



USER GUIDE

femfit® Pelvic Floor Training Tool
Model JFF-003

PREAMBLE

The femfit® is a low-risk medical device. It is generally intuitive and easy to use. However, failure to use the femfit® and its components according to the information in this user manual may result in unintended harm. Users are encouraged to discuss the benefits and risks of using the femfit® with their healthcare professionals prior to using this device. If you experience injury or harm, seek medical attention immediately.

Indications, contraindications, warnings, precautions and other important user information can be found in this user guide and in the printed quick guide accompanying the femfit®.

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2 What is femfit®?

2.1 Introduction

femfit® is a smart, multiple-use, intra-vaginal medical device that has been developed by a team of bioengineers, physiotherapists, and urogynaecologists. It provides women with targeted exercises to strengthen their pelvic floor muscles, to help alleviate the symptom of urinary incontinence.

Urinary incontinence is a common complaint for many women. One in three women will experience involuntary leakage of urine at some stage of their lives. Leakage is most common when laughing, jumping, sneezing or even during some types of exercise. UI is particularly common in women who are pregnant, have given birth, who have a chronic cough are pre- or post-menopausal. This is often caused or made worse by weak pelvic floor muscles.

There is good evidence that effective and long-term pelvic floor muscle exercise can help prevent or treat the symptoms of urinary leakage and mild pelvic organ prolapse. The femfit® App allows real time biofeedback via smart-phone technology and the ability to track the improvement of your pelvic floor muscle function over time.

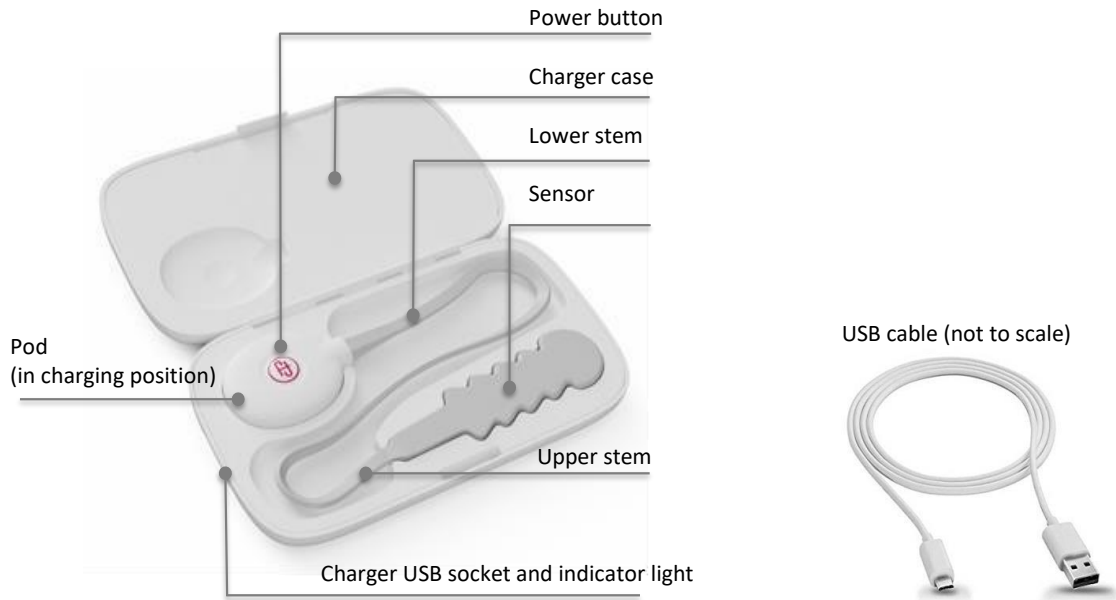
The femfit® is unique. It has multiple pressure sensors that measure both your pelvic floor pressure and your abdominal pressure at the same time, so you can differentiate between the two. This is important as you want the pressure from your pelvic floor muscles to be higher, or at least equal to, the pressure from your abdominal muscles, during a pelvic floor muscle contraction. Other devices on the market give no indication which muscles you are using or how effectively you are exercising them. The femfit® allows you to see that you are engaging the correct muscles as you contract them and adapt your technique until it is your pelvic floor, not your abdominals, doing the work.

Once you have mastered engaging the correct muscle group, there is strong scientific evidence that following a programme of pelvic floor muscle exercises, usually for twelve weeks, will significantly improve the ability of your pelvic floor muscles to work correctly. This is particularly important when your body is under load or a sudden pressure (e.g. when you sneeze or cough) as it decreases the chance of urinary leakage. It is wonderful if you are seeing a healthcare professional such as a physiotherapist or urogynaecologist, but you need to exercise – with the correct technique – five times a week. femfit® allows you to do this in the privacy of your own home at a time that suits you.

NOTE:

The pelvic floor muscle exercise programme, currently installed on the femfit® App, was developed and tested following individual pelvic floor muscle instruction from a trained pelvic floor physiotherapist. It relies on the user being able to contract their pelvic floor muscles correctly. If you are unable to visualize a pelvic floor muscle contraction using the femfit® as directed, please contact your clinician/physiotherapist.

©2004 Chantal Dumoulin, Pelvic floor muscle exercise programme: Université de Montréal. All rights reserved.



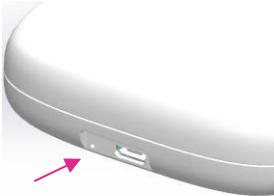
2.2 Components of your femfit®

femfit® model JFF-003	A type of perineometer. You use the device to measure your pelvic floor and abdominal pressures during exercise and track your progress as it gets stronger.
Sensor	The flexible array of sensors that measure your pressure data. This is the scalloped section that you insert into your vagina.
Pod	The device that powers the sensor and sends data to your femfit® App.
Stem - upper and lower	The extension of the sensor that connects to the pod.
Power button	The part of the pod that turns your femfit® device ON and OFF. It is located under the monogram.
Charger case	The container that securely stores and charges your femfit® device.
USB cable	The cable that charges your femfit® when it is connected to a USB power source. It is plugged into the charger case.

2.3 Pod light indicator status

Off	If the light is off, your femfit® is turned OFF, or the femfit® battery needs charging.	
On	A solid white light indicates that your femfit® is on but not connected to a smart device. Your femfit® will be broadcasting its Bluetooth ID.	
Blinking	A blinking white light indicates that your femfit® is ON and is connected to a smart device.	

2.4 Charger indicator light status

Off	If the light is off, no femfit® is detected by the charger. It may take up to 5 seconds for the charger to detect your device.	
On	A solid white light indicates that charging of your femfit® has completed.	
Blinking	A blinking white light indicates the charging of your femfit® is in progress.	

3 Safety statements

3.1 What is a safety statement?

A safety statement is a brief statement used to keep you and your femfit® safe while you are using the device. Below is a summary of the different types of safety statements you will see in this user guide.

Safety statement types	
Indications	Indications let you know who should use the femfit® and when they should use it.
Contraindications	Contraindications let you know when not to use the femfit®. If used in these situations, you may hurt yourself or damage the femfit®.
Warnings	Important hazard information. These describe circumstances to stay away from while using the system, their consequences, and how to avoid danger.
Precautions	Special steps you need to take while using the system to prevent minor or moderate injury to either you or the system.

3.2 femfit® system

Intended use

The femfit® is a perineometer designed to treat stress, mild-moderate urge, and mixed urinary incontinence in women, by strengthening of the pelvic floor muscles through exercise. This device provides biofeedback via smartphone technology.

Location of use

Home or healthcare clinic.

Contraindications

- Do not use if you are under the age of 18.
- Do not use if you are pregnant, less than 6 weeks after having your baby, and/or still have vaginal bleeding.
- Do not use if you have severe pelvic organ prolapse.
- Do not use if you have a vaginal infection.
- Do not use if you have a vaginal pessary ring.
- Do not use if you are currently menstruating or spotting

Warnings

- Do not use your femfit® if the pressure feedback of one or more sensors is behaving erratically as the feedback is no longer reliable.

