor is attached to the limb on which they had surgery, which transmits movement results to their tablet.

Attach sensor



Perform test

Review results



The test results from the sensor are also transmitted securely via the internet to the clinician. This enables them to remotely review their patient's recovery as they undertake their personalised daily rehabilitation programme. By reviewing the remotely gathered data, the clinician can assess the patient's progress and recovery trends and adjust their rehabilitation schedule as appropriate. **Remote reporting means the clinician can prioritise resources to those who need them most, whilst the patients progressing well can recover and undertake regular physiotherapy in the comfort of their home.**

A two-way messaging system means that patients and professionals can stay in touch throughout the recovery period. Should either one have questions or concerns, they can send a message, just like an SMS.



Professional and patient software

BPMpathway has two different types of software with individually designed user interfaces:

Professional software

This is designed for the set up and review of patient test programmes and for the remote reviewing of patient progress and compliance during their rehabilitation. The professional has an overview of and detailed information about all of their patients' progress. Should a patient fail to progress through their programme or undertake their tests, alerts appear in the software so that the clinician can take action.

Using BPMpathway wearable technology, clinicians remotely review the patient's post-surgical recovery and set them stretch goals accordingly. When they're progressing well at home, the clinician can decide that the patient can continue their rehabilitation in the comfort of their own home, thereby freeing up the resources that would otherwise have been allocated to them for those who need them most.

In the case of those patients who are struggling with their recovery, BPMpathway provides a means of identifying the potential need for early intervention and a communication link between the patient and clinician to establish whether they need to be prioritised for outpatient support.

Patient software

This is designed to take the patient through a clear path of what they need to do throughout the rehabilitation process, with videos to help them with the set up and performance of tests and exercises. All the patient sees are the test and exercises they are required to undertake at each stage in their recovery, as they are gently progressed through their programme with ever increasing test limits as they achieve their targets. After they complete their daily routine, they are provided with a clear graphical depiction of their progress and recovery trends.

During their tests, the patients have the opportunity to record points of discomfort or restriction which are recorded against the session data for comparison. After their test, they are required to record a pain score as required for PROMs using the internationally recognised Wong-Baker Pain Rating Scale. During the rehabilitation process, the sensor can also be used as a general activity tracker as it has been shown that joints heal in motion.^{1,2}

¹ AAOS. Ortho Info. Your connection to expert orthopaedic information. 2014. [Internet, 10.02.2017] http://orthoinfo.aaos.org/topic.cfm?topic=a00233&_sm_a_u_=i5V6dBqPpL7NrtZr.

² Pozzi F, Snyder-Mackler L, Zeni J. Physical exercise after knee arthroplasty: a systematic review of controlled trials. *Eur J Phys Rehabil Med*. 2013 Dec;49(6):877-92.



Personalised patient programmes

What is a patient programme?

A programme is a combination of one or more tests to assess range of motion and physiotherapy exercises to help with rehabilitation. Normally the patient will be asked to do their programme three times each day. The patient is gradually stepped through their programme as they reach their targets.

How is it personalised to the patient?

The purpose of personalised programmes is to set the patient realistic tests, targets and exercises appropriate to the stage of recovery and their overall fitness.

There are several ROM tests for each joint, which can be selected depending on the degree of mobility post medical intervention. For each test, the clinician can specify exercises and targets. The target ROM for the test is gradually increased through the use of phases. The difference between the start target ROM and the end target ROM for the test is divided by the number of phases into increments. Upon successful completion of a phase, the limits are automatically increased by an increment. A motivational comment can be set up against each phase.

If a programme needs to be adjusted, this can be done via the professional software and transmitted over the air to the patient. The programme is linked to the patient's sensor, which means the patient software downloads only the settings for that sensor.



Default Patient Programmes

Default programmes enable you to set up predefined tests, limits and exercises stored against each joint depending on the patient's capabilities. This removes the need to create personalised programmes for each individual patient. A patient can be assigned a default programme when they are created in the system for speed and ease of use, which can then be modified to their specific requirements if required.



Patient Management



Downloading the BPMpathway software

Please download the BPMpathway software by following instructions below.

System Requirements

The professional version of BPMpathway works on any Windows-based laptop/PC but has been designed specifically for devices running Windows 10 to benefit from its touch-screen capabilities. The laptop/PC must be able to support Bluetooth if you wish to connect a BPMpro sensor. Your device must have external internet access to be able to connect to patient tablets. Patient Health Information is stored locally and must be configured as defined by your own PHI storage regulations.

To download BPMpathway to your laptop/PC:

- Go to **www.bmpathway.com/downloads**.
- Follow the on-screen instructions.
- Click on the BPMpathway download.
- Download the BPMpathway installer as directed.
- Run the installer, noting where the application is stored.

Please ignore any security warnings about the application during installation. This is due to the limited number of times the application has been downloaded and is nothing to be concerned about.

A full user guide is also available to download from the same location.

Getting started

- Locate the BPMpathway application.
- ***Ensure that the laptop/PC is connected to the internet.***
- As soon as you have an internet connection, start BPMpathway by clicking on (shown right) to start the application.



If you have any problems using BPMpathway, please contact your local B. Braun representative.



Starting the software



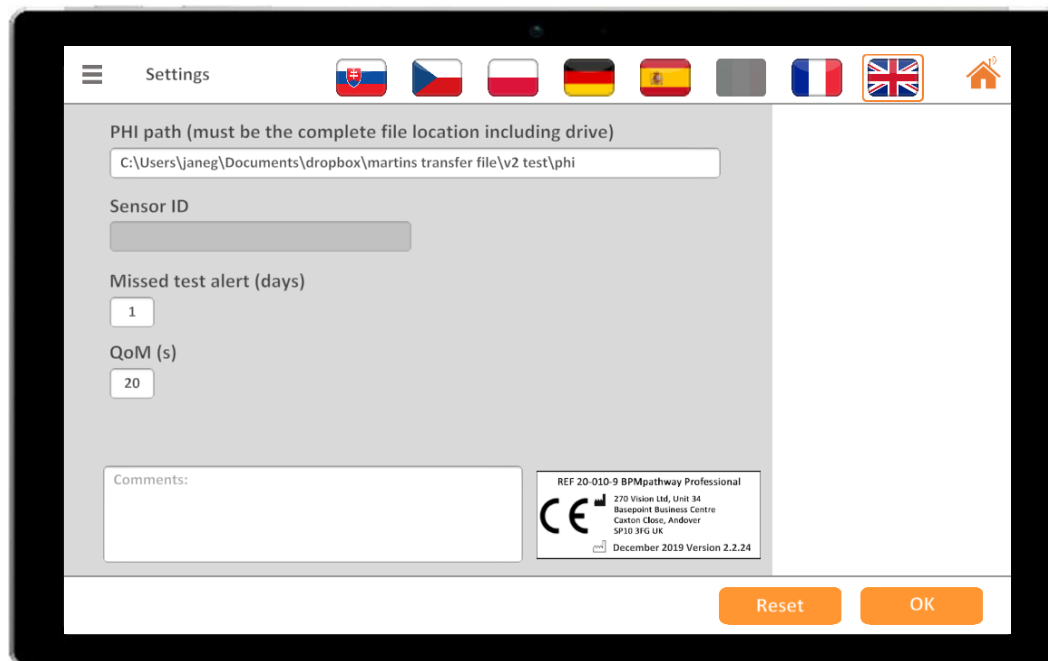
- Language - to change the language of the application, click on the relevant flag at the top of the screen. Languages not available are greyed out.
- Enter the access code. This is entered every time the application is used.
- The first time you enter the access code, you will be required to enter a licence key.
- To access PHI information, you will need to have access to the relevant data folder, as determined by your own PHI data storage and access regulations.
- The software will now load and display the **Launch** screen.

Note: A professional licence enables the user to work on- and off-line. If, however, you wish to use the licence on more than one device, you may do so, but will no longer be able to work off-line as a consequence. You may also be required to enter both the access key and licence key when starting the application.



Settings

To access the Settings screen, click on the burger menu in the top left-hand corner of the **Launch** screen and select **Settings**.



- **Language** - to change the language of the application, click on the relevant flag at the top of the screen. Languages not available are greyed out.
- **PHI path** - the storage path is shown for PHI purposes. This must be the full, specific path including the drive name. ***Please set this before creating any patients. The path should be set according to your own regulatory requirements for PHI. You are responsible for this data.***
- **Sensor ID** - You can connect any BPMpro sensor to this system. If you need to find out the sensor ID of the sensor (MAC code), the connected sensor ID code is displayed on this screen.
- **Missed test alert** - to change the alert period, enter any number between 1 and 31. The default setting is 3 days (see [Alerts](#)).
- **QoM (s)** - to change the duration of the QoM trace, enter any number between 5 and 60. The default setting is 20 seconds.
- **Comments** - this is an open text field where you can make notes about your licence or software.
- **Reset** - this restores the default settings.

