



TENZR™ Trainer & Tracker. Instructions for Use

Model #: DISC-001

Part #: 000-0001-0001

Wristband #: 100 – 0001 – 0001

Hand Sensor #: 100 – 0002 – 0001

Dongle #: 100 – 0003 – 0001

Reset Key #: 100 – 0004 – 0001

Firmware/ Desktop App #: 400 – 0001 – 0001

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Warnings

1. The TENZR Trainer & Tracker is intended to be used under the guidance of a Physical Therapist, Occupational Therapist or other healthcare professional. Always consult a licensed healthcare professional before commencing use and throughout the duration of use.
2. Only charge the TENZR Wristband and Hand Sensor with the wall charger provided in the kit. Charging with other off-the-shelf wall charger may result in overheating, leading to melting or explosions, and may adversely affect battery health or performance. In sever cases it may cause harm to the user.
3. The skin contacting parts of the TENZR Wristband and Hand Sensor are made of Thermoplastic Polyurethane (TPU). Individuals with allergies to TPU should not use TENZR.
4. Only use the body tape provided in the TENZR Trainer & Tracker Kit. Individuals allergic to silicone should not use TENZR.
5. Excessive tightening of the TENZR Wristband can lead to skin sores and rash. Do not use the TENZR Wristband if doing so results in discomfort.
6. Do **not** use the TENZR Wristband or Hand Sensor while it is charging.
7. Resetting the TENZR Wearables may lead to data loss.
8. Over or under exercising can lead to physical harm. To ensure proper treatment consult a physical therapist to prescribe a precise quantity of exercise to complete.
9. The TENZR Wristband and Hand Sensor must be donned in the exact orientation shown in the TENZR Companion App. Incorrect donning of may lead to erroneous data and/or performance degradation.
10. The calibration, measurement, and games in the TENZR Trainer & Tracker system must only be used when the user is sitting upright in a chair with their hand in a loose fist and their forearm parallel to the floor. Failure to do so may lead to erroneous data and/or performance degradation.
11. The user must not incline their forearm more than 15 degrees, from the horizontal plane, when performing pronation/supination. Doing so may lead to erroneous data and/or performance degradation.
12. The body tape used on the TENZR Hand Sensor degrades over time. The use of tape that has degraded or is starting to degrade may lead to erroneous data and/or performance degradation.
13. When performing Flexion/Extension, the user must stay within the following parameters to avoid erroneous data and/or performance degradation:



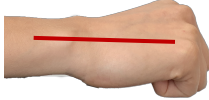

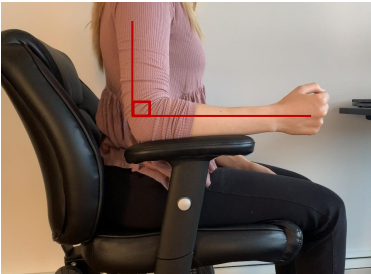
- a. Forearm must not be pronated or Supinated more than 10 degrees, from the vertical plane.
 - b. The forearm must not be inclined more than 15 degrees from the horizontal plane.
 - c. The radial and ulna deviation of the wrist should not exceed 5 degrees from neutral.
14. The accuracy of TENZR Trainer & Tracker system is only guaranteed between the range of 50 degrees in flexion and extension.
 15. Clothing and other objects interfering with the TENZR Wristband or Hand Sensor may lead to erroneous data and/or performance degradation.
 16. Sweat, oils, dirty or other surface level grim on the skin of the user may affect the TENZR Wristband and/or Hand Sensor which may lead to erroneous data and/or performance degradation.
 17. Failure to calibrate the TENZR Trainer & Tracker system before each session, measurement or game may lead to erroneous data and/or performance degradation. It will also need to be calibrated after each donning and doffing as well as after each gaming session longer than 15 mins.
 18. Only use the TENZR Wristband and Hand Sensor on the wrist and hand, respectively.

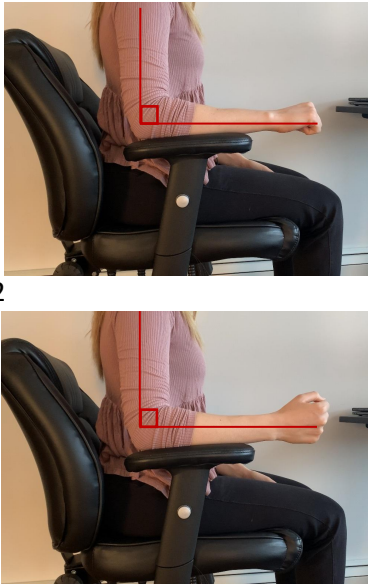




Cautions

1. The TENZR Wristband and Dongle use semiconductor components that can be damaged by electrostatic discharge (ESD).
2. The TENZR Wristband is designed to only fit wrists between 15cm and 19cm.
3. The TENZR Wristband, Hand sensor and Dongle are not waterproof or dustproof.
4. Only clean the TENZR Wristband, Hand Sensor, and Dongle with the isopropyl alcohol wipes provided in the kit.
5. The performance of the TENZR Wristband, Hand Sensor or Dongle may be affected by electromagnetic interference.

Definitions

Table 1 - Definitions

<p>Mid-prone position</p>	<p>This position requires a chair with an armrest or the edge of a table. The user plants the elbow on the flat surface, with the hand and wrist off the edge unsupported and able to move freely, creating a 90-degree angle between the forearm and upper arm.</p>
<p>Neutral hand and wrist position</p>	<p>Hand is in a loose fist, not fully closed, but in a comfortable manner. Wrist is flat as shown.</p> 
<p>Pronate arm position with neutral hand</p>	<p>This position is required for flexion/extension and pronation/supination measurements. The user plants the elbow on the chair's armrest and maintains a 90-degree angle between forearm and upper arm. Hand is neutral as shown.</p> 
<p>Mid-prone arm position with neutral hand</p>	<p>This position is required for radial and ulnar measurements. The user plants the elbow on the chair's armrest and maintains a 90-degree angle between forearm and upper arm. Hand is neutral and pronated as shown.</p> 
<p>Calibration poses 1 & 2</p>	<p>This position is required for calibration only. The user plants the elbow on the chair's armrest and maintains a 90-degree angle between forearm and upper arm. Hand is neutral and in a light fist as shown.</p> <p>Calibration pose 1</p>

	 <p>Calibration pose 2</p>	
Range-of-motion or ROM	Measures the amount of movement for a set of wrist and forearm motions. The wrist motions include the following: flexion, extension, radial, and ulnar. The set of motions for the forearm are: pronation, and supination.	
Warnings and Cautions		Manufacturer
		Caution
		Consult instructions for use
		Keep dry



Package Contents

Each TENZR Trainer & Tracker kit contains the following:

- TENZR Wristband
- TENZR Hand Sensor
- TENZR USB Dongle
- TENZR Micro USB Reset Key
- TENZR Companion App, delivered digitally
- TENZR Trainer & Tracker IFU, i.e. this document delivered digitally
- USB Charging Cable
- Wall Charger
- 4 pieces of reusable body tape for TENZR Hand Sensor
- 5 pieces of isopropyl alcohol wipes
- TENZR Case

Note: The TENZR Trainer & Tracker System has been designed to work with the Companion App running on a Windows Laptop or Tablet Computer, such as the Microsoft Surface Go 2. A Microsoft Surface Go 2 may have been included in your shipping package.

Overview

Welcome to TENZR, an integrated wearable platform that is based on BioInteractive Technologies' proprietary sensing technology.

This TENZR Trainer & Tracker Kit includes a TENZR Wristband, a TENZR Hand Sensor, a TENZR USB Dongle, and a TENZR Companion app, as shown in Figure 1.

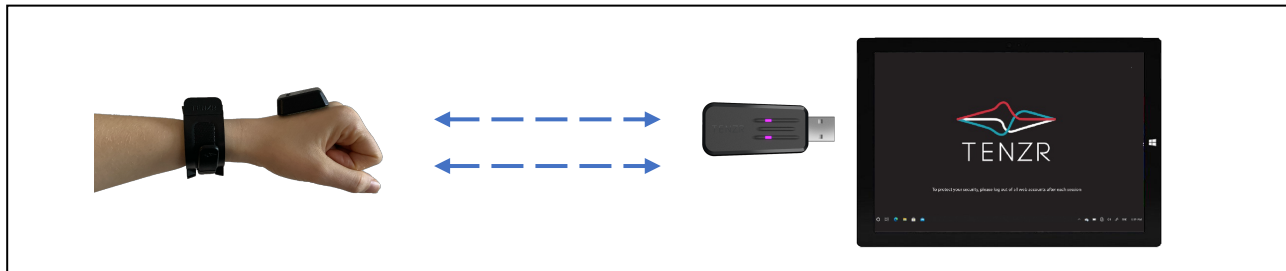


Figure 1 - Overview of TENZR Discover Kit.

Intended Functionality

The TENZR Trainer & Tracker is intended to be used as a tool to facilitate Physical Therapy (PT), with a specific focus on rehabilitation of injury or impairment related to the wrist and forearm.

The TENZR Trainer & Tracker has three main functional tools:

The **Measure** tool is intended to measure maximum ROM of the wrist and forearm joints. The tool tracks the angles of wrist in flexion/extension and radial/ulnar deviation, as well as forearm pronation/supination movements. The maximum angles achieved are recorded and can be compared to previous ROM measurements.

The **Train** tool encourages users to achieve the target wrist and forearm movement profiles in a fun and engaging manner. In each game, users can choose the wrist or forearm ROM and configure the movement pattern, under the guidance of a licensed healthcare provider. The Train tool then presents a visual representation of their current wrist or forearm angle in relation to the target movement profile as part of gameplay.

The **Export** tool allows users to share their measurement and training progress with a therapist. The tool allows individual monitoring of each range of motion over specified time periods.

Important Information

- For accurate results, it is recommended that users recalibrate after every donning or adjustment of the Wearables.
- It is recommended that the user to maintain a loosely closed fist and a neutral wrist with hand and forearm in line while calibrating and performing activities.

