



**SmartView  
Connect**

Your remote monitoring system  
with **SmartView Connect™ App Mobile**

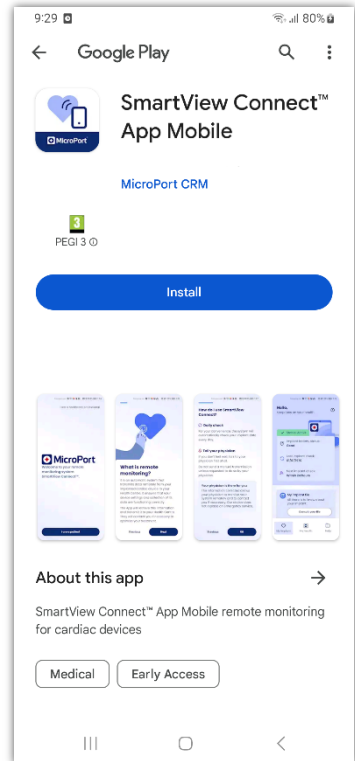
Quick Start and  
User Manual



## Quick start

### Step 1: Scan the QR code to download the app

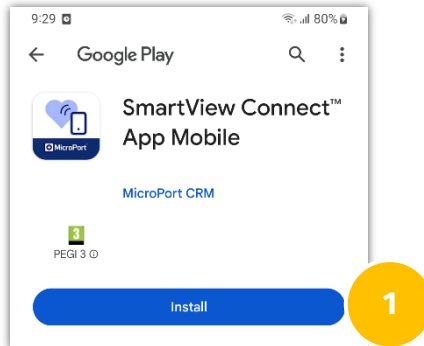
- Scan the QR code using your phone's camera to open the SmartView Connect™ App page on the Play Store.



MicroPort Technical Support  
Toll-free number **0800 026 0213 (UK)**  
**1 800 832 675 (Ireland)**  
**1 800 10 0816 (Australia)**

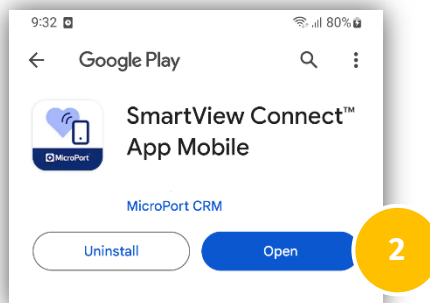
## Step 2: Check compatibility and download

- Tap “**Install**” to check that your mobile is compatible and download the app (1).



If you see “**Your mobile is not compatible with this version**”, please contact your doctor.

- Tap “**Open**” to launch the app (2).

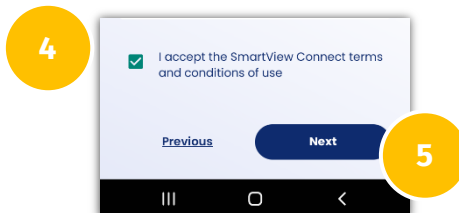


### Step 3: Installing the app

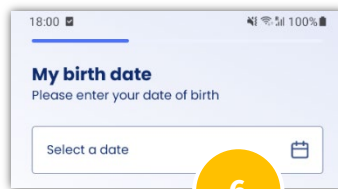
- Tap “I am a patient” (3)



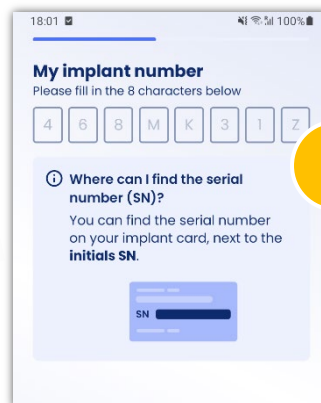
- Accept the terms and conditions of use by clicking the checkbox at the bottom of the page (4)
- Tap “Next” to continue (5)



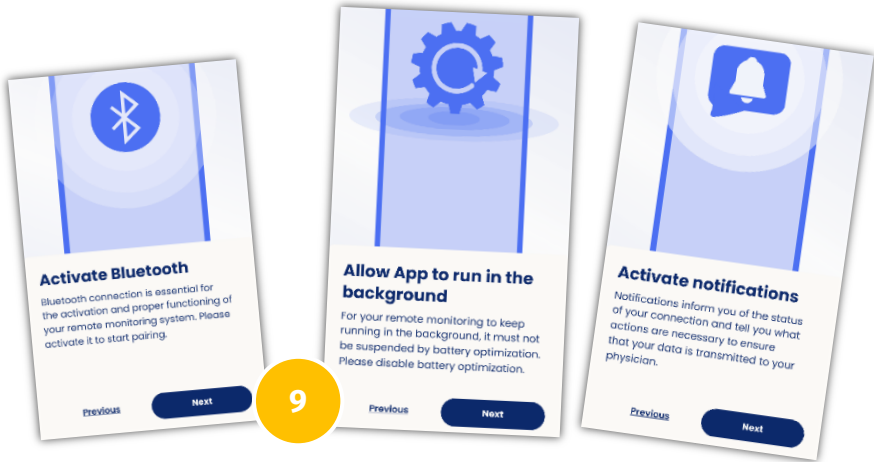
- Fill in your date of birth by clicking “Select a date” (6)



- Have your implant card ready (7)
- Type on the displayed keyboard the characters (8) of your serial number, one by one, from left to right, as they appear on the implanted cardiac device card that your doctor has given you to fill in your implant's serial number



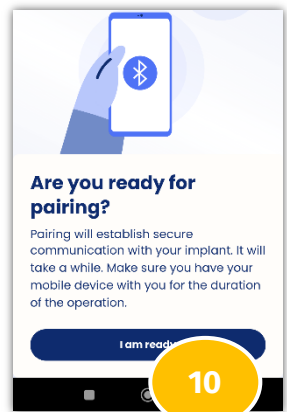
- Authorize the app to use Bluetooth, location (Android 11), background running, notifications (from Android 13) and auto start (Not on Samsung). Tap “**Next**” (9) and follow the instructions.



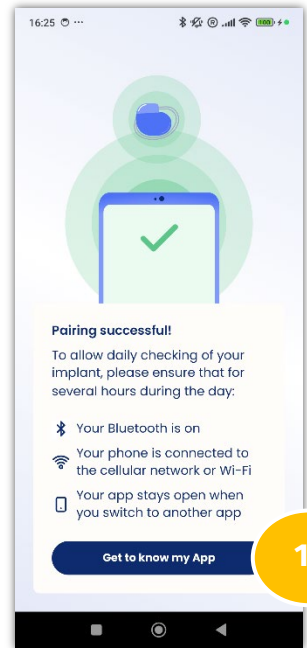
## Step 4: Pairing with your implant

- Tap “**I am ready**” to begin pairing (10)
- This operation takes a little time. Make sure your mobile device is charged and keep it with you until pairing is complete.

Keep your mobile between 15 cm and a maximum of 2 meters from your implant. The app will also access the network during pairing. The network must be available.



- On Samsung phones, keep the app open on the screen throughout the pairing operation
- When you see the “**Pairing successful!**” screen, the app has exchanged data with your implant and has been able to transmit the data to your doctor.
- Tap “**Get to know my app**” (11).



Your app is now running in the background. Do not quit the app.

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# I. Introduction

## Remote monitoring

You have been implanted with a cardiac device to treat your heart rhythm problem. People with an implantable cardiac device must continue to take their treatment as instructed by their doctor and have their implant checked regularly.

Your doctor has prescribed remote monitoring of your implant with the **SmartView Connect™ App**: called “app” in the rest of this document. This app makes it possible to check your implant’s settings. This app is part of MicroPort’s **SmartView™** remote monitoring system.



## SmartView Connect

The app that runs on your mobile is designed to **communicate with your cardiac device** and **transmit the information collected** to your remote monitoring center **on a regular, scheduled basis**.

In addition to scheduled transmissions, your app will check that your implanted cardiac device is functioning normally **every day**. To do this, your app uses Bluetooth to communicate with your implant and if necessary, use your mobile data or Wi-Fi to transmit the data.

The information collected will be available **to your doctor** on the SmartView™ remote monitoring system website.

A wide range of information is collected during **transmissions**, enabling your doctor to check the proper functioning of your implant, including the battery life and status of the leads that connect your implanted cardiac device to your heart. Your doctor can also determine if your heart has been beating regularly.

## Confidentiality and Cybersecurity

The data collected on your implant is sent to a secure MicroPort data server. During transfer, the data is protected and can only be read on the server.

Access to your personal data is restricted to your doctor and the clinicians managing your care. Limited access is also allowed to the technical teams responsible for proper functioning of the monitoring service.

## Cybersecurity residual risks

At MicroPort CRM®, the security of MicroPort® CRM's medical devices is a major concern. All actions to ensure the highest cybersecurity level of the SmartView Connect App Mobile has been taken. Despite all applied counter measures, the residual risk of patient data leak or compromise of Application integrity still exists.

## Data protection

MicroPort commits to taking all necessary security measures to protect your clinical data and in particular, to strictly restrict access to such data. For any information regarding the processing of your personal data, please refer to the information and patient consent that you have signed with your physician who is the data controller.

## II. Configuration and first step

### Configuration of your mobile

#### **Storage space**

To enable the app to send the data, always make sure you have 50 MB of storage space available on your mobile.



This storage space is needed for temporary data or updates.

Depending on your mobile's model and configuration, you may receive an alert when the storage space is full.

#### **Clock setting**

To ensure that data exchanged between the app and the SmartView™ system are correctly time-stamped, you need to set your mobile phone's clock to automatic.



Please keep the default clock settings: “[Set time zone automatically](#)”.

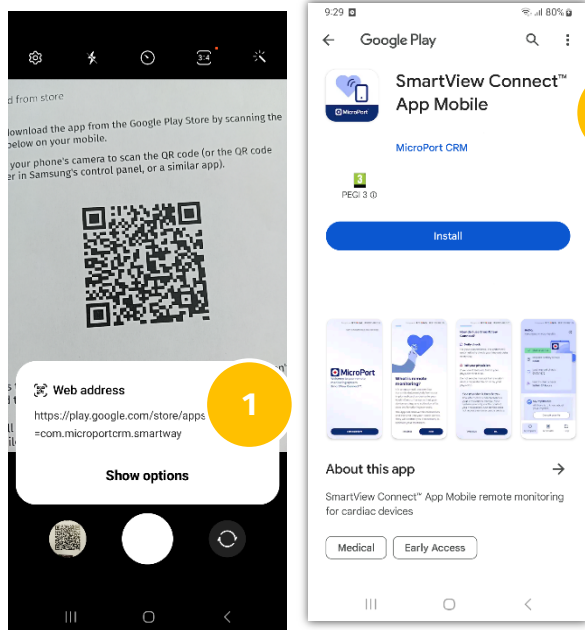
## Download from store

You can download the app from the Google Play Store by scanning the QR code below on your mobile.

