Atris Software:

Instruction for Use

for Healthcare Providers

Version 1.1

These Instructions for Use (IFU) were last updated on 25 March 2024 to version 1.1 and is based on the following versions of the application:

AtrisApp
Android v4.3.3 and iOS v4.3.3

Atris Patient Monitor
v4.7.0

Atris BigScreen
V2.1.0

AtrisCare App
Android v2.2.1 and iOS v2.2.1

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1. About Atris

1.1. Product Information

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Version:	**AtrisApp:** v4.3.3 **Atris Patient Monitor**: v4.7.0 **Atris BigScreen**: v2.1.0 **AtrisCare App**: v2.2.1
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The goal of Atris is to improve the well-being and disease status of patients and users by sending notifications to patients and health care providers based on the interpretation of collected health data. This is done by offering and maintaining a clear, efficient, effective, and user-friendly software tool. Atris helps patients and healthcare providers gain insight into their well-being and disease activity.

Atris is a software platform intended for patients and their healthcare providers. Atris imports measured data from a patient and compares the data to patient-specific threshold values set by their healthcare provider. When the data exceeds the threshold value, a notification/alarm will be sent to with monitoring and/or therapeutic purposes. The thresholds for disease specific parameters will be set by a doctor, who will consider the individual patient's disease status. Patients and healthcare providers can receive notifications through AtrisApp and Atris Patient Monitor, respectively.

Atris is compatible with the following medical sensors: accelerometer for physical activity (PAM- sensor), scales, blood pressure sensors and heart rate monitors.

More information about Atris can be found at https://atris.life.

1.2. Company Information

Atris has been developed by Peercode, which was founded in September 1999 and consists of a balanced team of experienced and well-trained professionals from various fields including: software development, web hosting, mobile app development, user experience design, app design and (cognitive) ergonomics. Peercode has continued to develop in recent years and is now also active on the international market.

More information about Peercode can be found at www.peercode.nl.

Peercode BV
Oudenhof 4c
4191 NW Geldermalsen
The Netherlands
medicaldevices@peercode.nl

1.3. Important Contacts

1.3.1. Atris Support

If you have questions about personal care issues, illness or welfare questions, you should contact your healthcare provider (HCP). If you have any questions about the use of Atris, you can ask the manufacturer via medicaldevices@peercode.nl or through support@atris.nl.

Users are required to report any serious incidents related to the device to Peercode or the competent authority of the country in which the user is located. To contact Peercode regarding incidents, you may contact the manufacturer via medicaldevices@peercode.nl.

As the device is integrated into third-party systems, such as electronic patient medical records and home monitoring applications, we kindly request that you direct any questions or inquiries regarding the third-party product to their respective support teams. For any concerns or assistance related to Atris specifically, please don't hesitate to contact our own support team, and we will be happy to help.

If you prefer a paper version of the Instructions for Use, you can request one by sending an e-mail to medicaldevices@peercode.nl. Your request will be processed within 7 calendar days, and you will receive the paper version accordingly.

1.3.2. Regulatory Compliance

Any questions or comments regarding regulatory compliance can be directed to:
Dr. Erwin Waas - erwin.waas@peercode.nl

1.3.3. GDPR Compliance

Atris has been developed according to the guidelines of ISO27001 and NEN7510. These standards represent a process-based approach to implementing, monitoring, maintaining and improving information security. In this way, Atris guarantees the privacy of your patients and you can be sure that their data is in safe hands.

Any questions or comments regarding GDPR compliance can be directed to: medicaldevices@peercode.nl

2.   Intended use of Atris Software

Atris is a software platform for patients and HCPs intended for telemonitoring. Atris records patient outcome information and presents this to the patient and HCP. Outcome information is compared with HCP's set patient-specific thresholds, to trigger a notification with monitoring and/or therapeutic intend. The thresholds, not related to an immediate danger to the patient, can be set by the physician considering the individual patient health status. Patients may receive notifications in the AtrisApp and HCPs on the Atris Patient Monitor website.

Note: Outcome information is defined as (medical) information which is key in facilitating an optimal treatment process. This information is based on clinical information registered by the HCP or found within the patient's electronic dossier, or data collected by the patient through clinical surveys or by using devices such as weight scales or step counters.

2.1.   Audience

The following types of users will use the Atris:
- Patients who want/need to improve their health (rehabilitation) / reduce the burden of their disease.
- Patients whose physical condition/ health status needs to be monitored. For example, because they have a (chronical) disease such as: COPD, diabetes, Alzheimer's, asthma, cancer or heart disease.
- HCPs with specializations for example in:
    - Dietetics
    - Oncology
    - Orthopedy
    - Vascular surgery
    - Geriatrics
    - Heart rehabilitation
    - Physiotherapy
    - Chronic heart failure

2.2.   Main functionalities

Atris consists out of the following software:
- **AtrisApp** is an app for mobile phones intended to be used by the patients to record and display their outcome information.
- **Atris Patient Monitor** is a web application which is intended to be used by the HCPs to view their patient's recorded outcome measures. The web application enables the HCP to set a threshold on input data and if the threshold is exceeded the software will provide an alarm notification. An example of a threshold could be the increase in weight over several days.
- **Bigscreen/Gateways** is intended to be used by the patients to record movement data in the hospital/clinic. Bigscreen displays the patient's movement data and progress towards their goals on-screen.
- **AtrisCare** is intended to be used by the HCPs to read-out movement data of movement sensors. The app shows the currently read data before sending it to Atris Patient Monitor.