- The TENZR Wristband and Hand Sensor included in this kit do not have a means to be turned off. Hence, the devices will continuously deplete the battery even when not in use. It is recommend that the devices be kept plugged-in and charging prior to use.
- Please note that the TENZR Wearables work for both Right- and Left-hand use. The handedness of the device can be changed in the TENZR Companion app.
- The TENZR Wristband strap is optimized to accommodate wrist circumferences between 15 to 19cm.
- For optimal wireless performance, it is recommended that the TENZR Wristband and Hand Sensor to be used in a workspace where the devices are at least 30 cm in front of the tablet. Always maintain a direct line of sight to the USB Dongle.

Getting Started

The following section describes setting-up the TENZR Trainer & Tracker kit.

1. Identify components of the TENZR Trainer & Tracker Kit

The TENZR Wristband and Hand Sensor will only communicate with the Dongle they have been paired with. Figure 2 shows labeling on the Wristband, Dongle and Hand Sensor.

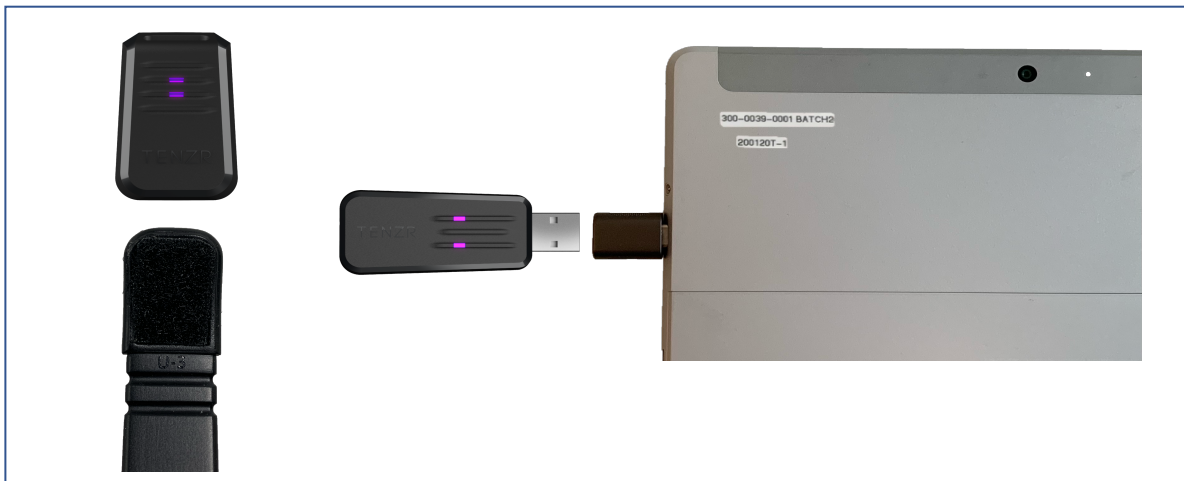


Figure 2 – An example set.

2. Charge the TENZR Wristband and Hand Sensor

Fully charge the TENZR Wristband and Hand Sensor before each use.

Do not use the devices while they are charging.

The Wristband and Hand Sensor will fully charge in 5 hours. Both Wristband and Hand Sensor will run for 15 hours once fully charged.

Charge the device by connecting the included USB Charging Cable and wall charger. Please do not connect to third party USB wall chargers.

3. **Open the TENZR Companion App on the tablet and verify connection with the USB Dongle**

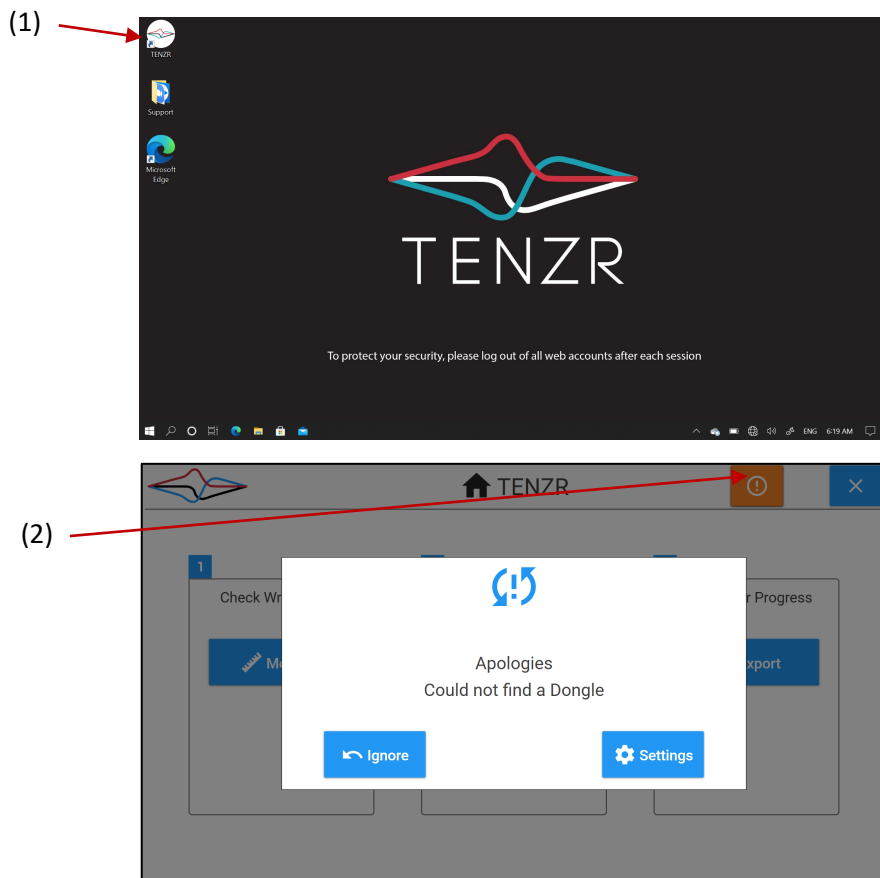
Connect the USB Dongle to the tablet.

Open the Companion App on the desktop by double clicking, as indicated by (1) in Figure 3. It may take a few seconds to open. Only one instance of the App can be opened at a time.

Click on Settings in the Companion App (2). Verify that all devices are connected wirelessly, as per (3), (4), and (5).

If the devices show a different connection status, fully charge the Wristband and Hand Sensor, and ensure USB Dongles are plugged into the tablet before attempting this step again.

If the problem persists, consult the section on Resetting the Wristband and Hand Sensor in the Troubleshooting Section.



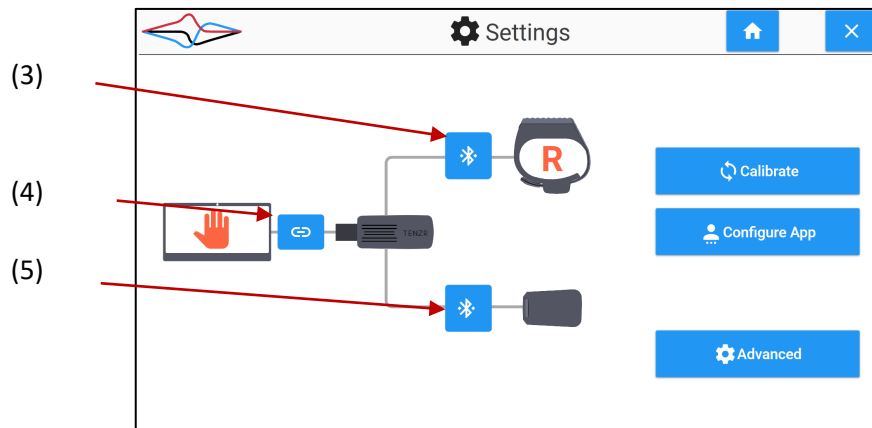


Figure 3 - Opening the Companion App and verifying connection with USB Dongle

4. The TENZR Wristband and Hand Sensor should now be connected to the USB Dongle.

Don the TENZR Wristband and Hand Sensor then Calibrate.

- To confirm the handedness of TENZR visit the settings screen. An “R” within the wristband represents right handedness, while an “L” represents left handedness.

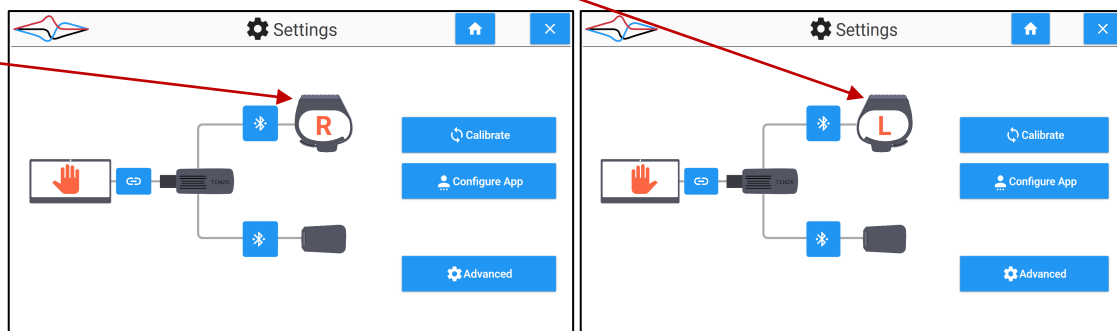


Figure 4 - Handedness of TENZR wristband

To change the handedness, select Configure App in Settings, then “Set to (left or right)”

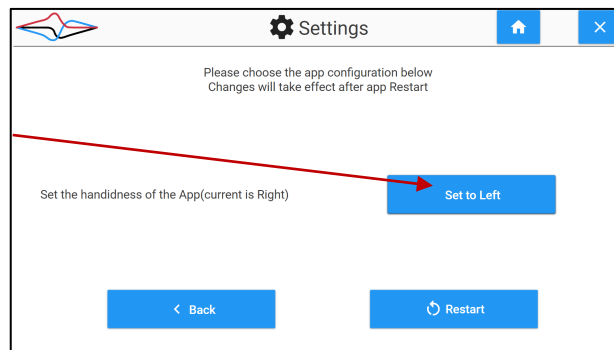


Figure 5 - Handedness of TENZR wristband

Put on the Wristband by following the steps:

- Don the Wristband, behind the wrist bone or ulnar protrusion.
- The **bulk of the band** or housing unit should **sit on top of the wrist**.
- The **charging port** should **face outwards** (i.e. away from the mid-line of the body).
- The **middle of the band** should be **aligned with the middle finger**.
- Adjust the strap until the wearable feels as tight as a heart rate monitor, it should NOT be able to move up and down the forearm. **Excessive tightening of the TENZR Wristband can lead to skin sores and rash.**
- Do not use the TENZR Wearables if doing so results in discomfort.
- Avoid bumping or resting the band on any surface.
- Ensure the Wristband and Hand Sensor are not obstructed by clothing such as jackets as this will render TENZR unable to accurately measure and play games.