- Start your phone's camera to scan the QR code (or the QR code reader in the control panel on Samsung or a similar app).

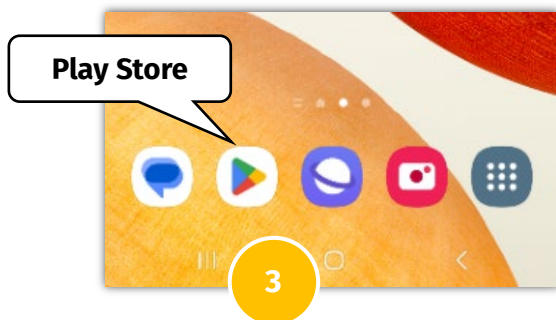


- Tap on the Play Store link displayed in the camera (1) (you don't need to take the photo).
- The Play Store opens on the SmartView Connect™. App (2) page.



You can also start the Play Store directly from your mobile's screen:

- Tap on your mobile's Play Store icon (3).
- Search for SmartView Connect™ App MicroPort® in the Play Store.



To start installation:

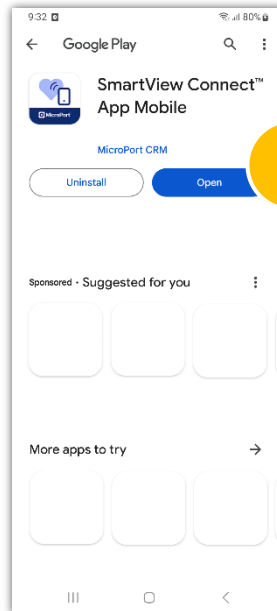
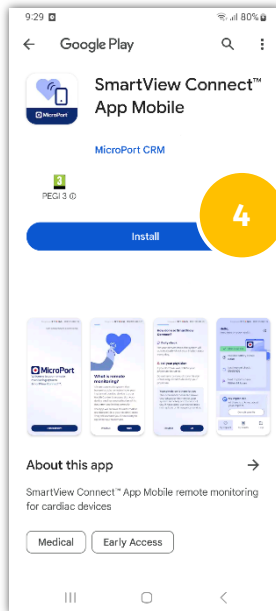
- On the app page, tap “Install” (4).



If your mobile is not compatible, you will see the message “Your mobile is not compatible with this version”.

Please contact your doctor about other remote monitoring options.

- When the app is downloaded (this may take several minutes), tap “Open” (5).



## Starting the app and pairing

Your app needs to be configured the first time you use it so that it links to your implant and automatically recognizes the implant any time after that.

This step is called **pairing**. The support team at your center will be able to help you if you have any problems.

You need to have the implant card your doctor gave you at hand, as it shows the implanted cardiac device serial number.



To start using the app, tap “**I am a patient**” (1).

You will be guided through the entire start-up phase. You can watch video tutorials to help you get started and use the app: Tap on “**Display video tutorials**” to open your Web browser (2)

If you are accompanied by a healthcare professional who is helping you to get started with your app, he or she can tap “**I am a healthcare professional**” at the top of the screen (3).

This will enable you to move faster past certain information screens.

On all start-up screens, follow the instructions and proceed using the blue buttons at the bottom of the screen.

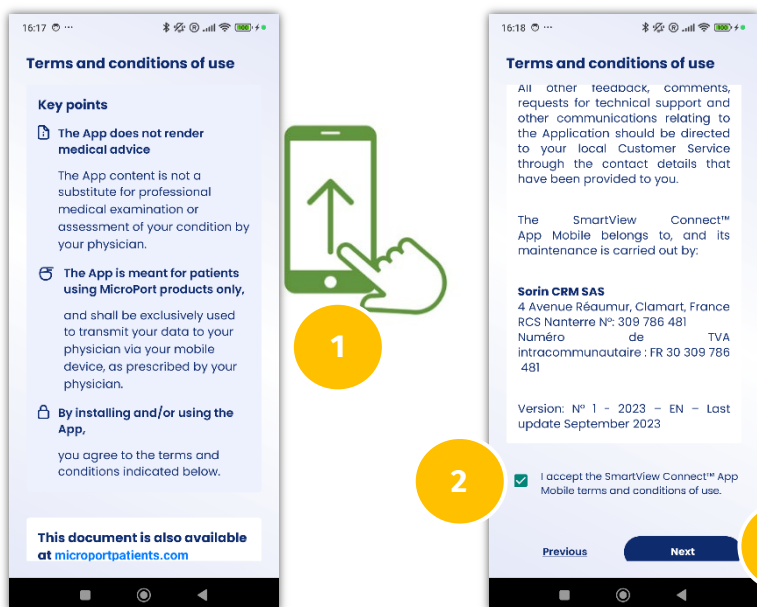


## Terms and conditions of use

You must accept the terms and conditions of use when using the app for the first time. Three key points are shown at the top of the page. To read the text, scroll the screen by **moving your finger upwards** (1) as shown below.

If you want to read the terms and conditions of use in detail, they can be accessed at any time in your app's **"Help"** menu; see chapter V Information about your app

At the bottom of the page, tap the **"I accept the SmartView Connect terms and conditions of use"** checkbox (2), then tap **"Next"** (3).



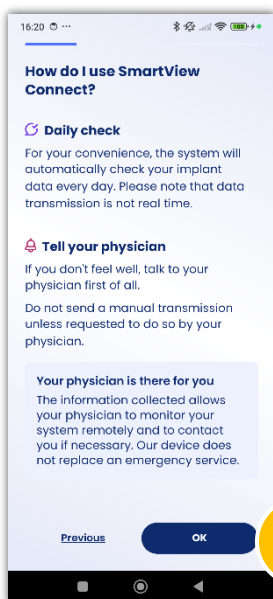
If you want to print the terms and conditions of use, they are also available at [microportpatients.com](https://microportpatients.com).

## Remote monitoring

The following screens provide information on the functioning of your remote monitoring system.

Tap “**Next**” to proceed (1).

Tap “**OK**” to go to the next step (2).



## My birth date

To confirm that it is you, we will check that your date of birth is the one recorded in the SmartView™ monitoring system.

To fill in your date of birth, tap **“Select a date”** (1).

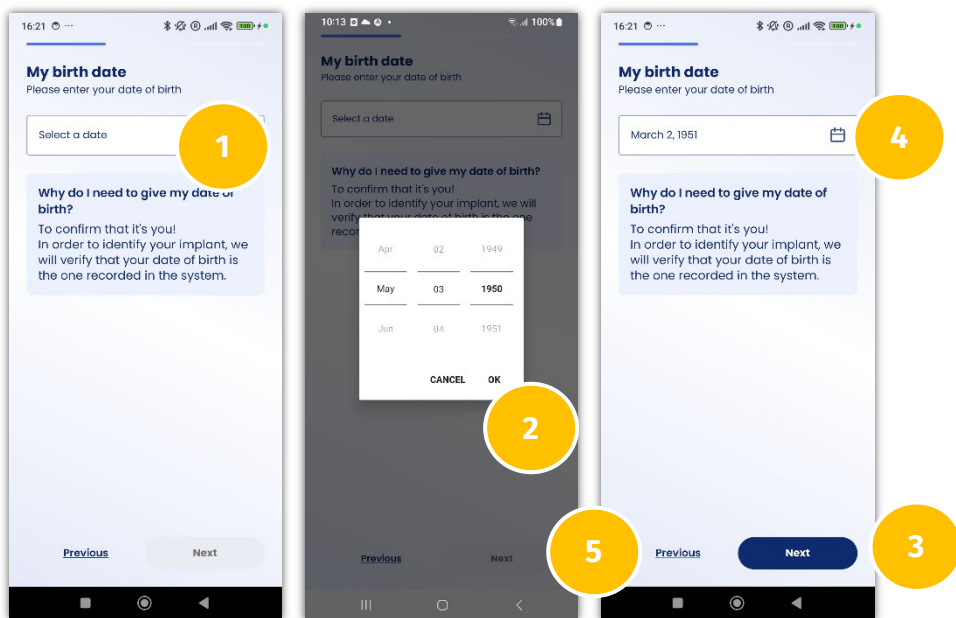
The date selection screen appears.

Scroll and select the day, month and year with your finger and tap **“OK”** (2).

Tap **“Next”** to continue (3).

If the date displayed on the screen is incorrect, you can make the selection again by clicking the date (4)

To go back and see previous screens, tap **“Previous”** (5).



## My implant number

Your implant number is used to identify you in the SmartView™ remote monitoring system.

Take your implant identification card

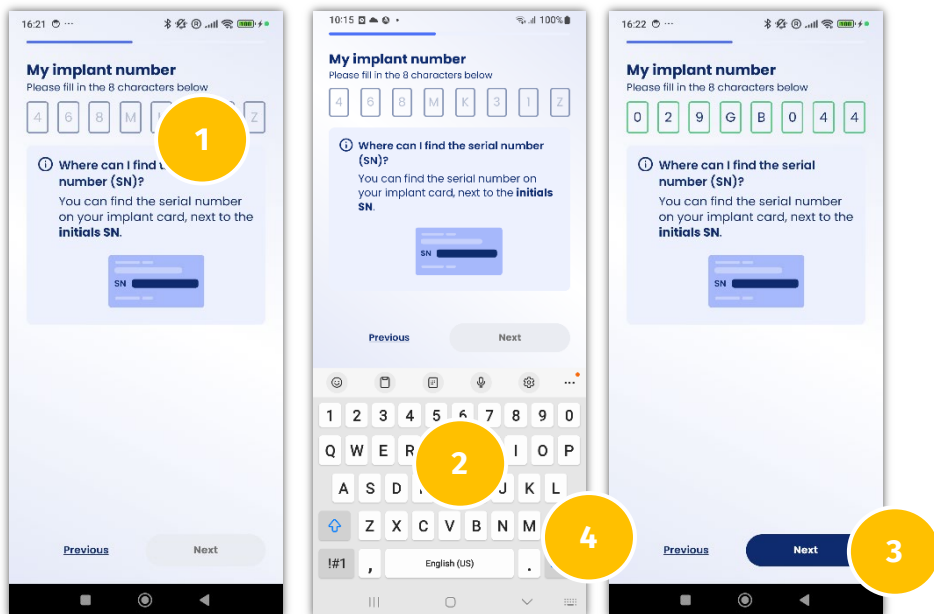
Tap on the number and letter boxes below ‘My implant number’ on the screen (1). The number selection keyboard displays (2).

Type on the displayed keyboard the eight characters of your serial number: three digits, two letters and three digits or letters (2).

If you type the wrong digit when filling in your implant number, you can go back by clicking the delete button, or by clicking on the number and letter boxes below ‘My implant number’ again (1).



Tap “Next” to continue (3) or “Previous” to check the previous steps (4).