Atris is able to connect to several sensors, for example PAM sensors, heart rate sensors, scales (as further specified in SRS, ref. 6), which can collect general health data. Atris connects/couples to these sensors to obtain the data from the device and present it in the AtrisApp and Atris Patient monitor. Atris does not send data back to any device.

2.3.   Limitations of use

Atris requires an internet connection to function. Atris is not intended to diagnose, recommend treatment options, or measure health parameters. Using this app is not a substitute for medical advice or treatment. This app is not intended to record the side effects of medical treatments. Atris uses validated measuring instruments to measure health parameters. The minimum age for use is 18 years old. In the event of a temporary failure of the application, it may happen that temporarily measured health data is not synchronized and/or is not communicated with the healthcare provider.

2.4.   Contraindications

The Atris Software is **contraindicated** for use in the following situations:

Not all patients may have access to smartphones required to use the Atris App. This may be a limitation for some patients, especially older persons or those with limited technological skills. In these situations, it is recommended to read PAM sensors in the hospital/clinic using the AtrisCare App or Atris Bigscreen/Gateways.

Although tele-monitoring with the Atris software offers the possibility of monitoring health from a distance, the lack of personal contact between patients and healthcare providers can pose risks. Some patients may need direct interaction and personal support with their health problems. So, before using the Atris Software, discuss clearly with the patient what his/her needs are.

3.   Clinical Performance of Atris

This section discusses the performance aspects of the Atris medical device. The evaluation is based on data collected from clinical trials and reviews of similar telemonitoring systems. Atris aims to provide remote patient monitoring and data communication between patients and healthcare professionals (HCPs). The following subsections elaborate on the performance considerations:

3.1.   Clinical Background

The use of smartphones has risen significantly over the years, and the potential for healthcare applications, such as telemonitoring, has grown with it. Atris is an example of a telemonitoring application that allows patients to share health data with their HCPs between appointments. Telemonitoring offers benefits like continuous patient monitoring and potential cost reduction in healthcare.

3.2.   Performance

Atris targets a diverse range of patient populations, including those with diabetes, cardiovascular disease, rheumatoid arthritis, and patients undergoing surgery. Telemonitoring systems commonly use wearable medical sensors to collect patient data, measuring vital signs like temperature, respiratory rate, blood pressure, and blood oxygen saturation. Atris aligns with these parameters, collecting data such as body motion, weight, heart rate, and blood pressure.

Research shows positive outcomes for telemedicine and telemonitoring systems. The adherence rates to telemedicine systems are promising, indicating patients' willingness to use these systems. The architecture of telemonitoring systems, including Atris, involves subsystems for user monitoring, healthcare practitioner monitoring, and remote data management, which ensures proper data collection, monitoring, and storage.

Studies also demonstrate the feasibility and effectiveness of telemonitoring systems post-surgery, for cardiovascular rehabilitation, and for patients with rheumatoid arthritis. Telemonitoring interventions have shown positive impacts on treatment adherence, patient self-care, and patient-physician communication. They also facilitate early detection of complications and symptoms.

3.3.   State of the Art

Atris' design and functionality align with the state-of-the-art telemonitoring systems. Usability and data security are essential components, and Atris meets these requirements. Future trends in eHealth solutions involve advanced technologies like robot companions, computer vision, speech processing, and data security enhancements.

3.4.   Safety

Safety considerations include recalls, incidents, vigilance issues, usability, data security, residual risks, and side effects. Similar devices have shown a low risk profile, and Atris has undergone usability testing to ensure ease of use. Data security is prioritized, with encrypted data traffic, secure backend requests, and ISO27001 certification. Atris' residual risks and side effects are deemed acceptable and will be continuously monitored.

3.5.   Device claims

The intended clinical benefit of Atris is to improve wellbeing and disease status of patients by interpreting data and sending notifications with monitoring and therapeutic intent to patients and HCPs.

4.   Warnings and precautions

Before using the Atris service, it is important to be aware of the following warnings, precautions, and potential risks associated with its use. Please carefully read and understand the information provided below to ensure safe and effective use of the Atris. Discuss the risks with your patients.

