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Ref: BSM_Session_Diary_v2.1.docx

Back Strain Monitor (BSM)

Frequently Asked Questions.





Frequently asked questions about the Back Strain Monitor technology:

1. What is the device?

The Back Strain Monitor (BSM) is a collection of four wireless sensors that adhere to the lower back and measure movement and muscle activity of the lumbar spine. The system is also able to analyse the movement data in real time and deliver biofeedback to improve the way a patient is moving.

2. What does the technology do?

The technology is worn for a whole day (at work or home) and accurately measures how far a person is bending forward, backwards (flexion/extension) and sideways (lateral flexion) during that time. In addition, it measures how much the muscles of the lower back are working to support the spine during movements. The system operates just like a heart rate monitor or a home use blood pressure monitor. The sensors are also able to be used to measure movement and muscle activity from other parts of the body.

3. Will the device help my low back pain?

This technology aims to help people recover from low back pain episodes sooner, and to help reduce the likelihood of more episodes occurring in the future.

The system aims to help you better understand how you are using your lower back, and how you should be using your lower back. It does this through measurements and clinician configured reminders that are specific to your condition.

Many research hours have been put into achieving this target, and clinical trials are currently underway to test if these treatment goals have been reached.

4. What are the major benefits of this treatment?

- Teaching the patient awareness of the correct posture following an injury or episode of back pain. This is done through visualisation software connected to the device at the clinic.
- Gathering information on back posture over a range of daily activities including walking sitting and lifting at home and at work.
- Using this information to better target treatment making intervention more efficient
- Improving patient self management leading to decreased recurrence of back conditions
- The configured device enables the patient to take the teachings of their clinician with them for the day. The device is like having your physiotherapist in your pocket, reminding you about poor postural behaviour.

5. Is it useful for all types of back pain?

No. The device is useful generally for low back pain that is caused or contributed to by movement and postural behaviour. Your clinician can assess you as to whether the device may or may not help your specific condition.

6. How long can you wear it for at any one time?

Around 12 hours is recommended. After this the information from the device is downloaded into the clinician's laptop computer and analysed in discussion with the patients.



7. Are the Measurements taken at the clinic?

The device is fitted by a qualified clinician, and some measurements may be taken at the clinic, but the true advantage of the system is that you can then wear it away from the clinic for up to 24 hours straight. The device will not interrupt your normal daily activities, and therefore captures how you truly move and work in your own environment.

8. Are there any side effects of using this treatment?

Pro-Active Medical have developed the technology using best practice engineering principles. The system is designed to comply with international regulatory standards for medical devices, and will be listed on the register of therapeutic goods later this year.

This ensures, as much as possible, that there are no adverse effects of using the device. The system is non-invasive and presents little risk of causing any harm. Your clinician will be able to assess your suitability for using the device and provide any further information you require.

9. As someone with low back pain, how can I get access to the device?

For use on people with pain, the device is not yet approved for sale in Australia. The only method of accessing the treatment is via the clinical trials being run.

10. When is the device available for use?

The device is available for assessment purposes now (on people without back pain), and is being used in the OH&S sector by ergonomists and in the sporting assessment by an elite sports club.

The clinical version that provides biofeedback requires TGA approval as a medical device. This process is well underway and the BSM device should gain TGA approval within 2-3 months.

In the future, following a larger clinical trial, we hope that the device will be funded by Medicare and by private health insurance funds (around 2012).

11. How much will it cost?

It will not be available for patients to purchase. For private patients, it will be hired out as required and steps are underway to have this hire paid for or partially paid for by Medicare. Following completion of the clinical trial at the end of 2011, Austin Health's Physiotherapy Department will have devices and provide them to patients for use as part of their treatment.

12. Can anyone apply it or do you need to be a clinician to use it?

There is quite a degree of skill required to correctly apply the wearable components in exactly the right place and then to calibrate the equipment. A clinician experienced in its use needs to do this.

13. What applications does the technology have?

The technology has a number of applications in areas listed below:

- a. Clinical: monitor lower back movements without impeding the patient and gathering data over a full day
- b. Sports: objective assessment and biofeedback to guide rehabilitation



- c. OH&S: work task assessment, risk assessment, measuring whether a worker is moving within OH&S guidelines, assessment tool for ergonomists

14. In the Medical arena, who will use this technology?

Clinicians (Doctors, Physiotherapists and other health professionals) who manage low back pain, are lateral thinkers and who want access to 'best available' information for their patients, will love this technology. The ability to gather unobserved real data about how people spend their day is providing some exciting insights for the management of low back pain.

15. What is the clinical trial being run at the moment?

The current clinical trial is a pilot study being conducted at Austin Health Physiotherapy Department and at three medical centres across Melbourne. The trial involves subjects/patients who have had low back pain for greater than 4 weeks and there are a number of other inclusion and exclusion criteria before a subject is eligible for the trial. People who are interested in being involved in the trial can go to the Pro-Active Medical website for further details (www.pro-activemedical.com).

It's exciting to see a real response to the biofeedback being delivered through the clinical trial with most subjects reporting a good response to the biofeedback. A new feature of the device, the live training software, allows a patient to understand and fully appreciate their posture and how small alterations can have a significant impact on how they recover from low back pain and reduce the chance of recurrence.

16. Why is this project so important?

Currently there is no agreed effective treatment method for the management of low back pain yet in Australia alone, back pain costs \$9.2 B and in the US, the figure is over \$100B, not to mention the social and emotional cost of this devastating condition. The 10 year project has been driven by a vision and passion to make a real difference to low back pain, at a local and international level. We firmly believe that what you can measure, you can manage.

17. What organisations are working on the project?

Pro-Active Medical is the company who has developed the technology and has a close collaborative arrangement with Austin Health Physiotherapy Department, working together to develop improvements to the system for different types of low back pain.

Pro-Active Medical also have a collaborative arrangement with the Monash University Physiotherapy Department at the Peninsula campus who have provided invaluable input in relation to the design of the clinical trial, the outcome measures to be used and the statistical analysis.