Recommended Hand Sensor donning steps:

- The TENZR Hand Sensor should sit directly behind the knuckle, centred between the index and middle fingers.
- The sensor should run in the same direction of the hand with the **USB port facing outwards**. Ensure the sensor does not rotate more than 5 degrees left or right off center.
- TENZR Hand sensor body tape may come loose during use, to ensure proper adhesion push down on the sensor. If unstable, body tape may be replaced.

A note about body tape:

- The body tape adheres on the curved side of the device with the TENZR logo on the other side, (See Figure 6)
- The white side of the body tape adheres to the device and the green to the skin.



Figure 6 - Hand Sensor with body tape.



Incorrect donning or use of the Wristband or Hand Sensor on any other body part will render TENZR unable to accurately measure or play games.

Please ensure your hands and wrist are clear of any moisture to ensure performance is optimal.

Significant physical harm such as skin irritation or trauma can occur from the use of non-TENZR body tape. Do not use the TENZR Hand Sensor if doing so results in discomfort.

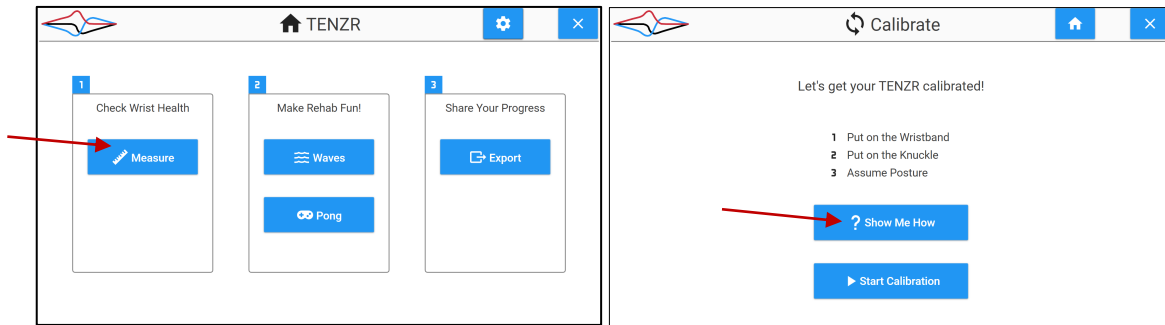
Calibrate in mid-prone position

With the Wristband and Hand Sensor donned, click the Measure button from the main page as indicated by (a) in Figure 7, and follow the on-screen instructions. Calibrate before each measurement and after each gaming session totaling more than 15 minutes.

For example, to don the Wristband and the Hand Sensor, follow images (b) – (o)

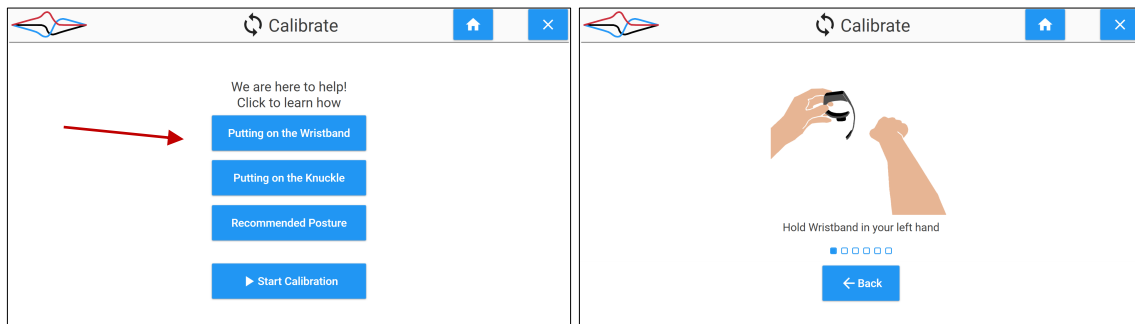
For example, for the correct seated posture for the exercise, follow images (p) – (u)

For example, to calibrate, follow images (v) – (x)



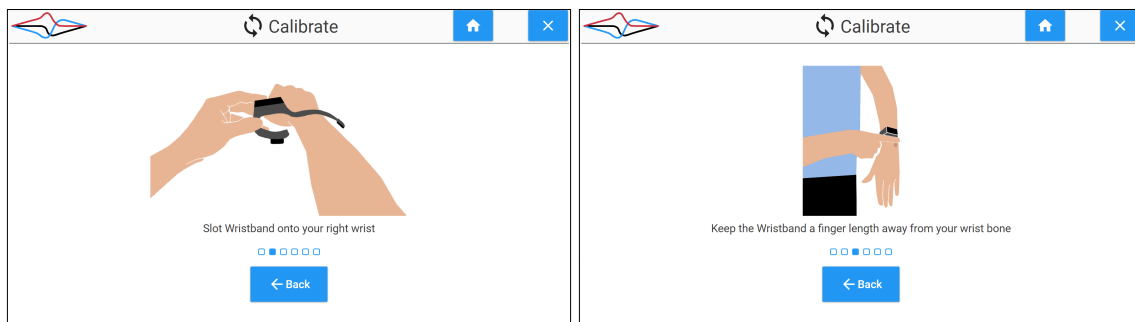
(a)

(b)



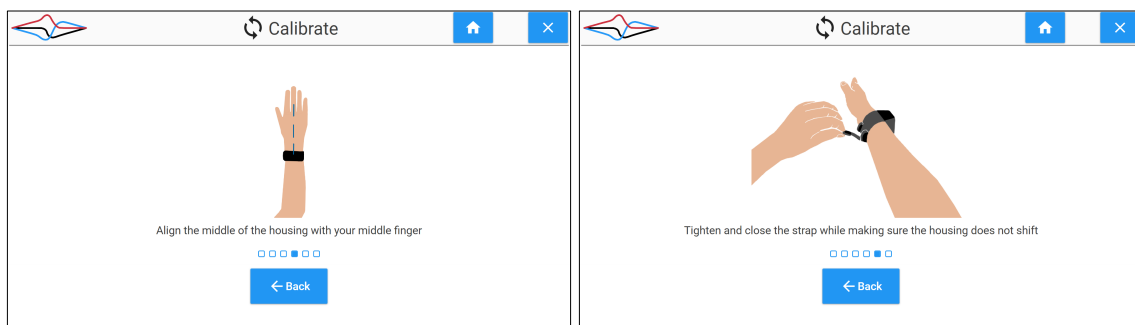
(c)

(d)



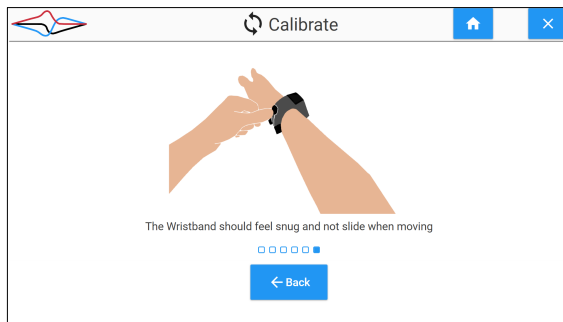
(e)

(f)

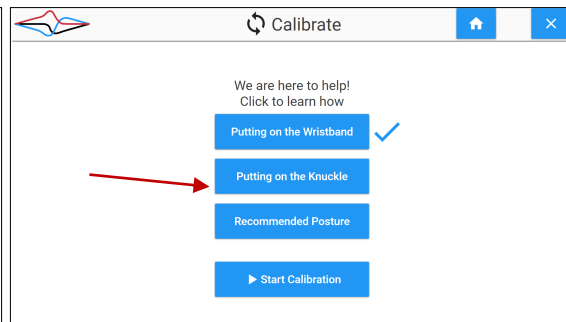


(g)

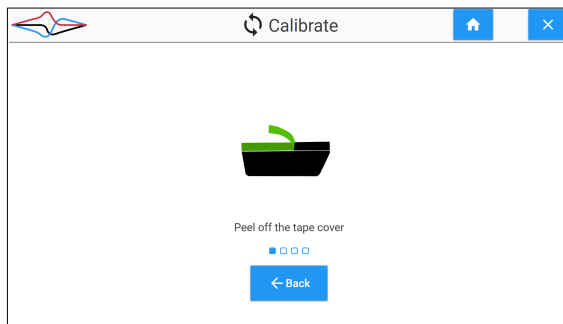
(h)



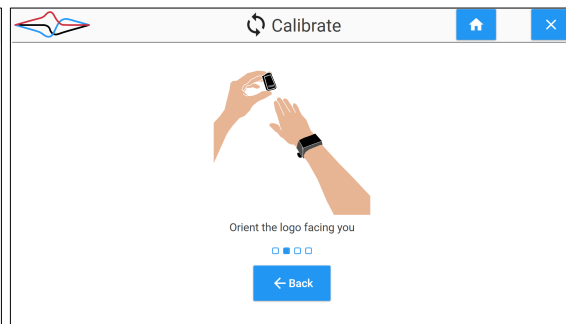
(i)