- Atris is not intended for diagnosing medical conditions, providing treatment recommendations, or acting as a standalone medical measurement tool. The use of Atris does not replace medical advice or treatment. It is also not meant to record the side effects of medical treatments.
- Internet connections are required at all times for Atris to function as intended.
- AtrisApp and AtrisCare will be subjected to software updates. Make sure to turn on automatic updates to guarantee that the app is state-of-the-art.
- Make sure that phones or computers with access to Atris are password protected to prevent unauthorized access to patient data.
- Instruct patients to turn on notifications on their smartphone to guarantee that they receive notifications based on their health information.
- The software employs validated measuring instruments to gauge health parameters.
- The minimum age for using Atris is 18 years.
- In case of personal health concerns, illnesses, or well-being questions, patient should contact their healthcare provider.

There are no known side-effects of Atris.

5.   Hardware and software requirements

The AtrisCare and AtrisApp are distributed through Apple's App store and the Google Play store. Both apps are compatible with mobiles phones running:
-        Android 5.0+
-        iOS 12.0+
Atris Patient Monitor requires the use of a modern web browser. The minimal hard- and software requirements of a modern web browser are as follows:

	Chrome	Safari	Firefox	Edge
Processor Windows	Pentium 4		Pentium 4	Pentium 4
Processor Mac	Intel	500-MHz Pentium-class	Intel	Intel
Min RAM	128 MB			
Recommended RAM		256 MB	512 MB	2 GB
Min Disk Space	100 MB			1.4 GB
Rec. Disk Space		unknown	200 MB	
Windows	Windows XP SP2	Windows XP SP2	Windows XP SP2 (FF 13)	Windows 7
OS X	OS X 10.5.6	OS X 10.5.8	OS X 10.5	OS X 10.13
Linux	Ubuntu 10.04	Not available	Any recent	Any recent
	Debian 6			
	OpenSuse 11.3			
	Fedora Linux 14			

5.1. About the PAM sensor

PAM is a system centered around motion tracking, facilitated by a small and clever device that captures all your daily activities (Figure 1). PAM's usability is remarkably straightforward. The device itself requires no configuration. PAM gauges activity intensity by meticulously monitoring your body's movements.

When PAM is worn on around the ankle throughout the day, it quantifies movement into a universal activity index known as the PAM score. Engaging in activities like brisk walking for half an hour might yield 4-6 points, whereas a half-hour jog could earn you a score of 20-30 points.

The PAM score is determined using "Metabolic Equivalent of Task" (MET). It is calculated using the formula: (MET-1) X 100. Additionally, an adjustment is needed for the activity's duration.

Within Atris, activity is measured across 3 levels based on the MET scale:
- Low intensity = 1.4 – 3 METs (Shuffling and leisurely walking)
- Moderate intensity = 3 – 7 METs (Normal-paced walking)
- High intensity = 7 METs and higher (Cycling and running)

Atris can also estimate the number of steps per day with the use of the PAM sensor. This 'steps equivalent' is calculated by multiplying the PAM score x500. A PAM score of 20 will mean that the patient's overall activity was equal to 10.000 steps.

A) PAM V1

B) PAM V2 (front and back)

Figure 1: The PAMs and location of the PAM-ID.

Batteries of PAM V1 cannot be replaced, as such, the sensor should be discarded with the electronic waste when the battery is drained. PAM V2 can be opened and the battery inside can be replaced with readily available button cell batteries.

New PAM sensors or PAM clips can be ordered by contacting support@atris.nl.

6.   Instructions for the use of Atris Software

6.1.   Installation of Atris Patient Monitor

Atris Patient Monitor is a web application that is compatible with commonly used web browsers such as:
• Microsoft Edge
• Google Chrome
• Firefox
• Safari

Peercode provides a ready-to-use instance of Atris; No further installation is required to use Atris Patient Monitor. PAM sensors are linked to the database by Peercode, but must be linked to patients by a healthcare provider or support staff (see section 1.3).

6.2.   Installation of Atris Bigscreen/Gateways

Atris Bigscreen hardware includes software pre-installed by Peercode. The Bigscreen or Gateway can be set up to connect to the internet over WiFi, Ethernet, or 4G connection.

To set-up the Atris Bigscreen, make sure to:
FIRST connect the HDMI cable to the TV.
SECOND Connect the AC Adapter or Power over Ethernet (PoE) cable.

For Atris Bigscreen/Gateways to function as intended, the following requirements need to be met:

- The TV to which the hardware is connected should have a resolution of 1920x1080. Other resolutions might cause distortions.
- The Bigscreen hardware only has an HDMI connection. We recommend using a HDMI cable to connect the device to the TV.
- Use the adapter supplied by Peercode.
- It is possible to use PoE while using the Bigscreen hardware. However, it is not recommended since it can cause ground-loops.
- If 4G is the preferred connection type, make sure that the signal strength is sufficient in the room where the device is placed. If the 4G connection is weak, the device can be switched to LAN-mode by Peercode.
- WiFi connections are typically unstable and are not recommended.
- The Bigscreen/Gateways hardware is delivered without an external Bluetooth antenna. If signal interference disrupts PAM sensor read-out, an external antenna can be ordered at Peercode.
- Do not place the Bigscreen/Gateways hardware near sources of signal interference.
- It is not recommended to place the hardware within a system-ceiling due to the potential signal interference.