## Activations and permissions

Your mobile controls the activation of features such as Bluetooth and the permission for apps to access them.

For SmartView Connect™ to work properly, the following features are required, as well as permissions for the app to use them:

- Bluetooth to communicate with your implant.
- Location on Android 11 only, as it is required for Bluetooth on this Android version.
- Notifications to inform you of your connectivity status for remote monitoring from Android 13. In earlier versions, notifications did not require user permission.
- Background execution to enable Bluetooth use while your phone is in standby mode.
- Autostart on all brands except Samsung, to allow the automatic restart of the App in the background after restarting your phone

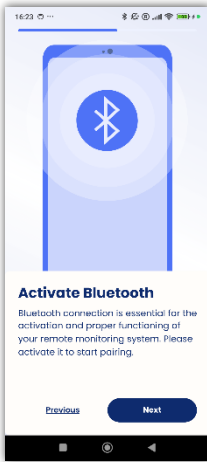
Each of those permissions will be asked, and dedicated screens will appear to guide you and allow you to authorize access to Bluetooth, location, notifications, background execution and auto start.



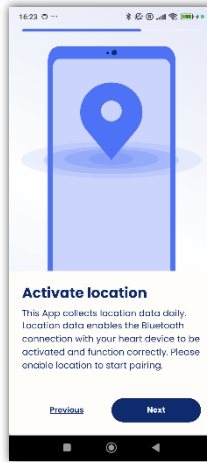
Depending on the brand of your mobile, different screens may be displayed to activate permissions.

The words used in these screens, like “Authorize” or “Allow” may differ. The shape, color and possible options of the screens for your mobile may be different from the screens shown in this chapter.

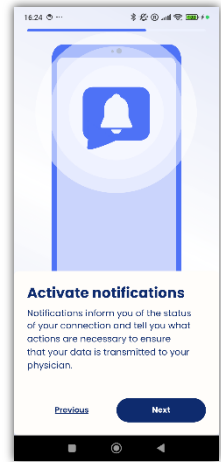
After several attempts to activate permissions, some of the Android screens triggered by the app may no longer appear (in this case, your Android phone is blocking the screens). Please be aware that authorizing permissions is always possible via the app [Settings](#) on your mobile.



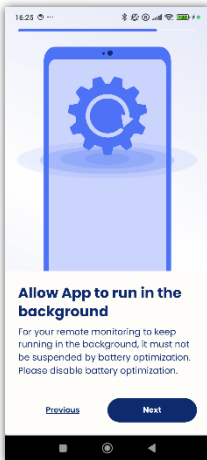
All Android versions



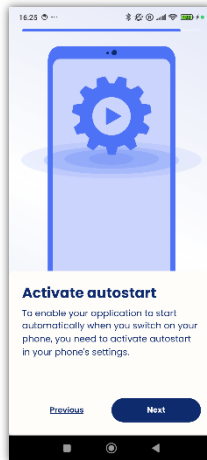
Android 11 only



Android 13 and up



All Android versions



Not on Samsung

## Activate Bluetooth

Tap “**Next**” to activate Bluetooth.

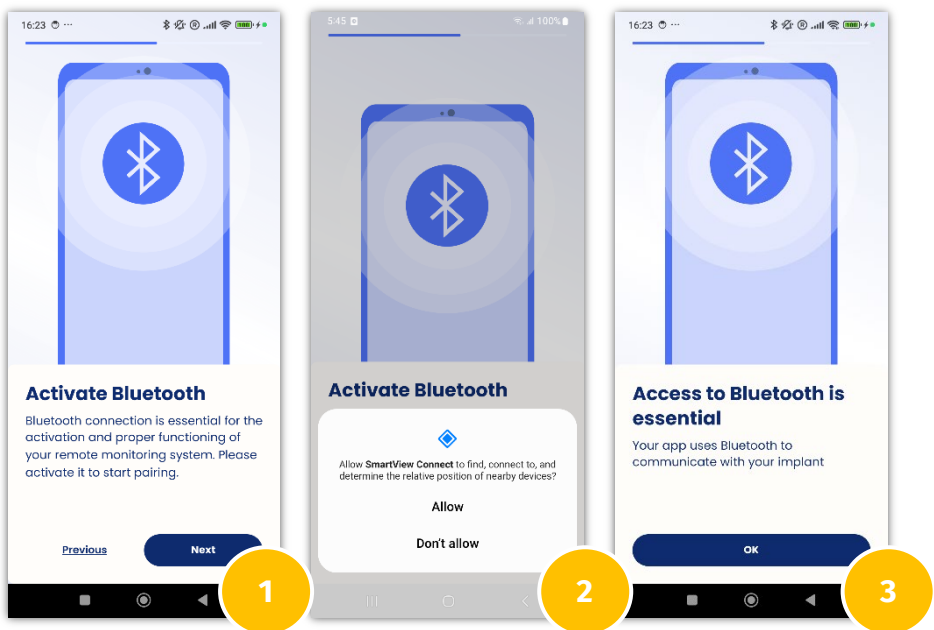
The permission window displays (display depends on your mobile) (1)

Tap “**Allow**” or “**Authorize**” or the maximum range possible option (2).

If you refused, or Bluetooth access is too restricted, the following screen appears: “**Access to Bluetooth is essential**”.

Tap “**OK**” to proceed with Bluetooth authorization (3).

Bluetooth must always be activated.

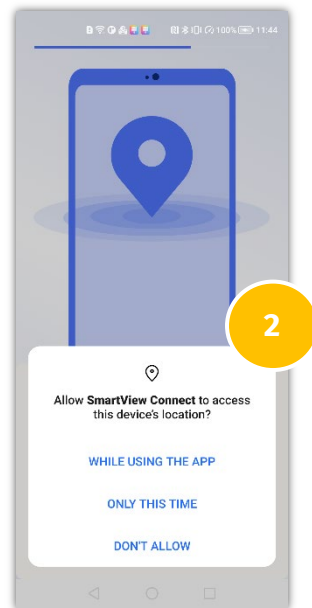
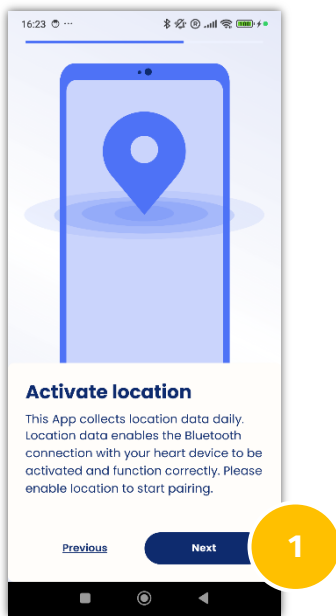


## Activate location

If your mobile is running Android 11, location must be activated to use Bluetooth. This is a technical requirement for using Bluetooth. For phones with Android 12 or higher, this requirement is not necessary.

Tap “**Next**” to activate location (1).

The permission window appears (display depends on your phone). Tap on the maximum range option available to you (2).





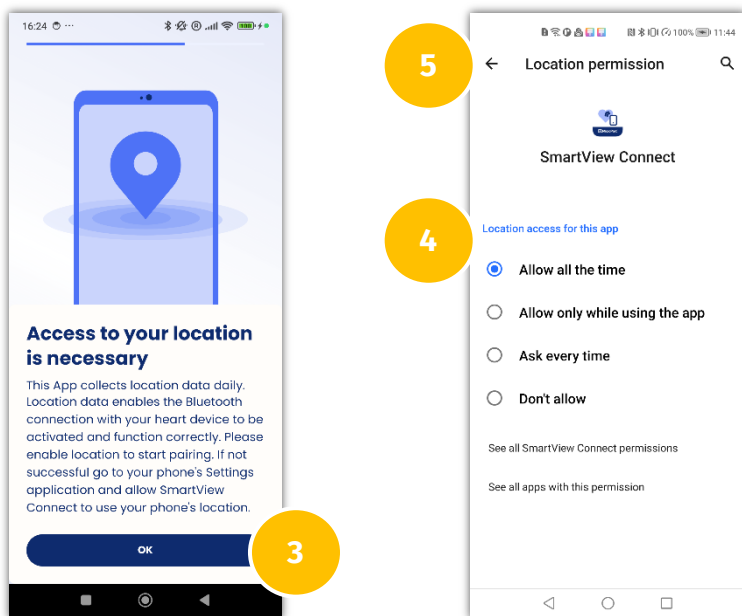
If you refused or the access is too restricted, the following screen displays: **“Access to your location is necessary”**. Tap **“OK”** (3).

Depending on your mobile model, the app’s location settings screen may appear when permissions are too restricted.

Tap **“Allow all the time”** or the maximum range option available to you (4).

Tap the arrow at the top left of the screen to continue (5). This will take you back to the **“Activate location screen”** shown previously.

Tap **“Next”** to continue.



App location settings screen

## Activate notifications

Your app cannot function without notifications because it runs in the background. If your phone is on Android 13 or higher, you must authorize notifications.

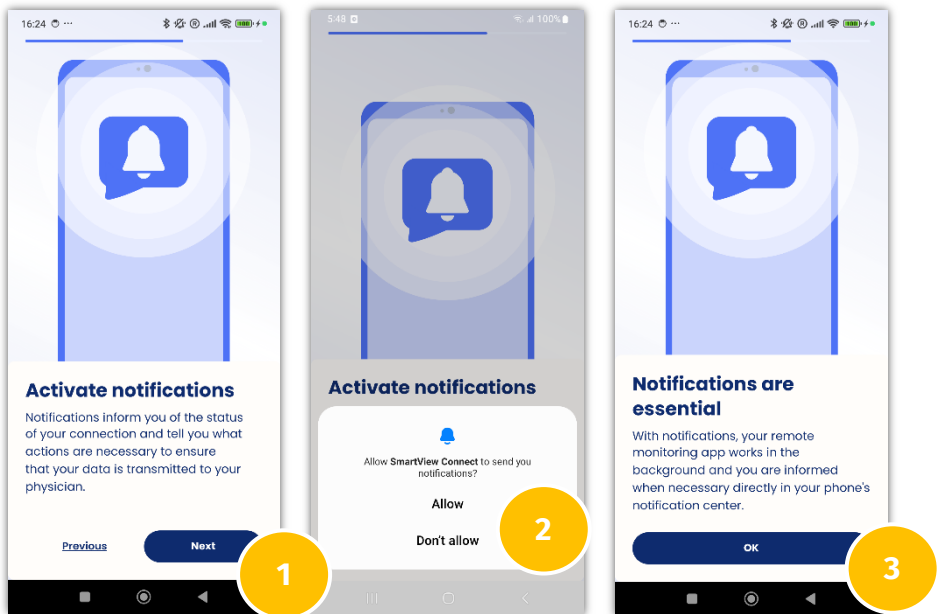
To begin activation, tap **“Next”** (1).

Tap **“Allow”** or **“Authorize”** or the maximum range option available to you (2).