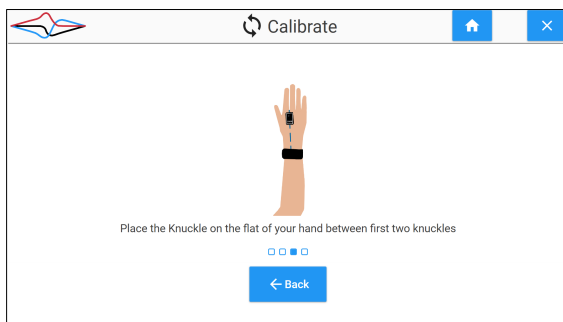
(j)



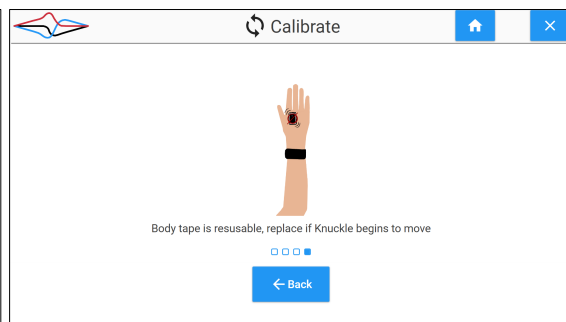
(k)



(l)



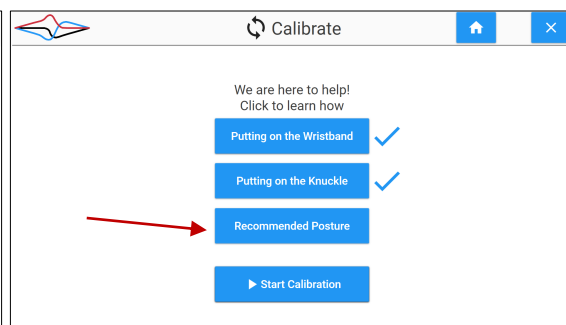
(m)



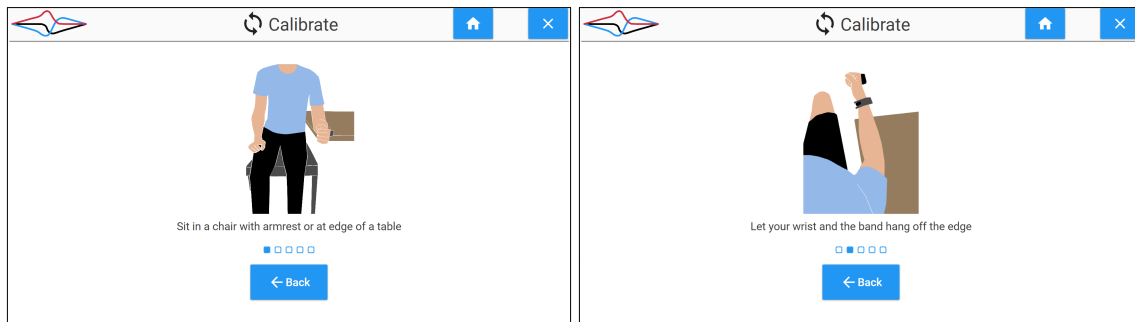
(n)



(o)

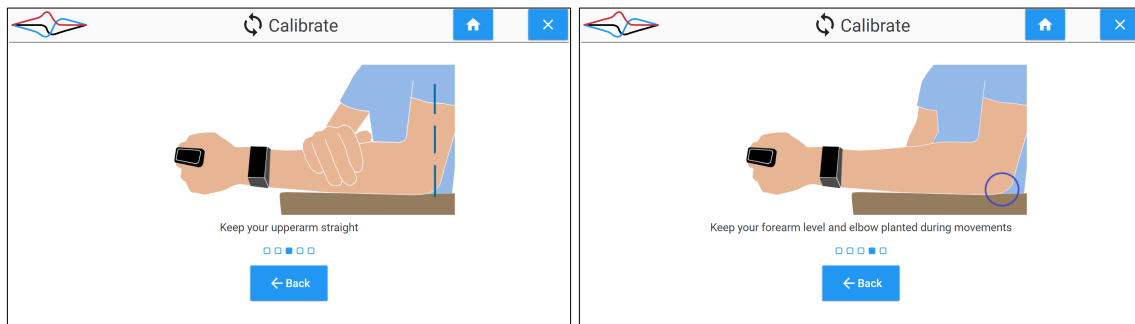


(p)



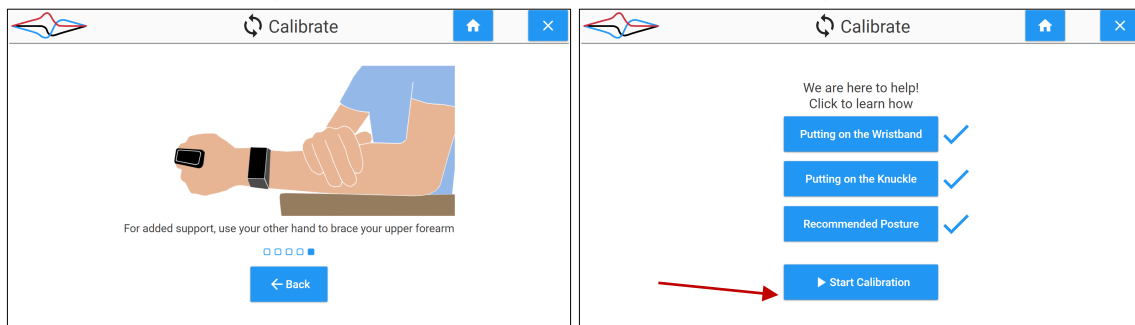
(q)

(r)



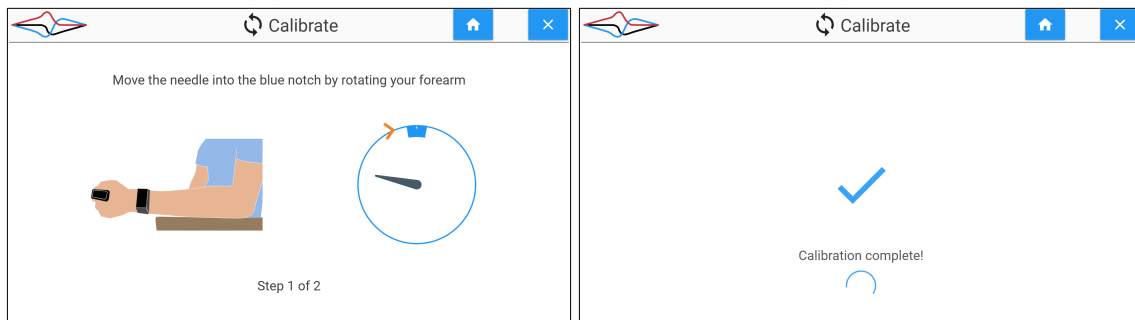
(s)

(t)



(u)

(v)



(w)

(x)

Figure 7 - Calibration sequence (a)-(x)

The user is in calibration pose 1, as shown in Figure 8(a).

- Sit in a chair with elbow planted firmly on the armrest. Only hand and wrist are not supported by the armrest.
- Position the forearm so that it is 90 degrees to the upper arm. Upper arm parallel to torso.
- Maintain a neutral wrist position by creating a flat line with the forearm.
- Make a loose fist with the hand and orient the wrist with thumb facing towards ceiling.

From calibration pose 1, rotate the wrist to calibration pose 2, as shown in Figure 8(b). The dial moves along with the user's rotation.

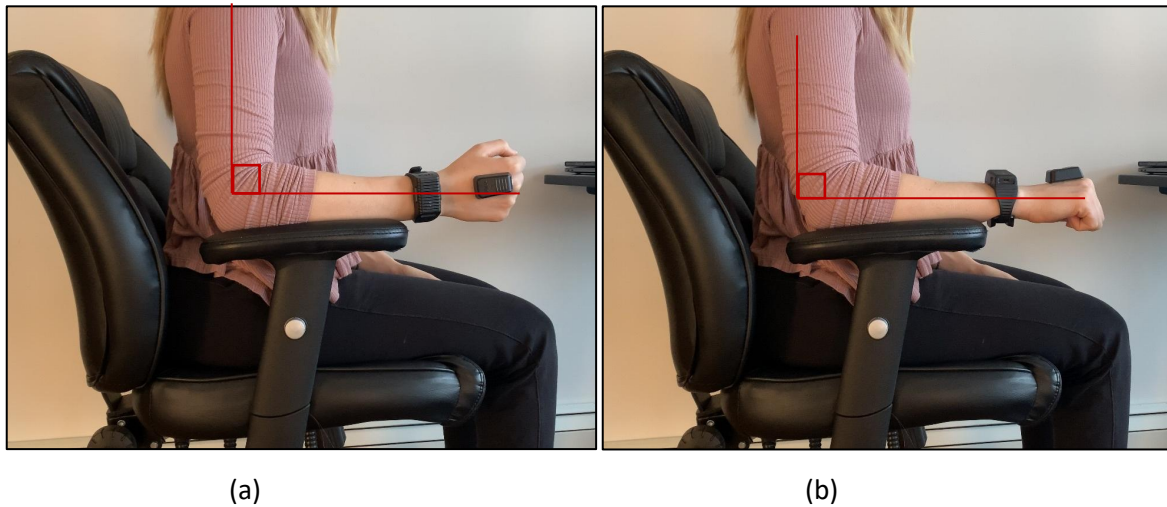


Figure 8 - Calibration pose.

Recalibrate after every re-donning of Wristband and Hand Sensor.

If Wristband, Hand Sensor or both are taken off and put back on recalibration is required. To do so select Settings from the home screen and Calibrate.

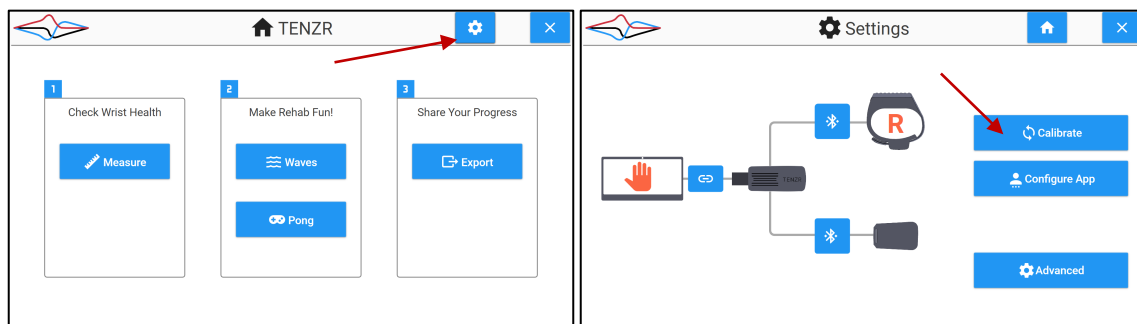


Figure 9 – Recalibration.