3.3 femfit® device

Warnings

- The femfit® sensor is a delicate component, handle with care.
- Do not share your femfit®. It is a single-user device.
- Do not soak your femfit® in any liquid. Immersion may damage the silicone.
- Do not expose your femfit® to direct sunlight for an extended period of time.
- If you experience redness or swelling near the insertion area, stop using your femfit® and contact a qualified medical professional.
- If your femfit® is damaged, inhaling or swallowing small parts could be a choking hazard.
- The USB Cable and stem of your femfit® could be strangulation hazards.
- Do not wash your femfit® with abrasive materials, bleach, or harsh chemicals, only clean it with mild, unscented soap and by rubbing with your fingers.
- Do not use your femfit® in the bathtub, shower, or pool. Your femfit® is not designed to be used underwater.
- Only store your femfit® in the provided charger case.

- Only use your Charger case to charge your femfit® device. Do not attempt to use any other type of charger.
- Always fully dry your femfit® with paper towels before storing it in its charger case.
- Keep your femfit® out of children's reach as the device is considered to be a choking hazard if it is bitten or swallowed.
- Do not modify or perform any maintenance on your femfit®.
- Do not put your femfit® in the washing machine, dishwasher or microwave.
- Do not use air hand dryers or other heated/high pressure devices to dry your femfit®.
- If there is a tear on the silicone of the stem/sensor, your femfit® is no longer safe to use.
- Do not get the pod wet or allow condensation to accumulate around the pod.
- If the silicone membranes of the sensor swell or the sensor is ruptured or inflated, do not use your femfit®. It is no longer safe.
- Improper or inadequate cleaning of your femfit® could increase the likelihood of you contracting a urinary tract infection, vaginal candida, or other vaginal infections.
- Cleaning your femfit® with a substance other than water and mild liquid soap, may result in a rash or allergic reaction.

Precautions

- Before using your femfit®, ensure that there are no cracks on the sensor and pod. If you do find a crack, do not use the device. Contact JUNOFEMs technical support (contact details in section 14).
- Do not use if you experience persistent pain while using or inserting your femfit®.
- Do not use if you have a medical condition affecting your pelvic health (e.g. abnormal vaginal discharge or severe prolapse).
- Do not bend the sensor and stem excessively during washing.
- Do not leave your femfit® in your vagina for more than one hour at a time.
- Wait 10 minutes before use if your device has been in storage below or above room temperature. This will give your femfit® a chance to warm up or cool down to room temperature before you use it.

3.4 femfit® charger case

Warnings

- Do not submerge or run water over the charger case.
- Do not modify or perform any maintenance on your femfit® charger case.
- Only use power supplies from reputable manufacturers or reputable stores. The USB supply uses a micro-Type B connector and must have a rated voltage output of 5V and current of less than or equal to 3A.

4 Setting up your femfit®

This section will help you set up your personal femfit® device.

4.1 Installing the femfit® App

Information from your femfit® is displayed through the femfit® App.

The App will guide you through pelvic floor exercises, keep track of your exercises, and monitor how your pelvic floor muscles are improving. It will also allow you to view pressure data from your femfit®.

The App is available for both Android and iOS devices:

- For Android devices, download the App from the Google Play store by searching “femfit”.
- For iOS devices, download the App from the App store by searching “femfit”.

4.2 Creating an account

When you first use the App, you will be asked to create an account. This is so you can keep track of your exercise programme, what day you are on, and maintain your diary data. You will need to enter:

- Your first name
- Your last name
- Your email address
- Password

Your name enables us to create messages that are personalize to you, it also helps us link your account with our customer relationship manager software which looks after shipping and customer support.

The email address provided will be used to send App related information and, if needed, to reset your password. We will not sell your email address (or name) to third parties for advertising. Please see our Privacy Policy for how we manage personal data.

4.3 Charging the femfit®

Your femfit® device contains a rechargeable Li-ion battery which is delivered to you in a low state of charge for transportation purposes. It will need to be charged before you use it.

Your femfit® is charged wirelessly when it is stored inside the Charger case, and the case is plugged into a USB socket. There are no physical electrical connections to the pod.

1. Place the pod securely in the Charger case with the monogram facing upwards.
2. Close the Charger case.
3. Plug the JUNOFEM USB Cable into the Charger case socket and connect to a USB power supply. The indicator light on the Charger case will blink when it is charging.
4. We recommend letting your femfit® charge for at least 1 hour before turning it on for the first time. A full charge will take approximately 2 hours. The light on your Charger case will stop blinking and stay fully on when charging is complete.



Use only the supplied 80cm (31.5 in) micro USB cable with the femfit® logo to charge the device. The battery level of your femfit® can be viewed via the femfit® App. The femfit® will last well over a month during normal use between charging.

If the indicator light on the charger is not turning on after you have placed your femfit® device into the charger case, please check the following:

- Make sure the USB cable is plugged in properly at both ends.
- Take your femfit® out of its charger case and then place it back in the correct position. This will re-activate the charger.

4.4 Turning ON your femfit®

Remove your femfit® from its Charger case and press the Power button (centre of the pod where the femfit® monogram is located). The pod light indicator beside the femfit® monogram will light up. This indicates that your device is ON.

A steady white light means that your femfit® is advertising its Bluetooth ID for your phone to detect. A blinking white light indicates your femfit® is now fully connected to your phone.

4.5 Connecting and pairing your femfit® device

Once your femfit® device is ON, open the femfit® App on your phone.

Connect the femfit® to your phone through the femfit® App (do not use phone settings). See Section 6 for more details.

If you cannot connect your femfit®, please check the following:

- Make sure Bluetooth is enabled on your phone.
- For Android devices, it is important to enable location services for the femfit® App to allow the Bluetooth connection.
- Reset your femfit® by turning it OFF (hold Power button for 2 seconds) and then turning it ON again.
- Reset the Bluetooth on your phone, by disabling and re-enabling the Bluetooth function.

Please see Section 6 of this user guide to navigate your way through the femfit® App.

5 Using your femfit®

5.1 Introduction

The femfit® is a single-user, multiple-use device. Your femfit® should never be shared with anyone else and it must be cleaned before and after each use. Improper or inadequate cleaning could increase the likelihood of you contracting a urinary tract infection, vaginal candida, or another vaginal infection. It is easy to keep your femfit® clean, provided you always follow the steps below.

Tips:

As with any exercise, rest days are important! We recommend using your femfit 5 days per week and resting for the other 2.

You can mark your rest days on your femfit Diary so you don't lose your streak

5.2 Cleaning your femfit® device

Your femfit® must be cleaned before and after each use, including its first use. Your femfit® is delicate and although the sensor is flexible, it should not be forcefully twisted or bent in half.

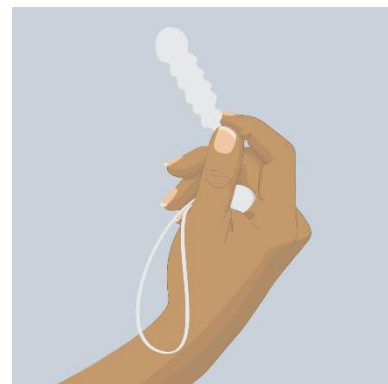
1. Remove any jewellery on your hands prior to cleaning so there is nothing that will catch on or scratch your femfit®.
2. Wash and dry your hands.
3. Open the Charger case and remove your femfit® device.
4. Rub some mild liquid soap onto the sensor and upper stem of your femfit®. Keep the pod dry. You should clean to approximately halfway down the stem.
5. Gently rub the soap, warm water, sensor and upper stem between your palms for twenty seconds. Never scratch at the surface of the sensor.
6. Rinse the sensor and upper stem with warm water.
7. Pat your femfit® dry with a clean paper towel. Your femfit® should always be completely dry before you put it back into its Charger case.
8. You can clean the pod and Charger case with wet wipes, as needed.