If you refused or if the notifications are too restricted, the following screen displays: **“Notifications are essential”**.

Tap **“OK”** to come back to the **“Activate notifications”** screen (3).

Tap **“Next”** to continue (1).



## Activate background execution

For your remote monitoring to keep running in the background, it must not be suspended by battery optimization.

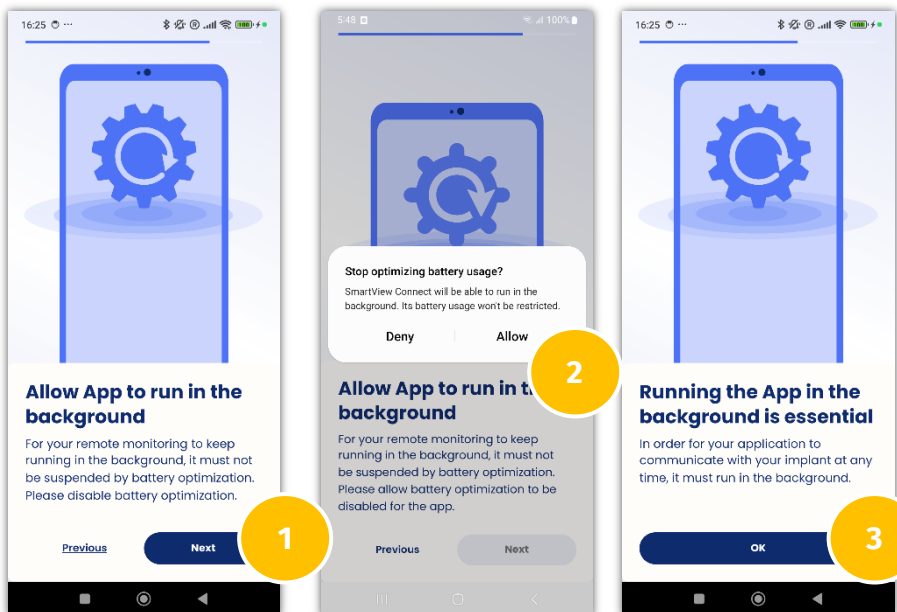
To begin activation, tap **“Next”** (1).

Tap **“Allow”** or **“Authorize”** or the maximum range option available to you (2).

If you refused or the permissions are too restricted, the following screen displays: **“Running the App in the background is essential”**.

Tap **“OK”** to come back to the **“Allow App to run in the background”** screen (3).

Tap **“Next”** to continue (1).



## Activate autostart

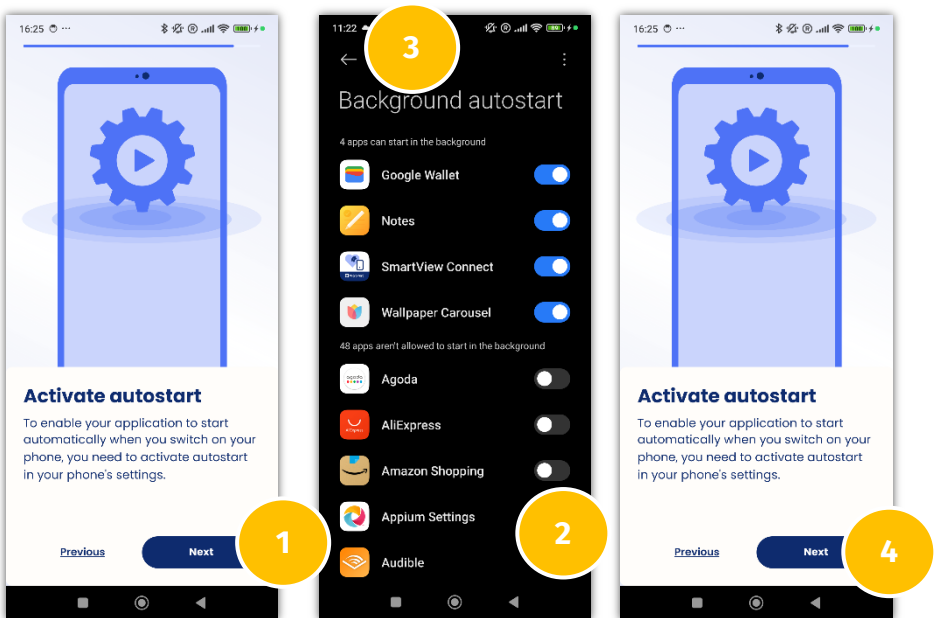
Depending on your phone brand, you may need to allow the App to restart after you've rebooted your phone. This activation is not needed on Samsung. When the App is allowed to restart automatically, it will restart checking your cardiac device daily even if you don't open the App.

To allow autostart, tap **"Next"** (1).

The **"Background autostart"** screen appears. Its presentation will depend on your telephone brand. Scroll down to locate **"SmartView Connect™"** in the list, then toggle the switch (2) to allow autostart. The App will move to the list on top.

Tap the arrow on the top left of the screen to come back in the application (3).

Tap **"Next"** to continue (4).



## Start pairing

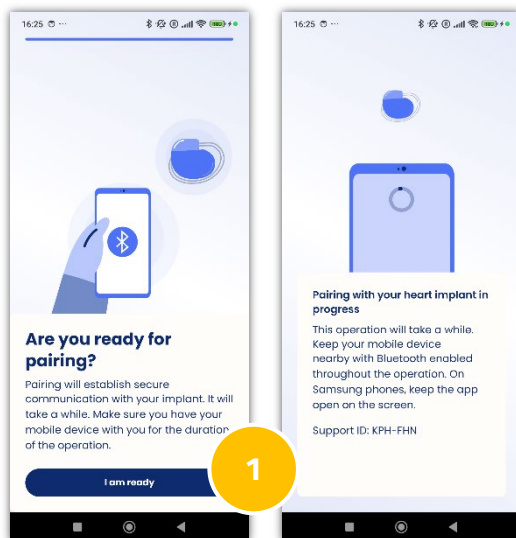
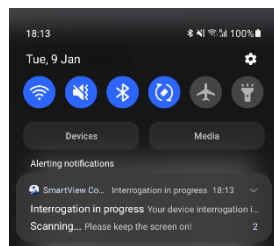
Pairing can now begin! Keep your mobile nearby so that the app can communicate with your implant. The mobile must be between 15 cm and a maximum of 2 meters from your implant. The app will also access the network during pairing. The network must be available.

Tap “**I am ready**” to begin pairing (1).

This operation takes a while.

Typically this takes an hour, but it may be quicker or longer.

You will receive a notification at the start of pairing to confirm that pairing with your implant is in progress.





**For Samsung phones**, keep the app open on the screen for the duration of pairing.

If you answer a phone call during pairing, please return to the app after your call.

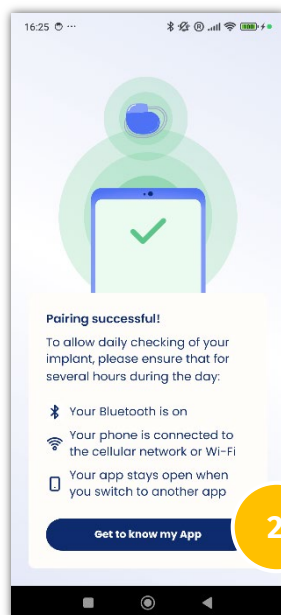
Keep the app open on the screen during pairing.

When pairing is complete, the “**Pairing successful!**” screen appears and you will receive a notification that pairing has been completed.



Your app will send you notifications to inform you or alert you when action on your part is required

Tap “**Get to know my app**” to go to the main app screen (2).



Pairing is a one-off operation. Once pairing is complete, each time you open the app you will go straight to your home screen.

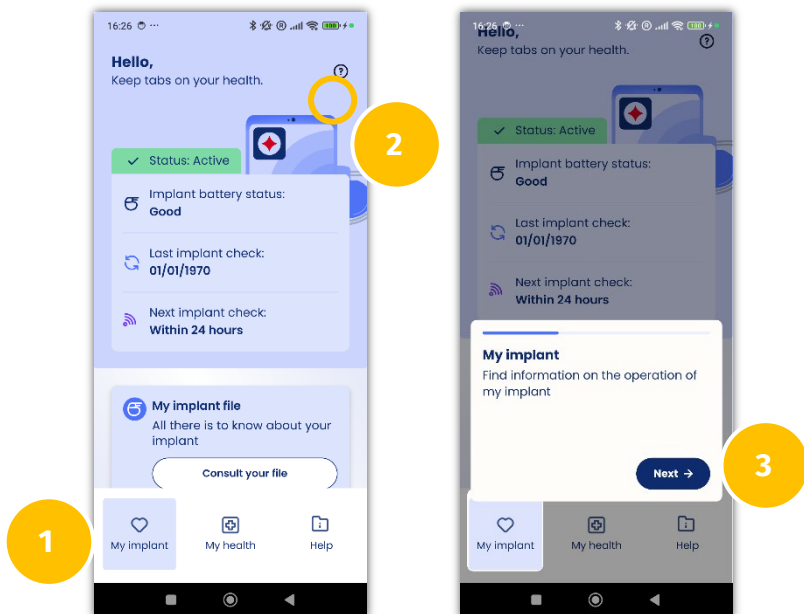
See chapter III **Daily life**

## Discovering your app

From the home page you can access all the app's menus.

To navigate to other menus, tap one of the buttons at the bottom of the app screen (1).

To get more information about the app screens, tap the **question mark** icon (2) at the top right of the display.



Each part of the screen is highlighted with a description. In all screens where you see the **question mark** icon (2), you can get more information about each screen.

- Tap the **question mark** icon (2) to get more information about each screen.
- Tap “**Next**” to find out more (3)
- Tap “**Finish**” on the last screen.

### III. Daily life

#### Every day

Once your app has been downloaded and installed, it will run in the background: the app will connect to your implant every day to check it.



Please remember to open the app when you switch on your phone.

For the app to be able to check your implant every day, you must keep your mobile close to you for a few hours during the day, the mobile must be switched on, Bluetooth must be enabled and the network must be available.



The mobile must be between 15 cm and a maximum of 2 meters from your implant.

Remember that if you have Bluetooth active, if the network is activated on your mobile at night and if your mobile is not too far from you, the check can be done at night too.

#### My home screen

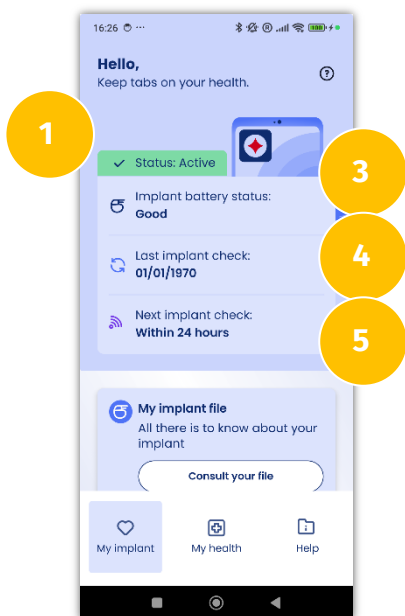
The “**My implant**” screen is designed to give you an overview of your monitoring at a glance.