6. Following successful calibration, all of the tools are now unlocked.

Consult Companion App Features for information on their usage.

7. Closing procedure

When finished, unplug the USB Dongle before closing the Companion App.

Store all the devices in the case when not in use.

Companion App Features

Following successful calibration, the user can use the Measure, Train, and Export tools.

The user is encouraged to maintain a loose fist, keeping the forearm planted flat on a surface such as an armrest.

For pronation/supination and radial/ulnar activities, the user should begin in a pronated arm position with neutral hand, as illustrated in Figure 10(a). For flexion/extension activities, the user should maintain a mid-prone arm position with neutral hand as in (b).

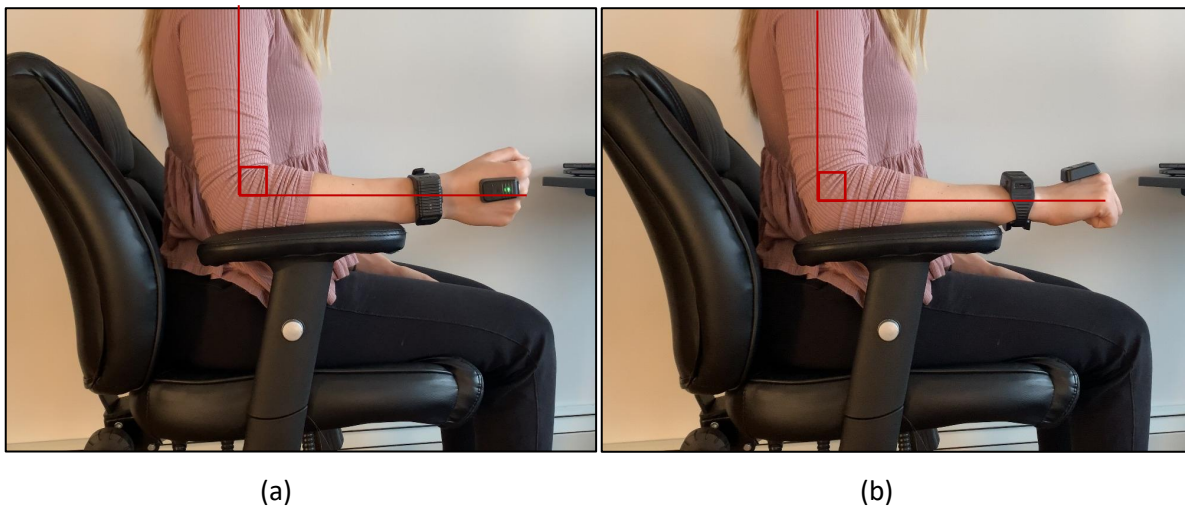


Figure 10 - Pronate arm position with neutral hand (left). Mid-prone arm position with neutral hand (right).

Measure

The Measure section reports the user's wrist ROM.

Pronation/Supination Assessment

Materials

TENZR Wristband, TENZR Hand Sensor

Neutral Position

Sit upright in an armchair with upper arm parallel to torso, and forearm firmly planted to the armrest. Begin with the forearm in neutral: thumb facing up, no more than 10 degrees beyond pronation or supination as in Figure 11(a). The wrist should remain flat, not inclined beyond 15 degrees from the horizontal plane.

Usage

Performing pronation and supination poses, as illustrated in Table 2, will move the blue bar accordingly. Select start to begin and stop to end each measurement. Select save and next to ensure data is stored as shown in Figure 12.

Should the user’s wrist go out of alignment at any time, the App displays instructions to return to the neutral position.

The maximum angles are reported in degrees.

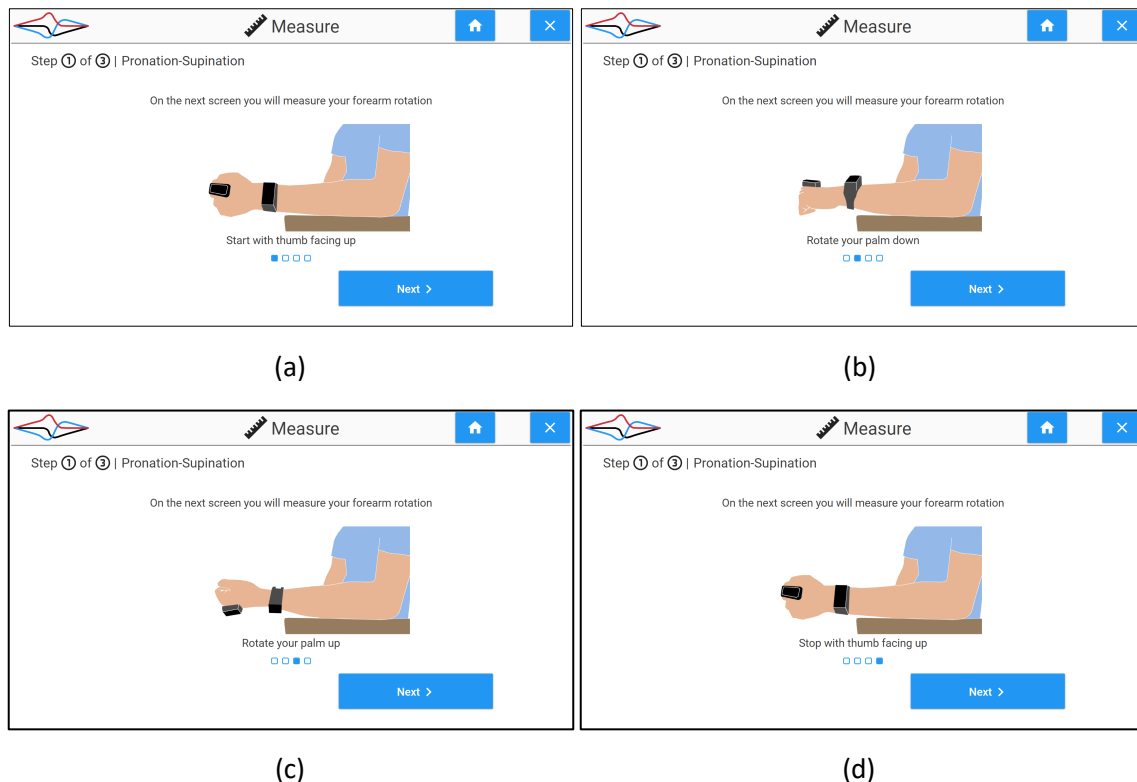
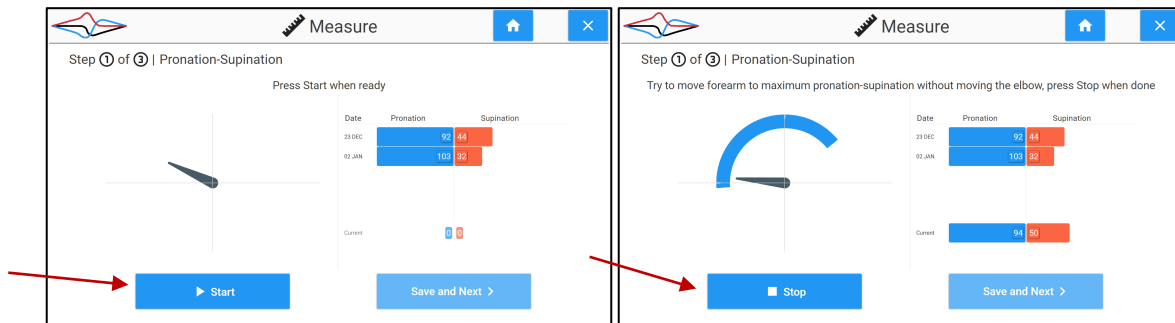
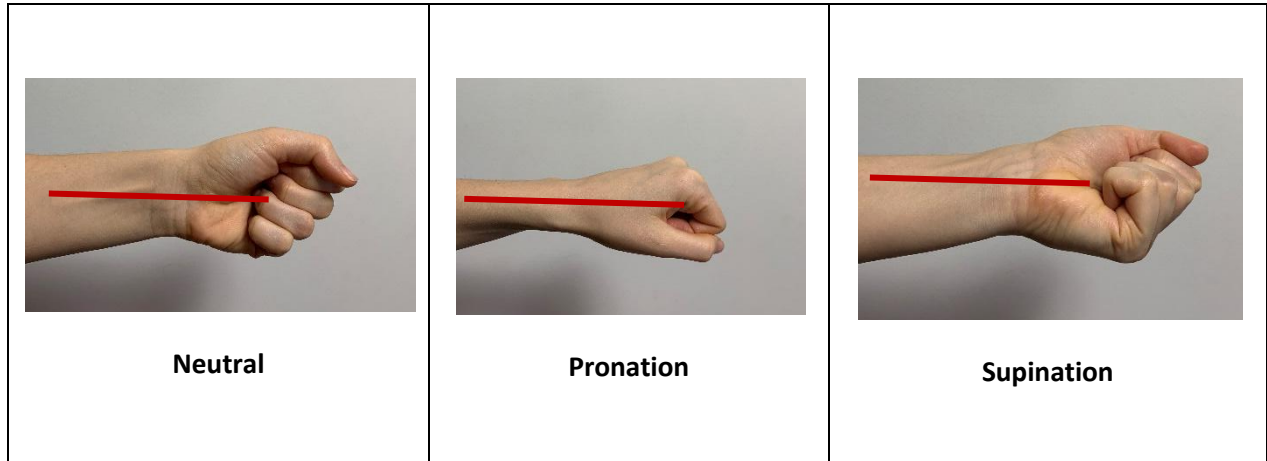


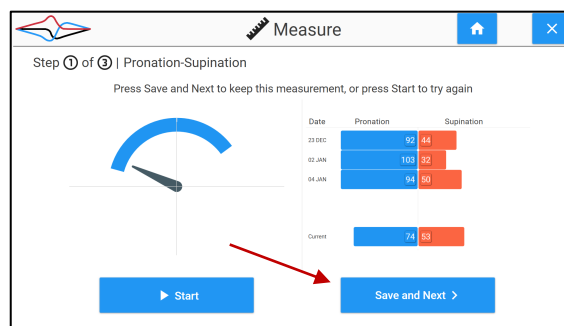
Figure 11 - (a) – (d) Pronation/Supination Assessment posture guidelines.