Press **OK** to store any changes and to go back to the **Launch** screen.



Launch Screen



The Launch screen has the following areas:




1. **Patient Management** link - click here to see your patients and their details, including any unresolved alerts.
2. **New Patient** link - click here to set up a new patient (see [Patient Details](#)).
3. **Test Settings** link - click here to review Default Test Programmes, edit or set up tests.
4. **Review Tests** link - after selecting a patient, click here to go to their current active test.
5. **Sensor Management** link - click on the link to pair a sensor to a patient or to cancel a pairing.
6. **Patient Alerts** - this box shows patients who have alerts against them. Click on the patient's name to get details of the alert.
7. **Patient shortcut** click on the name in this box to go to the Patient Overview screen.
8. **Home** icon - click here to return to the Launch Screen.
9. **Exit** icon - click here to exit the application.

If a button is greyed out, it means that the option is not available.



Home icon

The Home icon also shows the different states of server connection, as shown below:

	No server connection, working offline
	Connected to server
	Not connected, files waiting to be updated

If the Professional user loses connection to the server, the Home icon loses its small aerial to indicate offline mode. The software checks the presence of the server connection approximately every 10 seconds. The Home icon only changes state when the network condition changes and the users switch screens, which is the point at which any changes are uploaded.

While offline, the Pro software stores the changes made to patient data. This is indicated by the red box around the Home icon which remains until the system has been able to connect and update the server.

Note: In order to see the most up to date data for a patient, you must select or re-select them.

Burger menu

The burger menu in the top left-hand corner of the screen is a shortcut to:

- Launch screen
- Patient screen
- Settings
- Screen size – switches between full and windowed screens
- Print screen
- Exit



Patient Management

Reference	Joint	L/R	Surgery	Sensor	Tests	Default	% Complete	Alerts
Andrews, Mary	Knee	R	14/02/17		K1,K1		67	
Andrews, Colin	Knee	R	13/2/18		K1		20	
android 3, Testology	Knee	R	12/6/18		K1		0	
android 4, testology	Knee	R	12/6/18	00 80 25 CE 09 C2	K2		1	
Apple, App validation	Knee	L	10/7/18	00 80 25 CE 07 80	K1		0	
dan, David	Knee	L	6/6/18		K1		1	
Davidson, Louis	Hip	R	29/4/18		H6,H7	#2	0	
Grant, Jane	Knee	L	20/4/18		K3,K1		16	
h1 left, Oto45deg	Hip	L	3/9/18		H1		0	
h1 right, Oto45deg	Hip	R	3/9/18		H1		0	
h2 left, -20to+20deg	Hip	L	3/9/18		H2		0	
h2 right, -20to+20deg	Hip	R	3/9/18		H2		0	

The Patient Management screen shows a summary of the patients registered to the professional user:

- Name, listed by surname first or reference
- Joint affected – hip, knee, shoulder, etc
- Left or right limb
- Date of surgery
- Sensor ID registered to the patient
- Tests assigned to the patient
- 'Default' indicates if a default programme has been set for the patient
- Percentage of current programme completed





You can search on patient information by either using the search box or selecting from the dropdown:

- All - all patients ever treated
- Active - patients currently being treated
- Alerts - patients with alerts against them, see [Alerts](#)
- Joint - e.g. hip, knee
- % Complete – this displays 1% from the completion of the first test up to the completion of the first phase. Once the first phase is completed the percentage will increase as normal.
- M/F - gender of patient
- Defaults – default programmes

To see more information about a patient and/or to clear alerts, select their row and press **Next** to be taken to the Patient Overview screen.



Alerts

	Test fail	A patient has not reached their minimum and maximum targets.
	Phase fail	A patient has failed to move onto the next phase within 5 days.
	Missed test	The patient has not recorded a test result for a specified period. The default is set at 3 days.
	Message	See <i>Messaging</i> .

To pass a test, the patient must meet the required test targets on all reps once the first two reps have been completed. The first two reps of all tests are discounted to allow the patients to get moving before they start being measured. This means the patient must reach and/or exceed the minimum and maximum targets on each test rep from rep 3 onwards. *The fact that the first two reps are discounted means that if the number of reps is set to 1 or 2, the patient will automatically pass the test by default.*

Within each individual recorded test result, a test fail is noted against the session as a triangle located in the table of results in the Test Screen.

Phase fail

When a patient passes 3 separate tests at any time within a phase, they are automatically moved onto the next phase. The tests passed do not have to happen sequentially and the number of test sessions that can be carried out within any one phase is unlimited.

If a patient has not passed three tests in the same phase within 5 days, a phase fail icon will appear against the patient's name on the Launch screen.

Missed test

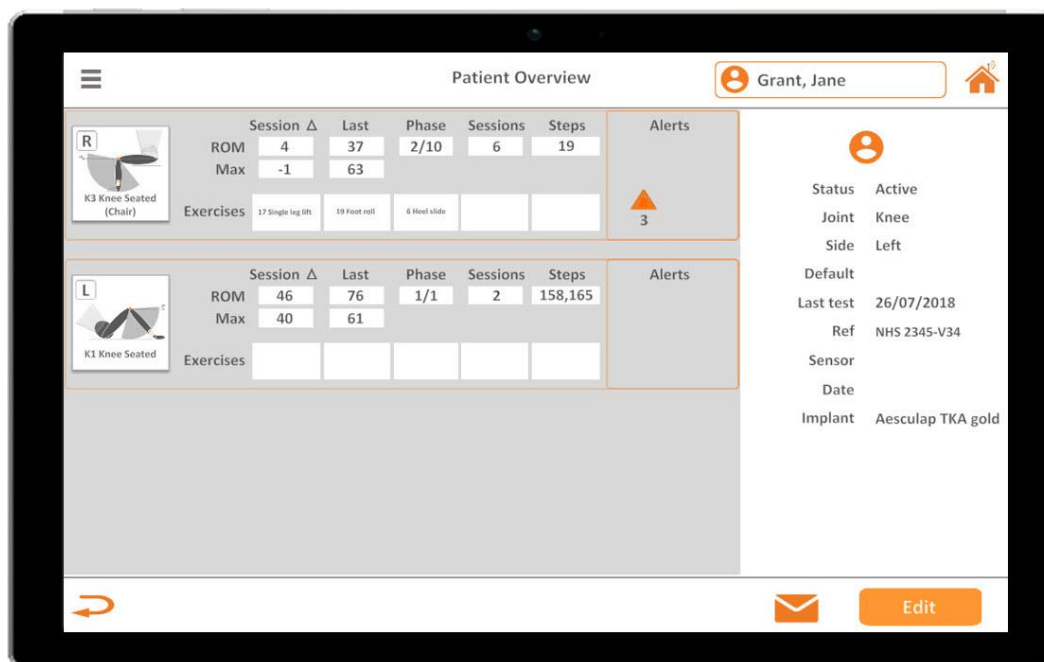
If a patient does not record a test for the number of days set in the Settings Screen, a missed test icon will appear against the patient's name on the Launch Screen.

Cancellation of alerts

- To cancel a **phase fail alert**, click on the patient's name to be taken to the Patient Overview screen.
- Click on the test icon with the alert to be taken to the Test Screen.
- The alert can be cancelled by clicking on the alert at the top of the screen.
- A **missed test alert** can only be cancelled by a patient carrying out a test.



Patient Overview



In the example shown above, the name of the selected patient is shown in the search field at the top of the screen. They have been assigned two tests, K1 sitting up and K2 prone. Having completed their first test, K1 Sitting Up, indicated by the orange tick, they have moved on to their second test, K2 prone.



1. **Session Δ** (delta) indicates the percentage change in ROM and flexion from the previous test.
2. **Last** shows the ROM of the last test.
3. **Phase** shows where the patient is in terms of completing the current phase of their programme.
In the above example, 7/10 indicates that the patient has completed 7 of 10 phases.
4. **Sessions** records how many times the patient has undertaken the current test.
5. **Steps** shows the number of steps the patient has taken since beginning the current test.
6. This image shows the current test movement. Clicking on this takes you to their test screen.
7. **Exercises** shows the exercises that have been assigned to the patient to complement their current test.
8. **Alerts** - see [Alerts](#).