The upper part is your dashboard which shows:

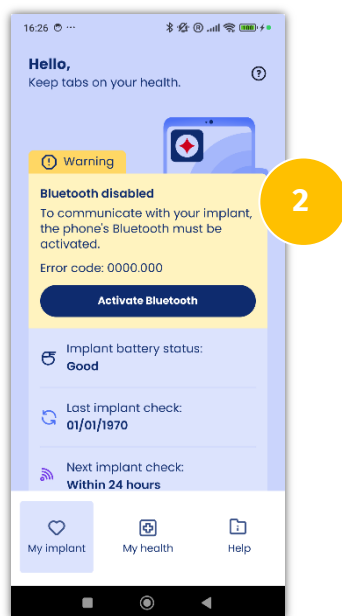
- Your connectivity status. When the status is “Active” with a green background, your app is working normally (1). Otherwise, information on a yellow background tells you what to do (2). In case of error, see chapter VI [Problems and solutions](#).
- My implant battery status (3).



- The last implant check, which will be today's date if everything is working well, or the day before date if the check has not yet taken place, otherwise an earlier date of last communication with your cardiac implant (4).
- The next check, which will always be the next day (5).



Your home screen when everything is working well



Your home screen when there is an error.  
Example: Bluetooth is disabled



The information you see in the app is information that is always available to your doctor in MicroPort's **SmartView™** remote monitoring system. You never have to tell your doctor about the information you see in the app.

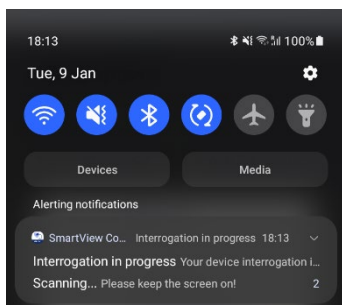
## Notifications

Your app sends notifications to keep in touch with you whenever it runs in the background.

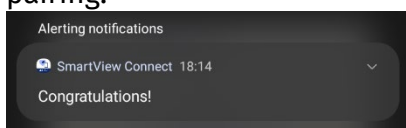
These notifications will show you the status of interrogations in progress, as well as alerting you to the error situations described in chapter VI Problems and solutions [in case of error](#).

If you tap on a notification, the app will open and you will see more details about your connectivity status and any errors on the home screen.

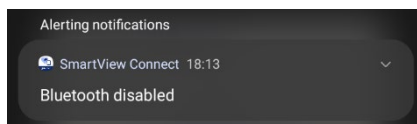
Some examples of notifications:



When you have started pairing.



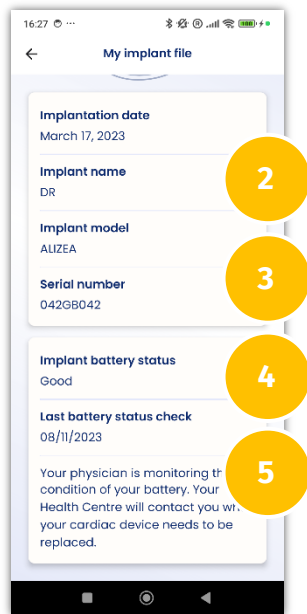
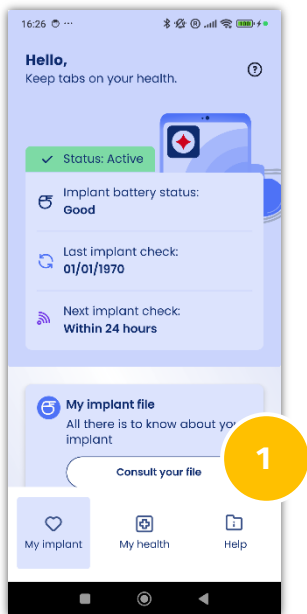
When pairing or manual transmission is complete.



When Bluetooth is disabled.  
Tap on the notification to open the app and see the instructions.

## Information about my device

Tap “**Consult your file**” (1) to display information about your implant.



In this screen, you will find the model of your implant (3) and the date it was implanted (2).

The battery status indicates whether your implant needs changing (4).

The date on which the battery was last checked is shown (5).

## Possible battery statuses:

- The status is “**Good**” as long as the estimated battery charge is more than one year.
- The status is “**Last year**” when the estimated battery charge is less than one year. Your monitoring team will contact you to arrange for your implant to be changed.
- In some cases, the status may be “**Not available**” when the battery charge level cannot be evaluated or the status has not yet been retrieved. This may take several minutes after pairing.



Your doctor is responsible for monitoring your device and will contact you when necessary.

## When I change my mobile

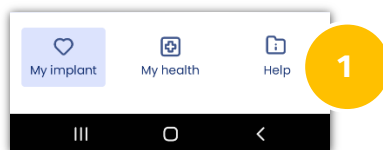
If you change mobile, please contact your doctor or MicroPort technical support to stop pairing with your old mobile.

On your new mobile, follow the instructions in Chapter II Configuration and first step to download and install the app again.

## IV. My health

### My transmissions

Tap the **My health** option at the bottom of the screen (1).



Every time your app sends data to your doctor, the data is exchanged through a **transmission**.



To send a **transmission**, your app will communicate with your implant and collect its data. The data collected is then sent to the SmartView™ remote monitoring platform for consultation by your doctor and his or her team.

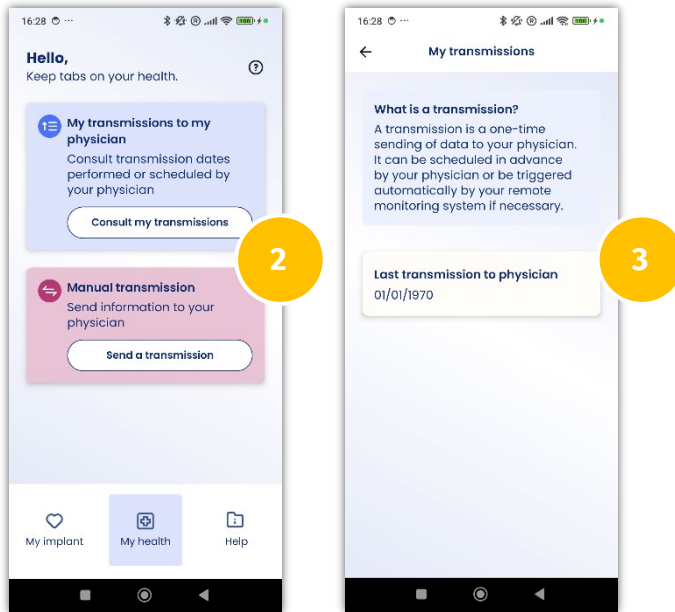
Your doctor can schedule transmissions for your monitoring. For example: every 6 months. These transmissions are sent automatically by the app.

In addition to scheduled transmissions, your app will check that your implanted cardiac device is functioning normally every day. This automatic check does not necessarily result in a **transmission**, but your monitoring team will know that your implant has been checked.

You can view the date and time of the last transmission and date of the next transmission in the app.

To view transmission dates:

Tap “[Consult my transmissions](#)” to bring up the “[My transmissions](#)” screen (2).



During a data transmission, all your implant’s data is sent to MicroPort’s SmartView™ monitoring platform for your doctor to consult.

- Last transmission to doctor: date and time of last transmission (3).
- Next transmission to doctor if a date has been set for a next transmission by your doctor.

## Manual transmission

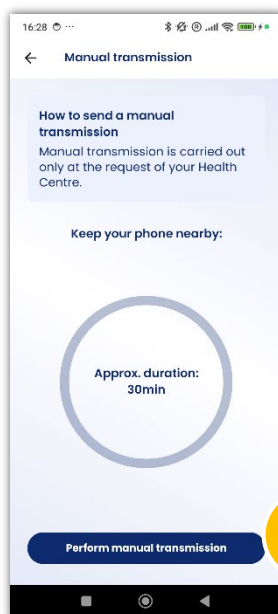
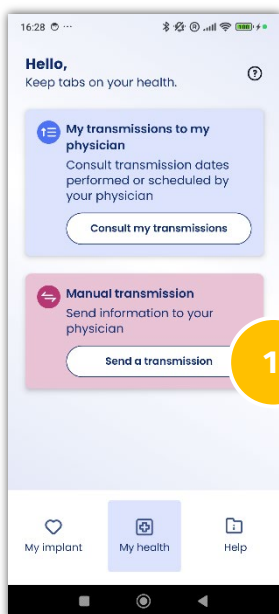
Although data transmission is fully automatic, in certain circumstances your doctor may ask you to start a transmission yourself. To do this, your doctor can authorize you to make a manual transmission



Remember: don't start a transmission on your own initiative unless your doctor has explicitly advised you to do so. If you don't feel well, the first step is to contact your doctor to describe your symptoms and receive the most appropriate indications.

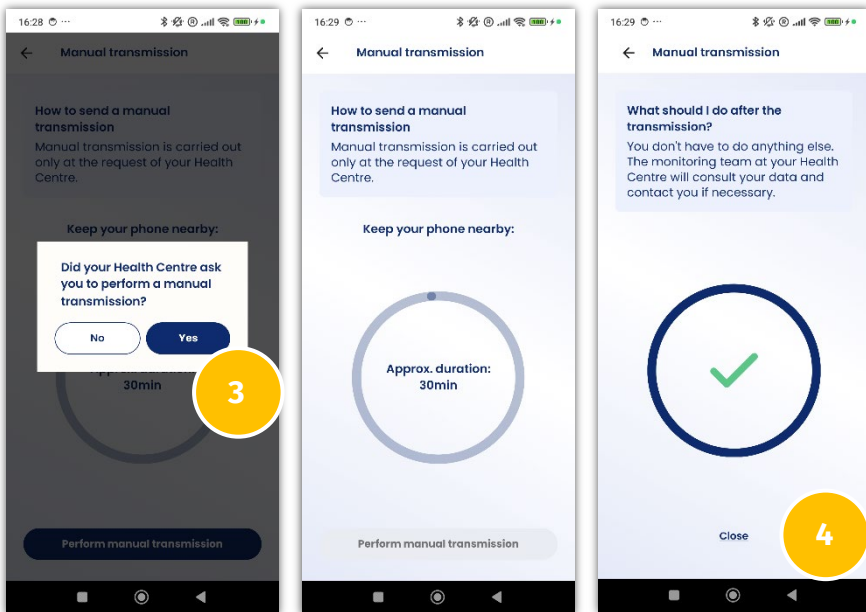
Tap “[Send a transmission](#)” to open the manual transmission screen (1).

