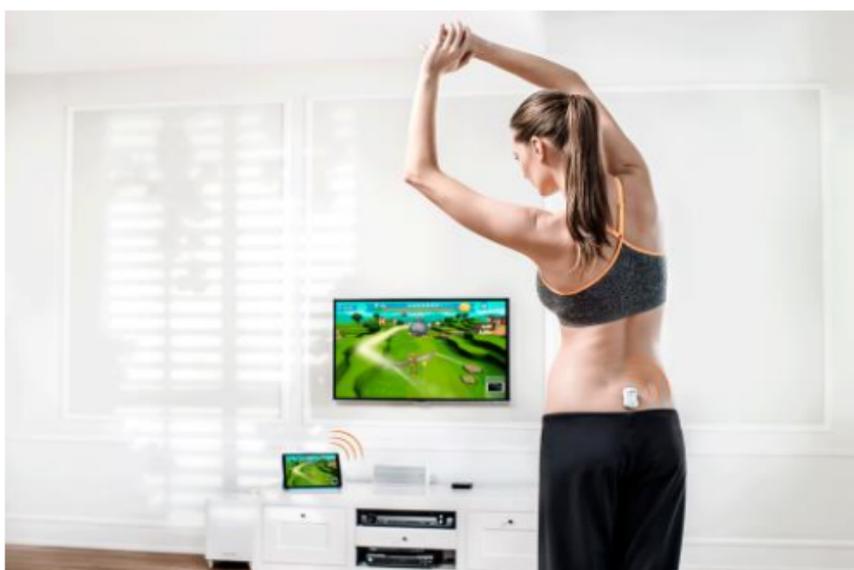


valedo



User Manual

EN

English

We move you

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This manual applies to Valedo®

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Subject to technical modifications. The most recent user manual is available online at www.valedotherapy.com.

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Introduction

Welcome and thank you for purchasing Valedo!

If you're reading this, that means you're one of millions around the world who suffer from lower back pain. The good news for you is that you've taken an important first step in treating this lingering epidemic.

Many people don't know that a Valedo workout can be done in only minutes. Keep Valedo around for a quick workout before work, during your lunch break or even while you travel!

For business or pleasure, you'll find that Valedo is easy to use, engaging and entertaining.

So what are you waiting for? Let's get moving!

A Little Background Info...

At Hocoma we're known for our large physical rehabilitation products such as Lokomat®, Armeo® and Erigo®, but we are also a pioneering company in the field of implementing sensor technology into functional therapy for lower back pain. That's where Valedo® and its clinical sister products Valedo®Motion and Valedo®Shape come in.

Find more information on all of our clinical products at www.hocoma.com and more information on Valedo® at www.valedotherapy.com.

This user manual describes the safe and correct use of Valedo. Follow the safety information and instructions in the user manual and general safety and hygiene norms.

When you are training with Valedo you are medically considered a user. For all other activities with Valedo, you are considered the operator.

Keep this manual handy for quick reference, and read through again from time to time.

In the interest of ease of reading, we use the male form (he, him, his) when referring to both male and female.

Chapter 1: Overview and Safety

Getting to Know Valedo®



Figure 1: Overview of Valedo

Valedo comprises the following components:

- Sensors
- Double-sided medical tape
- Cable for charging or firmware updates
- Valedo case for transport and storage

The Valedo System is understood to mean all components **plus** your own computing device.

Trunk and pelvis movements are measured from two wireless sensors attached to your body and transferred to a personal computing device (such as a tablet). These movement signals are analyzed and provide accurate real-time functional feedback in a game setting (Augmented Performance Feedback) of how you are moving and if you are moving correctly. Augmented Performance Feedback gives you a motivating and safe way to do movement training. The system monitors your movement performance and guides you through exercises specifically designed for general lower back pain therapy.

The Sensors

The two sensors that come with Valedo are lightweight and easy to operate. They are equipped with one button, one LED and one micro-USB port for charging and firmware updates.

- ① The LED is only visible when illuminated.

Turning the sensors on and off

If used on a regular basis, awaking the sensors from standby mode is as easy as gently shaking them. If the sensors are in standby mode for more than 48 hours, they will enter deep sleep mode.

- If the sensors are in standby mode, gently shake them to wake them up.
 - If the sensors are in deep sleep mode, push the button to wake them up.
 - To enter deep sleep mode manually, press and hold the button for 4 seconds.
- ① Sensors will enter standby mode after 30 seconds if they do not detect a computing device to pair to.
 - ① Sensors will enter deep sleep mode after approximately 5 minutes when they cannot connect to your computing device but they sense continual movement; this is important during transport to save battery power.

Once awake, the sensors will indicate with their LEDs that they are searching for a Bluetooth® connection (see table below); when Bluetooth has appropriately been enabled on the computing device, you can pair the sensors to it (see The Computing Device later in this chapter).

Charging the sensors

1. Plug the micro-USB ends of the charging cable into the sensors.

2. Plug the regular USB end of the charging cable into your personal computer OR into an IEC 60950 approved USB charger.

① You may have a charger already; many new mobile phones and other mobile products come with an IEC 60950 compliant USB charger.

① Charge the sensors for at least 90 minutes for a full charge.

① While the sensors are charging it is impossible to train.

The sensors are equipped with an LED and blinks and flashes to communicate what it's doing or if it needs charging. Below is a table with the different LED modes and their explanations.

LED mode	Sensor status	Mode explanation
On	Charging—fully charged	The sensors are plugged in and are fully charged.
Inverted pulse: Long on - short off	Charging—not fully charged	The sensors are plugged in but are not yet fully charged.
Off	Standby	The sensors are not actively searching for a Bluetooth signal. Shake to turn sensors back on.
Off	Deep Sleep	The sensors have turned themselves off. This happens after 48 hours in standby mode. Press button to turn sensors back on.
Pulse: Short on – Long off	Awaiting connection	The sensor is on and waiting for the Bluetooth connection with the computing device.
Slow flash (1 second on, 1 second off)	Connected	The sensor is on and correctly connected via Bluetooth with the computing device.
Fast flash (~0.5 second on, ~0.5 second off)	Connected—alert	The sensor is on and connected with the computing device, but there is a warning message.*
Triple flash (3x per second)	Battery low	The sensor is running low on battery and needs to be charged.*

* Warning messages and low battery alerts will also appear on the computing device.

 Do not soak or submerge the sensors in any liquid. Use a damp cloth to wipe surfaces.

The Cable

The cable that ships with Valedo is a standard USB to dual micro-USB cable. Use this cable for both charging and firmware updates of the sensors.