To adjust Bigscreen/Gateways Settings: Navigate to the Gateways tab in Atris Patient Monitor with as an administrator. Select Edit for the device to be configured. The following settings can be adjusted:
- Patient Group assigned to the Bigscreen.
- Progression towards goal in Numeric values or percentages.
- Amount of days of inactivity needed to remove patient from the screen.

6.3.   Installation of AtrisApp / AtrisCare

Both applications can be downloaded and installed from the Apple App Store or Google Play store. See below for instructions:

Installing from Apple App Store:

1. Open "App Store" on iOS.
2. Search for AtrisApp or AtrisCare.
3. Tap the app's name.
4. Click "Get" then "Install."
5. Authenticate with password, Touch ID, or Face ID.
6. Wait for download and find the app on your home screen.

Installing from Google Play Store:

1. Open "Play Store" on Android.
2. Search for AtrisApp or AtrisCare.
3. Tap the app's name.
4. Press "Install."
5. Review permissions and tap "Accept."
6. Wait for download and find the app in your app list.

6.4. Logging in for the first time on Atris Patient Monitor

Care providers and support staff are invited by an Atris Administrator to work with Atris via email (Figure 2). Open the email and select 'Register Now' to activate your account. Fill in the requested information and press register. Then Atris asks to activate two-factor authentication. This is mandatory for all users of Atris Patient Monitor. Use Authenticator applications, such as Microsoft Authenticator or Google Authenticator (available for smartphones via the Google Play store or Apple App store) and follow the instructions in Atris to activate two-factor authentication. Enter the 6-digit code generated by the Authenticator app within the TFA code field in the atris software and select 'verify' to complete the process.
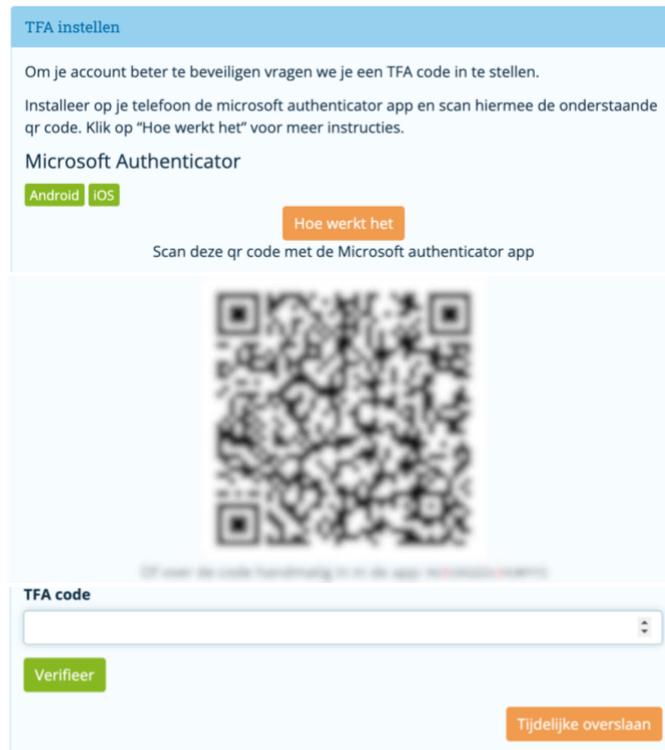
Figure 2: TFA Screen in Atris.

After successful activation, Atris will open Patient Monitor on the Dashboard Page. At the top of this page is a row of tabs that can be clicked to navigate to various functions within Atris Patient Monitor:

Dashboard	Overview of general data, problems and patients Alarms.
Patients	Overview of the patients within the clinic/hospital. New patients can also be created here and patient-specific data can be viewed.
Sensors	List of all sensors and associated patients.
My Account	Your account information and the ability to change it.

6.5. My Account

To manage your own personal data, press the "My account" button in the navigation. You can change your name, email address or password here. Confirm your changes with "Save". If you have lost the two-factor authentication code, ask your Atris Administrator to reset it. The next time you log in, you can go through the process of section 6.4 again.

6.6. Add New Patient to Atris Patient Monitor

If a patient already has a profile in Atris, this step can be skipped.

Open Atris Patients Monitor and select "Patients" from the main navigation at the top of the page. The Patient Summary – Activity Today page will open (Figure 3A). Select the blue 'Add' button here. After which the 'Add patient' screen will open. Enter the following information about the patient on this page:

- First name
- Last name
- Unique Number (e.g. a patient number)
- Show on Bigscreen (IMPORTANT: Select No).
- Date of birth
- Gender (M/F)
- Use training kit (Leave this set to NO).
- Group/Department: Assign the patient to the department where he/she will work with the Bigscreen.