Tap “[Perform manual transmission](#)” to start (2).



Tap “Yes” or “No” to answer the question: “Did your health center ask you to perform a manual transmission?” (3). If you tap “Yes” and are authorized by your doctor, manual transmission starts. If you tap “No”, you return to the “My health” menu.

Keep your mobile phone nearby for the duration of the transmission so that data can be retrieved through Bluetooth. The mobile must be between 15 cm and a maximum of 2 meters from your implant. The network and Bluetooth must be enabled for manual transmission. This operation takes a little time.

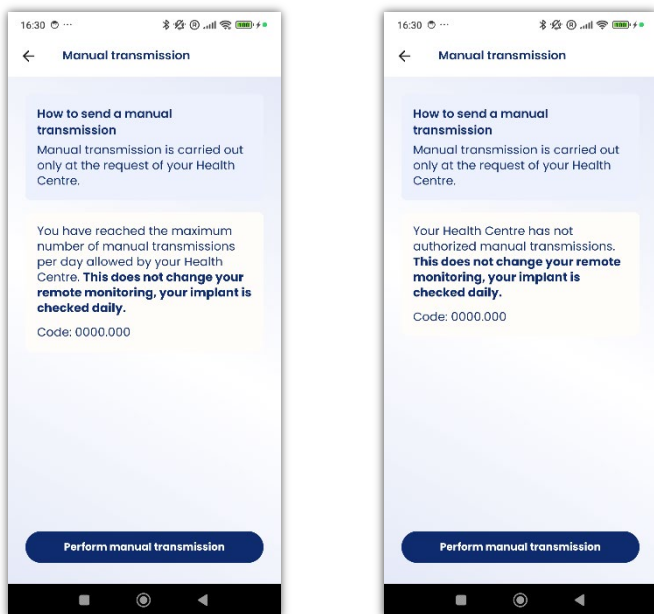


When data is transferred, they are available to your remote monitoring team on MicroPort’s SmartView™ platform. You can return to the menu by clicking “Close” (4).



During manual transmission, the following messages may appear:

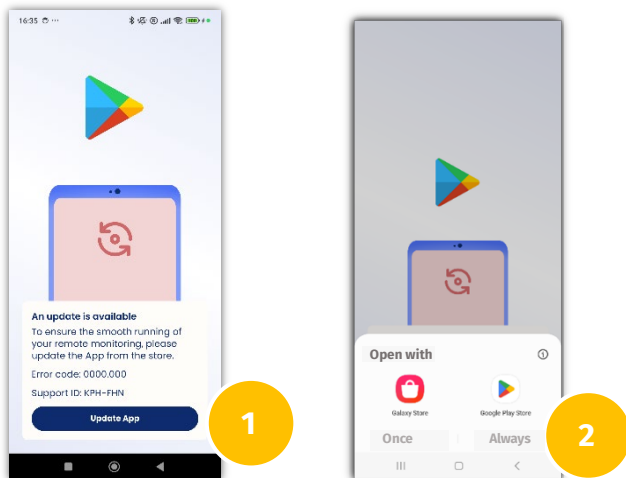
- “**You have reached the maximum number of transmissions**” when you have reached the defined transmissions limit per day (maximum one per day) or the maximum number of transmissions authorized by your doctor.
- “**Your center has not authorized manual transmissions**” when your center has chosen a monitoring policy for you that does not include manual transmission.



In the event of errors, see chapter VI Problems and solutions.

## App updates

When an app update is available, you will be notified with the screen shown below. The update will take place in the Play Store like for your other apps.



Tap “[Update App](#)” to start (1).

Depending on the brand of your phone, the following screen may be different.

Samsung example:

Tap “[Google Play Store](#)” and then “[Always](#)” to enter the store and make the update. (2)



To ensure continuity of your monitoring, we recommend that you install all updates.

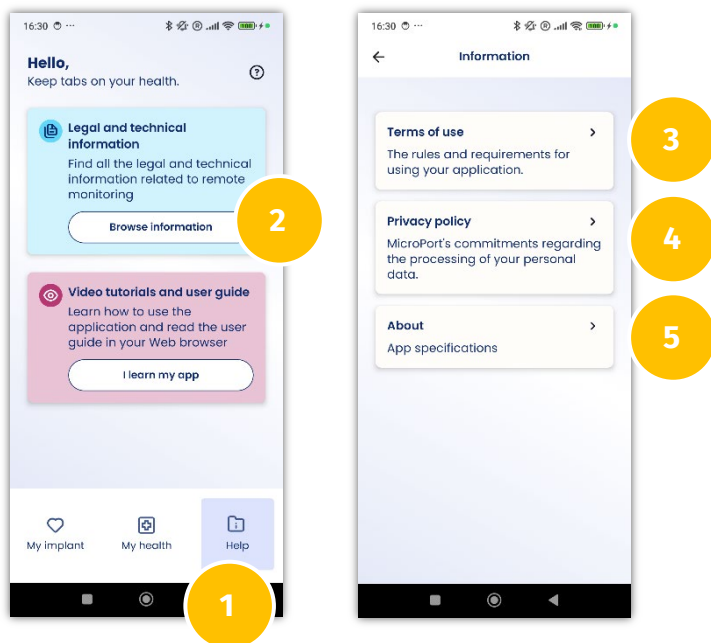
These updates may contain performance improvements for your tracking app.

Under no circumstances will updates lead to changes in the software of your implantable cardiac device. Only your doctor can change that software.

## V. Information about your app

Information about your app is available in the “**Help**” menu at the bottom of the screen (1)

Tap “**Browse information**” to display legal and technical documents (2).

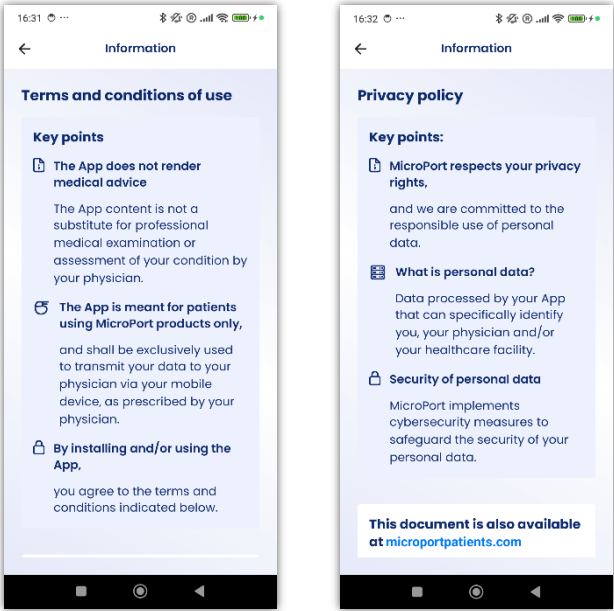


In this screen you can access the following information:

- Terms of use (3)
- MicroPort's privacy policy (4)
- The “**About**” screen to access the app's technical information and update the configuration (5).

# Terms of use and privacy policy

You can read the terms of use and privacy policy in the app or online at [microportpatients.com](https://microportpatients.com).



## Technical information

In the “**About**” screen, you will find technical information about your app.

You can also update the configuration of your app if MicroPort technical support asks you.

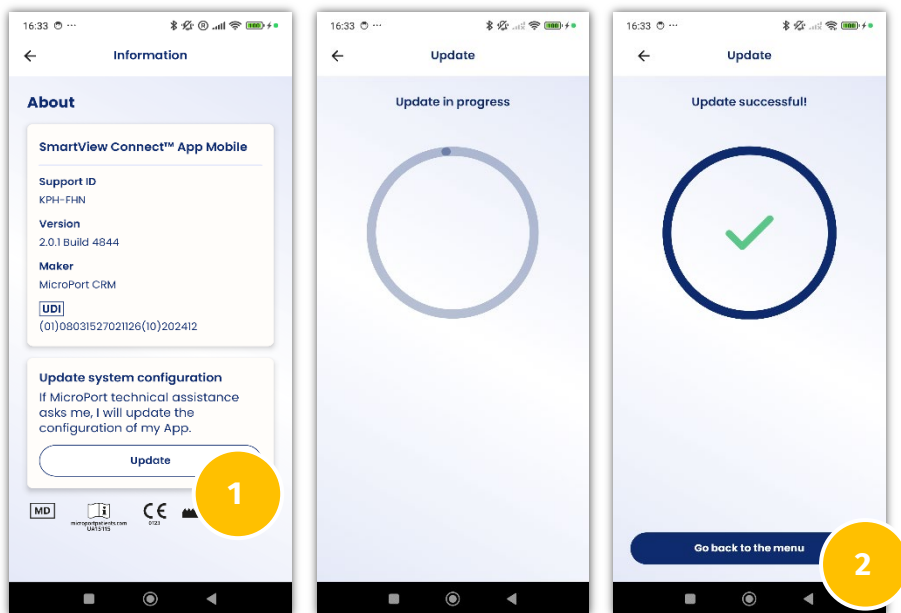
## Updating the configuration

The app’s configuration is updated automatically several times a day, although MicroPort® technical support may ask you to update the configuration during a telephone call to support.

Tap on “**Update**” to run the update, which will execute quickly (1).

In case of error, see chapter VI **Problems and solutions**.

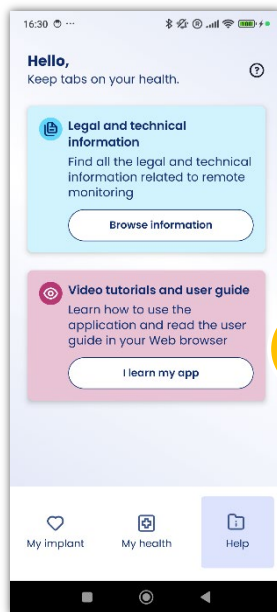
Tap “**Go back to the menu**” when the update is complete (2).



## Video tutorials and user guide

You can find video tutorials and this user guide on the Website [microportpatients.com](https://microportpatients.com). You can find printable versions of “Terms of Use” and the “Privacy Policy” on the Website as well.

Tap on “[I learn my app](#)” to open your Web browser (1) on [microportpatients.com](https://microportpatients.com).