Both micro-USB connectors can be used to charge, but only one can be used for firmware updates. Simply put, you can charge both sensors simultaneously, but you can only update one sensor at a time. For information on updating the sensors, see the Maintenance section later in this chapter.



Figure 2: USB head on the left, two micro-USB heads on the right. Micro-USB head in the middle can be used for both charging and firmware updates.

The Valedo Belt (optional)¹

If you wish to train without using the double-sided medical tape, consider our specially designed belt.



Figure 3: Training belt. Hand wash and hang dry.

The Computing Device

All training requires a computing device. For a list of supported devices, consult www.valedotherapy.com. Take care of your computing device by regularly updating your operating system.

On the computing device you will need to download and install the Valedo application (see Chapter 3).

Pairing sensors and computing device via Bluetooth

1. Enable Bluetooth on your computing device (usually in “settings” or “configuration”).
2. Turn on sensors.
3. Open the Valedo application.
4. Create new profile making sure to indicate that you have sensors. See Chapter 3 for more information on creating a profile.
5. Connect sensors in the Sensor Management screen.

For initial operation you must go through steps 1-5; for subsequent use, the Bluetooth connection will automatically pair the sensors to the computing device upon opening the Valedo application.

The Valedo Case

The case Valedo came in did not just keep it safe during its journey to you; the case will also keep Valedo safe when you store or transport it. See case in Figure 1.

We recommend always keeping the Valedo sensors in the case between training sessions.

The Valedo Application

The standard Valedo application for lower back therapy is available for free download. Additional features or applications may be made available for purchase. The computing device you have will dictate where you need to go to download the Valedo application; when there, search for “Valedo”. For example: iPad users can go to the App Store.

For complete details on the Valedo software application, see Chapter 3.



Protect your computing device from viruses.

- ① The Valedo application stores only a minimum amount of information including the profile information given for each user and their performance on the exercises they have done.
- ① Regularly check www.valedotherapy.com to see if there are available updates for the Valedo application.

¹ The Valedo Belt is an optional accessory. Go to www.valedotherapy.com for availability.

Safety Regulations

You must comply with the security precautions listed below and those found throughout the manual to ensure safe use of Valedo.

-  Every and all warning messages must be observed without fail.
-  Valedo sensors are not toys and can present choking hazards. Keep out of reach of children and pets.
-  Do not use Valedo if any of the components are damaged or modified.
-  Take note of indications, contraindications and risk factors before use.
-  When using tape, use medical tape only.
-  You must wipe the sensors off before and after use. We recommend a soft damp cloth.
-  Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
-  Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
-  Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Valedo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Intended Use

Valedo will assist to improve back health and to better prevent nonspecific low back pain, by providing structured exercises combined with Augmented Performance Feedback. It encourages and enables proper training of essential muscle groups in the pelvic and lumbar regions. Furthermore, it enhances movement awareness without the necessary presence of a therapist.

Application

Valedo was designed to be used anywhere the wireless signal between the sensors and the computing device can be established. The sensors must be kept at least 1 m (39 in.) from large electromagnetic or ferromagnetic devices (large speakers, appliances or metallic devices).

Indications

- Non-specific low back pain
- Stability training of trunk and spinal musculature
- Mobility training of spinal column and pelvic girdle
- Training body balance and posture.

If you are unsure if you have an indication, consult with your medical expert (this may be a doctor, physical therapist or chiropractor). You can still use Valedo if you have the following conditions, but only in consultation and under supervision of your medical expert.

- Problems with the sacroiliac joint (e.g. pelvic girdle pain, blocking)
- Fibromyalgia (persistent, widespread pain and tenderness, generally presents with symptoms of sleep problems, fatigue, joint stiffness, among others)
- Benign hypermobility syndrome (joint or limb pain with attendant symptoms of joint subluxation, joint dislocation, among others)
- Neurological conditions (e.g. stroke patients) less than three months after last incidence

- Neurological conditions (e.g. stroke patients) requiring improved trunk stability and body perception (with little or no apraxia (inability to execute learned purposeful movements))
- Herniated disk, including post-operative state
- Spinal stenosis (narrowing of the spinal canal), including post-operative state
- Stable vertebral fractures
- Ankylosing spondylitis (type of arthritis that may lead to stiffness or fusion of the vertebrae in the spine) with painful limitation of spinal movement
- Osteoporosis (decrease in bone mass) (light or middling level) with accompanying pain
- Multiple Sclerosis (central nervous system disease) (non-progressive stage) with disturbed body perception
- Parkinson's disease (progressive nervous system disorder) with disturbed body balance and posture.

Contraindications

Valedo is passive in nature insofar as it does not impose any movements on the user. Instead, it only detects movements and, through the exercises, encourages the user to complete movements himself. Therefore the same contraindications apply for Valedo as for any conventional therapy modalities for the same conditions.

Consequently as for any therapy approach, functional training with Valedo is not possible or indicated in every case.

Valedo is, in general, used directly without consultation of a medical expert. However, if you are unsure whether you have a contraindication or risk factor, you should first consult your medical expert. No training with Valedo may be conducted in the presence of a contraindication. You can continue to use the Valedo even if you suffer from a condition listed as risk factor, but only with permission from your medical expert. If a medical expert is consulted, he must take into consideration the same factors that are listed below.

The medical expert in charge is always responsible for decisions regarding whether therapy with Valedo is indicated or not. Specifically, only when the potential benefits outweigh the potential risks for the individual in question. When deciding whether Valedo therapy is indicated with a certain patient, the responsible medical expert must carefully consider that the conditions listed below could increase the risk of harm to the patient. The lists do not claim to be exhaustive. No training with Valedo may be conducted in the presence of a contraindication. The presence of risk factors might require additional safety measures. The more risk factors present and/or the more serious they are in an individual, the more likely it becomes that use of the device could also be contraindicated.

The medical expert must also be aware that the risk/benefit profile of a certain patient could change over the duration of therapy as new information becomes available. Therefore, the medical expert must continually monitor the results of the therapy and periodically reconsider if Valedo therapy is still indicated.

Due to the constant advances in medical knowledge and treatment, the medical expert in charge must continually keep up-to-date by reading the latest scientific literature and being informed of changes in treatment recommendations.

Valedo is not meant to replace the expertise or experience of a medical expert.

- Bone cancer, including spinal tumors or vertebral metastasis
- Instability of the spine, such as unstable vertebral fractures or in spondylolisthesis (forward displacement of a vertebra) (grade II or higher), particularly with neurological signs
- Acute rheumatoid arthritis or acute spondyloarthritis (acute inflammation of bones or joints)
- Infection of bones or joints
- Acute sacral, lumbar or thoracic nerve root entrapments leading to sensorimotor function deficits
- Severe level of osteoporosis (decrease in bone mass) or osteomalacia (bone softening) with latent risk of fracture
- Severe neurological disability, including compression of the spinal cord or cauda equine (bundle of nerves in the lower back), nerve root compression, etc.