NOTE: If you are post-menopausal and/or are having difficulty inserting the device, you may want to leave the sensor and stem wet for insertion.

5.3 Inserting the sensor

Once your femfit® has been cleaned, insert the sensor into your vagina by following the steps below:

1. Empty your bladder and bowel.
2. Press the Power button once. The Pod light indicator (white light) will let you know that it is on and ready to be used. You can check the battery level on the femfit® App.
3. Stand or lie in a position that is comfortable for you to insert the sensor into your vagina.
4. Hold the sensor at the upper stem end between your thumb and forefinger, as pictured.
5. During insertion, you can hold the pod and sensor in one hand as pictured. Alternatively, you can hold the pod in your other hand.



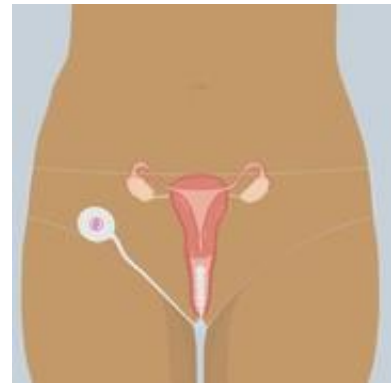
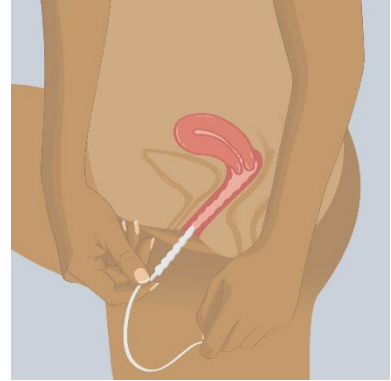
6. Ensuring that the dotted side of the sensor is facing towards the back, gently push the sensor inside your vagina. It is similar to inserting a tampon. The sensor must lie flat.
7. Insert the sensor until it is completely inside your vagina and only the upper stem is outside your body.
8. If it feels like the sensor is not sitting correctly, gently remove and reinsert it. You should be able to feel the sensor but still feel totally comfortable.
9. Once the sensor is inserted correctly, the pod can sit loosely in your underwear, as pictured.
10. You can now receive pelvic floor muscle feedback from your femfit® using the femfit® App. See Section 6 for a walk through of starting your training exercises with the femfit® App.

5.4 Removing the sensor

If you need to remove the sensor at any time, relax your pelvic floor and abdominal muscles and pull gently on the stem of your femfit®. Do not try to tug or jerk it out.

Press and hold down the Power button. The Pod light indicator will blink rapidly and after 1 second, the light will go out and the femfit® will be off.

Wash the sensor and upper stem as per Section 5.2 before putting your femfit® away in its Charger case.



6 The femfit® App

6.1 Introduction

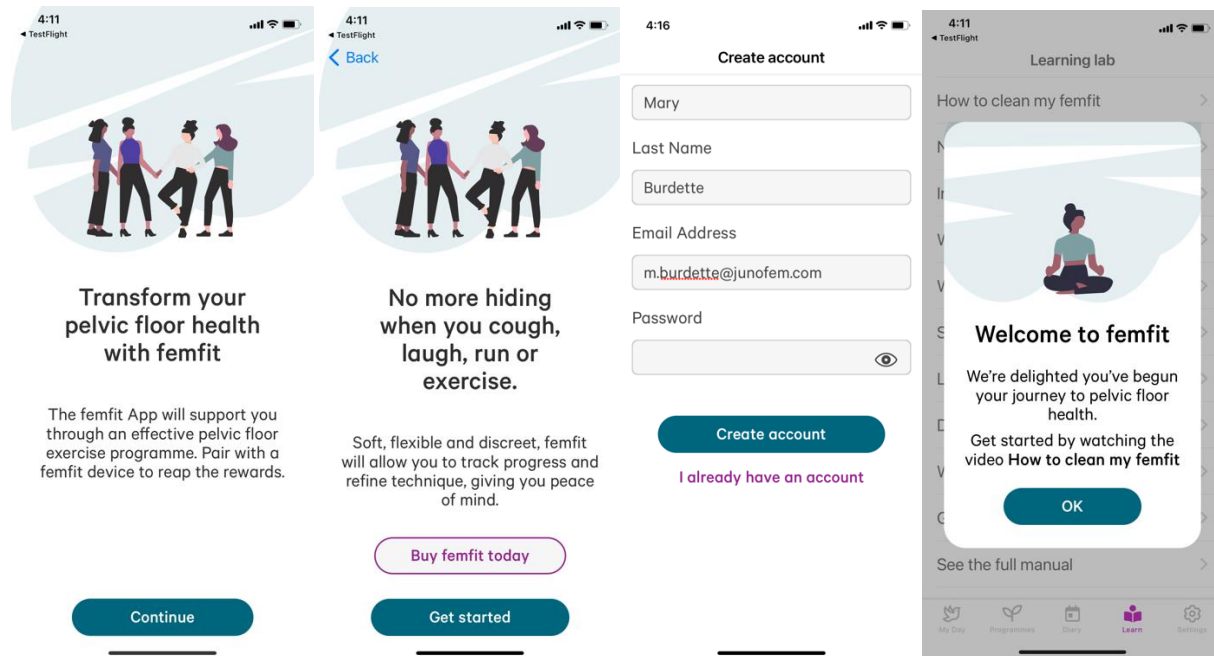
This section will walk you through the femfit® App. The App allows you to view live feedback from your femfit® device and see the pressures you develop from your pelvic floor muscles and abdominal pressure. It also gives you access to pelvic floor training programmes and keeps track of your progress towards obtaining a fit and healthy pelvic floor.

6.2 Phone settings

The femfit® App requires your phone to have an internet connection (Wi-Fi or mobile data) and Bluetooth 4.0 functionality. Make sure you have Wi-Fi or mobile data enabled and Bluetooth enabled before you open the femfit® App. For Android devices, make sure the location services are enabled to allow a Bluetooth connection.

6.3 The on-boarding process

The basic steps for onboarding are to create a user account, have a look at the cleaning video, head to **My day** and connect your femfit, then **Start exercises**.



The first time you use open the femfit® App you will see an introduction and also see a link to buy a femfit today. You don't need a femfit® device to get going with the App, but it is much more exciting and valuable because of the biofeedback to provide motivation and confidence that your technique will be effective.

Keeping your femfit® clean is simple, but very important. Watch the video "How to clean my femfit". You should clean your femfit® both before and after use.

