

motionsense[®]

Instructions for Use

FOR PATIENTS AND HEALTHCARE PROFESSIONALS



enmovi 

Welcome to MotionSense®

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Introduction

MotionSense® is your recovery companion and guides you through exercises following your knee surgery.

The MotionSense® App will be set up by your Care Team and will guide you through your recovery program.

The MotionSense® sensors are applied on the outside of the operative leg, above and below the knee using adhesive patches. These sensors connect to the MotionSense® App on your mobile phone. The sensors and app track your knee recovery by measuring the following:

- Range of Motion (RoM)
- Exercise Completion
- Activities of Daily Living (ADL) - Steps, Active Time
- Pain Scores
- Clinical Surveys

Glossary of terms

| | |
|-------------------------|---|
| ADL | Activities of Daily Living (daily activity including steps and active time) |
| Care Team (CT) | Surgeon OR Physical Therapist OR Healthcare Provider |
| Clinical Surveys | Patient reported outcome scores appointed by Care Team |
| Exercise Session | A group of exercises to be completed together |
| PT | Physical Therapist |
| RoM | Range of Motion (the extent of movement from bending to fully extending your leg) |
| Reps | Repetitions of an exercise movement |
| Sets | Groups of exercise repetitions |

Your recovery journey

Before your surgery, you will be introduced to MotionSense® and set up by your Care Team. You will then wear the sensors for at least 7 days to get familiar with the system. After your operation, you will continue to use MotionSense® (in collaboration with your Care Team) for up to 90 days.

You should use the system to help complete the daily tasks (including, surveys, knee photos and exercises) set by your Care Team.

System overview

Data recorded on your sensors is securely sent to your Care Team so they can monitor your recovery progress remotely.



Intended use

MotionSense® utilizes patient sensors and a mobile app to track, coach, and monitor knee arthroplasty patients remotely.

Use environment

The MotionSense® system is a prescription device in the USA and is intended for use in accordance with the directions of a Healthcare Provider. This device should be worn throughout the day, including during exercises.

Warnings

Warnings are statements of special safety alerts to allow you and your Care Team to avoid serious events or serious injury.



Always Use Cable and Parts as Directed

MotionSense® is intended only to be used by adults. Keep all parts and cables away from pets and children to avoid injury from strangulation from cables, avoid choking on parts, and avoid damage to parts that may impact device performance.



Always Use Power Plug In Wall Socket Only

Do not use power plug with external adapters, extension leads and splitters. Use of any power source other than the wall socket may lead to electrical injury.



Do Not Get Power Plug Wet

Keep the power plug away from water. Using the power plug near water may lead to electrical injury. Do not use in the event the power plug gets wet. Please dispose of this item safely and contact EnMovi Ltd Customer Services or your Care Team to organise a replacement.



Always Use Supplied Charger

Always use the wireless charger and power plug supplied by EnMovi Ltd. Using a power supply/plug not included with the sensors may lead to electrical injury.



Always Use Power Plug With Cable Pointing Downwards

The power plug should be used with the cable outlet pointing downwards. Do not use the power plug and the cable in the wrong orientation.

Cautions

Cautions are statements of special care to be taken by you or your Care Team for the safe and effective use of MotionSense®.

Set up MotionSense® With Your Care Team

MotionSense® and associated exercise plans must only be set up by a qualified healthcare professional. Any modification of exercise plans by anyone other than a qualified healthcare professional may result in injury and negative impact on your recovery process.

Follow Advice of Your Care Team

Always complete your exercises and activities of daily living as instructed by your Care Team. Not doing so could result in pain, injury or have a negative impact on your recovery progress.

Only Allow Trusted Clinicians To Use Your Phone

MotionSense® requires your Care Team to access your mobile phone to adjust exercises and monitor recovery. Only allow trusted clinicians access to your mobile phone. If someone other than a trusted clinician accesses your mobile phone, personal data may be at risk.

Contact Care Team If Your Skin Is Irritated

Contact your Care Team if you experience skin irritation from the patches or sensors. Continuing to use MotionSense® in this instance may result in further skin irritation or injury, negatively impacting your recovery progress.

Avoid Submerging Your Sensors In Water

Do not immerse the sensors in water deeper than 1 meter for more than 30 minutes, this may break or damage the sensors, negatively impact your recovery process.

Do Not Bend Sensors

Do not intentionally bend or fold the sensors as this may damage them and negatively impact your recovery progress.

Do Not Charge Sensors Whilst Wearing

Do not try to charge the sensors while they are attached to your body. Trying to do so may result in electrical shock or injury from excessive sensor heat.

Always Use Supplied Patches

Always use the weekly skin patches and daily sensor patches supplied to attach the sensors to your leg. If you do not use the supplied patches, the system may not accurately monitor your recovery.

Clean Sensors Regularly

Clean the sensors as instructed. Not cleaning the sensors increases the chance of infection and can lead to a build up of adhesive which can negatively impact the sensor performance.

Do Not Re-Use Patches

Do not re-use either the weekly skin patches or the daily sensor patches, as this will lead to poor sensor attachment and may lead to skin irritation.

Do Not Use MotionSense® If Expired

Check the package label for the expiration date and do not use the sensors if the shelf life has expired. Using expired sensors may give incorrect readings.

Do Not Share Sensors

Do not share the sensors with other patients. MotionSense® is a prescription-only medical device. The sensors are designed for your use only. If used by more than one person, the sensors may not monitor as expected.

Do Not Service or Modify MotionSense®

MotionSense® does not require servicing and maintenance while in use. Any attempt to perform maintenance or servicing may negatively impact system performance.

Do Not Use the Patch on Your Wound

Do not attempt to use the daily or weekly patches on your wound. The patches are not sterile and may lead to an increased risk of infection.

Do Not Use Physical Assistance During Exercises

Do not allow anyone other than a member of your Care Team to physically assist with exercise completion. Seeking physical assistance from anyone other than your Care Team may result in injury or have a negative impact on your recovery progress.