- Recent serious accidents (e.g. whiplash, spinal contusion) without prior consultation with a medical expert
- Implanted ferromagnetic materials or active devices within the body
- Spinal fusions within the first three months postoperative
- Skin disease or lesions in the vicinity of sensor placement (including cut or broken skin, eczema, etc.)
- Patients who have been subjected to long-term bed rest
- Having an implanted pacemaker.

Just like with any other training program, small steps at the beginning are critical in order to avoid overtraining and consequent injuries. With time your body will adapt to the training and you will be able to train longer and do more strenuous exercises.



CAUTION: IF AT ANY TIME WHILE USING VALEDO YOU EXPERIENCE DISCOMFORT, UNUSUAL FATIGUE OR EVEN SLIGHT PAIN, STOP IMMEDIATELY AND CONSULT A QUALIFIED MEDICAL EXPERT BEFORE RESUMING VALEDO TRAINING. DO NOT ATTEMPT TO EXCEED A COMFORTABLE RANGE OF MOTION. DISREGARD OF THIS CAUTION CAN RESULT IN PERSONAL INJURY.



Examine yourself regularly for any possible skin irritations or signs of allergic reactions. If a skin complication from the medical tape arises, discontinue training and consult a dermatologist.

Risk Factors

- Spondylolisthesis (forward displacement of a vertebra) (grade I without neurological signs)
- Acute spinal disc hernia (e.g. disc herniation) without nerve compression
- Severe cardiovascular or cerebrovascular event, like a myocardial infarction (heart attack), aortic aneurysm (enlargement of the aorta) or stroke, within three months of last incidence
- Severe balance deficits with increased fall risk
- Cognitive deficits which prevent comprehension of exercises
- Pregnancy
- Epileptic seizure within the past two years which are not controlled medically, or photosensitivity
- Retinal disease which may be exacerbated by watching video games.

If you are unsure whether you have a contraindication or risk factor, you should first consult your medical expert

Limitations of Performance

- The device is not designed for exercises performed while lying on the back.
- The device was not originally designed for use in open environments (for example, outdoors).
- The device is not designed to diagnose or analyze movement quality.
- If the Valedo sensors are used skin mounted, they are prone to soft tissues movements which may not reflect the underlying spinal movement. Users must be aware of the limitations on the effectiveness of using the sensors if there are thick adipose tissue deposits (fat) where sensors should be placed.
- Since the Valedo sensors use wireless communication technology (Bluetooth Low Energy 4.0) within a similar bandwidth as Wi-Fi, there may be instances where signal loss is experienced.

Adverse Effects

Hocoma AG has exercised great diligence in selecting the materials that are in contact with our clients in the clinic or at home. These materials have been assessed for their biological compatibility and are continuously monitored by the manufacturers. Nevertheless, there is always a small chance that some materials may lead to allergic reactions in individuals under exceptional circumstances.

Maintenance

Maintenance of Valedo is straightforward. Wipe the sensors with a damp cloth before and after training and store them in the Valedo case between trainings to protect them from excessive lint, dust, humidity or sunlight. Take care to remove

any residual adhesive should there be any. Before use, make sure the sensors are charged.

Firmware Updates

The USB to micro-USB cable supplied is used not only for charging but also for sensor firmware update. The sensor firmware can be updated by inserting the data transfer micro USB plug into the sensor (see Figure 2) and connect the USB end into a computer. Check www.valedotherapy.com for firmware updates; follow the instructions on the screen. Please do NOT unplug the sensor from your computer while updating the firmware.

Reporting Adverse Events

Adverse events with products of Hocoma which led or could have led to serious injuries to persons (life-threatening or serious injuries or death) and or damage to objects must be reported immediately after the adverse event to Hocoma AG by going to www.valedotherapy.com or by telephone.

After an adverse event the product may only be used again following approval and release by Hocoma AG.

Chapter 2: Training Setup

Initial Training Session

Turn on your sensors and pair them to your computing device. Now let's prepare the training space and learn where to put the sensors.

Preparing the Training Space

Make sure you have plenty of space around you to safely train. You have the option of training while holding the computing device or with it standing on a table in front of you.

- ① Many tablet computing devices have covers that also function as stands.
- ① With some computing devices it is possible to connect it to your television or computer monitor. Consult the user manual of your computing device for information.
- ① If you do connect your computing device to your television or computer monitor, remember to keep the computing device nearby as the sensors are connected to it and you will have to tap buttons on the screen.

- ⚠ Unplug your computing device from its charging cable for training.
- ⚠ Clear the space around your feet from any cables or other items you may trip on during training.
- ⚠ Be careful if you train on a rug; the rug might bunch and become a tripping hazard. We recommend either choosing a new training space or moving the rug for training.
- ⚠ Make sure the sensors are kept at least 1 m (39 inches) away from any electromagnetic, ferromagnetic (such as large speakers or appliances) or metallic objects.

Mobile phones, watches, power adaptors (for a laptop), or other devices containing magnetic elements can distort sensor signals. Keep these items an appropriate distance away from the sensors. Walls and floors may also contain electrical cables, metal pipes or reinforced frames.

Putting on the Sensors

Placing the lower back sensor

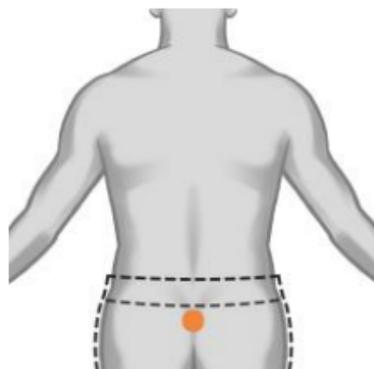


Figure 4: Correct placement of lower back sensor

Placing the chest sensor

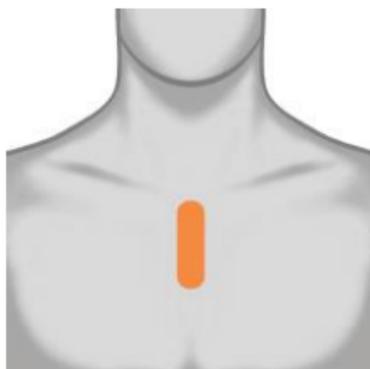


Figure 5: Correct placement range of the chest sensor

1. Wipe the sensors with a damp cloth.
 2. Place a piece of double-sided tape on the back of the sensor.
 3. Remove the backing of the double-sided tape.
 4. Place the sensor. (Make sure micro-USB port is pointing down.)
- ① Wearing a belt for your pants could cause the sensor to fall off or could lead to sensor signal distortion.
 - ① It may be easier the first few times to place the chest sensor without a shirt and in front of a mirror.
 - ① Always unplug sensors from charging cable before placing them on yourself.
 - ① We recommend wiping the backside of both sensors and the areas of your body where the sensors go with a damp cloth and then drying. This will help the double-sided tape to stick better to the sensor and to your skin.