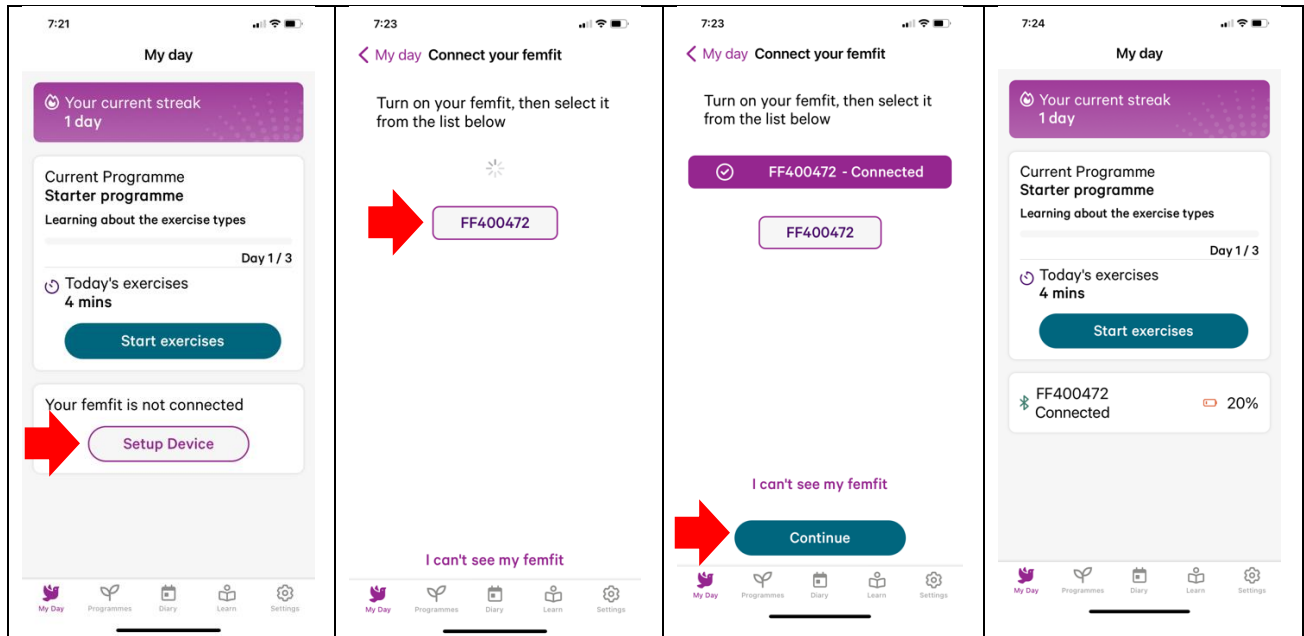
In the Learn tab there are multiple videos about how to get started, the pelvic floor and the App. Have a browse of topics that seem interesting and come back any time to find answers to your questions.

Time to choose **My day** from the bottom menu in the femfit® App. This will show that you are enrolled in "Starter programme". Next step is to get your femfit connected.

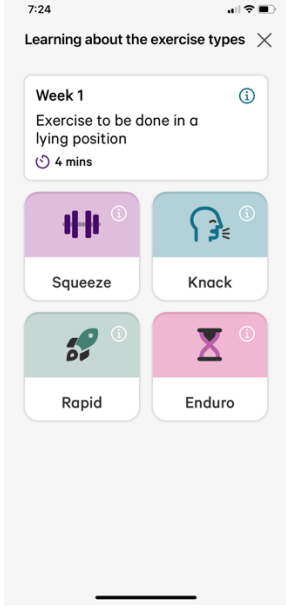

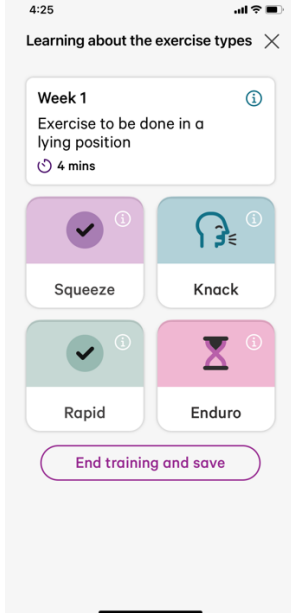
1. Turn on your femfit® device by pressing the Power button in the centre of the pod. The Pod light indicator will turn white to

let you know that it is on and ready to be used.

2. On **My day**, select Setup device
3. Select the box with the purple outline showing your femfit number (this can be found on the back of your Charger case, it will be in the format of FF4xxxxx, in the illustration, it is FF400472)
4. Once your femfit® is connected, it will remember your femfit® for next time. Now choose Continue.



Select Start exercises to be presented with the four exercise tiles, the four exercise make up a group of exercises for today. Click on each of the exercise tiles to activate them.

		
<p>Choose any of the exercise tiles</p>	<p>Now the goal is to use your pelvic floor muscles to get the bird to follow the line</p>	<p>After an exercise is complete, its tile will change to a tick, keep selecting the other exercise tiles to finish the session.</p>

NOTE: Once your account is set up, and you have connected your femfit® device for the first time, then next time it will connect automatically (provided the femfit® device is turned on). To connect to a different femfit® device, go to the Settings page, select *Device name:* and choose to *Forget this device*. The femfit® App will then start searching for a new femfit® device.

6.4 The main menu options

My Day

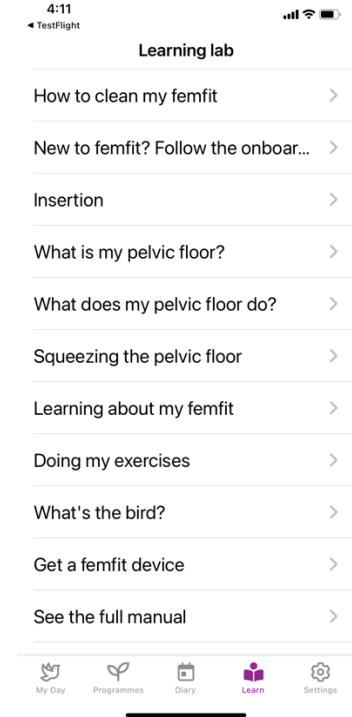
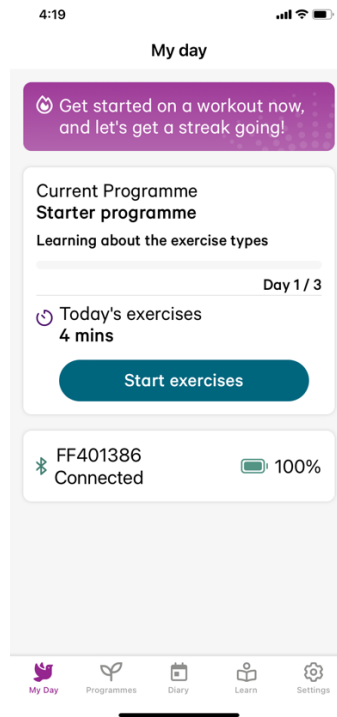
This screen gives you a summary of your scheduled activity for the day. It also shows you the battery and connection status of your femfit®.

When you are all set, tap on **Start exercises** to load your training programme for today.

Alternatively, along the bottom of the screen, you can navigate to one of the other main tasks of the App.

Learn

This will take you through the on-boarding and educational information. It is helpful if you want to remind yourself what a pelvic floor contraction should look like on the App display or how to insert your femfit®.



Diary

Here you can see your current training history and record any events such as leaks, mood, comments, etc. The current day will automatically be selected but you can select and edit other days on the calendar.

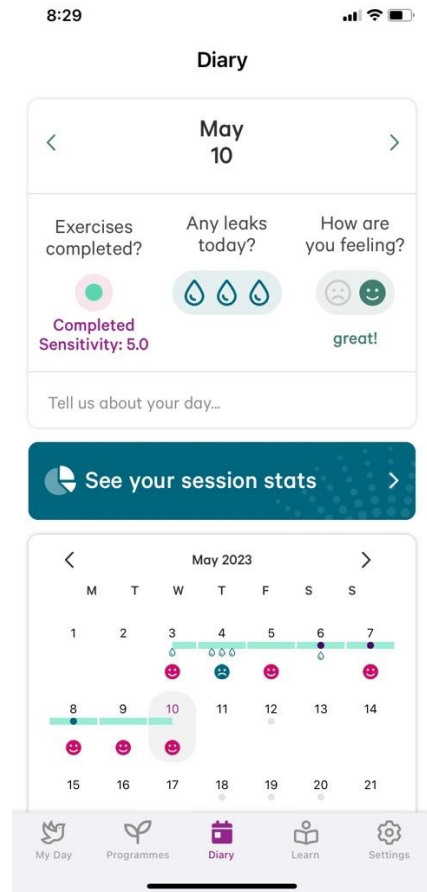
Under Exercises completed, you can select *No workouts completed*, *Rest day*, *Period day*, *Workout without device*. Keep pushing on the 'dot' to rotate through selection. *Workout with device* will autofill if you have used your femfit® device. If you choose Rest day, then your streak is maintained. We recommend two rest days per week.

The display of the calendar month provides summary information for the current month. You can select any day to revisit entries on a specific date.