Guide to Parts

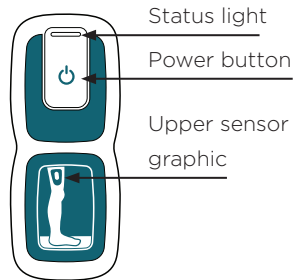
This pack contains:

- 2 Sensors
- 5 Week supply of patches (weekly skin patches and daily sensor patches)
- 1 Wireless charger
- 1 Power Plug and USB Cable
- 1 Skin Marker

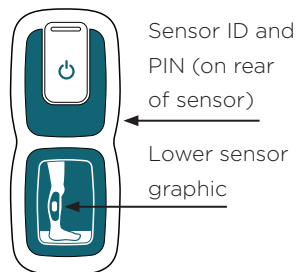
You will also need:

- The MotionSense® App (download via the link sent to your mobile phone)
- 1 Knee Alignment Block

Upper Sensor



Lower Sensor

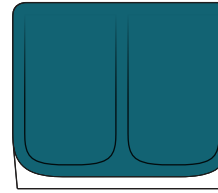


Sensors

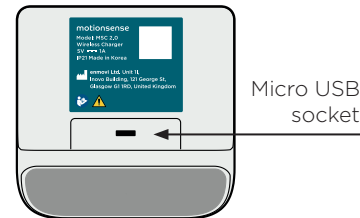
The sensors monitor how you bend and extend your knee during exercises and daily activity.

- The upper sensor goes on the outside of your upper leg
- The lower sensor goes on the outside of your lower leg
- The sensor ID and PIN are found on the back of each sensor (both sensors have the same ID and PIN)

Front of charger



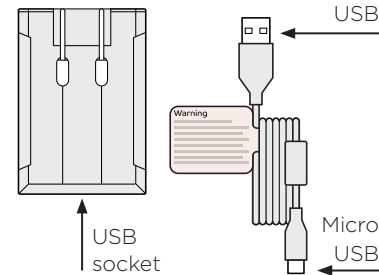
Back of charger



Wireless Charger

The wireless charger is used to charge the sensors at the end of each day. The sensors will fully charge overnight.

The USB cable plugs into the Micro USB socket on the back of the charger.

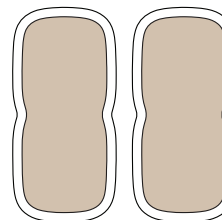


Power Plug and USB Cable

The power plug connects to the wireless charger via the USB cable.

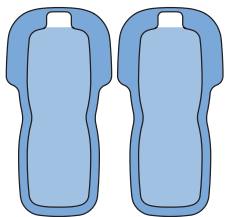
The power plug pins fold out and should be plugged into an electrical outlet for the wireless charger to work correctly.

Weekly Skin Patches



The weekly skin patches have a white backing and are applied directly to your shaved skin above and below the knee.

The weekly skin patches are designed to stay on your leg for 7 days and can be left on while sleeping and showering. Patches are single use. Once removed from the leg, do not reapply.



Daily Sensor Patches

The daily sensor patches have a blue backing and are used to attach the sensors to the weekly skin patches on your leg. They should be removed and disposed of each night before charging the sensors. Patches are single use. Once removed from weekly patch or device, do not reapply.



MotionSense®
App Icon

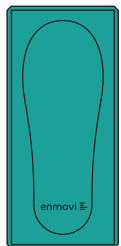
MotionSense® App

The MotionSense® App is installed on your mobile phone from the Apple App Store or Google Play Store and connected to your sensors.



Skin Marker

The skin marker is for use when removing the weekly skin patches, to help you replace them correctly.



Knee Alignment Block

The knee alignment block is for use when aligning the sensors.

Always use the supplied knee alignment block when aligning the sensors, to ensure the system remains accurate.

Ordering new patches

This pack contains enough patches for 1 week before and 4 weeks after surgery. Should you require more patches, please contact your medical practice.

Sensor Status Lights

When the sensor button is pressed:

Solid GREEN: Sensors are working correctly

Solid AMBER: Low battery

- Check **'Sensors'** screen for current battery level

Slow AMBER Flash: Sensors not aligned

- This indicates the sensors were removed from the leg
- Align your sensors to continue monitoring
- Go to **'Align Sensors'** and follow the on-screen instructions to complete alignment

Fast AMBER Flash: Second sensor is off

- Check second sensor:
 - Press and hold the button for 5 seconds on the second sensor to turn it on
 - Check the status light has started flashing amber on the second sensor
 - If not, proceed to **'Sensors are not responsive to button press'** in Sensor Issues

Flashing GREEN: Entering standby mode

- The sensor button has been pressed for 10 seconds and is about to go into standby mode to save power when not in use

No Light: No charge

- If no light after button press, the sensor requires charging. Follow **'Sensors are not responsive to button press'** in Sensor Issues

Without pressing the sensor button:

Dim GREEN: Sensors are charging

Continuous Amber Flash: Sensors are not set up

- Reconnect sensors to phone:
 - Go to the bluetooth settings on your phone and remove the MotionSense® sensors from the list of paired devices
 - In the **'More'** menu of your MotionSense® app, select **'Reconnect Sensors'** and follow the instructions

No Light: Collecting data

- If the light is off during normal use, the sensors are collecting data

1: Setting up MotionSense®

Your Care Team will complete the following steps during your first appointment. Before leaving the healthcare facility, check the following steps are complete.

1a: Installing the MotionSense® App



MotionSense®
App Icon

Your Care Team will create a patient account for you and help you install the MotionSense® App on your mobile phone. The MotionSense® App can be downloaded from the iPhone App Store and from the Android Google Play Store, or by following the link sent to your phone.

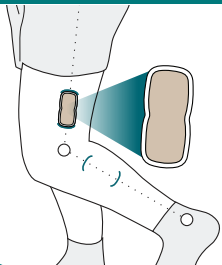
1b: Connecting the sensors



Your Care Team will connect the sensors to your mobile phone.

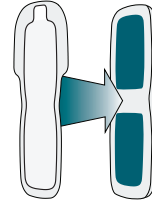
NOTE: The 2x sensors are put into pairing mode by holding both power buttons for 5 seconds, until the status lights flash amber.

