



# ViMove v6 User Manual



# Contents

1.	Regulatory Information	1
	1.1 Symbols and Labelling Information	1
	1.2 Indications for Use	2
	1.3 Warnings	2
	1.4 Contraindications	2
	1.5 Precautions	2
	1.6 Adverse Reactions	3
	1.7 Conformance to Standards	4
	1.8 FCC Compliance Statements	4
	1.9 How Supplied	5
	1.10 Patient Privacy & Confidentiality	5
2.	System Description	6
	2.1 Movement Sensors	6
	2.2 Muscle Activity Sensors	6
	2.3 Sensor Adhesives	6
3.	Setup and installation	6
	3.1 Before you Start	6
	3.2 ViMove App System Requirements and Compatability	6
	3.3 Software Installation Steps	7
	3.4 Activating Your Software	7
4.	Getting Started	7
	4.1 User Login	7
	4.1 Basic Navigation	7
	4.1.1 Home Screen	7
	4.1.2 Patient List Screen	8
	4.1.3 Patient Overview Screen	8
	4.1.4 Sensors Screen	8
	4.1.5 Feedback Screen	9
	4.2 Creating a patient	9
	4.3 Sessions	9
	4.3.1 Sessions Overview	9
	4.3.2 Create a New Session	9
5.	Available Modules	9
6.	Low Back	.10
	6.1 Overview	.10
	6.2 Sensor Fitment	10



6.3 Live Assessment	12
6.3.1 Beginning a Live Assessment	12
6.3.2 Low Back Live Assessment Test Protocol	14
6.3.3 View Session Data: Live Assessment Overview Screen	15
6.3.4 View Session Data: Live Assessment Detailed View Screen	15
6.4 Monitoring	16
6.4.1 Beginning a Monitoring Assessment	16
6.4.2 Ending a Monitoring Assessment	17
6.4.3 View Session Data: Monitoring Assessment Overview	17
6.4.4 View Session Data: Monitoring Detailed View	18
6.4.5 Monitoring Session Activity Types	18
7. Clinical Examples	19
8. Reporting	19
8.1 Create a Report	19
8.2 Exporting a Report	19
9. Device Specifications	20
9.1 Lumbar Spine Data Accuracy	20
10. Normative Data	21
11. Electromagnetic Emissions and Immunity	21
12. Troubleshooting	24
13 dorsal/i Contact Details	24



# 1. Regulatory Information

# 1.1 Symbols and Labelling Information

The following table lists the labels attached to various components of ViMove.

Symbol	els attached to various components of ViMove.  Explanation		
Symbol	Explanation		
<u>[i]</u>	Consult instructions for use		
	Class II equipment		
<b>†</b>	Type B Applied Part		
FC	FCC compliance		
SVDC 2A  ⊕ ⊕	Polarity of the power supply		
0805	CE mark		
<u>~</u>	Date of manufacture		
40%	Humidity limitation		
10°C 50°F	Temperature limitation		
RX ONLY	Caution: US Federal Law restricts this device to sale by or on the order of a licensed physician or healthcare practitioner		
REF	Catalogue number		
SN	Serial number		
LOT	Lot number		
C	AU / NZ safety certification		
EC REP Authorized European Representative			
	Use by date		
Do not use if packaging is damaged			



*	Keep away from heat
Ť	Keep dry
2	Do not reuse

#### 1.2 Indications for Use

ViMove is a wireless medical device that measures, records, and reports movements and muscle activity of the lower back / lumbar spine. The system also measures range of motion in the sagittal and coronal anatomical planes.

Caution: US Federal Law restricts this device to sale by or on the order of a licensed physician or healthcare practitioner.

## 1.3 Warnings

None noted.

#### 1.4 Contraindications

- Patients with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to use unless specialist medical opinion has first been obtained.
- Patients with undiagnosed pain conditions.
- Patients with diminished mental capacity or physical competence limiting the use of the device.
- Pregnant patients, unless specialist medical opinion has first been obtained.
- Patients with a known skin condition or allergy, unless specialist medical opinion has first been obtained.

#### 1.5 Precautions

The following precautions should be observed when using the ViMove device:

- When using any dorsaVi system, please plug the power supply directly into a wall socket. Do
  not plug via a power board / power strip unless the power board has been tested and
  certified to all relevant electrical safety standards and regulations.
- Please handle the power supply and cable with care. Do not twist the power supply cable. If twisting of the cable or other deformities are observed, please contact dorsaVi support.
- To preserve battery life, please ensure that the system is fully charged at least once every 3 months. Failure to do so may result in reduced battery performance (less than 12 hours).
- All skin mounted devices used to measure lumbopelvic movement are subject to errors due
  to soft tissue artifact. Determination of the pelvic orientation using ViMove has not been
  validated for use on patients with high Body Mass Index (BMI) or adiposity.
- Only use the unit for purposes which it is intended.
- Always ask the patient about skin allergies they may have prior to ViMove use. Gauge the
  severity of the allergy and assess whether a reduced session on ViMove, and / or using a
  protective film on the skin prior to application, would be safer for the patient, or whether
  they should not use ViMove at all if the allergy is of a serious nature.