You can also add diary notes to remind yourself what happened on this day.

See your session stats will take you a review of your performance during exercise sessions. These metrics are computed on femfit® servers and may take a few minutes after you finish a session to appear in your App.

We really value your feedback. This might be on the App, the femfit® device, what you find frustrating or motivating. The way to get that feedback to us is via email to info@junofem.com. The diary data is your diary, so this is not how to inform us of your feedback.



Programmes

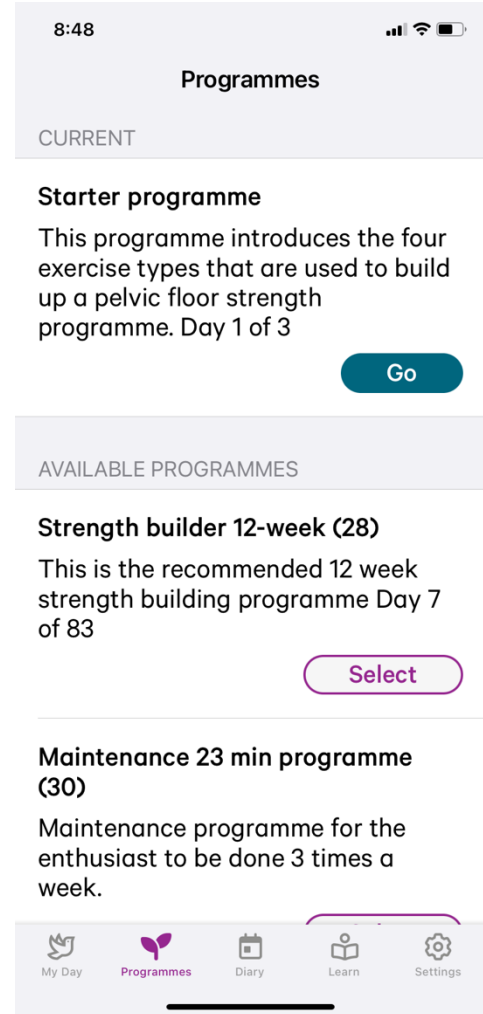
Here you select your training programme.

Starter programme: introduces the 4 types of exercises that are typically used in exercise programmes. This is a great programme to try first.

Strength builder 12-week (28): full clinically validate programme lasting 12 weeks. The intensity and repetition of the exercises increases every 4 weeks. For the first month, these exercises will take around 8 minutes to complete each day. In the second month, this will step up to 12 minutes. In your third and final month, the exercises extend to 16 minutes. Your posture to do the exercises changes from lying to sitting to standing.

Keep Strong with femfit – 15 min: A great way to keep your pelvic floor in great condition. Three times a week should do it.

If you have a personalized programme, created by your healthcare professional, this will appear in the list of programmes under *Custom program*. If you are interested in a personalized programme, contact us at info@junofem.com.



Settings

My femfit provides a means to connect with your device or switch to a different device.

User information: Your *Email address* is linked to your account and if you have forgotten your password, a reset link will be sent to this address. – see our privacy policy for details.

Sign out will sign you out of the App. You will need your email and password to log back in.

Delete account really will delete your account and cannot be reversed. You will be asked for confirmation.

Under **During my workout** you have some options which change the behavior of your live training display

Show numbers on bars: if selected then the values from each sensor will be displayed at the top of each bar. We are really interested in the shape, and one of the purple bars being higher than the grey bar. But if you want to know your numbers, you can see them by enabling this toggle.

Auto land the bird when resting: This should be selected. The App will adjust the height of the bird to fly at the bottom level of the path during resting periods – in preparation for your next squeeze effort. If it is de-selected, then the baseline (resting) level will be set at the very start of each exercise only and will not adjust during the exercise. Automatically adjusting baseline will allow the App to compensate for changes in posture during the exercise.

Clinic registration provides a means to share your data with your healthcare professional if they belong to a clinic registered with us.

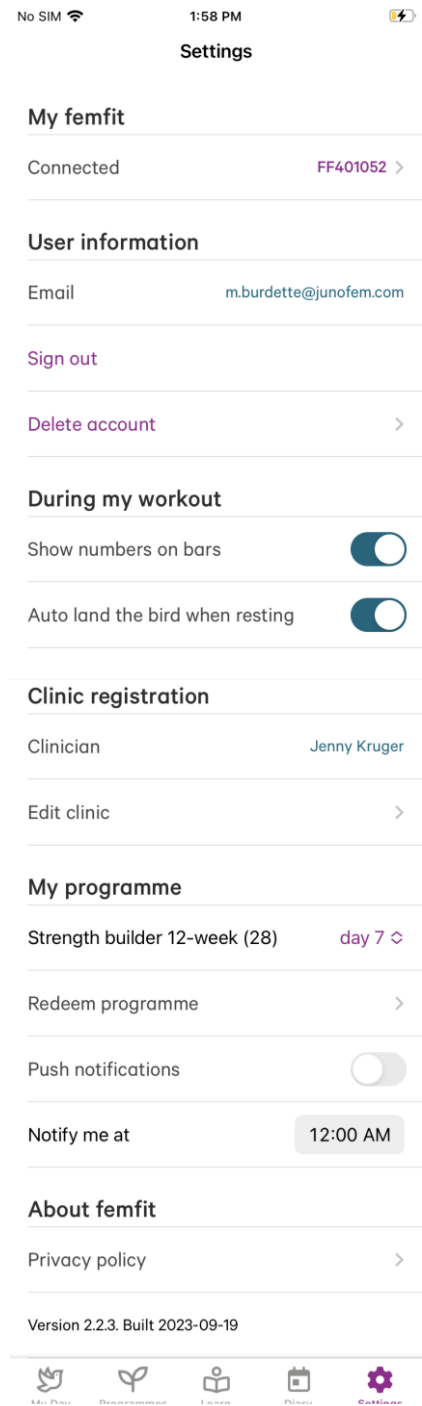
Edit Clinic contains the options to share and stop sharing. To share, a Clinic code provided by your healthcare professional must be entered.

The *Clinician* field will show your clinician's name if it was previously entered.

Under **My programme** you can have the ability to change your workout day for your current programme. Your workout day will normally increment every day automatically. This option lets you move back in a programme if you have had a break and want to adjust your workout day.

Redeem Programme: when your healthcare professional has made a special exercise programme, this is where you enter a registration code to retrieve your programme. Your healthcare professional will give you the code.

Push notifications will pop a reminder for you at the *Notify me at* time.



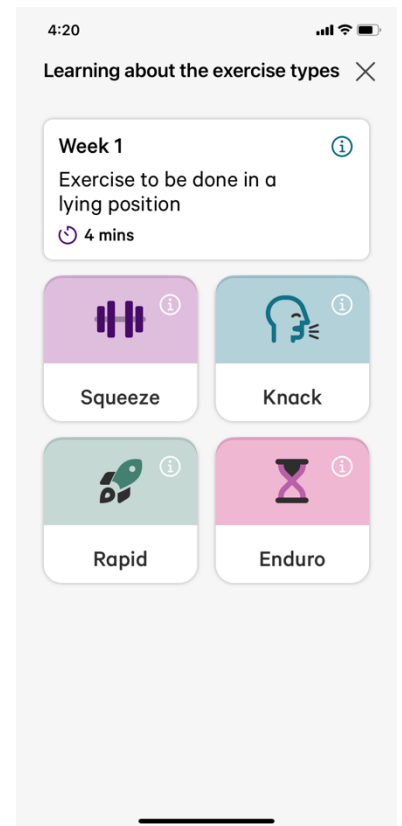
6.5 Live training

Once you press the *Start exercise* button on the *My Day* page, the live training screen will guide you through your exercises for the day. The number of minutes for today session will appear beside the clock, in the illustration, the session will take 4 minutes. You are also advised what posture is recommended.