1c: Applying the weekly skin patches



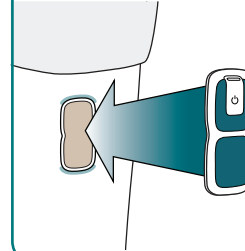
Your Care Team will show you how to attach the weekly skin patches on your leg. They may mark the position on your skin.

1d: Applying the daily sensor patches



Your Care Team will show you how to attach the daily sensor patches to your sensors.

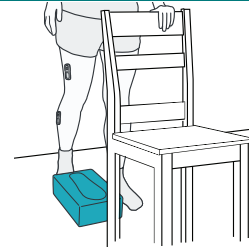
1e: Attaching the sensors



Your Care Team will show you how to attach the sensors to the weekly skin patches on your leg.

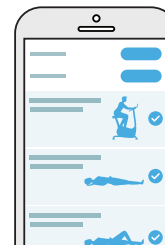
NOTE: The sensors are stuck to the weekly skin patches using the daily sensor patches.

1f: Aligning the sensors



Your Care Team will show you how to activate and align your sensors using the knee alignment block.

1g: Assign exercises



Your Care Team will assign you daily exercises to complete whilst at home.

2: Using the MotionSense® app

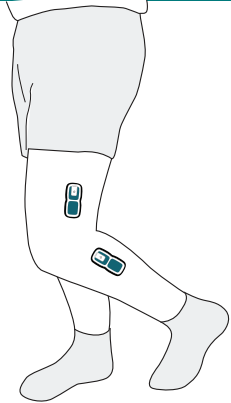
The following steps explain how to use the MotionSense® App.

Caution

Do Not Use Physical Assistance During Exercises

Do not allow anyone other than a member of your Care Team to physically assist with exercise completion. Seeking physical assistance from anyone other than your Care Team may result in injury or have a negative impact on your recovery progress.

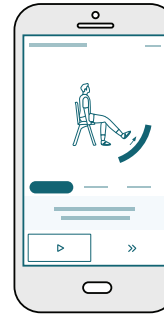
2a: Prepare for your exercise



Before completing your exercise check the following:

- The sensors are charged
- Your sensors are correctly attached to your leg
- The sensors have been aligned (see section 4)

2b: Exercise overview



You will be shown an overview of the exercises in your session.

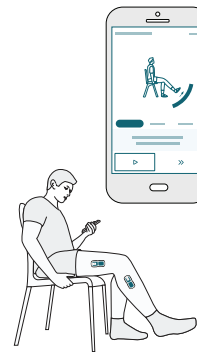
From the Home screen, select 'Exercise Session'. You must complete (or skip as appropriate) all exercises in your session as set by your Care Team.

Before you start each exercise, you will see an overview, including information set by your Care Team such as:

- Number of sets to complete
- Number of reps to complete
- Any notes set by your Care Team

Press 'Start Exercise' to begin guidance.

2c: Doing your exercise



Follow the in-app instructions to complete your exercise session as set by your Care Team.

Depending on the exercise, the screen may also give live exercise feedback on:

- Your current knee angle
- Your target knee angle
- The hold time
- The repetition count

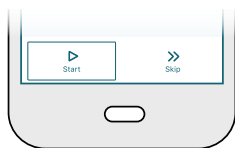
Caution

Do Not Over Exert Yourself During Exercising

Follow any instructions your Care Team have given you and do not over-exert your knee. If you feel uncomfortable or unstable, stop and skip your exercise.

Continued overleaf...

2d: (Optional) Skip your exercise



It is possible to skip your exercise and save your progress at any time by pressing 'skip' and following the instructions in the app.

You will be asked to provide a reason, which will be shared with your Care Team. The exercise will not be accessible again during this session.

NOTE: Talk to your Care Team if you have any questions about your exercise.

2e: (Optional) Exit your exercise



You can exit your exercise and save progress by pressing X. This will close your current session and it will be marked as incomplete.

You will be asked for the reason, which will be shared with your Care Team.

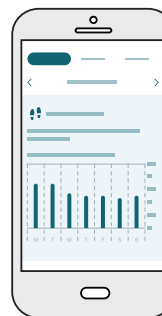
2f: Complete your exercise



Upon completing your exercise, recover before starting the next one. When ready, press 'Start' to begin.

If you have completed your final exercise of this session, you will return to the Home screen.

2g: Recovery Progress



From the Home screen select 'Progress' in the bottom navigation.

You can access progress data for the following:

- Range of motion
- Exercise completion
- Pain score
- Step count
- Active time

NOTE: You can select individual bars in week and month view to access the reading for an individual day.

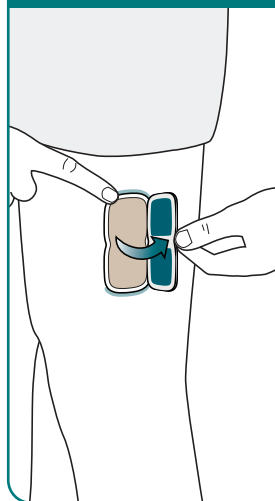
3: Replacing daily sensor patches

You should replace your daily sensor patches each day.

You should remove both your sensors each evening and charge them overnight on the wireless charger.

- Each evening, follow steps 3a-3e to remove the sensors and patches
- Each morning, follow steps 3f-3l to re-attach the daily sensor patches and sensors

3a: Remove the sensors from your leg



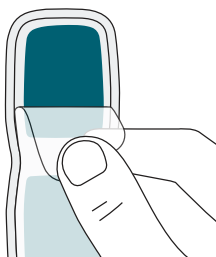
Every evening:

Take care not to remove the weekly skin patches and follow these steps to remove both sensors:

- Press the edge of the weekly skin patch against your leg
- At the same time, slowly peel the sensors away from your leg

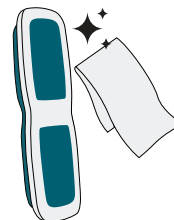
NOTE: It's easiest to remove the sensor by peeling it off side-ways as shown.