- ① Both sensors are interchangeable and can be used either on the chest or the lower back.
- ① Take care to place the sensors correctly. If the sensors are placed incorrectly it may cause different visual feedback and may lead to exaggerated movements on the screen.

Using the Valedo Belt



Figure 6: Insert sensor.



Figure 7: Hook buckle into loop to close.

Placing sensor in the belt and putting belt on

1. Fit sensor into the belt (see Figure 6).
 2. Pull belt around your chest or pelvis.
 3. Hook buckle into loop (see Figure 7).
 4. Move until sensor is in the correct position, either chest or pelvis (See Figure 4 and Figure 5 for sensor position).
 5. Tighten belt until sensors do not shift position while you move.
- ① Check www.valedotherapy.com for belt availability.

Training

Once you have put on the sensors, training can begin. Training involves various exercises in a game environment; each exercise is designed for you to execute specific movements.

Start training

Training is done through the Valedo application on your computing device. Tap the icon to enter the application.



Figure 8: Icon on computing device (example from iPad, icon may look slightly different across computing devices).

All training exercises are designed to target a specific lower back movement; each movement will be demonstrated before starting the exercise. Take care to mimic the movement exactly; this will minimize the risk of improper movements and injuries stemming therefrom.

- ⚠ Take care not to overtrain, especially during your first sessions with Valedo. While motivation in training is always positive, prolonged or overtraining can result in muscle fatigue, which may cause further injury when undertaking daily tasks. In general, overtraining is exercising more or more intensely than what your body can reasonably recover from. See the warning under Contraindications in Chapter 1.
- ⚠ If the exercise requires a movement that is outside of your capabilities, do not "push" to make the correct movement. The best way to avoid this situation is to redo the Range of Motion settings to reestablish the limits of your personal movement range.

Ending the training session

1. Close the software application on your computing device.
2. Remove the sensors.
3. Remove the double-sided tape (from you or the sensors).
4. Dispose of the double-sided tape.
5. Wipe the sensor with a damp cloth.
6. Store the sensors in the Valedo case.

Chapter 3: Valedo Application

Getting Started

Start up the Valedo application by tapping the icon .

① Understand “Tap” as tap or click depending on your computing device.

① For a list of supported computing devices, go to www.valedotherapy.com

First Time Installation

Before you can begin training you’ll need to set up Valedo. Tap on the start screen and if your sensors aren’t on yet, the software will ask you to turn them on and create your profile. Enter your name, date of birth and sex.

You can always come back and edit your information or add new profiles—which gives you the chance to share Valedo with others on the same computing device.

After you’ve entered your information, the Valedo application will guide you through the first sensor calibration and the Range of Motion (ROM) measurements.

Calibration is easy: with your sensors in place, stand still and then bow when indicated to continue.

Measuring your range of motion is also easy: in the ROM screens you will be instructed to mimic the pose in the example. Accurately assessing your range of motion is important because the application must know the limits of your ability to move in order to precisely recreate your movements on the screen. For more info on ROM setting, see Setting Range of Motion (ROM) later in this chapter.

If you need additional assistance visit www.valedotherapy.com to learn more about the movements and ROM.

After the initial setup you’ll be directed to the Home Screen; from there you’re free to explore the Village!

Home Screen



Figure 9: Home Screen

Here you are on the home screen.

Visit the different neighbors to see what exercises they’re working on.

① Swipe left or right to move through the neighborhood.

On the screen:

In the top left-hand corner of the Home Screen you’ll see this ribbon with the name you entered in your profile. This does not only indicate who’s playing, it’s also a button! This is a shortcut to the Profile Management screen.



Quick Therapy: Tap here to simplify the exercise selection and have Valedo randomly select exercises for you. Unlock five houses to activate this functionality; only exercises you’ve unlocked can be selected for you as the random exercises.



Stretching: Here you will learn and be instructed on how to do different stretching exercises.



Badges: As you play and progress through the various exercises, you will earn badges. Here you can see what you've earned and what's still missing!



Reporting: Curious as to your progress? Here you can see how long you've played, the number of pick-ups collected and more. See more on reporting on page 20.



Range of Motion: Re-establish your ROM here. The screen is identical to what you had to do for your initial setup—though it might be a good idea to revisit this section as you progress in the game. You might find yourself able to go a bit farther!



Valedo Button: Tap this button to go to www.valedotherapy.com or to send an email to Valedo.



Sensor Button: Indicates battery level and sensor connection strength. It is also a shortcut button to the Sensor Management screen.



Exercise Plan: Tap here to create and manage your personal exercise plan. More info on page 19.



Information: Clicking this will bring up information regarding Valedo. On the Home Screen the Info button is in the bottom right-hand corner.

Profile Management



Figure 10: Profile Management Screen. Notice the Back Up and Restore buttons.

In the Profile Management section you can add, edit or delete profiles. It is also here where you can back up and restore all profiles you've uploaded to iCloud.

① You must have iCloud installed on your device.

Tap [Back Up] to upload all profiles to iCloud and tap [Restore] to download your last uploaded profiles to your current device.

This means you can train across devices that have Valedo and your iCloud account installed without missing a step!

RANGE OF MOTION

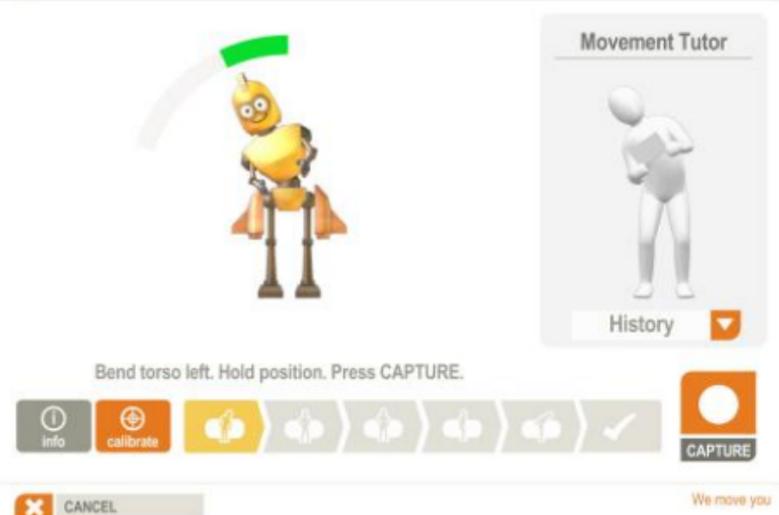


Figure 11: Example range of motion screen.