Each session has 4 types of exercises. The exercises are *Squeeze*, *Rapid*, *Enduro*, and *Knack*. You may do the exercises in any order. We recommend finishing with the *Knack* as the femfit® may shift within the vagina during the coughs.

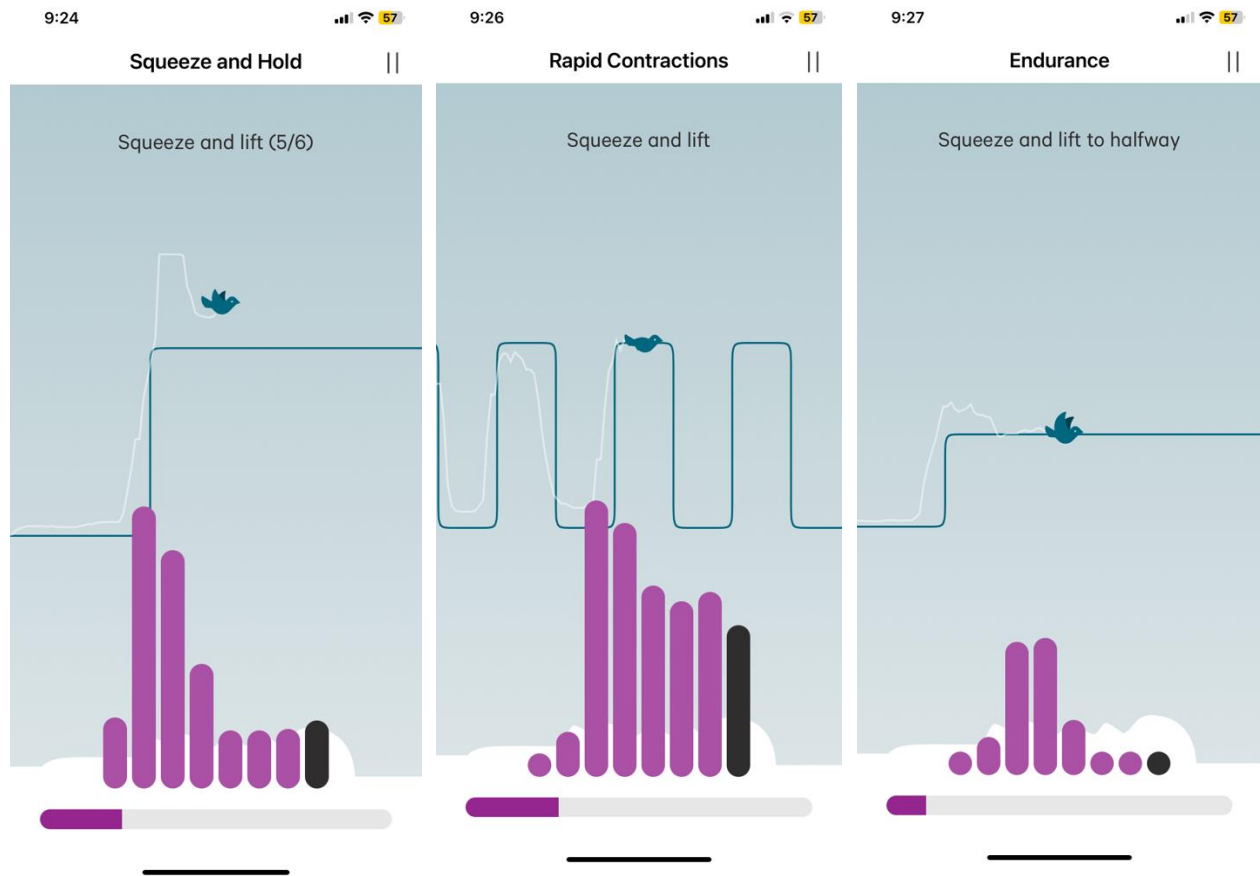
The App will guide you on the number and timing for each exercise. By clicking on the 'i' you will get tutorial information about what to do for each of the exercises. Once your exercise session starts, your femfit® will send live feedback to the App about how effective your muscle contractions are. Watch the bars, with the goal to keep any of the purple bars higher than the grey bar.

The movement for a pelvic floor muscle contraction is the same as if you were trying to hold the urge to urinate and stop yourself from releasing gas. Remember to keep your stomach and buttock muscles relaxed and breathe normally while exercising.



Squeeze Increasing muscle strength	Rapid Improving coordination and endurance
<p>For this exercise, you will squeeze, lift, and hold your maximum contraction, and try to hold this for a specified duration. You will then release and relax.</p> <p>The path will scroll across the screen, indicating the timing and magnitude of the contraction. Your aim is to increase the height of the bird, according to the path, using your pelvic floor muscles. Then release and relax.</p> <p>The bars at the bottom of the screen show you what is occurring during the 'Squeeze and Lift'. Try to activate the purple bars as they represent your internal pelvic floor muscles. Two things to focus on: any purple bar up, while keeping grey bar low.</p>	<p>For this exercise, you will squeeze and lift your pelvic floor muscles rapidly, release and relax, and then repeat.</p> <p>The path will scroll across the screen, indicating the timing and magnitude of the contraction. Your aim is to increase the height of the bird, according to the path, using your pelvic floor muscles. Then release and relax.</p> <p>The bars at the bottom show you what is occurring during the 'Rapid'. Try to activate the purple bars as these represent your internal pelvic floor muscles.</p>
Enduro Endurance and control - the 'Podium'	Knack Coordination
<p>For this exercise, you will squeeze and lift to half your maximum, hold for several seconds; then, without relaxing, squeeze and lift to your maximum squeeze, hold for several seconds, relax back to half your maximum squeeze, hold for several seconds, then relax completely.</p> <p>The path will scroll across the screen, indicating the timing and magnitude of the squeeze. Your aim is to increase the height of the bird, according to the path, using your pelvic floor muscles, and then release and relax.</p> <p>The bars at the bottom of the screen show you what is occurring during the 'Podium'. Try to activate the purple bars as these represent your internal pelvic floor muscles.</p>	<p>For this exercise, you will do a maximum squeeze and lift immediately prior to a 'cough'. Then you relax and rest for several seconds before repeating.</p> <p>The path will scroll across the screen indicating timing and magnitude of the squeeze and 'cough'. Your aim is to increase the height of the bird; cough at the icon, and then release and relax.</p> <p>The bars at the bottom of the screen show you what is occurring during the 'Knack'. Try to activate the purple bars before you cough as these represent your internal pelvic floor muscles. All bars will increase during the cough.</p>

Below are screens showing a typical profile during an exercise session:








The idea is that during a pelvic floor muscle squeeze, some of the purple bars will be higher than the grey bar. It doesn't matter which purple bars – that is determined by anatomy and placement. Activating purple bars higher than the grey bar can take practice and time to learn. While getting this right, just squeeze gently, don't strain.

6.6 Your femfit® information

Your exercise session files are uploaded to JUNOFEM servers for analysis. This analysis will adjust the height of the path you are presented for your subsequent exercise sessions and provide feedback to you on your exercising history. For more information please refer to JUNOFEM's privacy policy and cyber-security statement.

6.7 Battery information

The following table gives an estimate on the maximum number of training sessions available based on the battery state of charge level. This is based on an assumed session duration of 30 minutes.

Battery indicator level in App	Maximum number of training sessions
 Battery information is not available	0, or unknown if the device is turned OFF
 Your femfit battery is low	1-16
 Your femfit battery is good	16-26
 Your femfit battery is charged	26-30
 Checking femfit battery	Unknown, the femfit® App is awaiting battery information from the device

7 Ending your training session

This section describes what to expect when your exercise sessions end and how to remove your femfit®.

7.1 Ending your exercise session

Once you have completed your four daily exercises and updated your diary page, you can close the App. You do not need to disconnect your femfit® before you close the App.