3b: Remove the daily sensor patches



Use the white release tab to remove the daily sensor patches from the back of the sensors, and dispose of them in a bin.

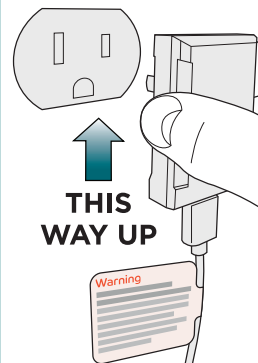
3c: (Optional) Clean the sensors



Some residue build up is normal. If necessary, you can use an alcohol wipe to remove the residue. These are available from your local pharmacy.

NOTE: If excess residue is causing you an issue using your sensors, contact your Care Team.

3d: Set up the wireless charger



Complete the following steps to set up the wireless charger:

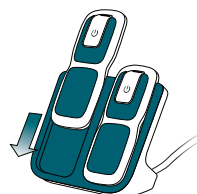
- Plug the large end of the USB cable into the USB socket on the bottom of the power plug
- Unfold the pins on the back of the power plug
- Plug the power plug into a wall socket making sure the cable points downwards
- Plug the small end of the USB cable into the USB socket on the back of the wireless charger (see guide to parts for USB socket location)

Warning

Always Use Power Plug With Cable Pointing Downwards

The power plug should be used with the cable outlet pointing downwards. Do not use the power plug and the cable in the wrong orientation. See Warnings, page 6.

3e: Charge the sensors overnight

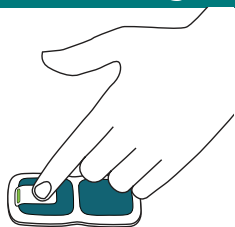


Place both sensors upright on the wireless charger to charge them overnight.

CHECK: Make sure the sensor status light is a dim green, showing the sensors are charging.

Continued overleaf...

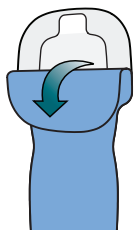
3f: Check your sensors



Each morning:

Remove the sensors from the wireless charger and check the status by pressing the power button for 1 second. A solid green light means the sensor is charged.

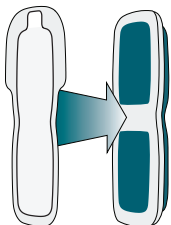
3g: Prepare a new daily sensor patch



Get a new daily sensor patch ready by peeling away and disposing of the blue backing material.

NOTE: The daily patch should stay attached to the clear backing material.

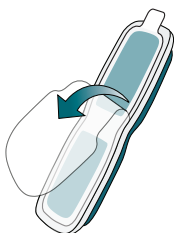
3h: Apply the daily sensor patch



CHECK: Make sure the sensor is clean and dry.

Then stick the patch centrally on the back of the **upper** sensor.

3i: Remove remaining backing material



With the patch stuck on the sensor, remove and dispose of the remaining clear backing material.

NOTE: Avoid touching the adhesive before attaching to your leg, as sensors may not stick properly.

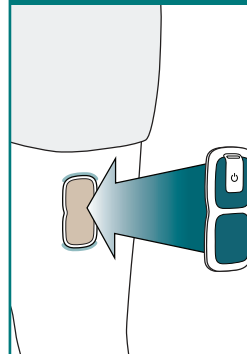
3j: Check the sensor orientation



Make sure the sensor is upright, with the power button at the top as shown.

CHECK: Make sure the weekly skin patches on your leg are clean and dry. If they are not, the sensors may not attach correctly.

3k: Place upper sensor on the weekly skin patch



Stick the **upper** sensor **upright** on top of the weekly skin patch on your **upper** leg. Take care to position the sensor centrally on the weekly skin patch with the button facing upward as shown.

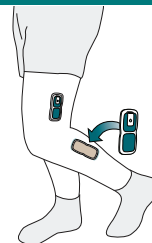
Press the sensor against the leg for 3 seconds.

Caution

Do Not Reapply Used Daily Patches

Always use a new daily patch, even if they fall off during the day. Never reuse patches as the sensors may not stick properly, negatively impacting system performance.

3l: Repeat for the lower sensor



Repeat steps 3f-3k to fit the **lower** sensor to the weekly skin patch on your **lower** leg.

NOTE: You must now complete the steps in section 4: "Aligning your sensors" before you do your exercises.

4: Aligning your sensors

The following steps explain how to align your sensors in a repeatable position using the knee alignment block supplied.

The sensors need to be aligned each morning, if they fall off your leg during the day or if required by the app. This helps to ensure the sensors remain accurate.

Caution

Do Not Complete Alignment if You Feel Unstable

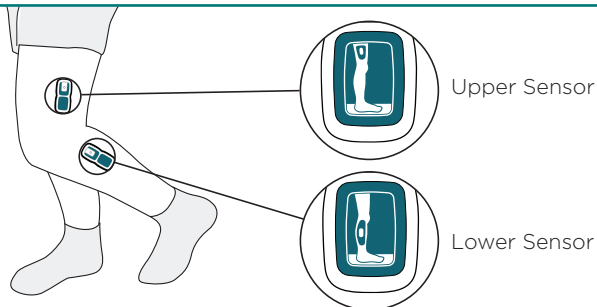
Check you are able to enter and exit the alignment pose safely using a walker or chair for support. Instability during the alignment process may result in injury. Stop and contact your Care Team if you feel unstable.

4a: Check attachment

Check your sensors are correctly positioned:

- The upper sensor should be on the upper leg
- The lower sensor should be on the lower leg
- Both sensors should be upright, with the button at the top

NOTE: You can tell the difference between the upper and lower sensors by looking at the graphic on each device:



4b: Get into position

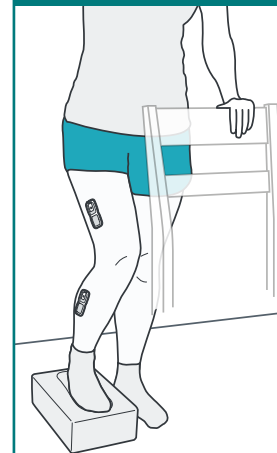


Place the supplied knee alignment block flat on the floor, in a clear space.