The Patient Overview screen also shows the following in the right-hand panel:

- Status - active/inactive
 - Joint and side upon which the patient had their surgery
 - Date that test results were last recorded
 - Patient reference
 - Reference of the sensor assigned to the patient
 - Assigned - the date upon which the sensor was assigned to the patient
 - Implant details
-
- To view an unread message, click on the orange envelope at the bottom of the screen to go to the *Message Centre*.
 - The **Edit** button takes you to the patient details to review and/or amend their details.



Patient Details

Click on **New Patient** on the Launch screen to be taken to the Patient Details screen:

- The orange boxes are required fields to be completed in order to set up a patient.
 - **Side** - left, right or left and right - must be selected for all treatment types apart from 'Neck' and 'Other'.
 - **Default** is where a Default Programme can be assigned to the patient if required. (See [Default Programmes](#)).
 - **Implant** - here you can record details of the patient's implant.
 - **Comments field**
- Once you have entered the patient's details, press **Save** to save and continue.

Removing inactive patients

To remove a patient from the patient list, select 'Inactive' on the Patient Details screen. An inactive patient's data can still be viewed by going to the Patient Management screen and selecting 'All' from the dropdown list. This shows all patients, both active and inactive, and allows you to view any tests performed by the patient.

Tab function

The Tab key can be used to move between text fields when setting up a patient or test to facilitate data input.



Implant system

If you wish to record details of the patient's implant system, click on the **Implant system** box to be taken to the relevant Implant System screen:

Hip implant screen

Knee implant screen

- Select from the dropdown lists to record the patient's implant system.
- Press OK to return to the Patient Details screen.
- The selected details will appear in the 'Implant system' box on the Patient Details screen.



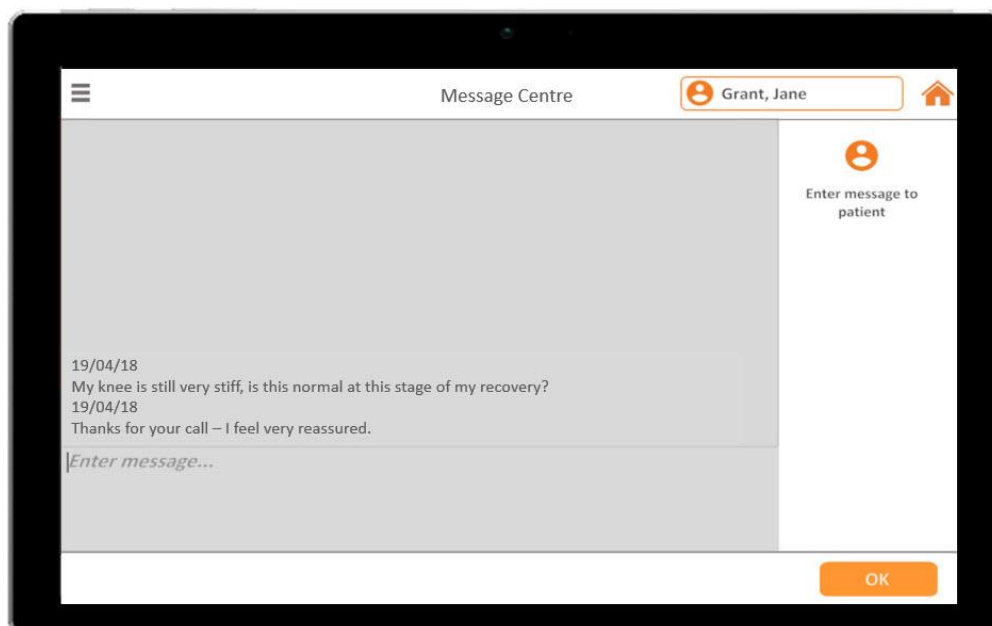
Messaging

The messaging function within the application accepts the following characters and extended ASCII characters:

`~! " £ \$ % ^ & * () _ - + = { [] } ~ # : ; @ ' < , > . ? / | \ , f , , ... + ‡ ^ % Š ‹ Œ Ž ‘ ’ “ ” • – — ~ ™ š › œ ž Ÿ
ı ċ £ ¤ ¥ ¦ § ¨ © ª « ¬ ® ¯ ° ± ² ³ ´ µ ¶ · ¸ ¹ º » ¼ ½ ¾ ¿ À Á Â Ã Ä Å Æ Ç È É Ê Ë Ì Í Î Ï Ð Ñ Ò Ó Ô Õ Ö × Ø Ù
Ú Û Ü Ý Þ ß à á â ã ä å æ ç è é ê ë ì í î ï ð ñ ò ó ô õ ö ÷ ø ù ú û ü ý þ ÿ

Any unsupported characters appear in the display as '□' in the message panel.

If a patient has sent you a message, an orange envelope icon will appear in their alerts on the Patient Management screen.



- **To read the message**, go to the patient's details and click on the orange envelope at the bottom of the screen.
- Unread messages are highlighted in yellow.
- **To reply to a message**, start typing using your device's keyboard.
- You can scroll back through previous messages using the scroll bar on the right-hand side of the message box.
- Press **OK** to send and exit.
- **To send a message to a patient**, select the patient and click on the envelope at the bottom of the screen.
- Type the message using your device's keyboard.
- Press **OK** to send and exit.

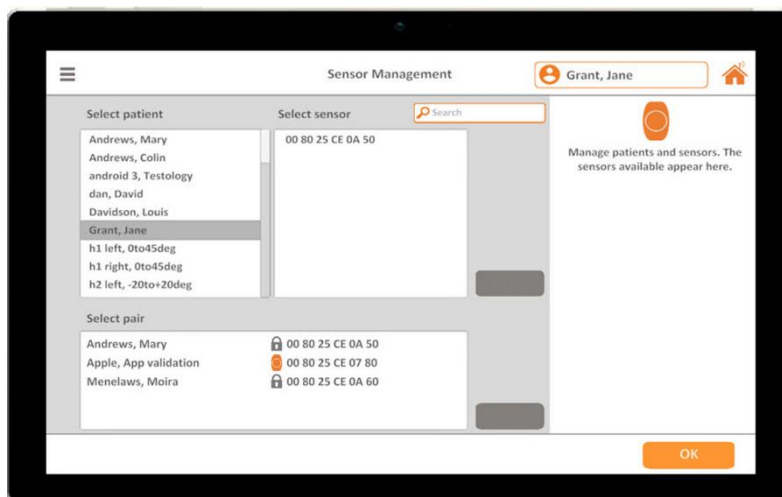


Sensor Management

Programmes are set up in the professional software and transmitted over the air to the patient, controlled through the issue of the specific sensor. When the programme is set up it is linked to the specific sensor and when the patient connects that sensor to their software, the software downloads the settings set up for that specific sensor.

The sensor is key to the system working so they must not be misplaced or re-issued without the sensor be reallocated to a different patient. This ensures that no PHI information is transmitted outside of the hospital.

- Click on **Sensor Management** on the **Launch** screen to be taken to the Sensor Management screen:



- To assign a sensor** to a patient, highlight the patient and a sensor ID.
- Press **Confirm** to record the pairing.
- The pairing will now appear in the box at the bottom of the screen.
- The date of assignment sets the start date for patient phasing.
- The sensor is now paired to the patient.
- Pairings which have a padlock next to them cannot be cancelled. This is because there is data associated with the pairing.
- If an orange sensor icon appears next to a pair it can be cancelled.
- To cancel a pairing** select the pair and press **Cancel**.
- The pair will no longer appear in the box at the bottom of the screen, instead they will appear separately in the Select patient and Select sensor boxes.
- Press **OK** to return to the Launch screen.





Sensor lock and changing the sensor ID

To ensure that a Patient's app only connects to their own sensor, the app software will lock to the first BPMpro sensor it detects by reading and storing the unique sensor ID. This is key to ensuring that the Patient always receives the correct test programme. Once locked, the app will ignore any other BPMpro sensors. The sensor ID (serial number) can be found on the box label.

The bespoke Patient application allows a Professional user to manually enter a sensor ID or to adjust an incorrectly locked sensor ID. This is available through the Patient Welcome Screen app via the Professional software and is accessed by touching the 'holding hands' area of the Welcome screen image, shown right.



- Enter the **sensor ID**.
- Press **Save**.
- Press **Return** to return to the Patient Welcome screen.

00 80 25 CE 40 BD
Save

Example sensor ID

The Patient app will continue to search for the sensor with the associated ID.