Table 2 – Recommended pronation and supination hand poses.



(a)

(b)



(c)

Figure 12 (a) – (c) Pronation/Supination Measurement Access.

Radial/Ulnar Assessment

Materials

TENZR Wristband, TENZR Hand Sensor

Neutral Position

Sit upright in an armchair with upper arm parallel to torso, and forearm firmly planted to the armrest. Begin with the forearm in neutral: thumb facing up, no more than 10 degrees beyond pronation or supination as in Figure 13(a). The wrist should remain flat, not inclined beyond 15 degrees from the horizontal plane.

Usage

Performing the exemplary ulnar and radial poses, as shown in Table 3, will move the blue bar accordingly. Select start to begin and stop to end each measurement. Select save and next to ensure data is stored as shown in Figure 14.

Should the user's wrist go out of alignment, the App instructs the user to return to the neutral position.

The maximum angles are reported in degrees.

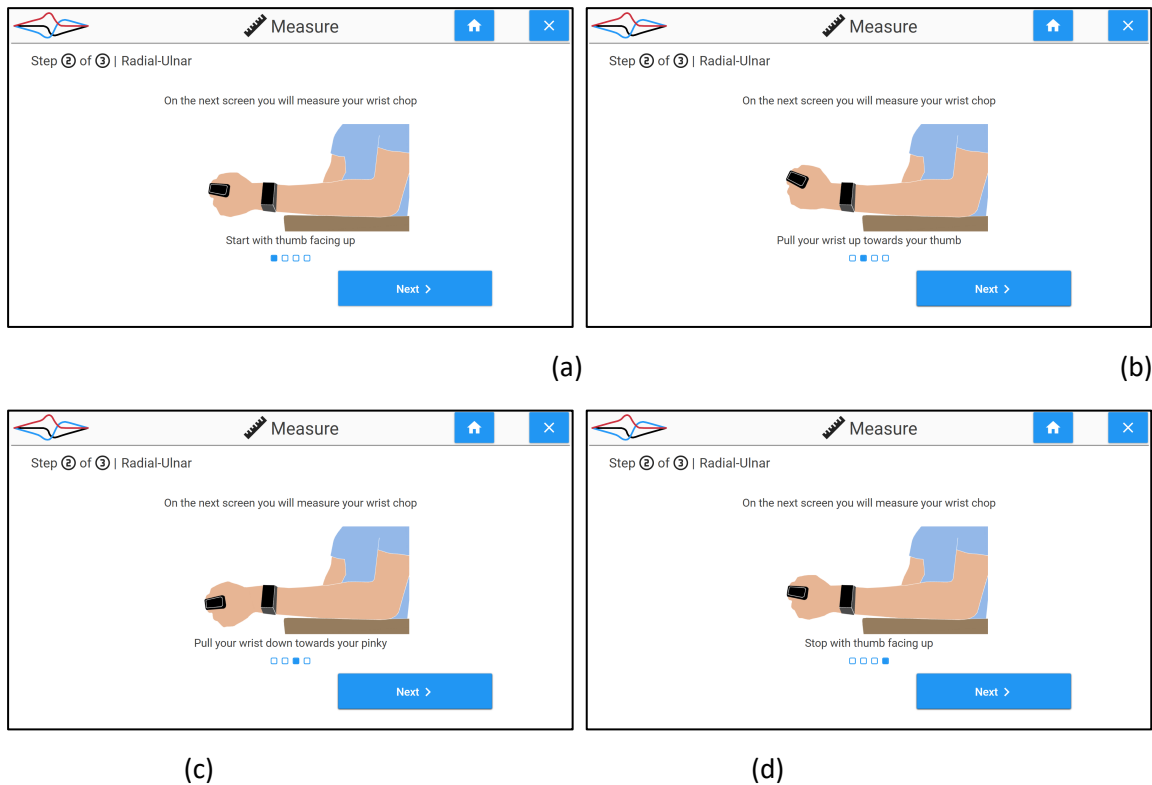
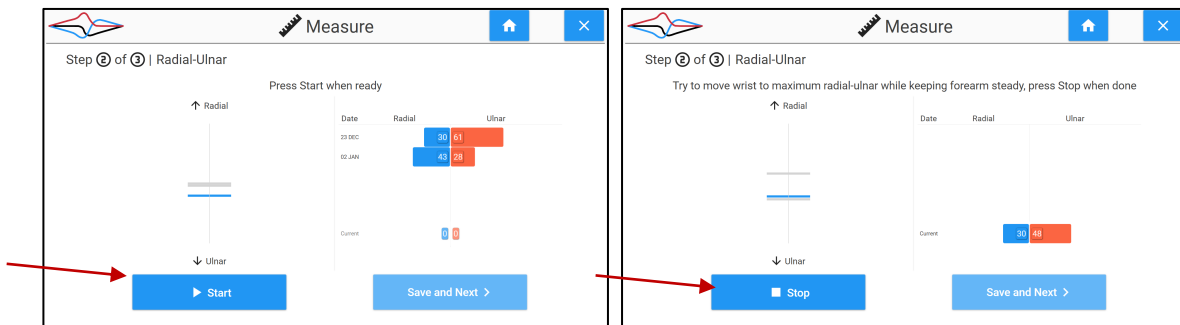
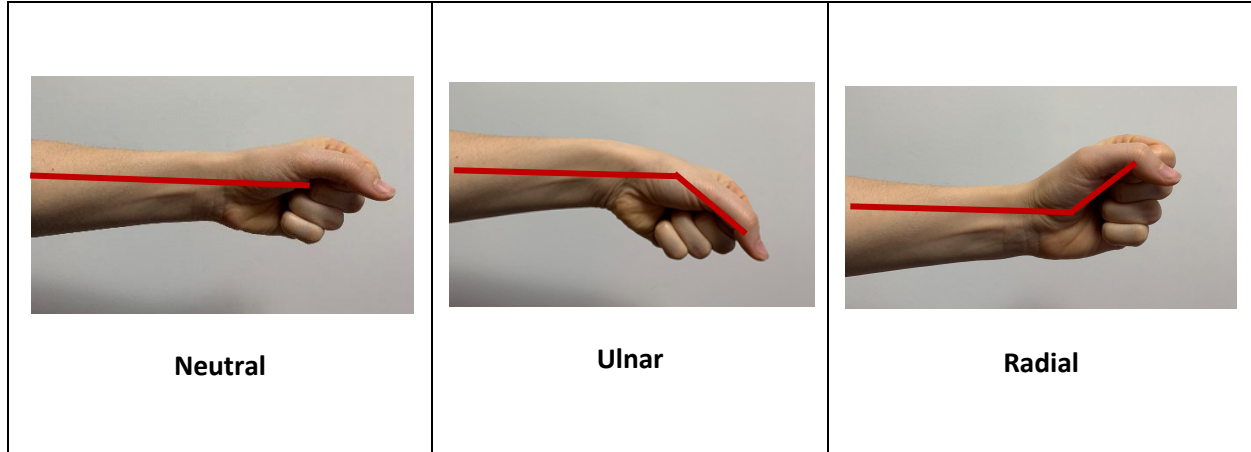


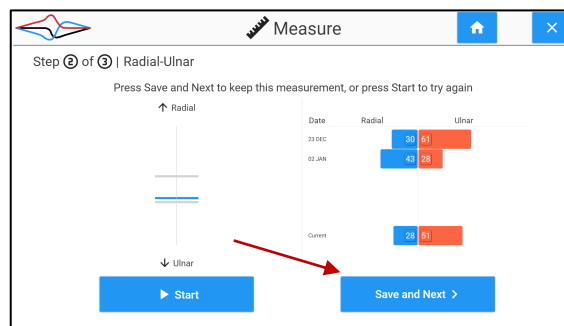
Figure 13 - (a) – (d) Radial/Ulnar Assessment posture guidelines.

Table 3 – Exemplary hand poses for ulnar and radial.



(a)

(b)



(c)

Figure 14 - (a) – (c) Radial/Ulnar Measurement Access.

Flexion/Extension Assessment

Materials

TENZR Wristband, TENZR Hand Sensor

Neutral Position

Sit upright in an armchair with upper arm parallel to torso, and forearm firmly planted to the armrest. Begin with the forearm in pronation: palm facing down as in Table 4. The wrist should remain flat, not inclined beyond 15 degrees from the horizontal plane.

Usage

Performing the exemplary flexion and extension poses, as shown in Figure 15, will move the blue bar accordingly. Select start to begin and stop to end each measurement. Select save and next to ensure data is stored.

Should the user’s wrist go out of alignment, the App instructs the user to return to the neutral position.

The maximum angles are reported in degrees.