Then, following the instructions in the app:

- Find a clear space, free from obstructions and position a walker or chair in front of you to help you balance
- Step operated leg onto block using a walker or chair in front of you to aid balance (as shown)
- Line up both feet at hip distance apart making sure your foot is in the foot outline, and your toes are in line with each other

4c: Enter the alignment pose



Continue following the instructions in app:

- Relax and make sure your hips are level and not tilted (as shown)
- Hold this position for 3 seconds
- Once the countdown is complete, press 'Update Alignment'
- Follow the on-screen prompts to check the sensor measurement. If the app angle visually matches your actual knee angle then select 'Confirm Alignment'
- Carefully get out of position to go about your day

Caution

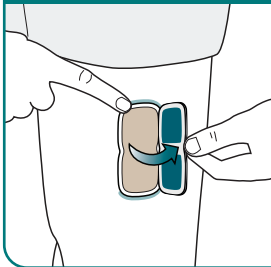
Remain Still During Alignment

Ensure you do not move once in the alignment position as this can lead to incorrect sensor readings. If you move your leg during alignment you will receive a prompt to restart.

5: Replacing weekly skin patches

You should replace your weekly skin patches every 7 days.

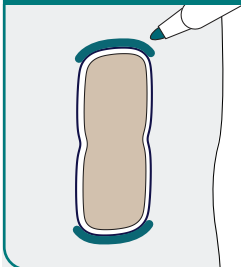
5a: Remove your sensors



In the evening:

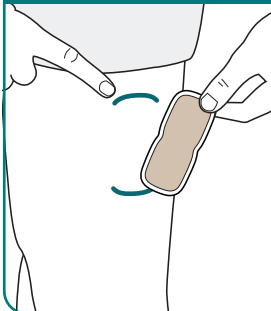
Follow steps 3a-3d to remove both your sensors and charge them overnight.

5b: Mark the location of the old patches



Use the skin marker provided to mark the location of the old weekly skin patches on your skin. Draw around the top and bottom curve of the patch to help ensure the newly applied patch is placed in the same place.

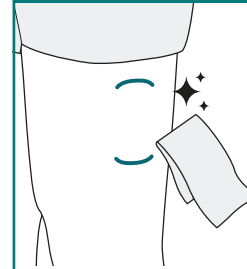
5c: Remove the old weekly skin patches



Press down on the skin outside of the weekly skin patch and gently lift an edge. Remove the weekly skin patch and dispose in a bin. Repeat for both patches.

You will fit your new weekly skin patches the following morning.

5d: Prepare the attachment area



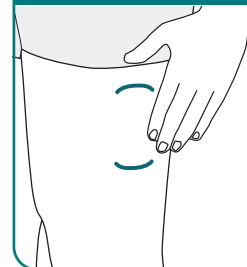
The following morning:

Prepare the skin by:

- Removing any hair in the attachment area
- Cleaning the attachment area with warm soapy water and a damp cloth. Make sure not to remove the pen markings

NOTE: Some residue build up is normal but if you are having difficulty attaching the weekly patches to your leg, contact your Care Team.

5e: Check the attachment area



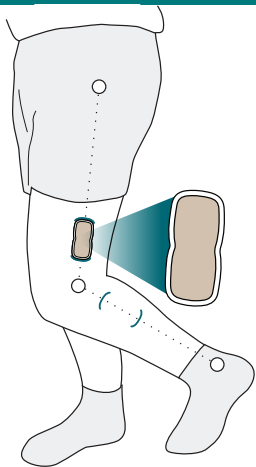
CHECK: Make sure the attachment area is clean, dry and free of any oils.

5f: Prepare a new weekly skin patch



Then, remove and dispose of the backing material from the back of the weekly skin patch.

5g: Apply the first patch



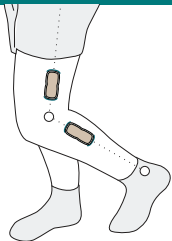
Align the new weekly skin patch with the two lines marked on your skin and smooth down the edges.

Then place your hand on top of the weekly skin patch and hold for 10 seconds. This will enhance the adhesion of the patch.

Alternatively, without skin markings

- Align the weekly skin patch along the outside of the upper leg, at least a hand's width distance away from the joint center as shown
- Position the patch along the joint center line as shown
- Place your hand on top of the weekly skin patch and hold for 10 seconds

5h: Repeat for the second patch



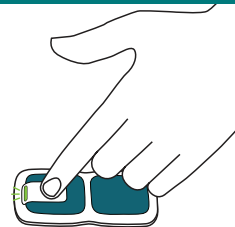
Repeat steps 5d-5g to attach the second weekly skin patch to your lower leg.

Now follow steps 3f-3k to attach your sensors.

6: Turning off the sensors

You should turn off your sensors if they will not be worn for more than a day.

6a: Press and hold the button



- Press and hold the power button on the sensor until the status light starts flashing green, then let go. The sensors are now in standby mode
- Repeat for the other sensor
- Store the sensors on the wireless charger

7: Setting up MotionSense®

FOR HEALTHCARE PROFESSIONALS ONLY

You should help your patient to set up MotionSense® and ensure they are comfortable and able to use the system safely at home with the following steps.

7a: Register patient and enable MotionSense®

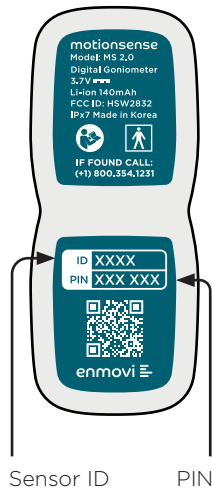


Register your patient in OrthoLogIQ (OIQ) by:

- Adding new patient information
- Adding new case details
- Enabling MotionSense® for the patient

Once registration is complete, an email and sms will be sent to the patient.