During the initial installation or if you tap the  button on the Home screen you can set, update and track your range of motion (ROM). Setting the correct ROM is important for accurate gameplay and safe training.

The purpose of establishing your individual ROM is simple: with the ROM values the software can adjust the exercises to your personal movement ability so they're not too difficult or too easy. If the exercises are too difficult it can stunt motivation or increase chance of injury due to overcompensated movements. If the exercises are too easy, they quickly become boring.

How it's done

The software will show you a pose to mimic; you must hold that pose briefly and tap [Capture], the software then calculates your range of motion for that specific movement. The range of motion bar must be green (see Figure 11); this is to ensure the range of motion is sufficiently large for sensible exercise movement and playability. If it is red, you will not be able to tap [Capture] and move on to the next movement. There are multiple poses but setting the range of motion should not take more than a minute.

- ① In the ROM screens, the figure is doing a MIRROR image pose of the one you must do. Imagine the movement tutor is a little mirror.

Playing the Exercises

Let's say you're in the Torso District. The houses on the left represent the first exercise you can do. Unlock the houses in the middle and the right side of the district by completing these exercises.

For each exercise take the robot out to gather gems. When you've returned you'll have the resources to build up the house and unlock new movements and districts! The size of the house indicates the level of difficulty you've achieved so far in the exercise (see Figure 9).

Tap one of the buildings in a district to get started. You'll see the exercise introduction.

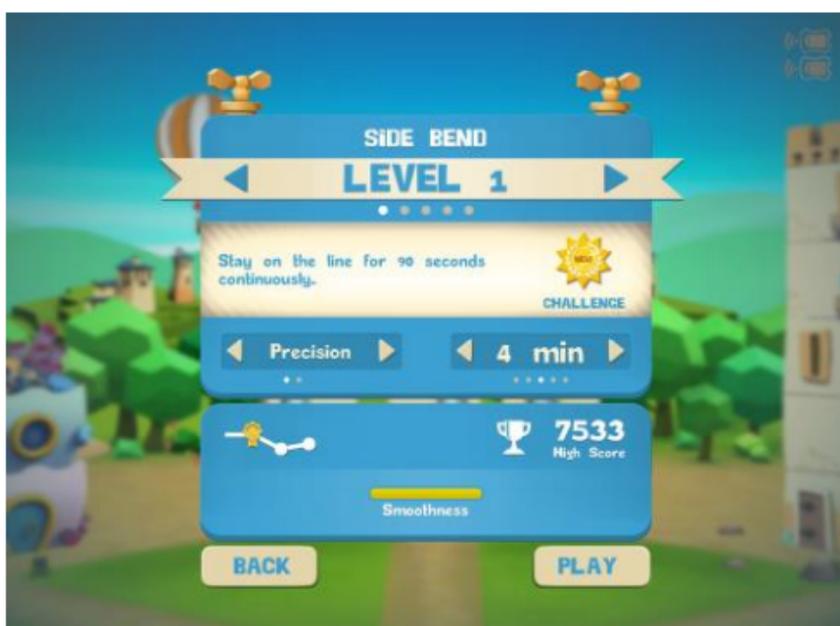


Figure 12: Example of a training introduction screen.

In order for you to advance to the next level, you must complete a progress challenge. For example, to go from level 1 to 2, the challenge might be “stay on the line continuously for 90 seconds”. During the exercise a special challenge progress bar will display (see Figure 15) and only when you’ve completed the challenge will the next level be available to you.

If a progress challenge requires a different exercise configuration than what is currently applied (e.g. requires at least 4 minutes of exercise time, and the time is only set to 2 minutes), you will see an [Activate] button (see Figure 13). Tap to automatically configure the exercise so the progress challenge can be attempted.

- ① Tapping [Activate] will set the *minimum* configuration for the challenge. If, for example, the exercise requires at least 4 minutes of playtime, tapping [Activate] will set the exercise to 4 minutes, but you can always set more time.
- ① You can also manually change the configuration in order to activate the challenge.



Figure 13: Tap [Activate] to automatically set the necessary conditions to attempt the challenge.

There are also replay challenges. This is a fun way to challenge yourself while replaying a level. After unlocking a new difficulty you will also have the opportunity to attempt replay challenges for the levels you’ve already unlocked to achieve a higher score.

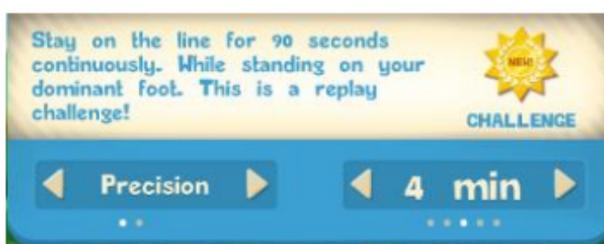


Figure 14: Example of a replay challenge.

In the introduction screen you’ll also have the chance to toggle the exercise mode. In general, the exercise modes are as follows:

- Precision: how precisely you control the movements of both sensors
- Isolated Precision: how precisely you control the movement of one sensor while holding the other still (available from level 3)
- Stabilization: how well you hold a position
- Isolated Stabilization: how well you hold a position concentrating on one sensor while maintaining the other still (available from level 3)

- Free Mode: do squats at your own pace, not according to the timing bar as in Precision and Stabilization

❶ Not all modes are available for all exercises.

❶ Exercise modes are explained in the application.

You can see your previous high score and your bests in three movement categories: accuracy, smoothness and isolation.

- Accuracy rates how precise your movements were toward the exercise goal.
- Smoothness rates how smooth your movements were.
- Isolation (only for isolation modes) rates how well you moved one sensor while keeping the other still.

Tapping [Play] will bring you right into the exercise. There will be a quick calibration and then a brief introduction of the movement. After that, away you go!

Do the movements as demonstrated to correctly move the robot—and if you're not moving correctly, it'll let you know! Some exercises require you to follow a path, some to fly through hoops and some have completely different goals. Make sure to read the instructions at the start of each exercise so you know what you're to do!



Figure 15: Example of in-game screen. Notice the challenge progress bar showing you how close you are to completing the challenge. In this example, the line to follow has been widened by a powerup; there are 14 seconds left until the power-up runs out.