A)

B)

C)

Figure 3: A) Overview of patient page in Atris Patient Monitor. B) Patient detail page in Atris Patient Monitor. C) The Sensor Information field in Atris Patient Monitor.

Then press the blue "Add" button. The 'Detail' page for the newly created patient will then open (Figure 3B). Scroll down this page until the 'Sensor Information' field is visible (Figure 3C), and follow the steps in section 6.7 to pair the sensor.

6.6.1. Add New Patient to Atris Bigscreen

Open Atris Patients Monitor and select "Patients" from the main navigation at the top of the page. The Patient Summary – Activity Today page will open (Figure 3A). Select the blue 'Add' button here. After which the 'Add patient' screen will open. Enter the following information about the patient on this page:

- First name
- Last name
- Unique Number (e.g. a patient number)
- Show on Bigscreen (IMPORTANT: Select YES).
- Alias for Bigscreen (IMPORTANT: in consultation with the patient, enter a nickname here that allows the patient to recognize himself on the Bigscreen, but which is not related to his/her real name).
- Date of birth
- Gender (M/F)
- Use training kit (Leave this set to NO).
- Group/Department: Assign the patient to the department where he/she will work with the Bigscreen.

Then press the blue "Add" button. The 'Detail' page for the newly created patient will then open (Figure 3B). Scroll down this page until the 'Sensor Information' field is visible (Figure 3C), and follow the steps in section 6.7 to pair the sensor.

6.7. Pair PAM sensor

In order to measure the activity of a patient, a sensor must be connected to the patient. Enter the sensor ID at the bottom of the "Sensor information" block. For the PAM V1 (Figure 1A), this can be seen on the side of the PAM. For the PAM V2 this can be found on the bottom of the PAM under the SN number (Figure 1B). Then press "Add" to pair the sensor. **Important**: Only 1 sensor should be connected to a patient at the same time.

If the sensor you want to pair is already paired with another patient, you will be asked if you want to pair the sensor again. Press "Yes" if you want to use the sensor for this patient. The sensor is then automatically disconnected from the old patient.

When the sensor is connected to the patient, the patient can use Atris Bigscreen to read his or her data without any further action.

6.8. Disconnect PAM sensor

To unlink a sensor from a patient, press the red button with the trash can to the right of the sensor you want to unlink on the patient detail page of Atris Patient Monitor. You will then be prompted to confirm the disconnection (Figure 4).

Figure 4: Disconnecting a PAM by pressing the trashcan symbol.

6.9.   Using Fitbits with Atris

To integrate a Fitbit account with the Atris Patient Monitor, follow these steps:
1. Access the Atris Patient Monitor using your Administrator Account credentials.
2. Navigate to the 'Fitbit Accounts' section.
3. Click on the 'Add' option.
4. Review the instructions for adding a Fitbit account provided (Figure 5A)
5. Follow the embedded link to the Fitbit website to create a new Fitbit account. Ensure that you keep the Atris Patient Monitor screen open throughout this process.
6. Create a Fitbit account. For details see steps below
7. Link the Fitbit account with Atris patient monitor, see detailed steps below
8. associate the new Fitbit account with a patient within Atris, see detailed steps below

6. To create a Fitbit account at Fitbit.com, follow these steps:
6.1. Open a web browser and visit https://accounts.fitbit.com/signup, or use the link provided in step 5 above.
6.2. Complete the required information, including your email address. Accept the terms of use and data policy, then select 'Word lid van Fitbit.'
6.3. Access your email and open the received "Actie vereist: bevestig e-mailadres van het Fitbit-account" email.
6.4. Inside the email, click on 'Je e-mail adres verifiëren.'
6.5. Return to the original browser tab, scroll down the privacy notice, and agree to the privacy policy.
6.6. Provide the requested account details and select 'doorgaan.'
6.7. Complete the remaining account details and select 'account maken.'
6.8. Leave the Fitbit dashboard open, as shown in Figure 5B.

7. To link the Fitbit account with the Atris Patient Monitor, continue with the following steps:
7.1. Return to the Atris Patient Monitor, logged in with Administrator credentials.
7.2. On the 'Add a new fitbit account toe' screen, choose 'Authorize.'
7.3. On the subsequent screen, select 'Accept all' and 'Accept.' Refer to the screenshot for clarity.
7.4. Fill in your Fitbit account username (email address) and password, then click 'next.' Refer to the provided screenshot.
7.5. Confirm that the account has been successfully added on the next screen (Figure 6A).