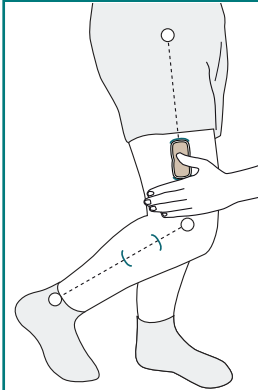
7b: Install app and connect sensors



When introducing the patient to MotionSense®, you should help them set up with the following steps:

- Download the MotionSense® App from the iOS or Android App Store, or follow the link sent to the patient's mobile phone
- Open the app, select 'Set up your account' and follow the instructions in the app to create an account for the patient
- Login to the 'Care Team Mode' using your OIQ account details
- Connect the sensors. You will need to enter the Sensor ID and PIN during the connection process

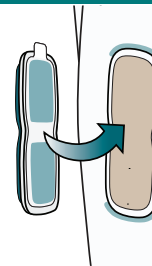
7c: Apply the weekly skin patches



Once registered, the app will prompt the patient to wear their sensors. You should help the patient by doing the following:

- Explain that the weekly skin patches attach to the leg, and the daily sensor patches are applied to the sensors
- Shaving any hair in the sensor attachment area
- Follow steps 5d-5g to attach the weekly skin patches to the affected leg, at least a hand's width distance away from the joint center as shown
- Mark the location of the applied patches with the skin marker included
- Explain that the weekly skin patches must be replaced every week

7d: Apply the daily sensor patches and sensors



Follow steps 3f-3k to apply the daily sensor patches and attach the sensors.

- Explain that the sensors must be removed every evening, charged overnight and re-attached every morning as shown in Section 3

8: Setting sensor alignment

FOR HEALTHCARE PROFESSIONALS ONLY

The following steps explain how to set sensor alignment using the knee alignment block supplied.

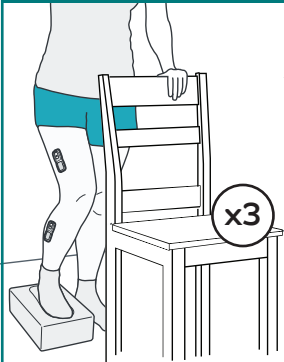
You will be prompted to 'Practice Alignment' and 'Set Sensor Alignment' as part of patient onboarding in the app. You might need to repeat the alignment process with the patient periodically during recovery if measurement issues arise.

Caution

Check Patient Is Stable When Completing Alignment

Check the patient is able to enter and exit the alignment pose safely using a walker or chair for support. Instability during the alignment process may result in injury.

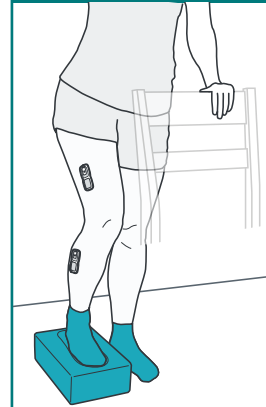
8a: Practice alignment position



Log in to the 'Care Team Mode' in the app and select 'Set Sensor Alignment'.

- Find a clear space, free from obstructions and position a walker or chair in front of the patient to help them balance
- Place the supplied knee alignment block flat on the floor, in a clear space
- Following the instructions in the app, it is recommended you practice 3 times with your patient to ensure they can achieve a relaxed, repeatable position on the alignment block at home (see steps 4a - 4c)
- Once you have completed alignment practices with your patient, select 'Final Alignment'

8b: Get into final alignment position



Then, following the instructions in the app:

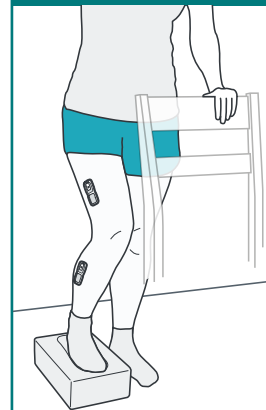
- Step operated leg onto block using a walker or chair in front of the patient to aid balance
- Line up both feet at hip distance apart making sure the patient's foot is in the foot outline, and their toes are in line with each other

Caution

Remain Still During Alignment

Ensure the patient does not move their legs once in the alignment position as this can lead to incorrect sensor readings. If the patient moves their leg during alignment you will receive a prompt to restart.

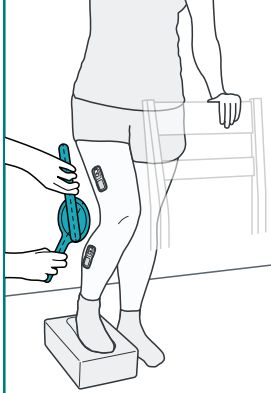
8c: Enter the alignment pose



Continue following the instructions in the app, helping the patient to:

- Relax and make sure their hips are level and not tilted (as shown)
- Instruct the patient to hold this position for 3 seconds

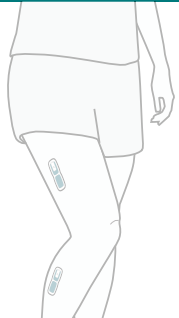
8d: Measure knee flexion



Ensure the patient remains **in the same position** and does not move their legs. Then:

- Use a goniometer to measure the knee angle of the patient's affected leg

8e: Enter and confirm the knee flexion angle



Following the instructions in the app:

- Ensure the patient remains still then enter the knee flexion angle and select 'Set Angle'
- Follow the on-screen prompts to check the sensor measurement. If the app angle visually matches the actual knee angle then select 'Confirm Alignment'

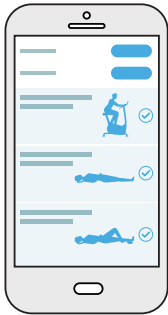
The alignment process is now complete. Ask the patient to return to a normal standing position.

9: Assigning exercises

FOR HEALTHCARE PROFESSIONALS ONLY

The following steps explain how to assign a list of exercises to your patient.