Notes

- *The sensor ID in the Patient app requires spaces between the pairs of numbers and letters as shown above.*
- *If the Save button does not appear, the sensor ID is incorrect. Check that you have the right number of digits.*
- *To start a new search, clear the sensor ID, press Save and the system will search and connect to the first sensor it finds.*

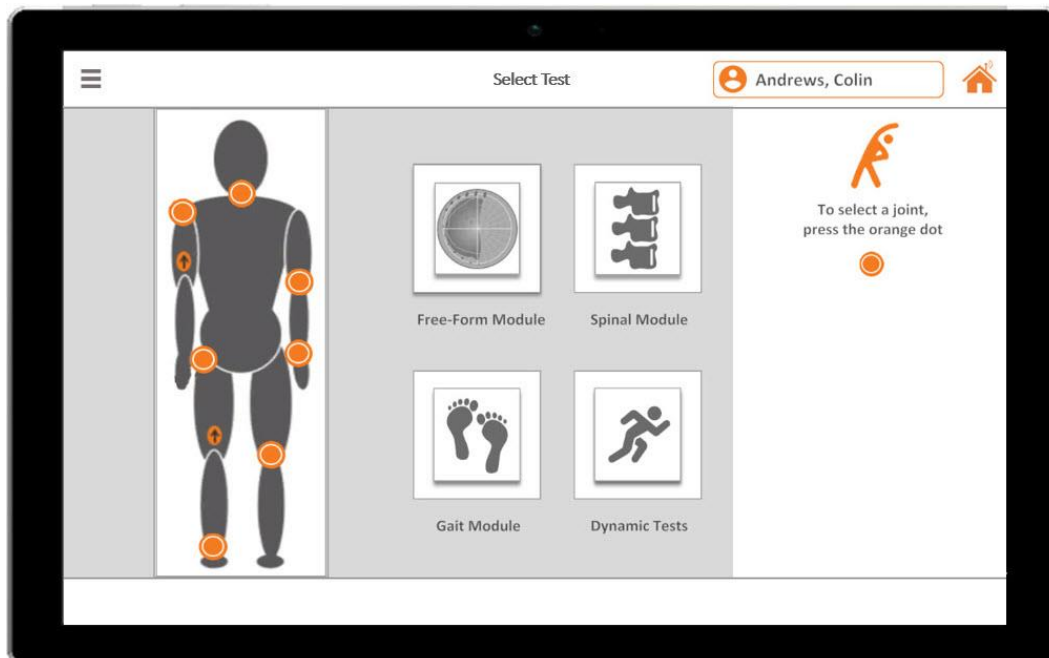


Test Setup



Test Selection

Having selected a patient, click on **Test Settings** on the Launch screen to be taken to the Select Test screen:



Modules

- The items in the square boxes are modules. To select a module, click on the square box. When not available, modules are greyed out.

Joint Tests

- To go to the tests available for a joint, click on the orange symbol on the appropriate joint to be taken to the test selection screen for the joint.



Note: Only hip and knee are currently available.

Default setup programmes

- Default programmes are intended to take patients through different rehabilitation programmes depending on their surgery and ability level.
- The advantage of default programmes is that once set up, they can be assigned to numerous patients, removing the need to set up individual programmes for each patient.
- Each default programme is designed to include tests, exercises and progress comments.
- See [Default Setup Programmes](#).



Test Settings

Note: the way a test is set up as part of a default programme is exactly the same as if it were being set up as an individual test. The same steps apply to both.

- Select **On** to activate the test.
- The screen will change to show the Test Screen:



1. **Test name**

2. **Test parameters:**

- **Alarm** - When **Inside** is selected, a fail is recorded when the patient does not reach the defined limits. When **Outside** is selected, a fail is recorded when the patient exceeds the defined limits.
- **Phases** - Each test can split into 1-10 phases. By entering a value greater than 1, the test parameters are automatically divided by that number into separate phases. These phases break down the patients' targets into stages more appropriate to their level of recovery. To move onto the next phase, the patient must reach the targets during three separate sessions. Once all the phases have been completed, the patient is moved onto the next test.
- **Start position** sets the automatic starting angle of the test. (See *Assessing a patient and setting their test start position using a sensor*).
- **Minimum limit** - this is the minimum target angle for the test (see *Setting minimum and maximums test limits*).
- **Maximum limit** - this is the maximum target angle for the test.
- **Test Reps** - the number of times the patient performs the action (3-99).
- **Exercise Reps** - the times the patient performs the exercise up to a maximum of 10.



3. **Orientation icon** - when the sensor is connected, the orange sensor icon moves as the sensor moves.
 4. **Comments** - each phase can have a physio comment assigned to it. See [Setting up comments](#).
 5. **Exercises** - each test can have up to 5 exercises assigned to it. See [Setting up exercises](#).
 6. **Left/Right** – the test automatically defaults to the side upon which the patient has had surgery. These buttons can be used to change the side.
 7. **Description of test movement**
 8. **Avatar** - this is an anthropometric representation of the test position and movement:
 - The grey area represents the typical range of movement for the test and the range over which the sensor has been calibrated.
 - Orange lines display the set points/targets for the test once they have been entered.
 - The dotted orange line denotes the start point once it has been entered.
 - The dotted grey line denotes the zero angle.
 - The sensor icon shows the sensor position and alignment.
 - Purple lines denote the final start, minimum and maximum targets
 9. **Clear Alert** - to clear an alert, touch the alert icon at the top of the screen.
- Press **Save** to save the test.
 - Select another test to modify or exit the screen by clicking on the **Home** icon.

Setting minimum and maximum test limits

Given that the start point for most tests, especially hip and shoulder tests, is the zero (neutral) position of the joint, the minimum and maximum test limits may be negative and/or positive depending on the test and the progress of the patient.

The table (right) shows how these limits equate to the medical definition of movement around a joint.

Test #	Min (-ve)	Max (+ve)
K1	Extension	Flexion
K2	Extension	Flexion
K3	Extension	Flexion
H1	Extension	Flexion
H2	Adduction	Abduction
H3	Adduction	Abduction
H4	Adduction	Abduction
H5	Flexion	Extension
H6	External	Internal
H7	Internal	External
H8	Internal	External

For tests where the movement is mainly in a single plane of motion, for example, K1-3, the minimum and maximum settings will probably both be positive i.e. flexion.

A test cannot be set with a maximum limit lower than the minimum limit. If you try to do this you will see a warning message when you go to save the test settings. This has been done to prevent a test being set up with an end target that is lower than the start target.



Control icons

Test results can be displayed in different formats using the control icons at the top of the screen. See [Reviewing test results](#).

- The left-hand side of the screen can show the QoM, test settings or results table.
- The right-hand side can show the avatar, test video or results graph.

	QoM	See Quality of Motion (QoM) .
	Results table	Switch view to display test results in a tabular format.
	Test settings	See Test Settings .
	Graph	Switch view to display test results on a graph.
	Avatar	Switches view to display avatar
	Video	Takes the user to a video of the test

- The control icons have three different states:
 - Orange - selected
 - White - available for selection
 - Grey - unavailable for selection

Setting up comments

The Phase Comments screen enables the user to set up **motivational comments**, which appear after the patient has completed their test within each phase.

- Whilst in the **Settings** screen, press the **Comments** button to be taken to the **Phase Comments** screen.
- The number of comments boxes available is determined by the number of phases set for the test.
- Press **OK** to save the text and return to the **Settings** screen.



Phase Comments

Grant, Jane

Test Phase	Comments
Phase 1	Well done so far
Phase 2	Great job
Phase 3	Keep up the good work
Phase 4	Remember to carry on with your exercises
Phase 5	
Phase 6	
Phase 7	
Phase 8	
Phase 9	Nearly finished now
Phase 10	You are on the last part of this test, keep up the good work

Enter comments in the boxes

OK

Setting up exercises

- Whilst in the **Settings** screen, press the **Exercises** button to be taken to the **Test Exercises** screen.
- The screen displays limb-specific exercises.
- Each exercise video is accompanied by an exercise description which includes the number of reps required to be done.
- Select a maximum of 5 exercise videos to be assigned to the test by clicking on the test image.
- ***The exercises are carried out in numerical order.***
- Selected tests are highlighted in orange.
- Press **OK** to save the exercises and return to the **Settings** screen.