- In order to reduce the risk of skin irritation, it is advised not to wear the sensors for any more than 24 hours in any 72 hour period.
- There is the potential for patient injury or re-injury if there is a function failure and the
  device fails to alert the patient of risk related movements. To prevent this, the device has
  been programmed to alert the patient if a signal loss or other malfunction occurs. Ensure the
  patient is informed of these features and are aware they will not be receiving Biofeedback if
  one of these warnings is shown.
- Use only with supplied power supply.
- Recording and Feedback Device (RFD) Battery: As with all batteries, there is a risk of battery leakage or explosion; however, the manufacturer of the RFD battery has conducted safety tests, heating the batteries to 130°C for ten minutes with no rupture, no fire, bursting or explosion. In addition, the battery is housed in the sealed, splash resistant RFD unit.
- Do not clean the equipment with Acetone. Use alcohol wipes for cleaning.
- Do not immerse any components of the device in water or any other liquid substance.
- Use of any equipment should be immediately terminated upon any sign of treatment-related distress or discomfort.
- Not to be connected to a patient undergoing MRI (Magnetic Resonance Imaging), Electro surgery or defibrillation.
- Operations in close proximity to shortwave or microwave therapy equipment may produce instability in the output.
- Do not operate the device within 10 feet of powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, x-ray machines, or any other equipment that produces electrical sparks. Portable and mobile RF communication equipment may also affect this equipment.
- Radiated radio frequency electromagnetic fields can cause performance degradation in ViMove.
- After use, the Disposable Application Pads (DAPs) may be a biohazard. Following use, dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.
- The operator is responsible for ensuring the safety of any devices controlled or triggered by ViMove equipment or software, or by any software or hardware receiving data from equipment. dorsaVi USA, Inc. equipment must not be configured or connected in such a way that failure in its data acquisition, processing or control functions can trigger patient feedback stimulus that poses an unacceptable level of risk.
- Between uses of the device, wipe down components with alcohol wipes or swabs.

# 1.6 Adverse Reactions

The potential adverse reactions that may be experienced with the use of the device include: Skin irritation beneath the adhesive pads and / or electrodes (DAPs).



## 1.7 Conformance to Standards

#### Conformity Assessment Standard Applied:

ISO 13485	Medical devices – Quality management systems – Requirements for regulatory	
	purposes.	

### Medical Device Standards Applied:

Wiedlan Bevice Standards Applied.			
ISO 14971	Medical Devices – Application of Risk Management to Medical Devices.		
ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical		
	practice.		
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety		
	and essential performance.		
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety		
	and essential performance - Collateral standard: Electromagnetic compatibility		
	- Requirements and tests.		
IEC 62304	Medical device - Software life cycle processes		
IEC 62366	Medical devices - Application of usability engineering to medical devices.		
ISO 15223	Medical devices - Symbols to be used with medical device labels, labeling, and		
	information to be supplied - Part 1: General requirements.		
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.		
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin		
	sensitization.		
16 CFR 1500	Guidelines of the Federal Hazardous Substances Act (FHSA) Regulations for		
	Cytotoxicity, Sensitization and Primary Skin Irritation tests.		

# 1.8 FCC Compliance Statements

#### Information to the user (FCC Part 15.105)

#### CLASS B DEVICE

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 guarantee 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 encourage to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Cet appareil est conforme à la partie 15 des règles de la FCC et de l'innovation, des sciences et de développement économique RSS normes exemptes de licence de (ISED) Canada. Le fonctionnement est soumis aux deux conditions suivantes:

- 1. cet appareil ne peut pas provoquer d'interférences et
- 2. cet appareil doit accepter Toute interférence, y compris les interférences qui peuvent causer un mauvais fonctionnement du dispositive



#### **Modification Warning (FCC Part 15.21)**

Any changes or modifications not expressively approved by dorsaVi could void the user's authority to operate this equipment

#### FCC and RSS-Gen Section 8.4 and RSP-100 Section 4

This device complies with Part 15 of the FCC Rules and Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions:

- 1. This device may not cause interference; and
- 2. This device must accept any interference, including interference that may cause undesired operation of the device.

# 1.9 How Supplied

ViMove is typically supplied containing the following components:

- Two wireless movement sensors.
- Two muscle activity sensors.
- Disposable Application Pads to attach the sensors to the patient.
- ViMove software package.
- Sensor placement template, double USB cable and power plug.

# 1.10 Patient Privacy & Confidentiality

dorsaVi complies to patient privacy legislation and requirements in all countries in which it operates. A key part of protecting patient privacy also relates to the IT setup of our customers who use our software.

dorsaVi recommends that all customer computers and devices that run dorsaVi software be protected with a sufficient username and password policy. The following are characteristics of a strong password:

- At least eight characters long.
- Does not contain your username, real name or company name.
- Does not contain a complete word.
- Is significantly different from previous passwords.
- Contains uppercase and lowercase letters, numbers and symbols.

For more information on password policies, please contact your dorsaVi representative.