8. To associate a Fitbit Account with a Patient as a Healthcare Professional (HCP), log in to the Atris Patient Monitor with your professional account and follow these steps:

1. Log into the Atris Patient Monitor using your care professional account.

2. Access a Patient Detail Page and scroll down to the 'Fitbit Information' section.

3. Click on 'Add.'

4. Choose the desired Fitbit account from the dropdown menu. Only unassigned Fitbit accounts will be displayed.

5. If applicable, follow the provided steps to delete data (not necessary for new accounts) (Figure 6B and 6C).

6. Click 'Save.'

7. On the Patient Detail Page, confirm the successful linkage of the sensor under 'Fitbit Information.' (Figure 6D)

Please follow the instructions below if the steps to delete data are applicable:

1. Delete all current health data saved in the Fitbit account. Delete data for the past year or years individually (avoid using the "remove all data" option for each section). See the screenshot for visual guidance.

2. Remove all authorized devices associated with the account, except for the connected PC.

3. Erase all health data from the Fitbit device following the user manual.

4. Change the account password. Ensure that you change the password on the Fitbit account user page as well. An email will be sent to reset the password. Both Atris and Fitbit passwords should match.

A)

B)
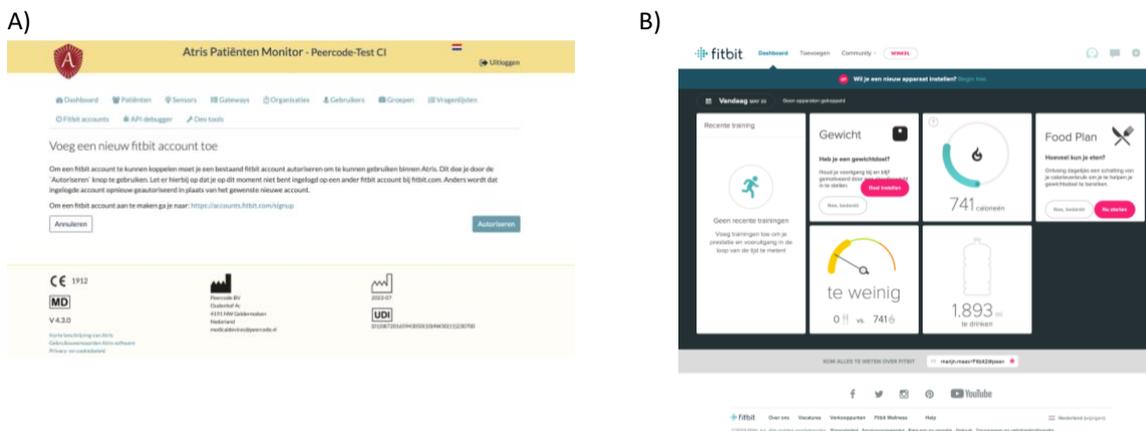
Figure 5: A) Information found in the Fitbit Account screen. B) Overview of the Fitbit Dashboard on Fitbit.com

To unlink a Fitbit sensor as an HCP, proceed as follows:

1. Log into the Atris Patient Monitor with an HCP Account.

2. Scroll down to Fitbit information.

3. Select the Garbage bin icon and confirm in the pop-up.

4. Repeat the process for the second Garbage bin icon and confirm in the pop-up.

5. Verify that the sensor is no longer linked under Sensor information.

To utilize the Fitbit with the AtrisApp, follow these steps:

1. Download the Fitbit app and AtrisApp from the App Store or Google Play store.

2. Open the AtrisApp and acknowledge the warning about securing your phone on the start screen. Proceed to find your healthcare provider.

3. Log in using the account associated with the linked sensor.

4. If applicable, pair the sensor with the Patient Activity Monitor (PAM). Follow the instructions for linking a Fitbit and click 'volgende.'

5. Copy your account credentials and open the Fitbit App. Paste the credentials and log in, as depicted in the screenshot.

6. Return to the Atris App and click 'volgende.' Review the provided instructions.

7. Switch back to the Fitbit App, access 'Account,' and choose '+ Set up a Device.'

8. Select 'Charge 5' from the list of available devices and proceed with the setup.

9. Accept the privacy conditions and set up the Fitbit device as per the instructions. Charge the device and click 'NEXT.'

10. Keep the charging Fitbit near your phone, select the displayed device, and input the number shown on the Fitbit into the app. Accept any prompts to connect Fitbit to your phone. Complete the setup process, skipping Fitbit Premium.

11. Swipe down in the Fitbit app to synchronize the device on the dashboard page.

12. Return to the AtrisApp and click 'Volgende.' Access the '...' (account page) and choose 'verander het dashboard.' Select 'active minuten (Fitbit)' and 'active minuten,' then synchronize by swiping down.