K1 Knee Seated

Test Exercises

Andrews, Colin

1 Ankle flexion	2 Heel slide	3 Supported knee bend	4 Knee extension	5 Hip lift	6 Heel slide	7 Heel side slide
8 Forward bend	9 Weight transfer	10 Stand up	11 Sit down	12 Walk with crutches 2pt	13 Walk with crutches 3pt	14 Upstairs with crutches
15 Downstairs with crutches	16 Supported leg lift	17 Single leg lift	18 Step over	19 Foot roll	20 Foot circle	

OK



Test programmes

- To set up a patient programme, first follow the instructions under **Test Settings**.
- Once you have set up the first test for the patient, press **Save** and either go to the **Launch** screen and press Test Settings to go to the Select Test screen to select the next test.
- **Note: A programme may consist of multiple tests, each with their own exercises and comments, but the order in which they are selected will determine the order in which the patient works through them.**

Test editing

- Tests can be edited on test setup for a patient. Any modifications to a test do not change the order in which the tests are setup for the patient.
- To remove a test from a patient, set the test to inactive. This will remove the test from the patient's programme and save.
- Any tests that have been disabled for a patient retain all recorded test data from the patient. This information stays hidden with the disabled test. To view the data, reactivate the test.
- Reactivating a test adds it to the end of the patient's programme. This functionality allows professional users to re-order tests if required.

Default setup programmes

To set up a default setup programme

- Go to the **New Patient** screen to set up a default template.
- Select the joint (treatment type), side and default number, leaving the other fields blank.
- Press **Save**.
- Go to the **Patient Management** screen and select '**Defaults**' from the dropdown menu to display the Default Programmes.
- The default you created will appear in the list.
- Select the required default and set up a test programme as if it is for a patient, see [Test Settings](#) and [Test Programmes](#).
- The programme may consist of multiple tests, but the order in which they are selected will determine the order in which the patient works through them.
- **Note: Each joint can have up to 5 default programmes set per side.**



To modify a default setup programme

- Having selected **Defaults** from the dropdown list on the **Patient Management** screen, highlight the programme to be modified and press **Next**.
- Click on the test to be modified to be taken to the **Test Screen**.
- The name of the default programme is shown at the top of the screen.
- Change the settings, comments and/or exercises in the same way as when setting a new test.
- Press **Save** to save.
- Press **Home** to return to the **Launch** screen.

Bilateral testing

- Both of a patient's limbs can be tested using the same sensor.
- By selecting both sides a patient can test their left limb first followed by their right limb during the same test session.
- To set up a bilateral patient programme, follow the instructions under **Test Settings** for the first limb.
- Once you have set up the tests and exercises for the first limb, press **Save**, select the other side and follow the same process to set up the test programme for the other limb.
- The results for both limbs are displayed on the **Patient Overview** screen.

Default bilateral test programmes can be set up in the same way as normal default programmes see *Default setup programmes*.






Network connection

The software indicates when there is a poor data network connection which may impede the transmission of updates to the server during:

- Patient creation and editing
- Test creation, editing and removal
- Sensor assignment and de-assignment

This is done by the application detecting if there is an internet connection at the time of saving the changes. If no network connection is detected, the information is stored locally until a connection is detected and the data is then updated on the system.

The Home icon also shows the different states of connection, as shown below:

	No server connection, offline
	Connected to server
	Not connected, files waiting to be updated

The Home icon has a red box around it until such time as the system has been able to connect to and update the server with saved offline files. The software checks the presence of the server connection approximately every 10 seconds. The Home icon only changes state when the network condition changes and the users switch screens, which is the point at which any changed data is updated.



Assessing a Patient



Using a BPMpro Sensor

Note: The sensor does not need to be connected unless you want to assess a patient and set their start position. If you wish to do so, go to the Test Screen and connect the sensor as follows:

- Charge the sensor for at least an hour using the charger lead supplied. Plug the charger lead into your tablet/laptop using a suitable adapter by inserting the charger lead into the socket at the base of the sensor.
- Charging should only be performed from a tablet/laptop and not from a mains-powered device or USB adapter.
- **It is critical that you do not use the sensor while it is charging.**
- The first time you connect the sensor to the software, wake the sensor by shaking it until it starts flashing blue, indicating it is ready to connect to the software.
- The sensor flashes different colours to indicate different states:
 - Slow-flashing green - sensor is on standby
 - Blue - Sensor is ready to connect
 - Orange - Sensor is charging
 - **Red - When the sensor flashes red, this is critical function. Exit the app, remove the sensor and place on charge immediately**



The sensor comes with a medium strap (450mm). You can also get a long strap, (650mm), which will probably be needed for hip tests or high-BMI patients. Select the appropriate strap to suit the limb under test. The strap tab is inserted through the belt loop with the Velcro side away from the body. Slide the sensor all the way along the strap until it is close to the strap loop and push the strap tab back through the strap loop and tighten securely using the Velcro. **The sensor is not certified for use directly against the skin.**

- The white sensor icon shows the position of the sensor. The arrow on the sensor should be pointing in the same direction as the sensor icon. For example, if the arrow is pointing to the knee, the top of the sensor must also point to the knee.
- The correct positioning of the sensor is also explained in the instructions on the right-hand side of the test screen.
- When the sensor is connected, the orange orientation icon moves as the sensor moves to indicate the sensor is connected to the software.





Connecting a sensor to the software

- Having selected a patient, click **Test Settings** on the **Launch** screen to be taken to the **Select Test** screen.
- Click on the image of the test required to be taken to the **Test Screen**. With the software running and the sensor flashing blue, press the orientation icon. A flashing blue dot shows that the sensor is trying to connect.
- Sensor connection can take up to 20 seconds. If the sensor cannot connect, the software will time out after 20 seconds.
- Check that the sensor is flashing blue before trying to connect again.
- Once connected, a battery meter appears next to the orientation icon indicating the level of charge.
- Data transfer is now in progress via Bluetooth. If Bluetooth is not enabled on your device, a warning will be displayed. In this case, close the application and activate the Bluetooth feature on your laptop/PC.
- Once connected, the sensor ID code can be read via the setting screens.
- To disconnect the sensor, press the orientation icon again and follow the on-screen instructions.



Assessing a patient and setting their test start position using a sensor

It is important to establish what range of movement a patient has, especially the start position they can achieve initially, before they start on their rehabilitation programme using BPMpathway. This can be determined in the Test Screen using a connected sensor.

- Before starting an assessment make sure you:
 - Select a patient
 - Select a test
 - Connect a sensor
- Once the sensor has been connected, the Start, Set and Cancel buttons are enabled and appear on the screen.
- Get the patient into a comfortable position following the on-screen instructions.
- Press **Start** to start displaying readings from the sensor between the **Start** and **Set** buttons.
- From this, you can determine the current minimum and maximum capabilities of the patient.
- To set their start position, press **Set** at the appropriate point. This can be changed by repeating the process or overwritten in the Test Screen manually.



Reviewing Patient Test Results

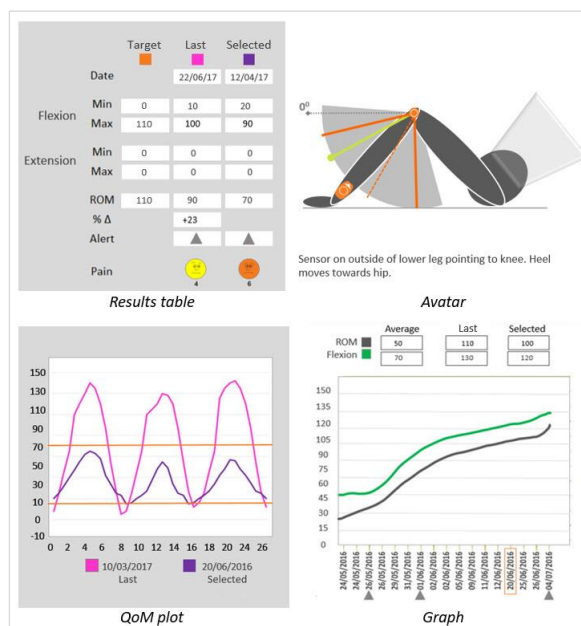


Viewing patient results

The outcome of a patient test can be displayed in different formats on the test screen for direct comparison of joint fitness.

For example, QoM and the graph can be viewed at the same time, which is important where the range is apparently unchanged, but, in reality, joint fitness is actually improving.

- The left-hand side of the screen can show either the QoM or test results table.
- The right-hand side can show either the avatar, test video or graph.



The different views are selected using the control icons at the top of the screen (see [Control icons](#)).

Graph

- Click on the graph icon.
- The avatar is replaced with a graph showing historical data for ROM (grey) and the key movement plane (green) for the current test.
- The user can switch between left and right limbs.
- The dates on the x axis are the sessions during which the test has been performed.
- To select data from a different session, click on the date required.
- To export the full test history for the current patient into a CSV file, click on the export icon to the right of the graph (shown right).
- To return to the screen showing the avatar, press the avatar icon.