# 2. System Description

ViMove is a wireless electronic device used by healthcare professionals to accurately measure, record and analyze movement and muscle activity of the lower back. The device objectively measures, records and analyzes angular movement, muscle activity, vibration and acceleration. Under the direction of the healthcare professional, the software guides the patient through a series of movements and postures in standing and sitting positions. ViMove then measures the movement and muscle activity, streams the data live via BTLE to an iOS tablet device and generates a personalized assessment including comparisons to normative values.

ViMove v6 is comprised of the following key components:

- 4 Wireless Sensors (2 movement and 2 muscle activity).
- Disposable Application Pads to attach sensors to the patient.
- ViMove software package.

#### 2.1 Movement Sensors



# 2.2 Muscle Activity Sensors



## 2.3 Sensor Adhesives

The Movement and Muscle Activity Sensor Adhesives are used to attach the sensors to the subject's skin. There are two types of Movement Sensor Adhesives:

- 1. 30-minute Sensor Adhesives for Live Assessments.
- 2. Monitoring Sensor Overwraps for use up to 24 hours during Monitoring Assessments.

# 3. Setup and installation

#### 3.1 Before you Start

Make sure you have the following items provided by dorsaVi:

- Hardware kit;
- ViMove application;
- Appropriate fitment templates;
- Your username and password.

## 3.2 ViMove App System Requirements and Compatibility

ViMove is compatible only with the following tablet devices:

- Apple iPad 4th generation (or newer).
- Apple iPad Mini 2 (or newer).



# 3.3 Software Installation Steps

ViMove software can be download from the Apple App Store on your compatible Apple tablet device. To download the software, open the Apple App Store, search for "ViMove" and follow the prompts to download and install the software. Once the installation has finished, a "ViMove" shortcut icon will appear on your home screen.

# 3.4 Activating Your Software

When the application is opened for the first time it will need to be activated with dorsaVi's central servers. To do so, please enter your username and password provided to you by dorsaVi.

Once your username and password are entered, press the next button. Your device will now connect to the dorsaVi server to download the software for the hardware devices and test procedures. This process will take some time depending on the speed of your internet connection.

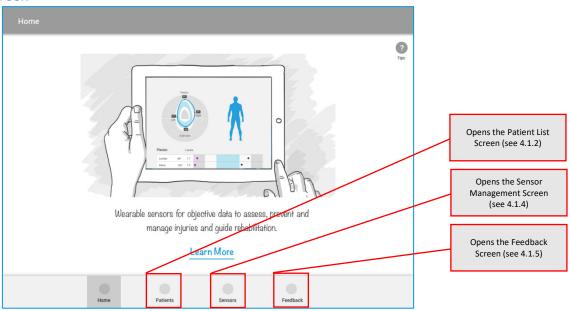
# 4. Getting Started

# 4.1 User Login

When you first open ViMove, you will be presented with a Login Screen. On this screen, you will need to enter your unique Username and Password provided to you by dorsaVi. If you cannot remember your username or password, please contact your dorsaVi representative.

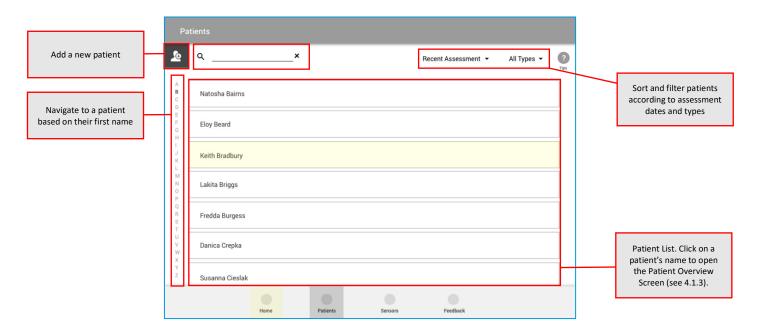
## 4.1 Basic Navigation

# 4.1.1 Home Screen

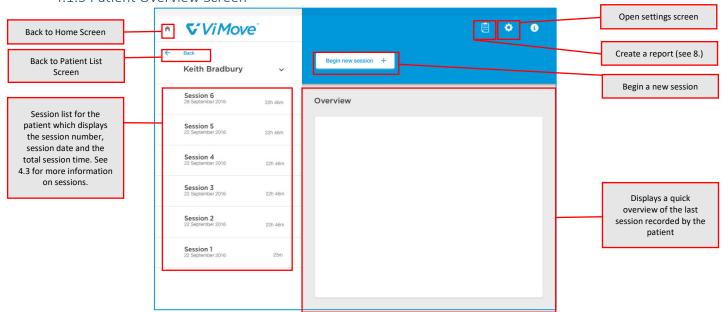




# 4.1.2 Patient List Screen



# 4.1.3 Patient Overview Screen



## 4.1.4 Sensors Screen

The Sensor Management screen allows the user to view the status of all sensors within their clinic with regards to:

- Sensor ID numbers currently owned by the clinic.
- Battery life of each sensor.
- Availability of each sensor.



#### 4.1.5 Feedback Screen

The feedback screen allows users to submit questions or comments about ViMove hardware and software to dorsaVi.