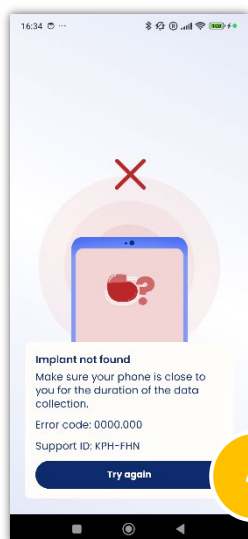
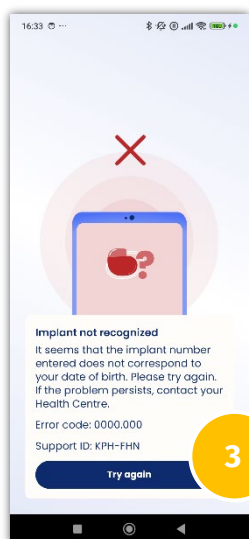
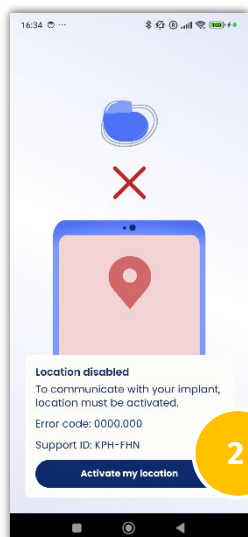
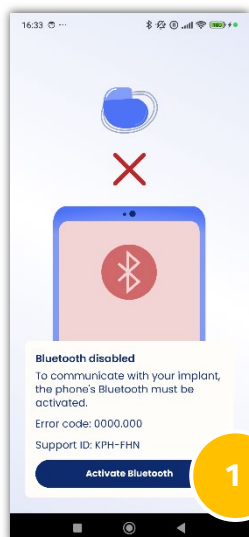


## VI. Problems and solutions

### Errors during pairing

During pairing, several errors may occur. These errors are shown opposite. In each case, if any action is required on your part, this is clearly shown on the screen and an action button (in blue) is available at the bottom of the screen.

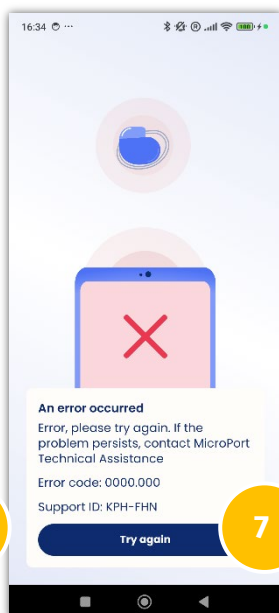
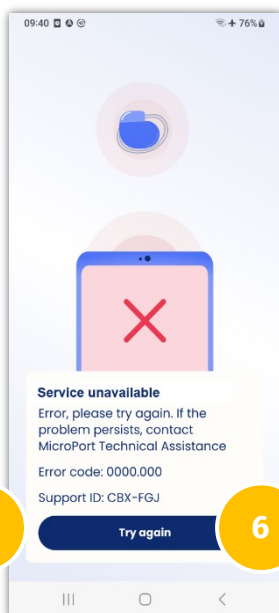
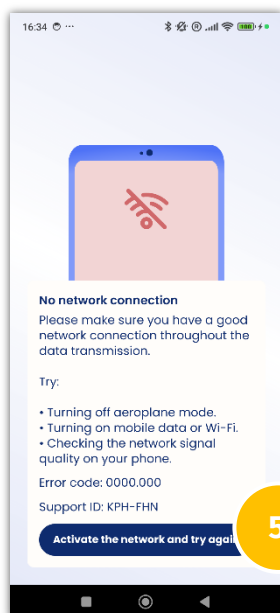
- **Bluetooth disabled:** When this error displays, the app cannot communicate via Bluetooth with your cardiac device. You need to activate Bluetooth on your mobile and/or Bluetooth for your app in the app **Settings** of your mobile. Tap **“Activate Bluetooth”** to display the Bluetooth activation screen (1).
- **Location disabled:** On Android 11 only. When this error displays, the app cannot access the location information needed to find nearby Bluetooth devices (your cardiac device). You need to activate location on your mobile and/or location for your app in the app **Settings** of your mobile. Tap on **“Activate my location”** to display the location activation screen (2).
- **Implant not recognized:** When this error displays, the app has not found your patient record in the SmartView™ remote monitoring system. Please retry filling in your date of birth or implant serial number again by clicking **“Try again”** (3). If the problem persists, contact your center to check that your patient record has been created and is correct.
- **Implant not found:** When this error displays, Bluetooth has not found your cardiac device. Make sure your phone is close to you so you can try again by clicking **“Try again”** (4). If the problem persists, contact your center.





You can also get the following errors, which are also shown opposite:

- **No network connection:** When this error displays, the network is not available to communicate with the MicroPort SmartView™ data server. Turn on mobile data or Wi-Fi so that the app can access the network and tap “**Activate the network and try again**” (5). If your network is correctly configured, it is possible that a problem on your operator’s network, independent of your mobile, may prevent communication.
- **Service temporarily unavailable:** When this error displays, your app cannot communicate with the MicroPort SmartView™ data server. The MicroPort servers may be temporarily unavailable or a network problem independent of your mobile or MicroPort may be preventing communication. Please try pairing again by clicking “**Try again**” (6). If the problem persists, please contact MicroPort technical support.
- **An error occurred:** When this error displays, an unexpected error has been encountered. However, you can still try to restart the pairing again by clicking “**Try again**” (7). If the problem persists, please contact MicroPort technical support.

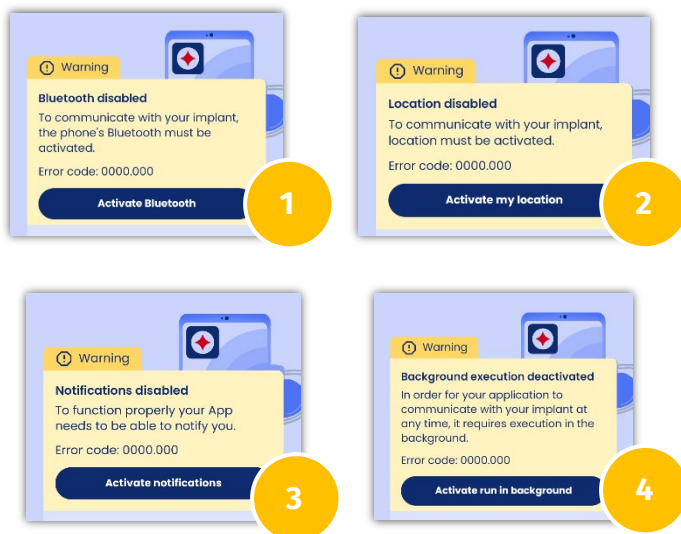


## Errors on my home screen

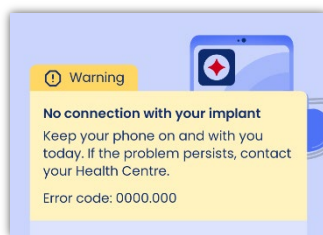
In daily life, many errors can occur with your remote monitoring system. They are displayed with an error message on your home screen.

In each case, if action on your part is required, this is explicitly indicated in the message and it may show a blue action button.

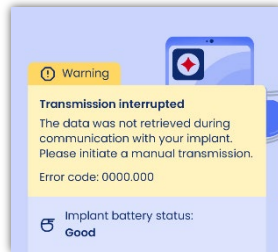
- **Bluetooth disabled:** When this error displays, the app cannot communicate via Bluetooth with your cardiac device. You need to activate Bluetooth on your mobile and/or Bluetooth for your app in the app **Settings** of your mobile. Tap “**Activate Bluetooth**” to display the Bluetooth activation screen (1). If necessary, tap the app **Settings** and go to the SmartView Connect permissions section.
- **Location disabled:** On Android 11 only. When this error displays, the app cannot access the location information needed to find nearby Bluetooth devices (your cardiac device). You need to activate location on your mobile and/or location for your app in the app **Settings** of your mobile. Tap “**Activate my location**” to display the location activation screen (2). If necessary, tap the app **Settings** and go to the SmartView Connect permissions section.
- **Notifications disabled:** From Android 13. When this error displays, the app is not authorized to send notifications. You need to activate notifications for your app in the app **Settings** of your mobile. Tap “**Activate notifications**” to display the notifications activation screen (3).
- **Background execution disabled:** This error displays when execution in the background is not activated. You need to activate run in background for your app in the app **Settings** of your mobile. Tap “**Activate run in background**” to display the background execution activation screen (4).



- **Communication failed:** When this error displays, Bluetooth has not found your cardiac device. Keep your mobile on and with you today so the app can connect with your implant. If the problem persists, contact your health center.

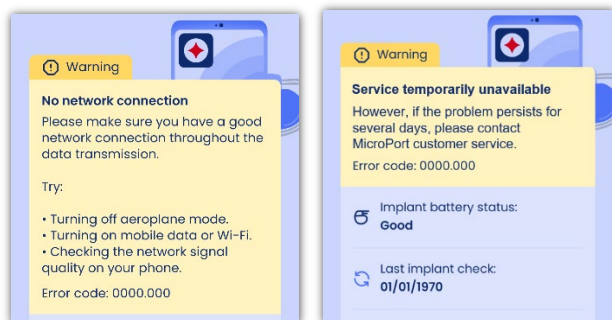


- **Transmission interrupted:** This error displays when several data transfers between your implant and the app were interrupted; for example, if you moved away from your mobile during the transfers. In this case, send a manual transmission as described in the section “**Manual transmission**”. This error is also resolved as soon as communications with your implant are re-established.



The following errors may also occur:

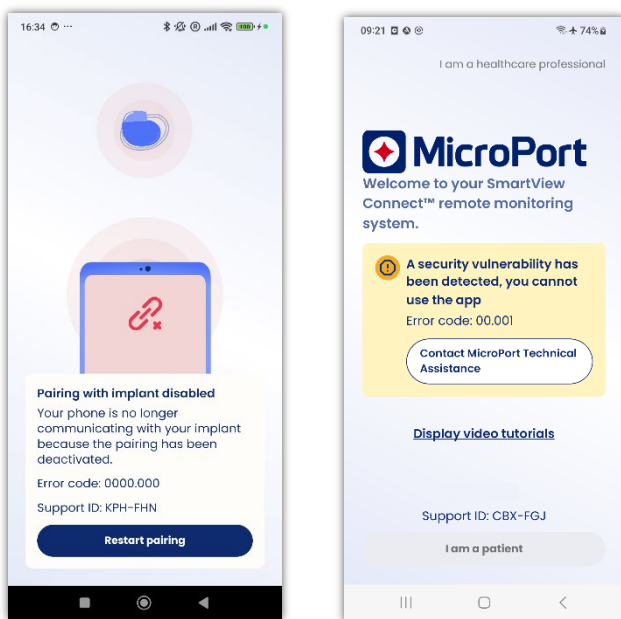
- **No network connection:** When this error displays, the network is not available to communicate with the MicroPort SmartView™ data server. Turn on mobile data or Wi-Fi so that the app can access the network. If your network is correctly configured, it is possible that a problem on your operator's network, independent of your mobile, may prevent communication.
- **Service temporarily unavailable:** When this error displays, your app cannot communicate with the MicroPort SmartView™ data server. The MicroPort servers may be temporarily unavailable or a network problem independent of your mobile or MicroPort may be preventing communication. If the problem persists, please contact MicroPort technical support.