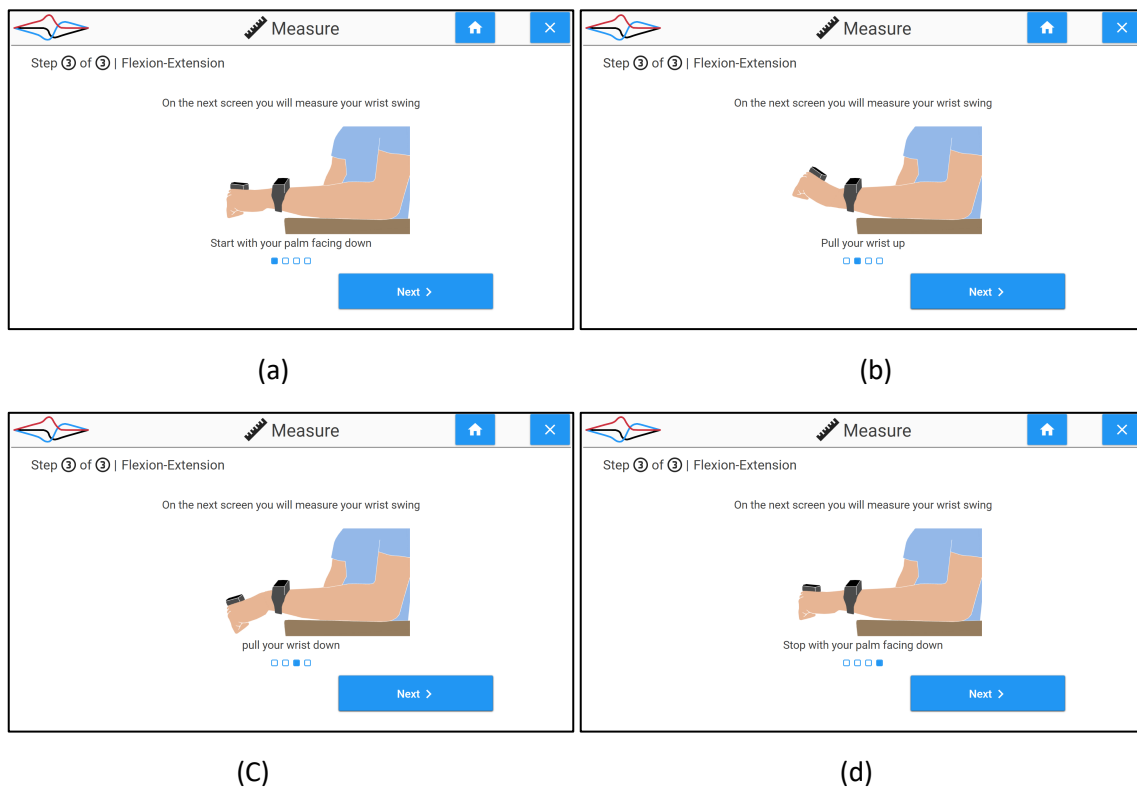
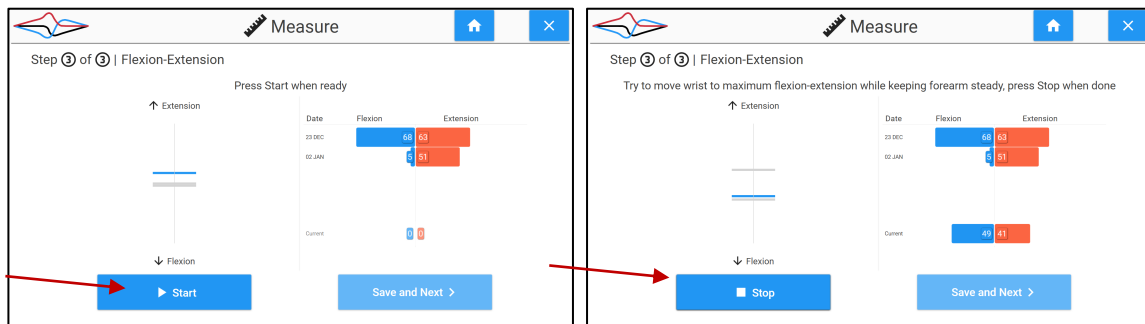
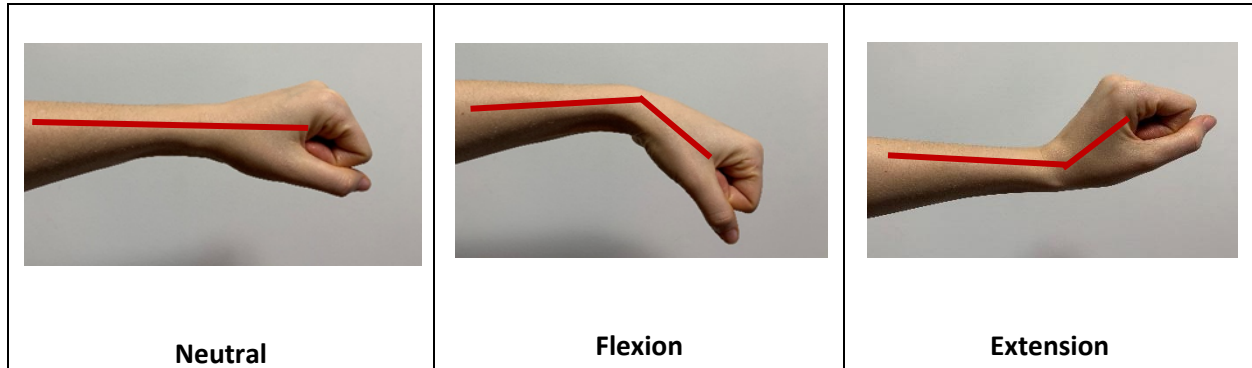


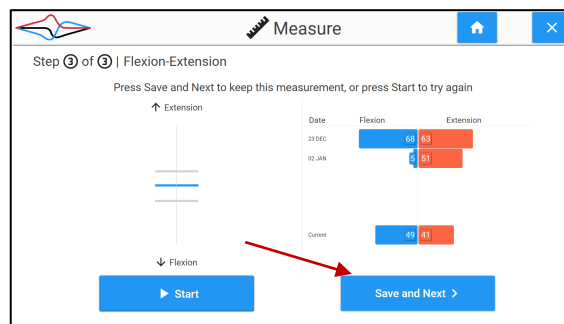
Figure 15 - (a) – (d) Flexion/Extension Assessment posture guidelines.

Table 4 - Flexion and Extension of forearm.



(a)

(b)



(c)

Figure 16 - (a) – (c) Flexion/Extension Measurement Access.

Train

Train encourages users to practice ROM exercises recommended by their licenses healthcare provider in their own time through game play. There are 2 games to choose from.

Materials Required

TENZR Wristband, TENZR Hand Sensor

Recommended Positions

For Pronation/Supination and Radial/Ulnar

The user should begin in neutral with a loose fist and flat forearm as in Figure 10(a).

The recommended hand poses can be found in Table 2 and Table 3.

For Flexion/Extension

The user should begin in a pronated arm position with a loose fist and flat forearm as in Figure 10(b).

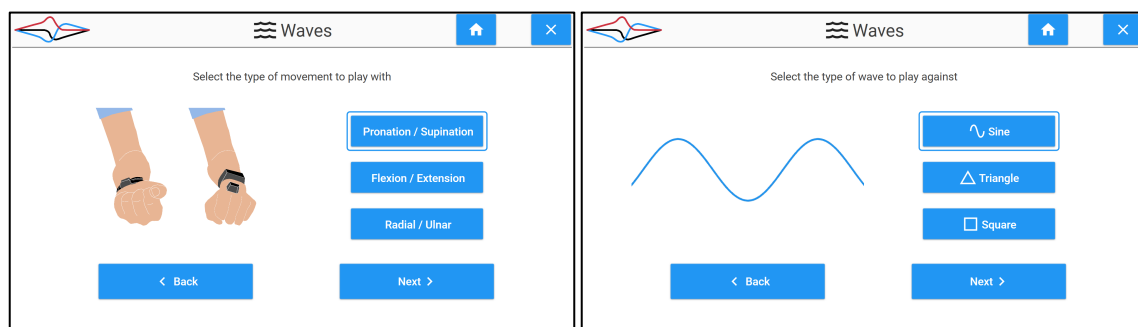
Exemplary hand poses can be found in Table 4.

Usage

Users can choose a type of ROM activity to practice and set the intensity level. The intensity level sets the initial game parameters. Should the user’s wrist go out of alignment, the App instructs the user to return to the neutral position.

1. *Waves - Sine*

The user controls the dot by moving the wrist or forearm according to the ROM activity selected. A higher score is achieved when the dot stays on the line, as shown in Figure 17.



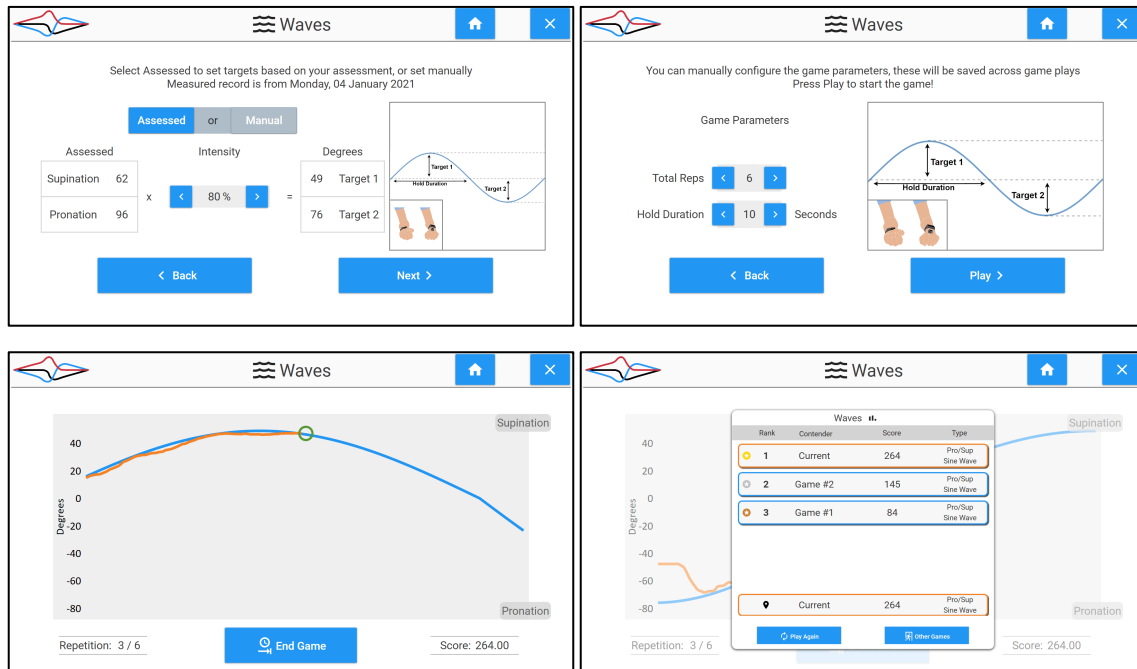


Figure 17 - Overview of Sinusoid Reps game.