### 4.2 Creating a patient

Navigate to the Patient List Screen and select the "Add Patient Icon" located at the top left of the screen. Follow the on-screen prompts to enter all relevant patient information. Once all information has been entered, click the "Add Patient" button to create your new patient.

#### 4.3 Sessions

#### 4.3.1 Sessions Overview

In ViMove, sessions are a group of live assessments and monitoring assessments performed during a ViMove session with the clinician. Each session can have one live assessment and one monitoring assessment associated with it. For each new live assessment or monitoring assessment, a new session will need to be created. A patient can have multiple sessions recorded against their name.

#### 4.3.2 Create a New Session

To create a new session, navigate to a patient's overview screen and select "Begin New Session". After pressing this button, you will then be able to set-up a Live Assessment or Monitoring Assessment against the new session created (See 6.3.1 and 6.4.1 for further steps on setting up live assessments and monitoring assessments).

# 5. Available Modules

Modules	Assessment Types	Usability
Low Back	Live Assessment	The Low Back module contains
	Monitoring	a series of tests designed to
		provide an objective measure
		of Range of Motion (ROM) and
		muscle activity for the lumbar
		spine for up to 24 hours in the
		patient's day to day activities.



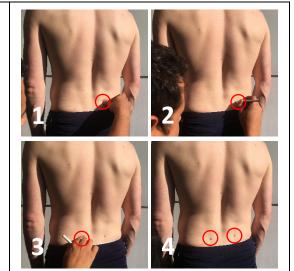
# 6. Low Back

#### 6.1 Overview

The Low Back module contains a series of tests designed to provide an objective measure of Range of Motion (ROM) and muscle activity for the lumbar spine.

## 6.2 Sensor Fitment

Locate the PSIS by palpating the superior aspect of the iliac spine. When located, mark the PSIS on both the patient's left and right by drawing small circles or crosses over them.



Use a ruler to draw a horizontal line through the centers of the PSIS circles / crosses.





Use the electric trimmer to clip the patient's back hair where the sensors will be placed (if required). For patients with sensitive skin, use skin protective spray or wipe on the MDM sensor placement area. Do not use protective spray under MDE sensors (EMG) because it reduces the electrical signal. Wipes can be used with MDE sensors.



Apply sensor adhesives to the back of the ViMove sensors. Once attached, place the pelvic (lower) sensor on the body in <u>landscape orientation</u> directly underneath the line, ensuring the sensor light is located in the top right hand corner. Do not push down firmly on the sensors at this stage.





Using the appropriately sized template, place the upper sensor on the patient so it sits at T12/L1 level. Ensure the sensor is placed in <u>landscape</u> orientation.







Using the appropriately sized template, place the two EMG sensors on the patient. Ensure the sensors are placed in portrait orientation with the sensor light located at the top.









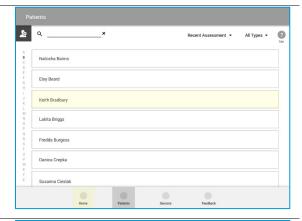




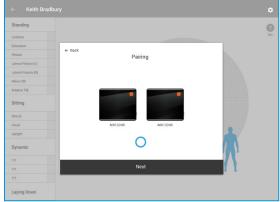
# 6.3 Live Assessment

## 6.3.1 Beginning a Live Assessment

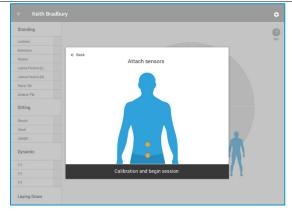
From the Patient List Screen, select the patient you would like to test. This will open the Patient Overview Screen. On this screen, select "Begin New Session".



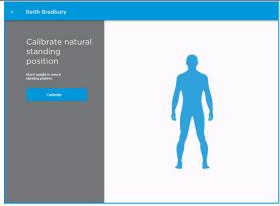
Follow the on-screen prompts to pair the sensors with the software. Begin by turning on the sensors and selecting them within the software. Now, commence pairing of the sensors to the software. Once complete, select "Next".



Using the on-screen prompts as a guide, or by following the steps in 5.1.2, attach the sensors to the patient. Once the sensors are applied select "Calibrate and begin session".



On the calibration screen, follow the on-screen prompts to ensure correct calibration of the sensors and the ViMove software. Once calibration is complete, choose the "Live Assessment" option from the software to proceed with a Live Assessment.



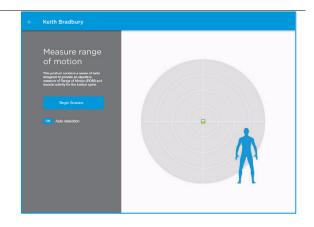


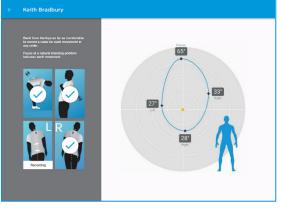
On the next screen, select "Auto Detection" if you would like the software to automatically detect flexion, extension, left lateral flexion and right lateral flexion movements performed by the patient. NOTE: Other tests in the Low Back Application will still need to be started and stopped manually.