7.2 Turning OFF and removing your femfit® device

After your training session, please follow the steps below:

To remove your femfit®, simply relax your muscles and pull gently on the stem until the sensor comes out of your vagina. Clean the sensor and upper stem of your femfit® with water and mild, unscented soap as per the cleaning instructions in Section 5.2.

To turn OFF your femfit®, hold down the Power button for about 2 seconds. The Pod light indicator will flash rapidly, then go off.

If your femfit® is not connected to the App (e.g. you close your femfit App), it will automatically turn off after about 10 minutes.

If your femfit® is connected to the App, it will turn off when the battery runs low.

7.3 Storing your femfit®

After using and cleaning your femfit®, store the device in its Charger case - as shown in the illustration to the right.

Check that your femfit® and its Charger case are clean and dry. You may wipe the Charger case clean with a clean, damp towel or wet wipe. Do not clean the Charger case under running water, submerge it in water, or use any harsh cleaning liquids on it.

Important: The pod monogram should be facing up and the stem should not be significantly twisted. This is necessary for the wireless charging function to work.



8 Taking care of your femfit®

8.1 Maintenance and storage

Storing your femfit® correctly helps to prevent system failures.

Clean and dry your femfit® after each use and only store it in the Charger case provided. Keep the Charger case out of direct sunlight and store it in a cool dry place.

The femfit® and its Charger case contain no user serviceable parts, batteries or electronics.

8.2 Disposal

Your femfit® contains a Li-ion cell battery. Different areas have different requirements for disposing of electronics, items that have come in contact with bodily fluids, and objects containing a Li-ion cell. Follow your local waste management requirements.

9 Troubleshooting

9.1 Introduction

These troubleshooting sections are organized by their function or system component. The latest version of this guide is available on junofem.com, the link to the latest User Manual is in the footer.

9.2 Charger case

Problem	Solution
Device is not charging	Remove your femfit® and reinsert it into its charger case according to section 4.3. The femfit® monogram on the pod must be facing up.
Device won't fit in its case	Take care to make sure that the stem has not been twisted and that the sensor is lying flat in the tray.
The charger light does not come on	Check you are using the JUNOFEM USB cable. The connector in alternative USB cables may be too short to make contact inside the Charger case.

9.3 femfit® device

femfit® is a pelvic floor training tool which measures a pressure profile in the vagina to track pelvic floor strength during a training programme. femfit® records the pressures accurately across eight sensors which respond independently to the vaginal pressure changes.

In order to perform its function, the femfit® needs to measure the pelvic floor pressure accurately. If your femfit® displays unusual pelvic floor responses (such as sensors not responding to pelvic floor contractions, sensor signals jumping randomly, or error messages in the App), please follow the trouble shooting instructions in section 9. If these do not address the issue, please contact JUNOFEM or your local distributor.

Problem	Solution
Device is not turning ON	Charge your femfit® according to section 4.3 for a period of two hours. Press the Power button (centre of the pod marked by the femfit® monogram). The pod light indicator (located next to the logo) should light up.
Device won't turn OFF	Hold down the Power button for 2 seconds. The pod light indicator will flash rapidly and then turn off. Alternatively, if you close down the femfit® App, then the femfit pod will turn itself off after 10 minutes.
Unsure what Pod light indicator means	Light on – device is on and looking for a smart device Light off – device is off Light is blinking slowly – device is connected to the App on your phone Light is flashing rapidly, shutdown mode has started, keep holding the Power button, and device will turn off very soon

9.4 femfit® App

Cannot download App

Ensure that there is enough storage space on your smart device. Follow the instructions from the manufacturer of your smart device to check.

Ensure that your Wi-Fi or mobile data connection is turned on and that the internet connection is stable.

Cannot install App

Ensure that there is enough storage space on your smart device. Follow the instructions from the manufacturer of your smart device to check.

App cannot detect device

Turn your Bluetooth OFF and then turn it ON again. Turn your femfit® OFF and then turn it ON again.

For Android devices it is important to enable location services to allow Bluetooth connection.

Lost connection

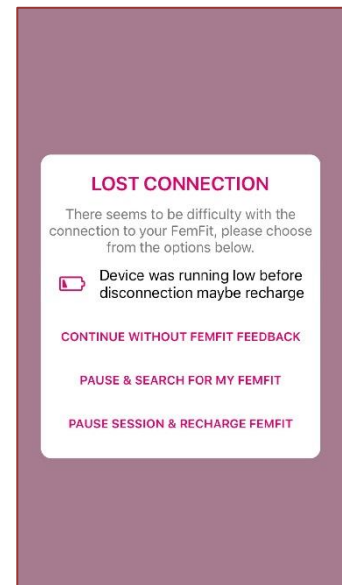
Ensure that your femfit® is turned ON. You can do this by checking the status of the pod light indicator next to the femfit® monogram. The light will be solid if the device is turned on and blinking slowly if it is connecting to the App. If connection is still lost, turn the Bluetooth connection OFF on your smart device and then turn it back ON. Close and reopen the femfit® App.

Low battery status

Charge your femfit® according to section 4.3.

Sensor feedback not making sense, App not responding to contractions or user input

Power off your femfit® device using the Power button. Shutdown/close the femfit® App (you do not need to log out, but you do need to close the App and not have it running in the background). Turn on your femfit® device. Open your femfit® App. Under My day, it should show that your femfit® is Connected.



10 Glossary

Abdominal muscles	The stomach or core muscles. Their pressure is indicated by the top sensors (number 8).
Account	The login for the femfit® App. It is individual to each user and tracks personal progress.
App	The femfit® software program that allows you to view live feedback of how your pelvic floor is behaving. It features different programs with pelvic floor targeting exercises.
Bars	The visual display of pressure being applied on each of the sensors. These are coloured according to whether they are pelvic floor or abdominal muscles.
Bluetooth	The wireless technology that connects your femfit® with your device and allows data to be transmitted live to the App display. For advice on using Bluetooth on your smart device, see the device's manual.
Charger case	The container for storing and charging the femfit®.
Contraction	The act of <i>lifting</i> and squeezing the pelvic floor muscles without overuse of the abdominal muscles.
Data transmission	The transfer of information from one device to another. We use Bluetooth to transfer data from your femfit® to your smart device.
Enduro	Squeeze and lift to half maximum, holding for several seconds. Then, without relaxing, squeeze and lift to maximum, holding for several seconds again. Then relax to half maximum, holding for several seconds before relaxing completely.
Exercise	Engagement and targeted strengthening of your pelvic floor muscles.
Biofeedback	The information displayed by the bars on the app to indicate how much pressure is being exerted by your pelvic floor muscles (purple bars) and abdominal muscles (grey bar) .
femfit®	A type of perineometer that is used to measure and differentiate between pelvic floor and abdominal pressures during exercise.
JUNOFEM Ltd	Parent company of femfit®.
Knack	A technique to re-train to pelvic floor muscles to contract just prior to a cough.
Monogram	The motif of femfit®.
Path	The line the bird follows, indicating the pressure being exerted by your pelvic floor, and the type of exercise that is required.
Pelvic floor muscles	The muscles that span from the pubic bone to the tailbone, forming the supporting 'floor' to hold up the bladder, uterus, and bowel. Pressure exerted by these muscles are indicated by sensors 1-6.
Pod	The device that powers the sensor and sends data to the femfit® App.
Pod light indicator	LED on pod that is a steady white light when turned on, blinking slowly during data transmission, blinking fast when turning off, and off when the femfit® is turned off or out of battery.
Pressure data	The information about how much pressure is being produced by your pelvic floor and abdominal muscles during and between exercises.
Programmes	A selection of pelvic floor exercises that are available on the App to train the pelvic floor muscles.
Power button	The part of the pod that turns your femfit® device ON and OFF - located under the monogram.
Rapid	Squeeze and lift rapidly, for a specified number of times.
Session	A collection of exercises to be completed in a single sitting.
Smart device	An electronic device, such as a phone or tablet, which can connect to the internet and download Apps.
Sensor	The flexible array of sensors that is inserted into the vagina to measure pressure data on the pelvic floor and abdominal muscles.
Stem upper	The half of the narrow extension of the sensor on the half closest to the sensor.
Stem lower	The half of the narrow extension of the sensor on the half closest to the pod.
Squeeze	Squeeze, lift, and hold maximum contraction; trying to hold this for a specified duration.
Starter program	The selection of pelvic floor exercises that you go through when you open your femfit® App for the first time. These are designed by a trained physiotherapist. The program teaches you how to do the exercises correctly before you embark on the 12-week training program.