On the screen:



Time remaining



Points earned



Point multiplier



Energy bar: Shows how much energy you have. Get energy by following the path, jumping through hoops, and more!



Power-up gem (not shown in image above): Collect these rare gems to earn a temporary power-up!



Power-up timer: Once you've collected a power-up gem, this timer shows you how long the power-up will last.



Pause button: (in exercise) Allows you to calibrate, quit the exercise or simply take a breather!



Movement tutor button: (in exercise) Tapping this icon in the bottom right-hand corner during gameplay will expand an in-exercise hint on how to properly execute the move for the game. It will shrink back down after two seconds.



Invert left/right and up/down: Tapping [Pause] will give you the option to toggle the hip movement control, where available.

Exercise Plan

The exercise plan feature allows you to set an exercise schedule of your choosing. Enter the number of weeks you would like your exercise plan to span and fill in for each week the exercises you would like to do, the number of repetitions and difficulty.

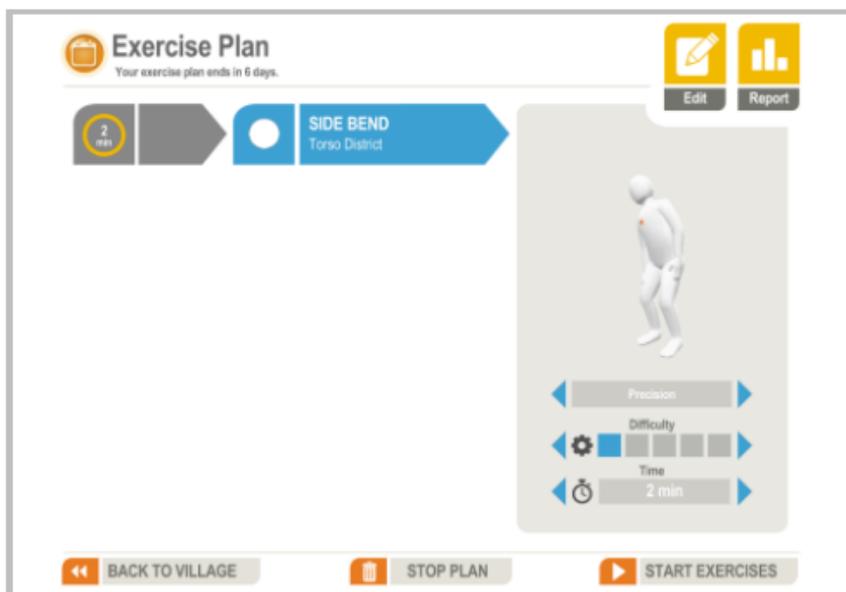


Figure 16: Exercise plan.

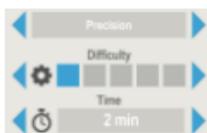
On the screen:



Edit button: click to change number of weeks in your plan and to add or remove exercises to these weeks.



Report button: click to generate a report on your exercise progress. See more on reporting on page 20.



Exercise settings: click the left and right arrows to change the exercise mode, difficulty and exercise duration.



Click to exit the exercise plan screen and return to the village.



Click to quit the current exercise plan, start the current exercise plan over, or begin a new exercise plan.

① If you quit in the middle of a exercise plan in progress, information will be saved as unfinished exercise plan in the report.



Click to begin the exercises as laid out by you in the exercise plan.

Reporting

The reporting section allows you to view your activity and progress over a specified period.



Figure 17: Exercise report.

There are three types of reports, each with varying levels of detail, that you can view or share:

- Basic
- Advanced
- Exercise Plan

On the screen:



Overview: Select Basic, Advanced or Exercise Plan and see a general overview of information derived from your activity.



Share button: click to generate and share the report (Basic, Advanced, Exercise Plan).



View button: click to generate and view the complete report (Basic, Advanced, Exercise Plan).



Click to exit Reporting and return to the village.

Chapter 4: Technical Information

Technical Specifications

The Sensors

General	
Dimensions (L x W x H)	42 mm x 32 mm x 16 mm (1.65 in x 1.26 in x 0.60 in)
Weight	18 grams (each)
Expected service life	3 years

Electronics	
Power supply	Integrated Recharging Solution (polymer Li-ion battery, 3.7V, 160mAh). Replacing battery is not permitted.
Wireless Transmission Frequency	2.4 GHz band (Bluetooth Low Energy)
Radiated Output Power	Max. 1 mW

Accuracy	
Gyroscope Range	Max. 2,000 degrees per second
Accelerator Speed	Max. ± 16 g
Digital Compass	1 to 2 degrees accuracy
Orientation	± 360 degrees on all axes
Operating Range	20 meters with a clear line of sight to the computing device. However, precise operating range of sensors depends on training environment.

The Valedo application will not recognize non Hocoma sensors.

Do not attempt to use third party sensors with Valedo.

Further complications of trying to use non Hocoma sensors may include but are not limited to corruption of your saved info within the Valedo application, corruption of information on your computing device outside of the Valedo application environment, damage to the third party sensors and personal injury.

The Cable

General	
Main cable dimensions (L)	900 mm (35.40 in)
Extension dimensions (L)	300 mm (11.80 in)
Weight	30 grams
Revision	USB revision 2
Expected service life	3 years

The Double-Sided Tape

General	
Dimensions (two pieces) (L x W)	39 x 38 mm (1.53 x 1.49 in)
Expected service life	3 years when stored at temperatures of 10 to 27°C (50 to 80°F) and a relative humidity of 40 to 60%.

General

Dimensions (L)	~60 to 120 cm (23.60 to 47.20 in) (exact dimensions on website)
Weight	~50 grams
Expected service life	3 years

General Operating Conditions

The device must only be used in clean, dry rooms with level floors. Make sure you have plenty of space around you while you train, and keep large ferromagnetic equipment (e.g. stereo system or large speakers) or devices at least 2 meters (6 feet) from you. We recommend that the device be used indoors.

Operating Environment

Temperature	15 °C to 35 °C / 59 °F to 95 °F
Air humidity	30 % to 75 %
Air pressure	700 to 1060 hPa

Packaging and Transportation

Temperature	-20 °C to 45 °C / -4 °F to 113 °F (3 month maximum)
Air humidity	45 % to 85 %, no condensation
Air pressure	700 to 1060 hPa

Storage

Temperature	-20 °C to 25 °C / -4 °F to 77 °F (12 month maximum) -20 °C to 45 °C / -4 °F to 113 °F (3 month maximum)
Air humidity	45 % - 85 %, no condensation
Air pressure	700 - 1060 hPa

Valedo must only be stored indoors. Valedo must also be charged at least once a year. If you plan on storing Valedo for up to 12 months, we recommend you do so with the battery at approximately half charge.