13. Confirm that the data is accurately displayed in the 'active minuten Fitbit' section.

To view Fitbit data as an HCP, perform the following steps:

1. Log into the Atris Patient Monitor using an HCP Account.

2. Scroll down to access Fitbit data.
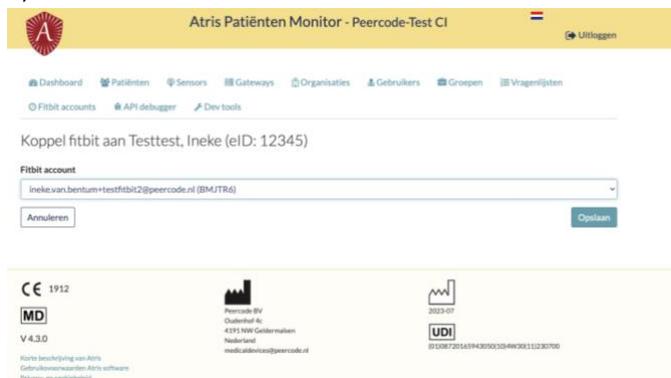
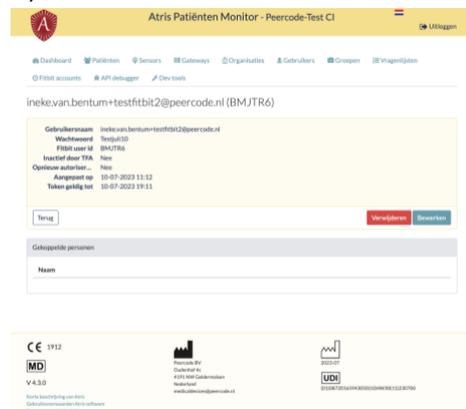3. Hover over the columns to view detailed information.
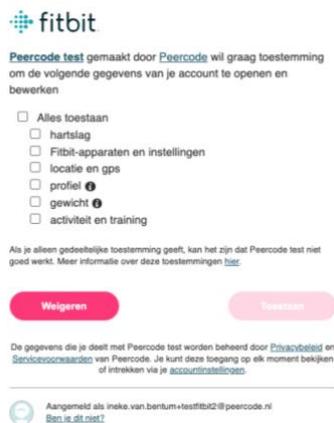
Figure 6: A) Permissions required for Atris to access the Fitbit Account. B/C) Linking a Fitbit to an Atris Account. More actions required if the Fitbit has been used by the previous patient to guarantee privacy. D) Screen indicating successful linking of a Fitbit Account to an Atris Account.

6.10.   Setting up Goals using Atris Patient Monitor

Atris Patient Monitor can be used to set up patient goals, which will be visible for the patient in AtrisApp or Atris Bigscreen. Navigate towards the patient detail page on Atris Patient Monitor and scroll down to 'doelen'. Here, goals can be set for the following parameters: Movement Minutes (Figure 7A), Regular Movement (Figure 7B), Protein Goals (Figure 7C).

The movement minutes provide the patient with an indication of how much they should move per day in minutes, based on 3 intensity levels (low, medium and high intensity). These intensity levels are measured while wearing the PAM sensor, and are calculated in MET scores. The patient will see these goals in the AtrisApp or Atris Bigscreen.

Regular movement provides the patient with an indication of how often they should move. Set the amount of MET and minutes the patient should move during a specific time interval, and set an optional time in which the patient is allowed to have a break. For an indication of which activity relates to an amount of MET, see table 1 below.

For the protein goal, a daily protein score can be set. The score is based on the 'EiFit' system. For more information, please see https://voedingenbeweging.nu/goed-eten-tijdens-ziekte-en-herstel/.

Figure 7: Setting patient goals.

TABLE 1: indication of MET values and associated activities.

Physical Activity Intensity	MET
Light intensity activities	**< 3**
sleeping	0.9
watching television	1
writing, desk work, typing	1.8
walking, 1.7 mph (2.7 km/h), level ground, strolling, very slow	2.3
walking, 2.5 mph (4 km/h)	2.9
Moderate intensity activities	**3 to <6**
yoga, Hatha	3
water aerobics, water calisthenics, water exercise	2.5
bicycling, stationary, 50 watts, very light effort	5.3
walking 3.0 mph (4.8 km/h)	3.3
calisthenics, home exercise, light or moderate effort, general	3.5
resistance training (weight) training, multiple exercises, 8-15 repetitions at varied resistance	3.5
calisthenics (e.g., push ups, sit ups, pull-ups, lunges), moderate effort	3.8
Pilates, general	3.8
walking 3.4 mph (5.5 km/h)	3.6
bicycling, <10 mph (16 km/h), leisure, to work or for pleasure	4
bicycling, stationary, 100 watts, light effort	5.5
Heavy intensity activities	**> 6**
jogging, general	7
calisthenics (e.g. pushups, sit-ups, pull-ups, jumping jacks), heavy, vigorous effort	8
running jogging, in place	8
rope jumping	10

Note: 1 MET = 1 kcal kg^{-1} hr^{-1} or 1 MET = 3.5 ml kg^1 min^1 of O_2

6.11.   Setting up Triggers using Atris Patient Monitor.

You can configure triggers to notify either you or your patient through the AtrisApp when specific situations arise. For instance, if a patient fails to meet their movement or protein intake goals, you can send them an in-app message to motivate or alert them. Before creating a trigger, ensure that you've already set goals for movement or protein intake.