2. Waves - Triangle

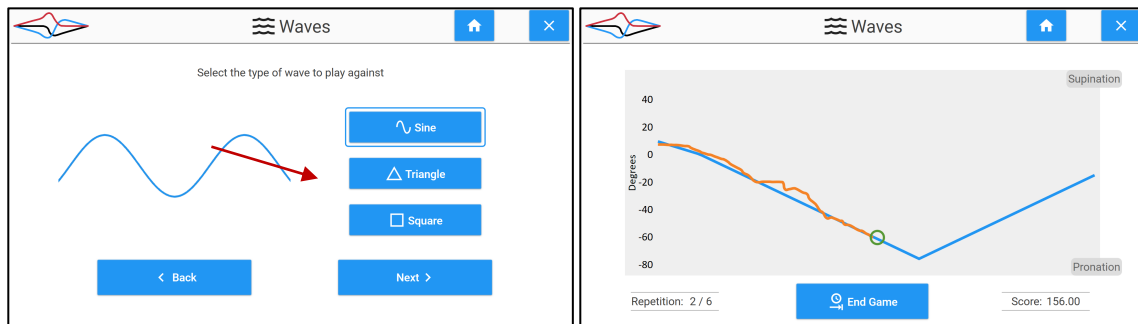


Figure 18 - Overview of Waves Triangle game.

3. Waves – Square

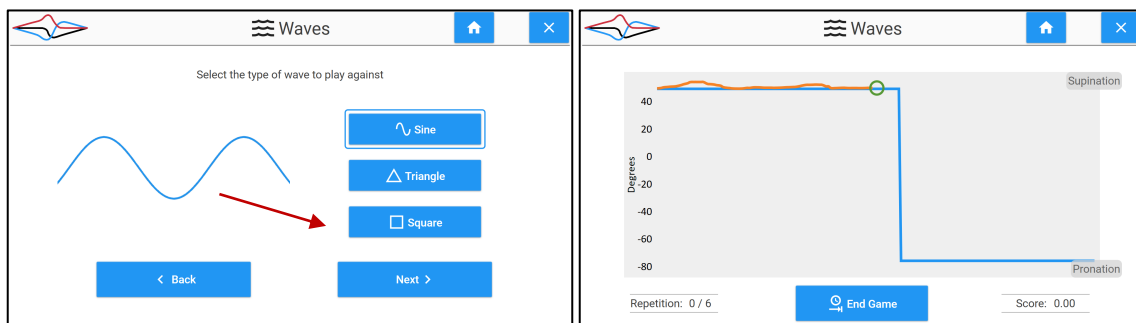


Figure 19 - Overview of Waves Square game.

4. Pong

Figure 20 shows the Pong game where the user controls the blue paddle by moving the wrist or forearm in the selected activity and the aim of the game is to hit the ball into the opponent's (computer's) goal. The intensity level sets the size of the user's goal post.

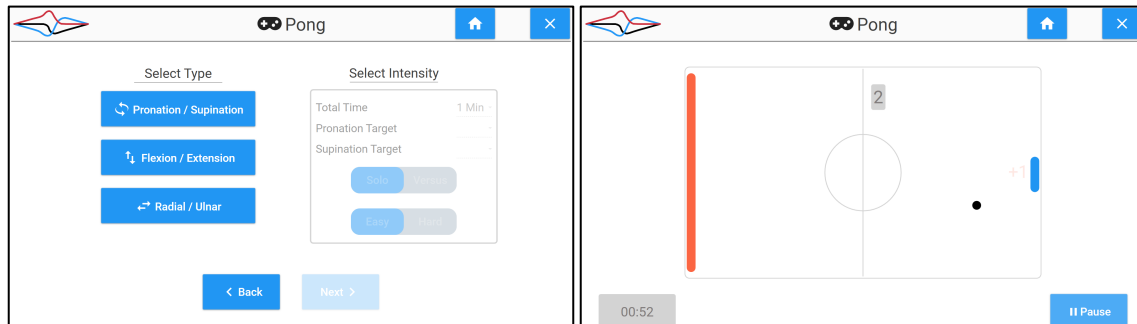


Figure 20 - Overview of Pong game

Export Data

All logs can be accessed via the Export section from the main page, as shown in Figure 21.

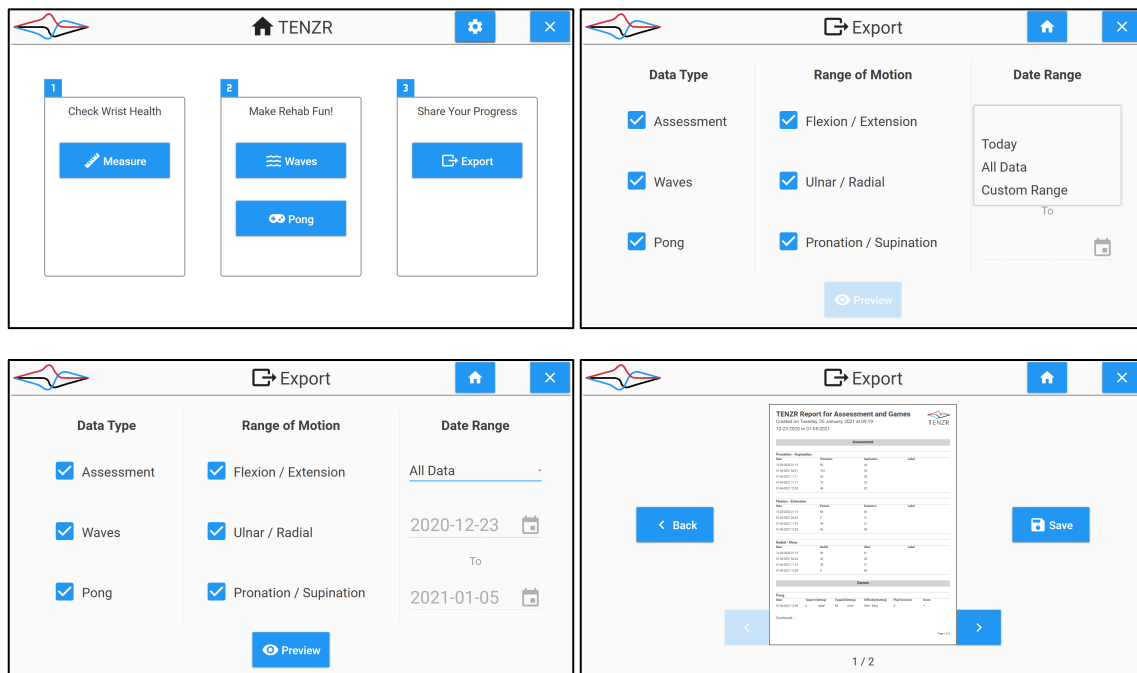


Figure 21 - Export.

Storage and Handling

Charging

Only charge TENZR Wristband and Hand Sensor with the included wall charger. **Do not connect the TENZR Wearables to third party USB wall charger.**

Storage & Cleaning

Store the TENZR Wristband and Hand Sensor in the provided case when not in use. To clean, wipe the parts of TENZR that make contact with skin using Isopropyl Alcohol Wipes. However, **do not introduce moisture to the main TENZR housing or to the charging port.**

Troubleshooting

Reconnecting Disconnected Devices

If a Wristband and/or Hand Sensor were previously working but become disconnected, follow these steps.

An error button will appear in the App's menu bar, as shown in Figure 22. Clicking on the button will display a prompt that describes the fault in more detail.

The Settings page will also show the disconnected device with an INFO message.

To resolve disconnections, charge the disconnected Wristband and/or Hand Sensor fully or plug in the USB Dongle to the tablet. The Wristband and Hand Sensor will automatically reconnect once sufficiently charged.

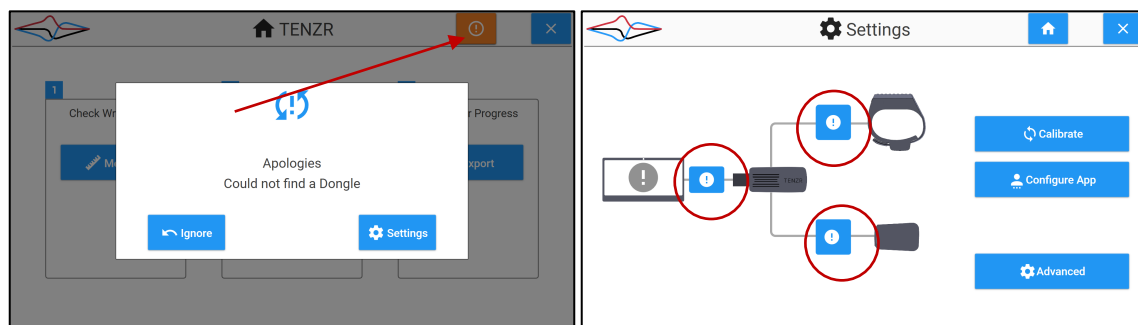


Figure 22 –Prompt indicating the disconnected device(s) and Examples of disconnected devices.

If this does not resolve the connection problems, follow the instructions below to reset the device.



Resetting the Wristband and Hand Sensor

Should Wristband or Hand Sensor not operate as expected, it can be reset. From the Settings page, identify the device to be reset and follow the steps:

1. Connect the Reset Key to the USB port on the TENZR device and disconnect after a few seconds. The device buzzes when the Reset Key is applied.
2. Wait 5 seconds.

The settings should now show all devices are connected, as per Figure 3.

Contact Us

For troubleshooting, please contact us at support@biointeractivetech.com.