Deselecting this option allows the clinician to manually start and stop each of the tests mentioned above.

Once an option has been selected, press "Begin Session".

Record flexion, extension, left lateral and right lateral movements as per the test protocol below in 5.3.2. The other Low Back tests can be added once these first 4 tests have been completed.

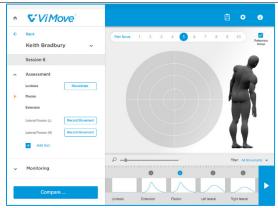




Once the first 4 tests have been completed, the following Session Overview screen will be displayed.

To add more tests to the current Live Assessment, select the "Add Test" button. To recalibrate Lordosis, select "Recalibrate".

For a detailed overview of this screen, see 6.3.3





#### 6.3.2 Low Back Live Assessment Test Protocol

For each of the tests in the software, the movements below can be tested: this is a typical movement protocol. Any pain experienced during the session can be recorded on a 1-10 scale by selecting a number on the top right hand corner of the screen (1 being not painful at all, and 10 being extremely painful).

#### Flexion

- 1. Ask the patient to stand upright and flex forward as far as comfortable without bending the knees, hold for 2 seconds and then return to standing position.
- 2. Once the patient has returned to standing position, ask the patient to repeat the movement until 3 repetitions are complete.
- 3. Note: the flexion movement usually takes 3-4 seconds to perform.

#### Extension

- 1. Ask the patient to fold the arms across the chest and stand upright.
- 2. Ask the patient to bend back (extension) as far as comfortable, and then return to standing position.
- 3. Ask the patient to repeat the movement until 3 repetitions are complete.
- 4. NOTE: The extension movement usually takes 3-4 seconds to perform.

#### Lateral Flexion (Left and Right)

- 1. Ask the patient to stand upright with arms along the sides of their body.
- Ask the patient to bend sideways (flex laterally) and slide their arm along the leg as far as
  comfortable while avoiding any flexion / extension, hold for 2 seconds and then return to standing
  position.
- 3. Ask the patient to repeat the movement until 3 repetitions are complete.

NOTE: the lateral flexion movement usually takes 3-4 seconds to perform.

#### Anterior Posterior Tilt while Standing

- 1. Ask the patient to stand upright with their hands on their hips.
- 2. Ask them to tilt their pelvis forward (anteriorly) and then backward (posteriorly) in a controlled manner. It may help to say "Make an arch in your back and then flatten your back".
- 3. Ensure the patient does not move their trunk.
- 4. Allow a few practice tilts in both directions prior to testing.
- 5. During testing ensure 3 repetitions are performed in the same test window.

#### Usual Sitting Position

- 1. Ask the patient to sit in a chair (ideally a desk chair) in their usual sitting posture.
- 2. Once the patient is seated, ask them to hold the position and begin the test.

#### Slouched Sitting Position

- 1. Ask the patient to sit in a chair and slouch as they usually would.
- 2. Once the patient is sitting in a slouched posture, begin the test.

## Upright Sitting Posture

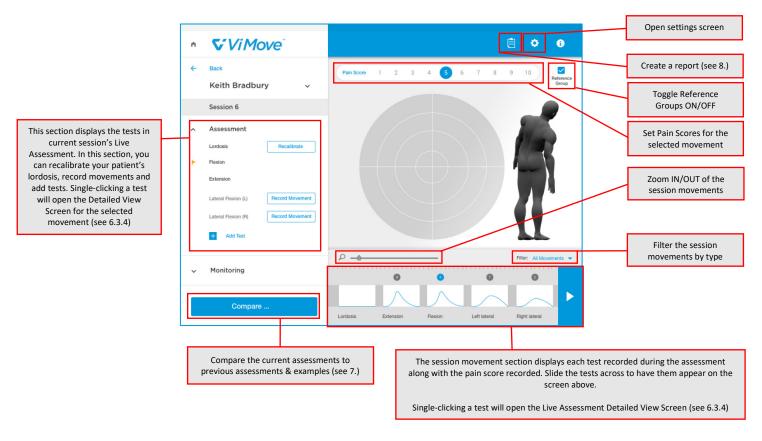
- 1. Ask the patient to sit in a chair in an upright posture.
- 2. When the patient is sitting in an upright posture, begin the test.