9a: Setting an exercise plan

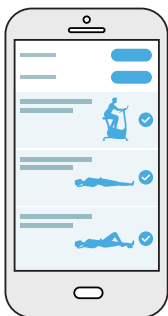


At the end of onboarding you will be prompted to select one of the following two ways of allocating exercises:

- Allocate Default Plan - This applies an initial list of exercises that can be adjusted
- Set Manually - This allows you to manually select your own list of exercises

You can also allocate exercises by logging in to the 'Care Team Mode' and selecting 'Exercise Plan'.

9b: Select exercises

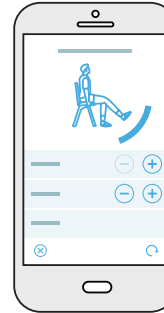


You can allocate either 1 or 2 sessions to be completed daily by your patient.

You can then add an exercise to your selected exercises by selecting the checkbox.

NOTE: If you select 2 sessions, each session will display the same exercises.

9c: Edit exercises



You can edit an exercise by selecting 'Edit' on your selected exercises. You can then adjust the details of the exercise and save by selecting 'Save Changes'.

Adjust the following according to your patient's capability:

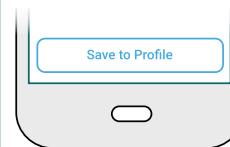
- Number of sets
- Number of reps
- Start angle
- Target angle
- Hold time
- Resistance weight

You can also add PT notes to guide your patient.

Caution

Angles entered here will be displayed back to the patient as 5° easier targets to achieve. This allows for any offset in sensor readings.

9d: Save to patient profile



Once you have finished adjusting your exercises, save by selecting 'Save to Profile'.

10: Reviewing recovery progress

FOR HEALTHCARE PROFESSIONALS ONLY

The following steps explain how to access and review your patient's recovery progress.

10a: Recovery Progress



You can access recovery progress by logging in to the 'Care Team Mode' and selecting 'Progress'. Alternatively, you can review this data in OIQ.

You can access progress data for the following:

- Range of motion
- Exercise completion
- Pain score
- Step count
- Active time

NOTE: You can select individual bars in week and month view to access the reading for an individual day.

Troubleshooting

Sensor and App Connection

| What to do if... | Solution |
|--|--|
| Sensors and app are working but the angle reading seems wrong | <ul style="list-style-type: none">• Sensors are not aligned correctly, repeat the align sensors process to continue monitoring• Read section 4 of the MotionSense® Instructions for Use and repeat the 'Align Sensors' process, following the on-screen instructions to complete alignment |
| Sensor Light is green but the phone cannot connect | <ul style="list-style-type: none">• Turn on Bluetooth on your phone:<ul style="list-style-type: none">- Check the phone Bluetooth is ON- If the problem persists then see 'Sensors do not behave as expected' to perform a sensor reset |
| App cannot detect the sensor | <ul style="list-style-type: none">• Go to the Bluetooth settings on your phone and remove the MotionSense® sensors from the list of paired devices• In the 'About and Settings' menu of your MotionSense® app, select 'Reconnect Sensors' and follow the instructions |

Sensor Issues

| What to do if... | Solution |
|---|--|
| Sensors are not responsive to button press | <ul style="list-style-type: none">• The sensor battery is empty. Charge the sensors:<ul style="list-style-type: none">- Ensure charger cradle is plugged in- Place sensors on charger- Check sensor light is dim green |
| Sensors are not charging | <ul style="list-style-type: none">• Ensure wall adapter is plugged into socket• Ensure charger cable is plugged into the wall adapter and the back of the charging cradle• Check both sensors are in the charging cradle the correct way up (with the button and light at the top) and the correct orientation (with the flat surface touching the charger)• Ensure both sensors are sitting properly in the charger and not sitting away from the cradle• You should see a green dim light on both sensors during charging |
| Sensors do not behave as expected | <ul style="list-style-type: none">• Your sensors need to be reset:<ul style="list-style-type: none">- Press and hold both sensor buttons for 30 seconds- Release the button and press again for 3 seconds- The sensor light should now flash amber continuously on both devices- Go to the bluetooth settings on your phone and remove the MotionSense® sensors from the list of paired devices- In the 'About and Settings' menu of your MotionSense® app, select 'Reconnect Sensors' and follow the instructions |

Adhesives Issues








| What to do if... | Solution |
|--|--|
| Sensors and daily sensor patch repeatedly falling off leg | <ul style="list-style-type: none"> Your daily patch needs to be replaced following steps in section 3 in the MotionSense® Instructions for Use: <ul style="list-style-type: none"> - Remove the sensors from the leg - Remove the daily sensor patches - Prepare and apply a new daily sensor patch to the sensors - Remove the remaining backing material - Check orientation and place sensors on the weekly patch |
| Weekly skin patch repeatedly falling off leg | <ul style="list-style-type: none"> Your weekly patch needs to be replaced following the steps in section 5 of the MotionSense® Instructions for Use: <ul style="list-style-type: none"> - Remove your sensor - Mark the location of the old patch - Shave and clean the attachment area - Prepare and attach a new weekly patch with two lines marked on your skin - Replace the daily sensor patch following steps in section 3 of the MotionSense® Instructions for Use |









Button Functions

| Function | Button Action |
|--------------|--|
| Status Check | Tap the sensor button. |
| Turn On | Press and hold the sensor button for 5 seconds until you see the sensor light flash amber and then let go. |
| Turn Off | Press and hold the sensor button for 10 seconds until you see the sensor light flash green then let go. |

Safety Information

Explanation of symbols used on labels

| | |
|---|--|
|  | Manufacturer |
|  | Temperature limit |
|  | Keep away from direct sunlight |
|  | Keep dry |
|  | Refer to Instructions for Use Icon appears inverted in white on sensors |
|  | Type BF applied part |
|  | Non sterile |

| | |
|---|---|
|  | Date of manufacture |
|  | Do not re-use |
|  | Humidity limitation |
|  | Use by date |
|  | Catalog number |
|  | Batch code |
|  | Class II equipment |
| IPx7 | Protection against the effects of temporary immersion in water |
| IP21 | Protection against solid foreign objects of 12.5 mm and greater in diameter and protection against vertically falling water drops |
|  | Hazard warning |

Contraindications

Absolute contraindications to the use of the MotionSense® system include lower limb skin conditions such as psoriasis and excessive scarring, physical and mental conditions that prohibit appropriate rehabilitation, and morbid obesity. Relative contraindications include active knee sepsis, previously untreated or chronic osteomyelitis, ongoing remote source of infection.