① For the technical specifications of the computing device, consult its user manual.

Electromagnetic Compatibility

Medical electrical devices are subject to special precautions with regard to electromagnetic compatibility (EMC), and must be installed and operated only according to the information specified in this document. Wireless communications equipment such as wireless home network devices, mobile phones, cordless phones and their base stations, walkie-talkies may interfere with Valedo. Only converters and cables supplied by or obtained from the manufacturer as spare parts may be used. Other cables and accessories not provided by the manufacturer may affect EMC performance and result in increased emissions or decreased immunity of Valedo. Only the following parts are compliant with Valedo:

- Sensor, part number 30814
- Cable, part number 30813

² The Valedo Belt is an optional accessory. Go to www.valedotherapy.com for availability.

- ① Keep mobile phones and other devices containing wireless or magnetic components more than 1 m (39 inches) from the Valedo sensors.

Emission (tested against IEC 60601-1-2-2014)	
Test	Limit
Conducted emission	CISPR 11, Class B
Radiated emission	CISPR 11, Class B

Immunity Test Levels (tested against IEC 60601-1-2-2014)	
Test	Test Level
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: 8 kV Air Discharge: 2 kV, 4 kV, 6 kV, 15 kV
Radiated RF EM field (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80%; 3 V/m
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, FM + 5 Hz deviation: 1 kHz sine; 28 V/m 710 MHz, 745 MHz, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810 MHz, 870 MHz, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720 MHz, 1845 MHz, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240 MHz, 5500 MHz, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz and 60 Hz

FCC and IC Statements

Statement according to Part 15.105

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 encouraged 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.

Statement according to Part 15.19 and RSS-210

Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s).

Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

Statement according to Part 15.21

Changes or modifications made to this equipment not expressly approved by Hocoma may void the FCC authorization to operate this equipment.

RF Exposure Information according to 2.1091 / 2.1093 / OET bulletin 65 Radiofrequency radiation exposure Information

The radiated output power of the device is far below the FCC radio frequency exposure limits.

Managing Computer Network Risks

While you can connect your device to a computer network, e.g. to back up and restore all profiles you've uploaded to iCloud or access data online, it is important that you keep network security in mind. The Valedo app may use connections to iCloud and other websites using standard security mechanisms. As manufacturer we are obliged to remind you that you should identify, analyze and control risks related to your network, which may result from, but are not limited to, viruses or network failure, and might distort your training settings and results. You should also be aware that subsequent changes to the network, e.g. of the configuration, connecting or disconnecting components, as well as update and upgrade of components, could result in risks that had not been identified previously.

Battery Removal and Disposal

Do not throw away the Valedo sensors or their batteries with the normal household waste at the end product life, but rather bring them in to an appropriate recycling facility. By doing this you help to preserve the environment.

NOTE: Instructions on battery removal and disposal at the end of product life are provided here, but are intended for those working at the appropriate recycling collection points.

NOTE: Opening the Valedo sensor to access the battery breaks the Valedo sensor and voids any warranty.

 Removing the batteries may lead to battery damage and subsequent overheating and possible fire.

Removing the battery

Please note that this process is not reversible. To remove the battery, a flat-head screw driver is needed. Make sure the battery is completely depleted before removing.

1. Press the top and bottom of the Valedo sensor firmly.
2. Insert a screwdriver into the seam between the gray and white sides of the Valedo sensor as shown in Figure 18.
3. Turn the screwdriver to separate the two sides.
4. Pull the cables from the circuit board (alternatively, cut the cables).
5. Pull battery up and remove.

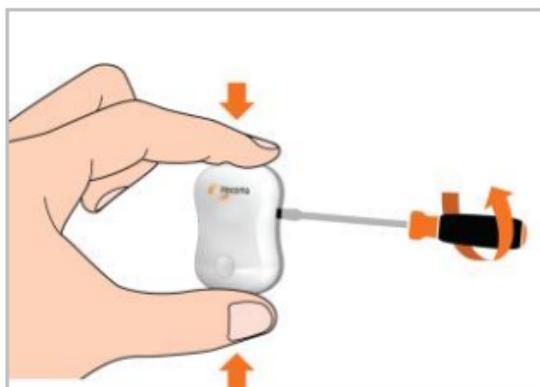


Figure 18: Opening the Valedo sensor to remove battery.

Chapter 5: Troubleshooting

Troubleshooting

If you are experiencing difficulties with the system please refer to the following website:

www.valedotherapy.com

This section enables Valedo users to check against the technical problems listed below and take relevant measures.

If you have any queries or need further clarification of issues for which we have not provided a satisfactory solution, first contact your local Hocoma service center. See copyright page at beginning of manual for contact information.

Problems with the Sensors

Issue	Action
The sensors are not turning on.	<ul style="list-style-type: none">• Gently shake the sensor to turn it on.• If that does not work, push the button to turn on.• If both actions above do not work, that means the batteries are depleted and must be charged.• If you suspect sensor failure check on www.valedotherapy.com for sensor diagnostics and procedures for replacement under warranty.

Problems While Preparing for a Training Session

Issue	Action
The computing device does not start.	<ul style="list-style-type: none">• Make sure the computing device has been charged or is plugged in.• For further troubleshooting tips for the computing device, please consult its user manual.
Valedo sensors are not connecting to the computing device.	<ul style="list-style-type: none">• Make sure your computing device is compatible with Valedo. For a list of supported devices consult www.valedotherapy.com.• Make sure your computing device is running the latest version of its operating system.• Make sure the sensors are charged before connecting to the computing device software.• Make sure the sensors are not connected to a power source via the USB cable• Make sure Bluetooth is enabled on your computing device.• Make sure you are close enough to the computing device (sensor icon on computing device will indicate if sensors and computing device are connected).• Turn sensors off and on again.• Restart computing device.• Restart Valedo application.