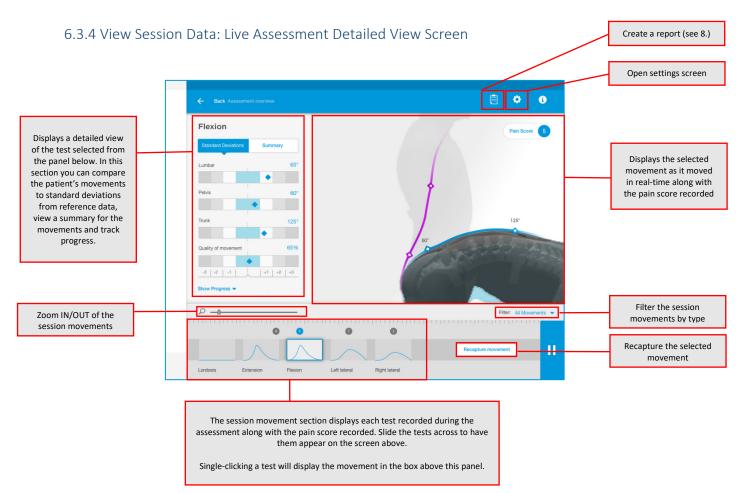
#### Anterior Posterior Tilt while Sitting

- 1. Ask the patient to sit in a chair with back unsupported and in an upright posture.
- Ask the patient to place their hands on their hips and tilt forward (anterior) and back (posterior).
   The patient must attempt to initiate and control the movement from their pelvis while avoiding any trunk movement.
- 3. During testing ensure 5 repetitions are performed in the same test window.



#### 6.3.3 View Session Data: Live Assessment Overview Screen



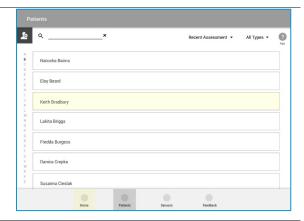




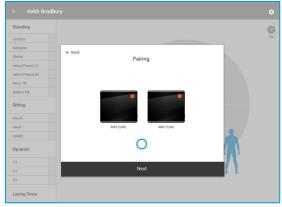
# 6.4 Monitoring

## 6.4.1 Beginning a Monitoring Assessment

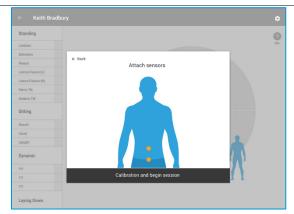
From Patient List Screen, select the patient you would like to test to open the Patient Overview Screen. On this screen, select "Begin New Session" to start a new session. Alternatively, select a session which already exists and select "Monitoring" to add an assessment to the session.



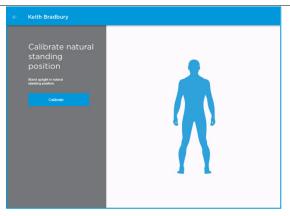
Follow the on-screen prompts to pair the sensors with the software. Begin by turning on the sensors and selecting them within the software. Now, commence pairing of the sensors to the software. Once complete, select "Next".



Using the on-screen prompts as a guide, or by following the steps in 5.1.2, attach the sensors to the patient. Once the sensors are applied, select "Calibrate and begin session".



On the calibration screen, follow the on-screen prompts to ensure correct calibration of the sensors and the ViMove software. Once calibration is complete, choose the "Monitoring" assessment option from the software to proceed. The sensors will now begin recording the patient's movement and muscle activity.



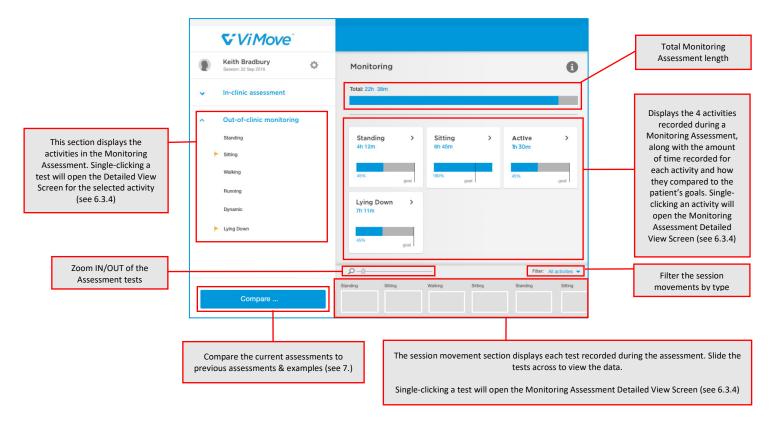


# 6.4.2 Ending a Monitoring Assessment

To end a Monitoring Assessment, remove the sensors from the patient. Next, go to the Patient's Overview Page and select the Offload icon to offload the data.

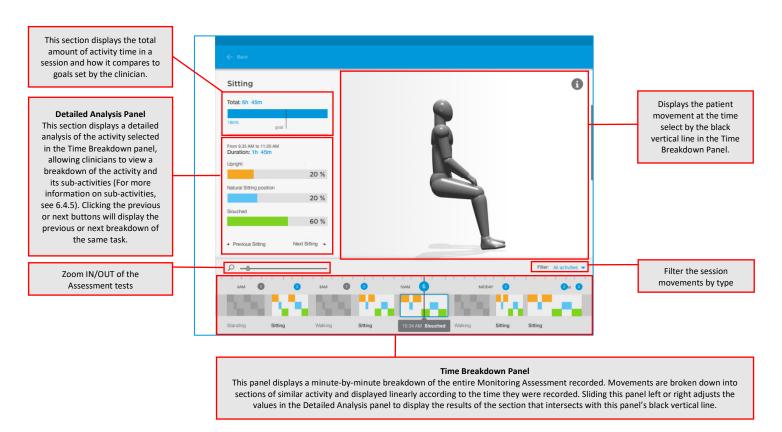
Once the data offload is complete, a notification will appear in the software. And you will be presented with the screen below.