To establish these goals, follow these steps:

1. Go to the patient detail page.
2. Scroll down to the 'alarmeringen' section and click 'Toevoegen' (Add).
3. First, choose a condition that needs to be met.
4. Next, specify whether the trigger should activate when a measurement falls outside, below, above a specific threshold, or when no measurements are received.
5. Enter the desired percentage of progress toward the pre-set goals and the required number of measurements for the trigger to activate.
6. Decide whether the notification should be sent to the Atris Patient Dashboard or directly to the patient.
7. If sending a message to the patient, compose the message they will receive in the AtrisApp.
8. Finally, click 'Save' to activate the trigger.

Here's an example of setting up a trigger:

Example Trigger: In the screenshots, you'll see how to set up a threshold. In this scenario, a notification will be sent to the patient if they achieve 50% or more of their movement goal for two consecutive days.

To address an alarm, follow these steps:

1. Navigate to 'alarmeringen' and select the relevant notification.
2. Enter your findings in the free typing field.
3. Click 'afhandelen' (Handle) to resolve the alarm.
4. To stop an alarm, simply select 'stop.'

7.   Troubleshooting Atris Q&A.

Q: Atris Patient Monitor, AtrisApp, AtrisCare, or Atris Bigscreen/Gateways do not work. What should I do?
A: Make sure to check, possibly in collaboration with the IT-department of your healthcare institute, that the devices running Atris software can connect to the internet. Internet connections are required at all times for Atris to function as intended. If the software still does not work as intended after confirming that the software have been correctly connected to the internet, and that your network is operational, you may contact the manufacturer via medicaldevices@peercode.nl or through support@atris.nl for support.

Q: What should I do if my patient cannot log into the AtrisApp?
A: Make sure that the patient has selected the correct healthcare institute during log-in in the AtrisApp. If that does not work, perform an in-app password reset by selecting 'wachtwoord vergeten' and request a new password. Still can't access the account? Revoke data sharing in Atris Patient Monitor, and re-invite the patient using the preferred mail address.

Q: What should I do if the PAM sensor does not connect to the AtrisApp, AtrisCare or Bigscreen?
A: The PAM needs to be shook to wake-up it up from stand-by mode. Try shaking it a bit more forcefully and try to connect again. If that does not work, try linking a different sensor to the patient by following the steps in section 6.6 and 6.7. The PAM battery might be running low, which can cause connection issues. Batteries of PAM V2 can be replaced.

Q: What should I do if the AtrisApp or AtrisCare does not synchronize health data?
A: Log-out of the app and log back in to see if function is restored. If that does not resolve the issue, check if you have the latest version of the app installed by navigating to the Google Play Store or Apple App Store.

Q: I tried to reset my Atris Patient Monitor Password but did not receive an e-mail, what should I do?
A: Try requesting the password reset again and make sure you entered the correct mail address. Make sure to check the SPAM folder of your mailbox.

Q: For how many days does the PAM store data?
A: For about 7 days. If your patient is very active, recommend that they read it out more frequently using the AtrisApp or Bigscreen to make sure that data is not lost.

Q: I got a new phone and lost access to my 2FA code for Atris Patient Monitor, what now?
A: Ask an Atris Administrator at the hospital or clinic to reset your 2FA code. Next time you log in, you are able to reset it.

Q: The Bigscreen is not reading out PAM sensors of patients, is there anything I can do to improve its function?
A: Ask IT to move the Bigscreen to a location with less interference or with better Wifi/cellular reception. It is also possible to attach a stronger Bluetooth antenna or LAN cable to the Bigscreen.

Q: The amount of recorded exercise from the PAM differs from the data shown by a smartwatch, such as the Fitbit, why is that?
Sensor Placement: The exact placement of sensors on the body can impact the data they collect. For example, if two people wear fitness trackers on different wrists or positions on the body, they may record slightly different motion patterns or physiological signals, leading to variations in the data.
Sensor Quality: The quality and accuracy of sensors can vary widely. Cheaper or lower-quality sensors may produce less accurate data compared to more advanced or expensive ones. Sensor calibration and manufacturing processes can also affect accuracy.
Sensor Technology: Different sensors use varying technologies to measure activity. For example, some may rely on accelerometers to detect motion, while others may use gyroscopes, heart rate monitors, or GPS. These technologies can have inherent limitations and biases.

Q: My Bluetooth heartrate sensor or Bluetooth scale does not connect to the AtrisApp, which devices are supported?
A: The following CE-certified devices have been verified for use with AtrisApp: iHealth Wireless Blood Pressure Monitor (model BP3L), Polar H10 of de Garmin HRM-DUAL, iHealth Wireless Scale Lina.