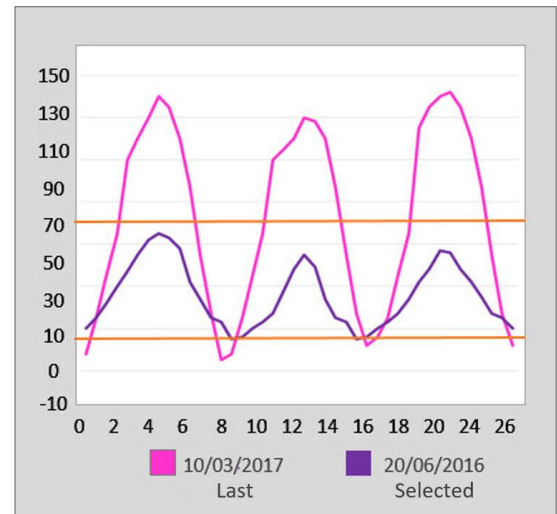




Quality of Motion (QoM)

QoM gives live feedback on the fitness of a joint and neuromuscular coordination, as well as in determining precisely where in the joint motion a tightness or pain point may be occurring. Angular displacement against time is traced automatically as the test is being performed.

The narrower the pulse, the fitter the joint, with the peak representing the maximum range of motion. A plateau would typically indicate a point of discomfort and/or weakness.



The horizontal orange lines are the final minimum and maximum targets set for the patient to reach at the end of the final phase of the associated test.

Last and selected sessions are displayed on the QoM trace for direct comparison of joint fitness. This is important where the range is apparently unchanged, but, in reality, joint fitness is actually improving.

To view the QoM plot

- Click on the QoM icon.
- The QoM plot for the last test done appears on the left-hand side of the test screen.
- The different coloured lines signify:
 - Last test - pink
 - Selected test - purple
 - Final target - orange
- The QoM and ROM graph can be selected at the same time to give a visual indication of the change in the range of movement over time and the associated change in joint fitness.
- To return to the table view, press the table icon.



To change the QoM timeline

- Select 'Settings' from the burger menu
- Enter a value between 5-60 seconds in the box 'QoM (s)'
- Entering a value outside of this range will cause the field to change to the closest number.



Results table

- Click on the results table icon.
- The table appears on the left-hand side of the test screen.
- The table shows the results for the target, last and selected test.
- To select a session for comparison, click on the graph icon and click on a date from the graph.



For each date, the table displays:

- **Minimum and maximum** data for each key movement plane – in this example flexion and extension.
- **Total ROM** – the sum of the key movement plane(s). In this example flexion plus extension.
- **% Δ** – percentage change versus the selected session.
- **Alert** - see [Alerts](#).
- **Pain score** – see [Pain scores](#).
- To change to the QoM view, press the QoM icon.

	Target	Last	Selected
Date		22/06/17	12/04/17
Flexion	Min	0	10
	Max	110	100
Extension	Min	0	0
	Max	0	0
ROM	110	90	70
% Δ		+23	
Alert		▲	▲
Pain		4	6



Pain scores

When a patient does their test via the patient software, they are required to enter a pain score afterwards. These pain scores have been licensed from the Wong Baker FACES® Pain Rating Scale. The patient selects from the following:



This value is recorded against the session. If a value has been recorded for a session, it will be displayed in the results table if that session is displayed.

Print

You can produce screen printouts from BPMpathway. They are automatically sent to the default printer using the current settings and will print out as they appear on the screen e.g. plot or avatar.

- Select **Print** from the burger menu in the top left-hand corner of the screen to send the on-screen image to the printer.



Appendices



Appendix 1 - Additional Information

Instructions for cleaning

If the device becomes dirty, gently wipe with a moist cloth. Do not immerse in water.

Performance issues

If the device appears to be damaged or stops working, please contact your clinician for advice. Do not attempt to open the device or fix it yourself.

Intended environment of use

The device is intended for use in clinical and home environments. Please keep it away from heavy machinery and equipment.

Skills needed

Your clinician will show you how to use and position the device, but if you have any questions, please contact your clinician.


General device information


The BPMpathway device is manufactured by 270 Vision Limited of Unit 34, Basepoint Business Centre, Caxton Close, Andover, SP10 3FG, UK, registered number 7505941. The sensor serial number can be accessed by your clinician via its unique serial ID if required.

Device markings

Device name: BPMpro MK2

GS1 code: 5060517690045

CE logo: 

FCC logo: 

WEEE logo: 

IP rating: IP33

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 to record the range of joint motion. 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.

Disposal of BPMpro sensors (WEEE Directive 2012/19/EU)



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.



Appendix 2 - EC Declaration of Conformity (Annex VII)

We, 270 Vision Ltd. of Unit 34, Basepoint Business Centre, Caxton Close, Andover, SP10 3FG, UK, registered number 7505941, declare in our sole responsibility as manufacturer that the products listed in the schedule below meet all the applicable requirements of the Medical Devices Directive 93/42/EEC (amended), and its transposition into national laws.



The BPMpro Mk2 sensor additionally meets all applicable requirements of the European Directive 2011/65/EU (RoHS 2).

Classification: Class I according to Rule 12, Annex IX of Directive 93/42/EEC.


Conformity assessment procedure was performed according to Annex VII of Directive 93/42/EEC.

Applied Standards

ISO 60601-1 Medical Electrical Equipment
 ETSI EN 300 328 V2.1.1 Wideband Transmission Systems
 ETSI EN 301 489-1 V2.2.0 Electromagnetic Compatibility for radio equipment
 ETSI EN 301 489-17 V3.2.0 Broadband Data Transmission Systems
 IEC 62133:2012 Safety requirements for portable sealed secondary cells

	For 270 Vision Ltd:	
	Name:	Peter Davidson
	Position:	Engineering Director
	Date:	5/11/2020

And as the appointed EU Authorised Representative for 270 Vision Limited:

	Company:	Emergo Europe
	Address:	Prinsessegracht 20 2514 AP The Hague The Netherlands

This declaration is valid for all products manufactured after the date of signature until a new declaration of conformity is issued.

Product Schedule

- BPMpathway system
 - GMDN Classification code: 33652-Clinical goniometer, electric

Consisting of:

- BPMpro Mk2 Sensor
 - Shipped as BPMpathway Sensor Kit

And

- BPMpathway Application, in two forms:
 - BPMpathway Professional Application (v2.2.60)
 - BPMpathway Patient Application (v2.2.60)



Appendix 3

Patient User Guide

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Before using BPMpathway, please do the following:

Charge the sensor

Prior to use, charge your tablet and then charge the sensor for at least an hour using the charger lead supplied. Plug the charger lead into your tablet/laptop using a suitable adapter by inserting the charger lead into the socket at the base of the sensor. Charging should only be performed from a tablet/laptop and not from a mains-powered device or USB adapter. The sensor will flash orange to indicate it is charging. ***It is critical that you do not use the sensor while it is charging.***

Downloading the BPMpathway software

If you are using your own touchscreen laptop or tablet, you will have to download the BPMpathway software by following instructions below. If you have a BPMpathway kit, which includes a tablet, the software has already been loaded on the tablet.

To download BPMpathway to your tablet:

- If your tablet has either of the logos shown right for the Apple App Store or the Android Play Store, click on the logo.
- Search for 'BPMpathway'.
- Download the BPMpathway application as directed.
- The BPMpathway icon (shown right) will appear on the start screen when you start your tablet.



If you cannot find the App Store or Play Store logo or cannot download BPMpathway, please go to www.bpm pathway.com/downloads and follow the on-screen instructions for Windows devices:

- Click on the BPMpathway download for your device.
- Download the BPMpathway installer as directed.
- Run the installer, noting where the application is stored.
- ***Please ignore any security warnings about the application during installation. This is due to the limited number of times the application has been downloaded and is nothing to be concerned about.***

A full user guide is available from www.bpm pathway.com/downloads.

If you have any problems or are unsure about what type of device you have, please ask your clinician for help with downloading the BPMpathway software.



Getting started

- Switch on your tablet/laptop and check that it is charged.
- **Ensure that the tablet/laptop is connected to the internet.**
- As soon as you have an internet connection, start BPMpathway by clicking on the orange icon (shown right) to start the application.
- When you click on the icon, you will be taken to the welcome screen.