# 6.4.3 View Session Data: Monitoring Assessment Overview





# 6.4.4 View Session Data: Monitoring Detailed View



#### 6.4.5 Monitoring Session Activity Types

The Monitoring Assessment records four different types of activities, as seen in 6.4.3. Each of these activities has three sub-activities which can be found in the Monitoring Detailed View (see 6.4.4). The following are the four activities and sub-activities found in the Monitoring Assessment.

Activity	Sub-activity
	Neutral
Standing	Flexion
	Extension
	Upright
Sitting	Natural
	Slouched
Active	Walking
	Running
	Dynamic
	Back
Lying Down	Front
	Side



# 7. Clinical Examples

You can compare your patient's session data to previous sessions performed by the patient and reference data sets. Available in Live
Assessment and Monitoring, you can access this panel by click the "Compare" button. See 6.3.3 to locate the button on the Live
Assessment Overview Screen and 6.4.3 to locate the button on the Monitoring
Assessment Overview Screen. When a data set has been dragged and dropped into the "Add comparison" box, the comparison data will appear on the applicable tests and activities in the Overview screen.



# 8. Reporting

# 8.1 Create a Report

On the Assessment Overview and Detailed views for Live Assessment and Monitoring, selecting the report button allows you to generate a report of the data you are viewing. When generating the report, follow the on-screen prompts to ensure the correct report is generated.

# 8.2 Exporting a Report

Once a report has been generated it can be saved, printed or emailed by selecting the appropriate option in the report view.



# 9. Device Specifications

Below are the specifications for dorsaVi's system hardware. If you have any questions, please contact your dorsaVi representative.

COMPONENT NAME CATALOGUE NUMBER	MDMv6b v6b4T				
Battery Use Type	Rechargeable				
Battery Voltage	3.7 Volt				
Battery Type	Lithium-Polymer				
Battery Capacity	165mAh				
Battery Life (Max)	≥300Cycles				
AC Adapter Model	UE10WCP2-050100SPC-M2				
AC Adapter Input Voltage	110 / 240V AC				
AC Adapter Output	5.5 V DC, 2A				
Charging	AC Power Adapter or USB				
Charging	Port (TypeA)				
Data Connector	USB Micro-B				
	Type	Axis	Min Range	Max Range	Bit Depth
Sensor Types	Accelerometer	3	2G	16G	16bit
	Gyroscope	3	250dps	2,000dps	16bit
	Magnetometer	3	±490	00μΤ	16bit
Memory Type	NAND Flash				
Memory Size	256MB				
Reset Button	Yes				
Display	No				
Input Buttons	1				
Visible LED's	2 x RGB				
Frequency	2.4GHz				
Band	ISM				
Wireless Range	Max 20m/60ft				
External Material	ABS				
RoHS	Yes				
Sensor Width	30mm / 1.18in.				
Sensor Length	42mm / 1.65in.				
Sensor Height	8mm / 0.32in.				
Sensor Weight	12g / 0.42oz.				

# 9.1 Lumbar Spine Data Accuracy

<b>Movement Planes</b>	1D Movements	2D Movements
Sagittal Plane Error	<3° RMSE	<3° RMSE
Coronal Plane Error	<3° RMSE	<3° RMSE



# 10. Normative Data

Normative values provided in the ViMove assessment reports are based on an analysis of lumbopelvic range of motion in 50 adults with no history of chronic lower back pain (LBP).

Participants in the study were guided through a set of simple standardized postures and movements, in standing and sitting positions, while wearing ViMove sensors. Range of motion data collected included standing lordosis, flexion, extension, lateral flexion, and pelvic tilt (anterior and posterior) in sitting and standing.

The age range for the normative data collection was 19-62 (mean  $35 \pm 12$ ). Normative data has not been collected outside this age range. Data was stratified according to gender and age groups (18-29, 30-39, 40-49, 50-65).

The following table summarizes the ViMove normative values established for males and females combined. Normative data was calculated for each age group, with the values summarized below presented as the minimum and maximum mean over all age groups.

NOTE: The normative values displayed in the ViMove Live Assessment reports are based on the mean and 95% confidence intervals calculated for each age group, using combined male and female values.

ViMove Normative Data			
Posture / Movement	N	Range of motion (º)*	
Lordosis angle	50	-(30-36)	
Flexion	50	46-54	
Extension	50	-(17-27)	
Right Lateral Flexion	50	22-25	
Left Lateral Flexion	50	-(23-23)	
Standing Anterior Pelvic Tilt	50	12-15	
Standing Posterior Pelvic Tilt	50	-(7-8)	
Standing Full Range Pelvic Tilt	50	18-23	
Sitting Anterior Pelvic Tilt	50	4-13	
Sitting Posterior Pelvic Tilt	50	-(23-28)	
Sitting Full Range Pelvic Tilt	50	28-40	

\*ROM data presented as the minimum and maximum mean values over all age groups (18-29, 30-39, 40-49, 50-65) for male and females combined.