## Exceptional errors on my home screen

The following errors may occur exceptionally:

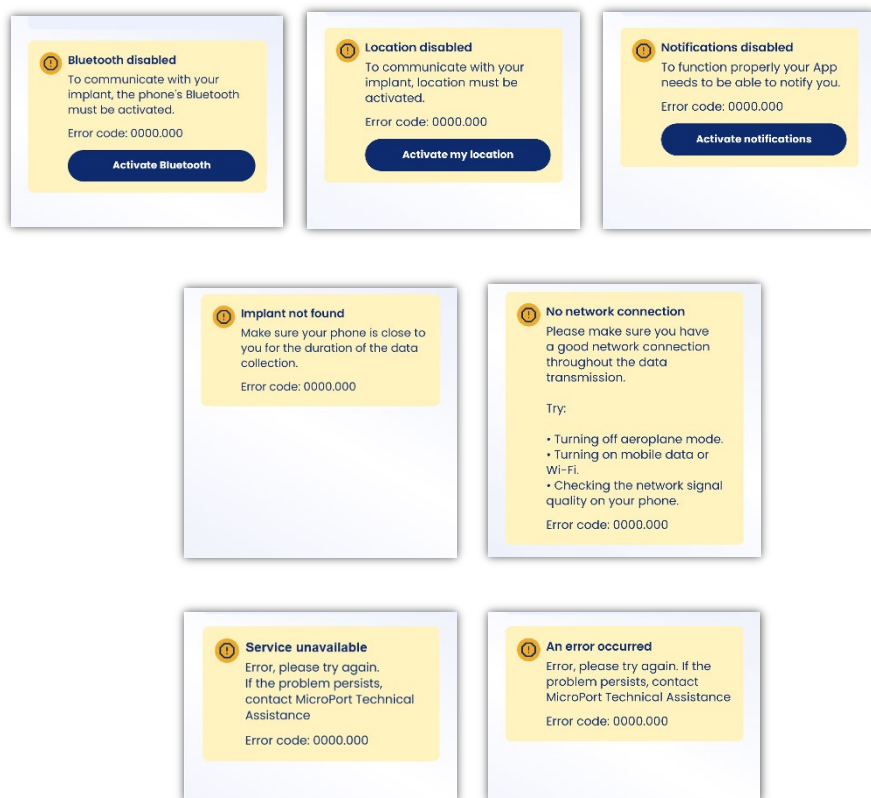
- **Pairing with implant disabled:** When this error displays, your cardiac device is no longer paired with your app on the SmartView™ remote tracking system. Clicking “[Restart pairing](#)” will take you to the screen where you can start the pairing process. See the chapter “[Starting the app and pairing](#)”.
- **A security vulnerability has been detected:** When this error displays, a security vulnerability has been detected in your phone and your data can no longer be transmitted securely. You cannot use the app on this phone. Contact MicroPort technical support by telephone to find out what to do.



## Errors during manual transmissions

During manual transmission, the same error messages as on your home screen may appear.

Refer to the previous paragraphs in this chapter to find out the cause of these errors.

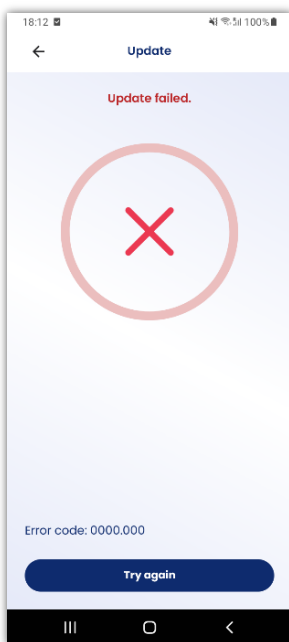




## Errors when updating my configuration

When updating your configuration, an error may occur. When this occurs, you can try again by clicking “[Try again](#)”. If the error persists, please return to the home screen by clicking the arrow at the top left of the screen, to check any error messages that are displayed.

See the “[Errors on my home screen](#)” paragraph.



## Unexpected Errors of your application

In rare cases, you may notice that the App is not responding, or not working as expected; for instance, when you notice repeated pairing errors, manual transmission errors, or any of the error messages.

In these cases, please quit the app and reopen the app.

If the problem persists, turn off your phone, turn it on and open the app again.

If the problem remains, please contact MicroPort CRM technical service.

## VII. Patient Information

### Intended purpose

The SmartView Connect™ App Mobile is a standalone software intended to:

- collect data from the BLE-enabled implanted cardiac device so that patients' heart rhythm data and diagnostic information can be retrieved,
- automatically and wirelessly transfer these data, on a periodic or events basis<sup>1</sup>, to MicroPort CRM's back-office data management system so that the SmartView™ Remote Monitoring Software (RMS) is able to make the information available to the physician, thereby ensuring patient management through the monitoring of patient status.

### Indication

The SmartView Connect™ App Mobile is indicated for the remote monitoring of patients who are implanted:

- with a compatible MicroPort pacemaker according to the applicable Medical Guidelines (2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay), or
- with a compatible MicroPort defibrillator according to the applicable Medical Guidelines (2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death).

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<sup>1</sup> The SmartView Connect™ App Mobile, designed by MicroPort® CRM, is fully automatic so does not require any specific patient interventions when working normally, in operational mode (periodic basis - scheduled transmission). A patient can, however, initiate a transfer of information manually (events basis – patients initiated transmission or PIT), if necessary (please note the application is not intended as an emergency response system).

The corresponding clinical conditions regarding pacemaker and defibrillator implantation are detailed hereafter.

**According to guidelines, a pacemaker is mainly indicated in the following conditions:**

Accepted patient conditions warranting chronic cardiac pacing include:

- Symptomatic paroxysmal or permanent second- or third-degree Atrioventricular (AV) block;
- Symptomatic bilateral bundle branch block;
- Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders;
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias;
- Vasovagal syndromes or hypersensitive carotid sinus syndromes.

Synchronous, atrioventricular pacing is indicated for patients who may benefit from maintenance of AV synchrony and for the treatment of conduction disorders that require restoration of both rates and which include:

- various degrees of AV block to maintain atrial contribution to cardiac output;
- VVI intolerance (e.g. pacemaker syndrome) in the presence of persistent sinus rhythm;
- low cardiac output or congestive heart failure secondary to bradycardia.

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in physical activity.

Guidelines on cardiac pacing are provided by the European Society of Cardiology (Glikson, M., et al., 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. Eur Heart J, 2021. 42(35): pp. 3427-3520.) and the American College of Cardiology and the American Heart Association (Epstein, A.E., et al., 2012, ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the

American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol, 2013. 61(3): p. e6-75.).

**According to guidelines, a defibrillator is indicated in:**

- Patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained Ventricular tachycardia (VT) after evaluation to define the cause of the event and to exclude any completely reversible causes.
- Patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.
- Patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study.
- Patients with reduced left ventricular ejection fraction LVEF due to prior myocardial infarction who are at least 40 days post-myocardial infarction and with symptomatic heart failure or left ventricle (LV) dysfunction.
- Patients with non-ischemic dilated cardiomyopathy and reduced LVEF with symptomatic heart failure.
- Patients with non-sustained VT due to prior myocardial infarction, reduced LVEF and inducible ventricular fibrillation or sustained VT at electrophysiological study.

**According to guidelines, a cardiac resynchronization therapy defibrillator is indicated in:**

- Patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes.
- Patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.
- Patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study.

- Patients with reduced LVEF due to prior myocardial infarction who are at least 40 days post-myocardial infarction and with symptomatic heart failure or LV dysfunction.
- Patients with non-ischemic dilated cardiomyopathy and reduced LVEF with symptomatic heart failure.
- Patients with non-sustained VT due to prior myocardial infarction, reduced LVEF and inducible ventricular fibrillation or sustained VT at electrophysiological study.

Biventricular pacing therapy is indicated in patients with symptomatic heart failure despite optimal pharmacological therapy, with reduced LVEF and wide QRS.

### Target population

The population targeted is the patient population for which the device is indicated excluding pediatric subjects.

### Intended user

The SmartView Connect™ App Mobile is intended to be used by any person who was prescribed for remote monitoring by and under the supervision of a physician.

The SmartView™ Remote Monitoring System, which contains the SmartView Connect™ App Mobile can be offered by physicians to patients that have been implanted with a MicroPort CRM Bluetooth® low energy-enabled implanted cardiac device according to medical guidelines.

No specific training is required by the patient to use the SmartView Connect™ App Mobile.

## Contraindications and/or limitations

No clinical contraindications to the use of SmartView Connect™ App Mobile are known.

No limitations to the use of SmartView Connect™ App Mobile are known.

**There is no expected side effect for the patient.**

## Intended clinical benefits

There is no direct clinical benefit of SmartView Connect™ App Mobile: this device is not claiming clinical benefit that can be specified through measurable, patient-relevant clinical outcome(s).

## Essential performance

The essential performance of the SmartView Connect™ App Mobile is to ensure data integrity when it transfers data from a compatible MicroPort CRM implanted cardiac device to the central data management system.

Any serious incident in relation to the app should be reported to the MicroPort CRM technical service.

The Summary of Safety and Clinical Performance (SSCP) will be available on <https://ec.europa.eu/tools/EUDAMED> after the launch of European Database on Medical Devices/Eudamed.

## Warnings and precautions



The SmartView™ remote monitoring system is not intended as an emergency response system.

If at any time you feel that you need a fast response, **CALL YOUR LOCAL MEDICAL EMERGENCY SERVICE IMMEDIATELY** and inform your physician.

The SmartView™ remote monitoring system is not intended to replace face-to-face follow-up with the physician.



## Precautions for proper operation

### **Interference**

The function of your mobile may be affected by other electrical appliances. Please avoid putting it near any electrical appliance that could emit interference.

### **Not too far away/not too close to you**

Your mobile must have a Bluetooth connection with your implanted cardiac device. It must not be too far away from the implant. However, we recommend not holding your mobile too close to the implant (due to the magnets it contains). The correct distance is between 15 cm and 2 meters.

### **Phone storage space**











To enable the app to send the data, always make sure you have 50 MB of storage space available on your mobile. This space is required for temporary data and updates.

## Setting the mobile clock

To ensure that data exchanged between the app and the SmartView™ system is correctly time-stamped, you need to set your mobile's clock to automatic.

Make sure you **set your mobile's clock** to automatic, keeping the default settings (Set time zone automatically).

## Explanation of symbols

General symbols	Explanation of symbols
	Consult instructions for use
	This symbol indicates that the SmartView Connect™ App Mobile is in full conformity with European MDR 2017/745
	Manufacturer
	Medical Device
	Batch code
	Unique Device Identifier
	Product serial number
	Catalog number
	Caution
	This icon is used to call your attention to a particularly important point.



**Video tutorials available on [microportpatients.com](https://microportpatients.com)**

**Manufactured in France  
by MicroPort CRM**



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