Connecting the sensor to the software

- The first time you connect the sensor to the software, shake it so that it flashes blue.
- You can change the language of the software by clicking on one of the flags at the top of this screen.
- You can download a digital version of the Instructions for Use (IFU) by clicking on the book logo to go to the IFU download page on the BPMpathway website.
- The screen will indicate that the sensor is trying to connect to the software.
- If the sensor needs charging, a message will appear on the screen and the sensor will flash red. **This is a critical function. Please exit the application, remove the sensor and place it on charge immediately.**
- If the sensor is not detected by the software, a warning message 'No sensor detected' will appear.
- If the sensor cannot connect, the software will time out after 20 secs and goes back to the welcome screen again and you are given the option to exit.
- Check that you have an internet connection and that the sensor is flashing blue before trying to connect again.
- Once the sensor has connected to the software, it will flash green and the screen will change to show the battery level. If the battery level is green the sensor is charged. If the battery level is red the sensor needs charging.
- If you have a message from your clinician, you will see an envelope icon.
- Before you can proceed with your test you will be taken automatically to the message centre (see *Sending & receiving messages*).
- If you do not have any messages, click on the **Start** button to go to your test.





How to do your test

- The first time you do your test, you are taken to a screen where a video will play of how to do the test.
- The video will be the same regardless of whether you are doing your right or left limb.
- If you want to watch the video again, press the Video button at the bottom of the screen.
- Press **Next** to move on to the test screen.



Attaching the sensor

- Attach the sensor before starting your test. Secure it using the strap as in the position shown on the screen.
- The sensor icon shows the position of the sensor. The arrow on your sensor should be pointing in the same direction as the sensor icon. For example, if the arrow is pointing to the knee, the top of the sensor must also point to the knee.
- The correct positioning of the sensor is also explained in the instructions on the right-hand side of the test screen.
- When the sensor is connected, the connection icon (shown right) moves as the sensor moves.
- The sensor has different colours to indicate different states:
 - Slow-flashing green - sensor is on standby
 - Blue - Sensor is ready to connect
 - Orange - Sensor is charging
 - **Red - When the sensor flashes red, this is critical function.**
Exit the app, remove the sensor and place on charge immediately



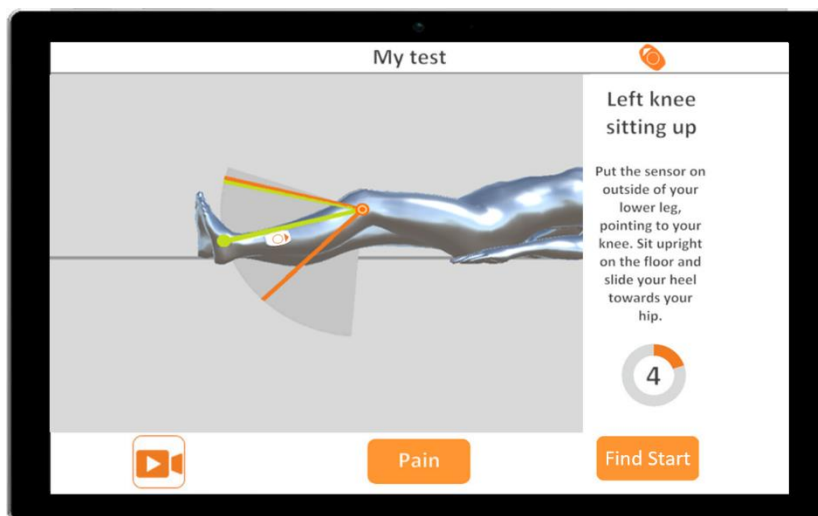
You are now ready to start your test. Please ensure you can see and reach your tablet or laptop, so you can see what to do.



Doing your test

- Press **Find Start** to begin the exercise
- Move your limb to the start point shown by the dotted orange line and wait for a long low tone to indicate you are in the starting zone.
- Maintain this position until a beep sounds and the **Find Start** button disappears. The test movement can now start.
- Move your limb, as your clinician has shown you and/or as shown in the test set up video, back and forth, trying to reach the solid orange lines. Each time you pass through the start position, the number of repetitions will count down and a low 'tick' will indicate the test is being performed correctly.
- Follow the test instructions on the right-hand side of the screen.
- The green line shows the current position of your limb.
- The solid orange lines represent your target range of motion.

Find Start



- Should you experience any discomfort or restriction during the test, you can register this by pressing the **Pain** button. A green diamond will appear on the screen at the point you have marked. You can mark two points in this way. Your clinician will then know where you experienced pain.
- Keep going until you hear a short high-pitched beep and you are told that you have finished your test.
- If you want to end the exercise early, you can do so by pressing the **Cancel** button which clears the test results. The test can be restarted by pressing **Start**.

Pain

Cancel



Pain scores

- When you press **Next**, you will be asked to record the level of pain you experienced during the exercise by clicking on the face that best reflects how you felt:



- The face you select is highlighted.
- You can change your selection by pressing a different face.
- Once you are happy with your choice, press **Next**.
- If you have exercises to do, you will be automatically taken to them.

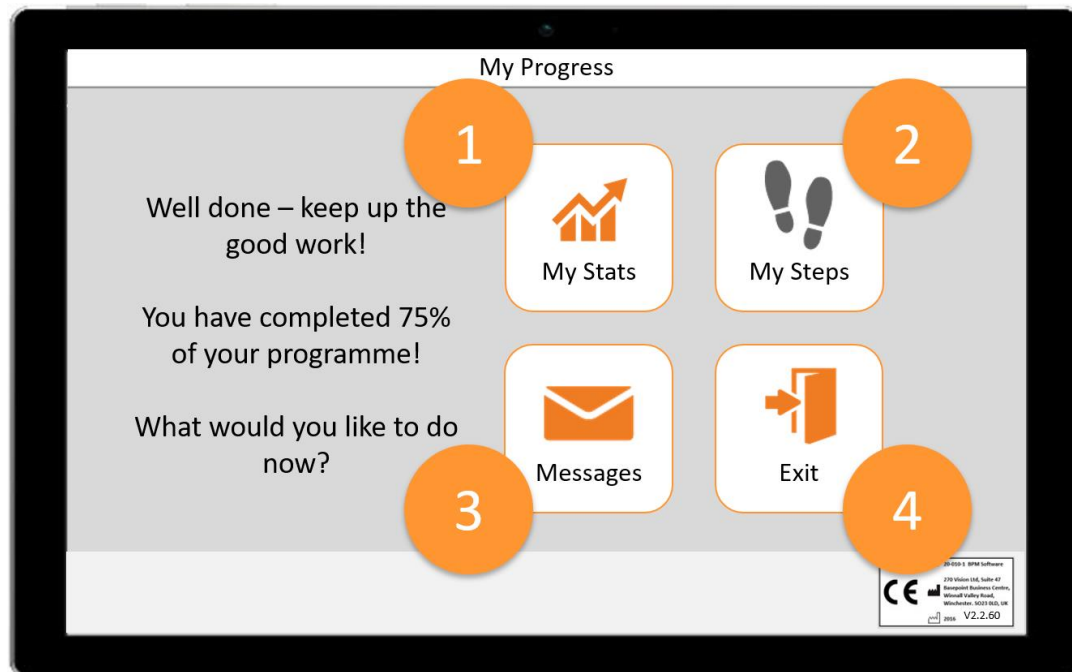
Exercises

- You don't need the sensor to do your exercises, but you can keep wearing it if you wish.
- For each exercise, there is an explanation of how to perform the exercise and a video, which starts automatically.
- The number of repetitions set for you is shown on the right-hand side of the screen.
- Once you have done the exercise, press **Next** to go to your next exercise.