Training programme	A selection of pelvic floor exercises to be done in daily sessions. These are designed by a trained physiotherapist to strengthen your pelvic floor in a targeted and effective way.
Urinary incontinence	Any involuntary leakage of urine. Stress incontinence is leakage during stress or load on the body such as a sneeze or cough.
USB Cable	The cable that charges that femfit® when it is connected to a USB power source.

11 Product specifications.

Model name

femfit®	JFF-003
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IP rating

Sensor	IP67
Pod	IP22
Charger case	IP21

Operating environmental conditions

Parameter	Min	Max
Temperature	5°C (41°F)	40°C (104°F)
Humidity	15%	90%
Pressure	700hPa	1060hPa

Transport environmental conditions

Parameter	Min	Max
Temperature	-20°C (-4°F)	60°C (140°F)
Humidity	0%	90%
Altitude	0m	12,800m

Charger case electrical specifications

USB type connection	Micro USB
Power Input Voltage	5 Vdc
Max power input current	200 mA
Typical power input current when in standby	50 mA

Battery specifications

Parameters	Min	Max
Battery voltage	3.5V	4.0V
Battery capacity	75mAh	85mAh
Battery life (from full charge)	10 hours	20 hours
Charge-discharge cycles before capacity drops <80%	200	

Wireless Technology

Type	Bluetooth 4.0 Low Energy
Frequency	2.40 - 2.48 GHz
Power	< 4.0 dBm

Material in contact with the user

Sensor	Medical grade (biocompatible) silicone and color pigments. Meets the requirements of ISO10993-1. Nature of contact: mucosal membrane. Duration of contact: < 60 minutes.
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Pod and Charger case	Biocompatible acrylonitrile-butadiene-styrene (ABS) plastic. Meets the requirements of ISO10993-1. Nature of contact: skin. Duration of contact: <60minutes.
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Surface temperature

Surface temperature of pod or Charger case insert	Surface temperature may get up to 60°C (140°F) during charging and feels warm to the touch. The temperature will quickly drop to ambient conditions when the device is completely charged or removed from the Charger case.
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Accuracy

Absolute pressure accuracy of each sensor	±5 mmHg
Pressure difference between any sensor in a femfit® device	±2 mmHg
Average pressure difference between femfit® devices	±2 mmHg

Service life

Shelf life	36 months
Service life after first use	12 months

Other

USB Cable	USB-A to micro USB-B, 0.8m (21 inches)
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12 Electromagnetic Compatibility

The femfit® does not perform any clinical function where loss or degradation would result in unacceptable risk.

WARNING: The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of your femfit® and result in improper operation.

WARNING: Portable RF communications and other equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of your femfit. Otherwise, degradation of the performance of your femfit could result. RF equipment includes baby monitors, Bluetooth wireless headsets, wireless routers, microwave ovens, laptops with internal Wi-Fi adapters, and GSM cell phones.

12.1 EMC — femfit® pod/sensor

Emissions/Immunity Test and Standard	Compliance Level
Radiated RF emission: CISPR 11	Group 1 Class B
Electrostatic discharge: IEC 6100-4-2	± 8 kV contact, ± 2/4/8/15 kV air
Radiated RF EM fields: IEC 61000-4-3	10 V/m: 80 – 2700 MHz
Proximity fields from RF wireless communications equipment: IEC 61000-4-3	9 V/m: 710, 745, 780, 5240, 5500, 5785 MHz; 27 V/m: 385 MHz; 28 V/m: 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz
Power frequency magnetic fields: IEC 61000-4-8	30 A/m

12.2 EMC – Charger case

Emissions/Immunity Test and Standard	Compliance Level
Radiated RF emission: CISPR 11	Group 2 Class B
Electrostatic discharge: IEC 6100-4-2	± 8 kV contact, ± 2/4/8/15 kV air
Radiated RF EM fields: IEC 61000-4-3	10 V/m: 80 – 2700 MHz
Proximity fields from RF wireless communications equipment: IEC 61000-4-3	9 V/m: 710, 745, 780, 5240, 5500, 5785 MHz; 27 V/m: 385 MHz; 28 V/m: 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz
Electrical fast transient/burst: IEC 61000-4-4	± 2 kV power supply line
Surges: IEC 61000-4-5	± 0.5/1 kV line to line; ± 0.5/1/2 kV line to earth
Conducted disturbances: IEC 61000-4-6	3 Vrms: 0.15 – 80 MHz; 6 Vrms in ISM bands
Power frequency magnetic fields: IEC 61000-4-8	30 A/m
Voltage dips/interruptions: IEC 61000-4-11	0% U_T for 0.5 cycle at 8 phase angles; 0% U_T for 1 cycle; 70% U_T for 25 cycles; 0% U_T for 250 cycles

12.3 FCC Statement (US)

The femfit® pod, with FCC ID 2AVF7FF40, complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

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

NOTE: “Harmful interference” is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

The Grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user’s authority to operate the equipment.

The Charger case, with FCC ID 2AVF7CC20, complies with Part 18 of the FCC Rules.

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment. No modification of the equipment is allowed as it could create an unsafe condition.

12.4 ISED Statement (Canada)

This device contains licence-exempt transmitters/receivers that comply with Innovation, Science and Economic Development Canada’s licence-exempt RSS standards. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

L’émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d’Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L’exploitation est autorisée aux deux conditions suivantes: (1) l’appareil ne doit pas produire de brouillage; et (2) l’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement.

femfit® regulatory statements

FCC ID: 2AVF7FF40

Your femfit® is compliant with part 15 of FCC regulations for Class B computing devices (47 CFR Part 15). Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by JUNOFEM Ltd could void the user's authority to operate this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving antenna; increase the separation between the equipment and receiver; connect the equipment into an outlet on a circuit different from that to which the receiver is connected; consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. No modification of the equipment is allowed as it could create an unsafe condition.

INDUSTRY CANADA STATEMENT

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

12.5 Guidance and manufacturer's declaration — Charger case

Charger case regulatory statements

FCC ID: 2AVF7CC20

This device complies with Part 18 of the FCC Rules.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. No modification of the equipment is allowed as it could create an unsafe condition.








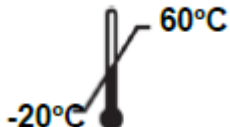







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13 Label symbols

The following symbols may be found on the charge case of the femfit®, label MN003 (UK, AU, NZ) and MN012(US). They tell you about the proper and safe use of the femfit® system. Below is an explanation of what each symbol means.

	Single patient multiple use	IP22	IP22: Protection against insertion of large objects and dripping water
	Serial number	IP 67	IP67: Protection from total dust ingress from immersion between 15 centimeters and 1 meter in depth
	Catalogue number		Manufacturer
	Great Britain technical conformity (applicable in UK)		Keep dry
	Consult instructions for use		Temperature limitation (storage & transport)
	Date of manufacture		Type BF applied part
	FCC mark		Use by date
	Humidity limitation (storage & transport)		Waste Electrical and Electronic Equipment (WEEE)
IP21	IP21: Protection against insertion of large objects and vertically dripping water		Refer to instruction manual (US)

	Radio transmitter (non-ionizing radiation)		
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14 Need help?

More information can be found at www.junofem.com

If you require further assistance or need to report unexpected operation or events, please contact us at:

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