Problems During the Training Session

Issue	Action
The sensor(s) fall(s) off.	<ul style="list-style-type: none">• Clean the back of the sensor with a soft damp cloth before placing a new strip of double-sided tape.• Wipe the areas of the skin where you will attach the sensor(s) with a soft damp cloth before reattaching.• Dry your skin and sensor before attaching the tape and mounting the sensor to your body• Reattach the sensor and press firmly for 5 seconds to make sure sensor sticks to your skin.• If all of the above suggestions do not work, then you may have to consider acquiring the training belt from Hocoma.
The avatar in the range of motion (ROM) settings screens does not show the correct movement.	<ul style="list-style-type: none">• Make sure that the sensors are still communicating with the computing device.• Redo the ROM settings making sure to stand very still while the sensors calibrate and only bow to confirm and proceed when indicated to do so.
During training exercises, the avatar moves about rapidly.	<ul style="list-style-type: none">• Stop the exercise and redo the range of motion (ROM) settings. Having a very small ROM will make for an exaggeratedly sensitive avatar movement during gameplay.• Turn sensors off and on again.• Restart computing device.• Restart Valedo App.
The avatar does not move when doing the exercises.	<ul style="list-style-type: none">• Make sure that the sensors are still on and communicating with the computing device.• Turn sensors off and on again.• Restart computing device.• Restart Valedo App.
The indicator LEDs show they are connected (see Chapter 1 for LED modes) but avatar does not move.	<ul style="list-style-type: none">• Make sure that the sensors are still communicating with the computing device.• Turn sensors off and on again.• Restart computing device.• Restart Valedo App.
The movement required in the game is larger than what you can do.	<ul style="list-style-type: none">• Reset Exercise ROM values.• Setting up correct and accurate ranges of motion during the Exercise ROM is critical; therefore, do not compensate or overexert when setting up these parameters. This will ensure that the in-game movements required do not exceed what you are physically capable of doing. See Chapter 3 for info on setting the ROM.
After training, you see reddening or irritation under where the sensors were attached to the skin.	<ul style="list-style-type: none">• This might indicate an allergic reaction to the double-sided tape. Stop training immediately and consult with your dermatologist before continuing Valedo training.

Alerts

The following alerts may appear on the screen during exercises. If so, follow the instructions below.

Alert	Action
	<p>In the top right-hand corner you will see the sensor signal and battery icons.</p> <p>As you can see here a sensor is not communicating properly with the computing device and the battery is depleted.</p> <ul style="list-style-type: none">• Remove the depleted sensor from your body and recharge (see Chapter 1 for charging information)• If the sensor is charged and still indicates that there is no signal with the computing device, turn sensor off and then back on again with the application still running.

Chapter 6: Legal Matter

Explanation of Symbols Used



Indicates potentially dangerous situations or actions. Symbol in accordance with ISO 7010-W001.



Highlights useful tips, recommendations and information needed to operate the device correctly and efficiently.

- 1.
2. Step-by-step explanation of tasks for proper use of the product.
- 3.



Manufacturer and year of manufacture.



Symbol indicates the manufacturer's reference number of the device.



Symbol indicates manufacturer's batch number of the device.



Complies with MDD93/42/EEC Requirements.



Type BF applied parts.



Double-sided medical tape is only for single use. It cannot be used for a second time.



Use-by date for the double-sided medical tape given in the following format: YYYY-MM (for example 2017-10 is October of 2017).



Symbol indicates temperature limits for operation, transport and storage.



Symbol indicates humidity limits for operation, transport and storage.



Symbol indicates atmospheric pressure limits for operation, transport and storage.



Protect the environment. When disposing of this unit, or the batteries it uses, do so in an environmentally friendly way.

The unit must **not** be disposed of in normal household waste. Dispose of old products in accordance with pertinent local regulations at an appropriate collection point. If you have any questions, contact your local competent waste management authority. Refer to page 24 for information on how a recycling facility may remove the battery.

IP22

The IEC Ingress Protection Rating.



Symbol for nonionizing radiation.

Symbols on Packaging or Device



2 Sensors



100 pieces of medical tape



1 USB cable



1 Case



Follow user manual and quick user guide.



Computing device (not included)



Bluetooth® compatible. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Hocoma AG is under license.



Valedo complies with electromagnetic regulations as laid out by the Federal Communications Commission. Symbol found only on devices sold in the USA, UK and Canada.

Disclaimer



CAUTION:

Valedo is a medical device and must be used in strict adherence to the user manual and only according to the recommendations contained therein; failure to do so may result in personal injury. Please contact Hocoma should you have any questions. For the latest available information about the medical indications, contraindications, side effects and risks associated with the Valedo® components and software application it is strongly recommended that you regularly consult Hocoma's website: www.hocoma.com/legalnotes.

Valedo is marketed for home use and is intended to improve back health and to prevent nonspecific low back pain by promoting specific movements and exercises. Movement and exercise are associated with potential risk of injury. Users of Valedo are responsible for their movement and exercise and manner in which they use the product. For specific product information you should regularly consult the current summary of product characteristics at www.valedotherapy.com.

While there may be information in Valedo, the user manual and in marketing materials related to certain medical conditions and their treatment, promptly consult your own doctor or qualified medical personnel about using Valedo if you are currently injured, medicated or under a doctor's care for a medical condition. Valedo is not designed or intended to diagnose specific ailments or conditions, nor does Hocoma offer personalized medical diagnosis or patient-specific treatment advice.

Failure to consult qualified medical personnel before using the product or any failure to follow either their recommendations or the product instructions can result in personal injury. If at any time after beginning use of the product you experience discomfort or pain, loss of range of movement, or any other problem, stop using the product immediately and consult qualified medical personnel.

DISCLAIMER: This information provides details about medical products, which may not be available in all countries and may not have received approval or market clearance by all governmental regulatory bodies throughout the world. Nothing herein should be construed as a solicitation or promotion of any product or of an indication of any specific use for any product which is not authorized by the laws and regulations of the country where the reader of this information resides.

Warranty Terms

Warranty terms: USA

Valedo is warranted to be free from defects in workmanship and materials within 12 months of the purchase date when used in accordance with the present user manual. The warranty extends only to the end user. Hocoma will at its own

discretion refurbish or replace Valedo covered by the warranty free of charge. Repair, modification or replacement lies solely within the competence of Hocoma AG. Hocoma AG does not warrant or guarantee any therapeutic result or success when using Valedo.

Warranty terms: EU

Valedo is warranted to be free from defects in workmanship and materials within 24 months of the purchase date when used in accordance with the present user manual. The warranty extends only to the end user. Hocoma will at its own discretion refurbish or replace Valedo covered by the warranty free of charge. Repair, modification or replacement lies solely within the competence of Hocoma AG. Hocoma AG does not warrant or guarantee any therapeutic result or success when using Valedo.

Warranty terms: Asia Pacific Region

Valedo is warranted to be free from defects in workmanship and materials within 12 months of the purchase date when used in accordance with the present user manual. The warranty extends only to the end user. Hocoma will at its own discretion refurbish or replace Valedo covered by the warranty free of charge. Repair, modification or replacement lies solely within the competence of Hocoma AG. Hocoma AG does not warrant or guarantee any therapeutic result or success when using Valedo.