My Progress

After you have completed your exercises, you will be taken to a summary screen – **My Progress**:

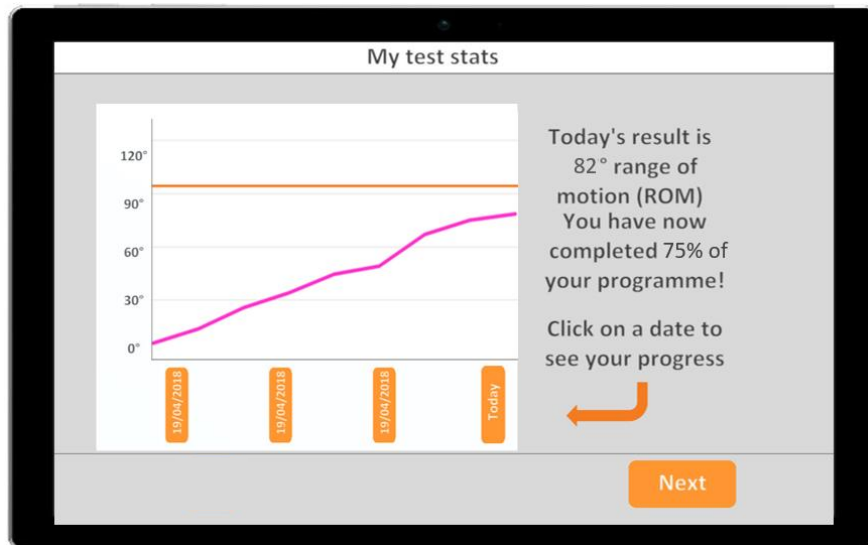


1. To review your results, click on **My Stats**.
2. To review the number of steps you have taken, click on **My Steps** (see [Using the step counter](#)).
3. To send a message to your clinician, click on **Messages** (see [Sending and receiving messages](#)).
4. To exit the application, click on **Exit**.

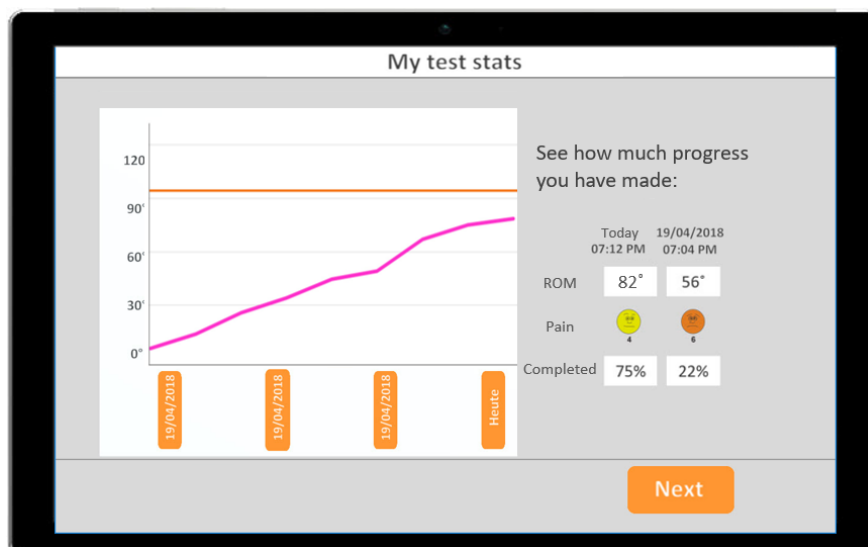
The sensor will automatically shut down after a few minutes of inactivity.



Reviewing your stats



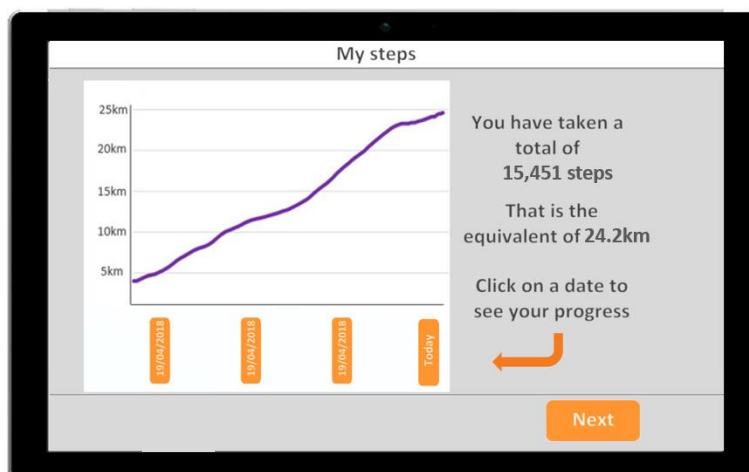
- The pink line shows a plot of your range of motion for your current test since you started it.
- The orange line is your current final target range of motion.
- By clicking on one of the dates along the bottom axis, you can compare today's results with the results from that date.



- After reviewing your progress, press **Next** to return to the **My Progress** screen.



Reviewing your steps



- The purple line shows the total distance you have walked since you started using the sensor.
- By clicking on one of the dates along the bottom axis, you can compare today's results with the results from that date.



- Click on **Next** to return to **My Progress**.

Using the step counter

- The sensor can be used as a step counter when you are not doing your tests.
- The sensor should occasionally blink green. If it does not, it requires charging.
- Place the sensor in your trouser or jacket pocket or handbag.
- If you put your sensor in your handbag and travel by car, please ensure it is placed on a seat.
- The sensor will count the number of steps you take and update your total number of steps the next time you connect it to the software to do your tests.



Sending and receiving messages

How to read a message

- If you have a message from your clinician, you will see an orange envelope icon when you start up BPMpathway.
- You need to read the message before you can start your test.
- Click on the envelope icon to go to your message.
- You will see the message from your physio at the top of the screen.
- If you wish to reply, type your message using the soft keyboard that appears on the screen depending on your type of tablet or laptop.
- If you want to scroll back through your message history, use the scroll bar on the right-hand side of the text box.
- When you are happy with your message, press **Next** and you will be taken back to the screen you came from.



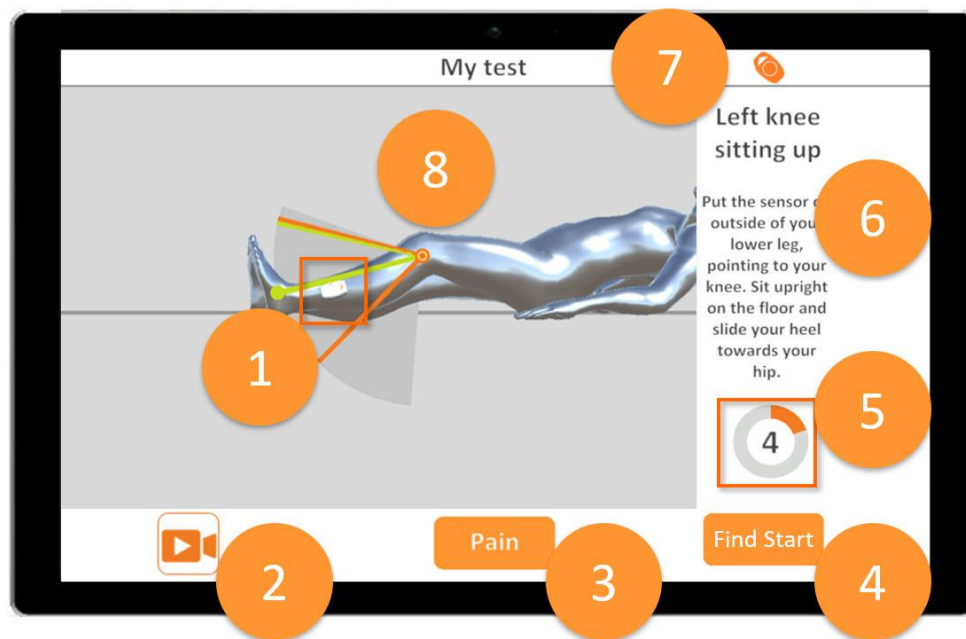
How to send a message

- You can send a message to your clinician by clicking **Messages** on the **My Progress** screen.
- Type your message using the soft keyboard that appears on the screen.
- If you want to scroll back through your message history, use the scroll bar on the right-hand side of the text box.
- When you are happy with your message, press **Next** to return to the **My Progress** screen.

Well done! We hope that you enjoy using BPMpathway during your rehabilitation. If you have any questions about BPMpathway, please contact your clinician.



Test screen



1. **Sensor icon** shows the position and orientation of the sensor. Always make sure that the arrow on the sensor is pointing in the same direction as in the illustration.
2. **Video button** – if you wish to play the test instruction video, press this button. If a button is greyed out, this means it is not available at this time.
3. **Pain button** – if you experience any restriction or discomfort during your test, you can mark two points in this way. A green diamond will appear on the avatar at the point you have marked. If you mark a third, the first one will disappear. Your clinician will then know at what point during the movement you experienced pain.
4. **Find Start button** - press this to start your test.
5. **Number of reps remaining** - each time you pass through the start position, the number of repetitions will count down.
6. **Test directions** - if you have any doubts about how you should do your test, please contact your clinician.
7. **Connection icon** - when the sensor is connected, the sensor icon moves as the sensor moves.
8. **Avatar** - this is a graphical representation of the test:
 - The dotted orange line indicates the start position.
 - The moving green line represents the current position of your limb.
 - The orange lines display the target range for the test.