Customer Service and Maintenance

Customer Service

(+1) 800.354.1231

support@enmovi.com

Manufacturer

EnMovi Ltd. Unit 1I, Inovo Building, 121 George St, Glasgow G1 1RD, United Kingdom

Cleaning and Maintenance

Use a new daily sensor patch for each application of the sensor to the bigger weekly skin patch.

To clean the sensors, you can use an alcohol wipe. These are available from your local pharmacy.

Use a new weekly skin patch every 7 days or when the adhesive starts peeling off or becomes dirty or grimy.

To clean the skin use warm soapy water to remove any adhesive residue before application of a new weekly skin patch.

Damage and Repair

MotionSense® does not have any user or patient serviceable parts inside. If the device appears damaged or to be defective, stop using the device immediately and contact Customer Service.

Do not attempt to repair or modify MotionSense® products on your own.

Disposal

Dispose of the patches in your household waste bin.

Dispose of the sensors in accordance with local guidelines. If you need to remove the battery for disposal, use scissors to carefully cut down the soft plastic in the middle of the sensors and pull out the battery. **Do not cut through the battery.**

Technical Specifications

Mobile Device Compatibility

- Android Running 8.0 and up
- Apple iPhone running iOS 11.0 and up
- Phone hardware must support BLE 4.2 Communication protocol

FCC Declaration

This device complies with Part 15 rules. Operation is subject to the following two conditions:

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

This equipment has been tested and found to comply with the limits of a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential environment. This equipment generates, uses, and radiates radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference. However, there is no guarantee that interference will not occur. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to correct the interference by one 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.

To which this declaration relates, is in conformity with the following standard:

- EMC FCC Part 15 (B) Class B
- Radio 47 CFR Part 15.247 Contains FCC ID: HSW2832 for wearable sensor
- Radio 47 CFR Part 15 FCC ID: 2AY5U-A for wireless charger

FCC Caution

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

RF Exposure

The wireless charger unit complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This wireless charger should be installed and operated keeping it at least 20cm or more away from person’s body.

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

MotionSense® has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices IEC 60601-1-2:2014.

| Emissions/Immunity Test | Compliance Level |
|--|---|
| RF Emissions CISPR 11 | Class B, Group 1 |
| Harmonic Current Emission IEC 61000-3-2 | Applicable, Class A |
| Voltage change, Voltage fluctuations and Flicker Emission IEC 61000-3-3 | Applicable |
| Conducted Immunity IEC 61000-4-6 | Applicable, 3 Vrms, 6 Vrms ISM Bands and amateur radio Bands |
| Immunity to Proximity Fields from RF wireless communication equipment IEC 61000-4-3 | 80 MHz to 2.7 GHz, 10 V/m |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV Contact, ±15 kV Air |

| Emissions/Immunity Test | Compliance Level |
|--|------------------|
| Electrical fast transient/burst IEC 61000-4-4 | Applicable |
| Surge Immunity IEC 61000-4-5 | Applicable |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | Applicable |
| Magnetic Immunity IEC 61000-4-8 | 30 A/m |

Technical Data

| | |
|---|---|
| Product description | Digital Goniometer |
| Brand | EnMovi Ltd. |
| Model | MotionSense |
| Model | Sensor: MS 2.0 Charger: MSC 2.0 |
| Resolution | 1° of knee angle and 5° of RoM ² |
| Operational conditions | +5°C to +40°C (+41°F to +104°F) RH greater than 15% up to 95% 70 kPa - 106 kPa |
| Transport and Storage between uses | -25°C to +5°C (-13°F to +41°F) for 72 hours, and +5°C to +35°C (+41°F to +95°F) RH up to 85% for 72 hours, +35°C to +60°C (+95°F to +140°F) for 6 hours |

| | | | | |
|---------------------------------------|---|----------------|------------|---------|
| Battery | Li-ion 140mAh x 2 minimum of 24 hours of operation | | | |
| Wireless Charger | 5V DC and 1A Input power, charging power < 5W | | | |
| AC DC power supply³ | ODF-007-00053 | | | |
| Size | Sensor: L = 85mm (3.34 in.) x W = 35mm (1.38 in.) x H = 8mm (0.31 in.) Charger: L = 45mm (1.71 in.) x W = 78mm (3.08 in.) x H = 69mm (2.70 in.) | | | |
| Weight | Wearable each less than 15g Charger less than 200g | | | |
| Water Resistance | Sensor IPX7 Wireless Charger IP21 | | | |
| Package contents | <ul style="list-style-type: none">• 2 Sensors• 1 Wireless charger, cable and power plug• 5 Week supply of patches (weekly skin patches, daily sensor patches)• 1 Skin Marker | | | |
| Wearable Contains FCC ID | FCC ID | Frequency Band | Modulation | EIRP |
| | HSW2832 | 2402-2480MHz | GFSK | 1.216mW |
| Charger FCC ID | FCC ID | Frequency Band | Modulation | |
| | 2AY5U-A | 1.047MHz | N/A | |
| Product life | 4 months | | | |
| Shelf life | 24 months | | | |

NOTE:

1. Specifications are subject to change without prior notice or any obligations on the part of the manufacturer.
2. Clinical Accuracy characteristics and procedures are available from the manufacturer on request.
3. Supply adapter plug serves as the mains disconnect device.

MotionSense is a registered trademark of EnMovi Ltd.

SDoC Information

- Unique Identifier: MSC 2.0
- Responsible Party – U.S. Contact Information
 - Company : OrthoSensor, Inc.
 - Contact person : Deborah Johnson
 - Address : Florida, Dania Beach 1855 Griffin Rd STE A310
 - Phone: +1 954 686 5235 / E-Mail: deborah.johnson@stryker.com

Notes