# 11. Electromagnetic Emissions and Immunity

ViMove® complies with the requirements of IEC 60601-1-2. The recommended tables for electromagnetic emissions per sub-clause 5.2.2.1(c) and electromagnetic immunity per sub-clause 5.2.2.1(f) & 5.2.2.2 are provided on the following pages:



# Table 1 - Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS (5.2.2.1 c).

#### Guidance and manufacturer's declaration - electromagnetic emissions

The ViMove System (RFD, MDE, MDM) is intended for use in the electromagnetic environment specified below. The customer or the user of the ViMove System (RFD, MDE, MDM) should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The ViMove System (RFD, MDE, MDM) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The ViMove System (RFD, MDE, MDM) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

# Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS (see 5.2.2.1 f)

#### Guidance and manufacturer's declaration - electromagnetic immunity

The ViMove System (RFD, MDE, MDM) is intended for use in the electromagnetic environment specified below. The customer or the user of the ViMove System (RFD, MDE, MDM) should assure that it is used in such an environment

IMMUNITY test	IEC 60601 test Compliance level		Electromagnetic environment – guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>U</i> <sub>1</sub> (>95 % dip in <i>U</i> <sub>1</sub> ) for 0,5 cycle 40 % <i>U</i> <sub>1</sub> (60 % dip in <i>U</i> <sub>1</sub> ) for 5 cycles 70 % <i>U</i> <sub>1</sub> (30 % dip in <i>U</i> <sub>1</sub> ) for 25 cycles <5 % <i>U</i> <sub>1</sub> (>95 % dip in <i>U</i> <sub>1</sub> ) for 25 cycles <5 % <i>U</i> <sub>1</sub> (>95 % dip in <i>U</i> <sub>1</sub> ) for 5 s	<5 % <i>U</i> <sub>T</sub> (>95 % dip in <i>U</i> <sub>T</sub> ) for 0,5 cycle 40 % <i>U</i> <sub>T</sub> (60 % dip in <i>U</i> <sub>T</sub> ) for 5 cycles 70 % <i>U</i> <sub>T</sub> (30 % dip in <i>U</i> <sub>T</sub> ) for 25 cycles <5 % <i>U</i> <sub>T</sub> (>95 % dip in <i>U</i> <sub>T</sub> ) for 25 cycles <5 % <i>U</i> <sub>T</sub> (>95 % dip in <i>U</i> <sub>T</sub> ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VilMove System (RFD, MDE, MDM) requires continued operation during power mains interruptions, it is recommended that the VilMove System (RFD, MDE, MDM) be powered from an uninterruptible power supply or a battery.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

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Table 4 – Guidance and Manufacturer's declaration – Electromagnetic Immunity – for ME Equipment and ME Systems that are NOT LIFE-SUPPORTING (see 5.2.2.2)

should assure that it is used in such an environment.						
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance Portable and mobile RF communications equipment should be user closer to any part of the VMove System (RFD, MDE, MDM), includic cables, than the recommended separation distance calculated from equation applicable to the frequency of the transmitter.  Recommended separation distance			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3V/m 80 MHz to 2.5 GHz	3 V	$d = [\frac{2.5}{3}]\sqrt{P}$ $d = [\frac{2.5}{3}]\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [\frac{7}{3}]\sqrt{P} \text{ 800 MHz to 2.5 GHz}$			
			Where P is the maximum output power rating of the transmitter in w. (W) according to the transmitter manufacturer and d is the recomme separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* should be less than the compliance levels.			
			each frequency range. <sup>5</sup> Interference may occur in the vicinity of equipment marked with the following symbol:			

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection form structures, objects and people.

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING (see 5.2.2.2)

# Recommended separation distances between portable and mobile RF communications equipment and the ViMove System (RFD, MDE, MDM)

The ViMove System (RFD, MDE, MDM) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ViMove System (RFD, MDE, MDM) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ViMove System (RFD, MDE, MDM) as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter m				
Rated maximum output power of transmitter  W	150 kHz to 80 MHz $d=[rac{3.5}{3}]\sqrt{P}$	80 MHz to 800 MHz $d=[rac{3.5}{2}]\sqrt{P}$	800 MHz to 2.5 GHz		
	$a = \lfloor \frac{1}{3} \rfloor \sqrt{P}$	. L <sub>3</sub> Jv-	$d = \left[\frac{7}{3}\right] \sqrt{P}$		
0.01	0.12m	0.12m	0.23m		
0.1	0.37m	0.37m	0.74m		
1	1.17m	1.17m	2.33m		
10	3.69m	3.69m	7.38m		
100	11.67m	11.67m	23.33m		

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this equipment is used exceeds the applicable RF compliance level above, this equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this equipment.

 $<sup>^{\</sup>rm b}$  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.



# 12. Troubleshooting

Unsure about a part of our software or need extra help to use ViMove? Visit <a href="http://support.dorsaVi.com">http://support.dorsaVi.com</a> to watch video tutorials and read Q&A's related to every part of our software and hardware.

# 13. dorsaVi Contact Details

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