



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 the femfit?

2.1.Introduction

The 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 are able to 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.

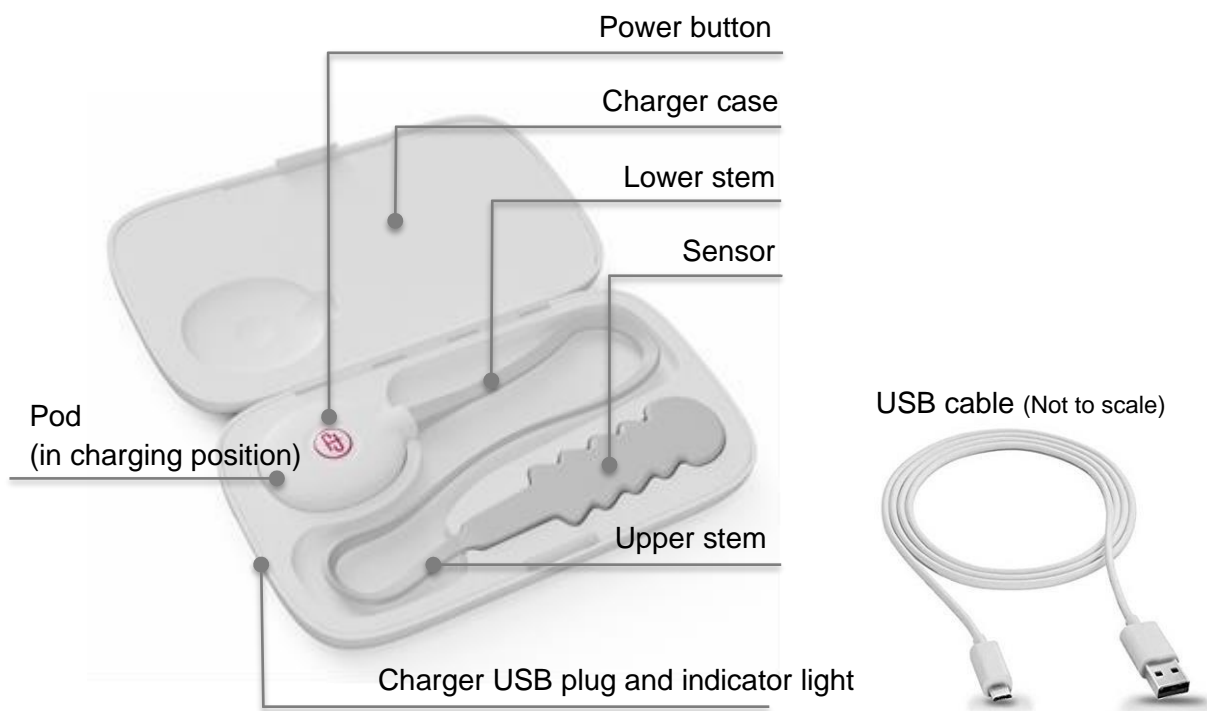
Once you have mastered engaging the correct muscle group, there is strong scientific evidence that following a programme of pelvic floor muscle exercises, usually for twelve weeks, will significantly improve the ability of your pelvic floor muscles to work correctly. This is particularly important when your body is under load or a sudden pressure (e.g. when you sneeze or cough) as it decreases the chance of urinary leakage. Traditionally, treatment has involved seeing a clinician (physiotherapist or urogynaecologist). But this can be time-consuming and expensive. The femfit allows you to do this work 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.

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2.2.Components of your femfit

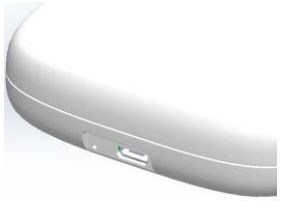


femfit (model JFF-003)	A type of perineometer. You use the device to measure your pelvic floor and abdominal pressures during exercise and track your progress as it gets stronger.
Sensor	The flexible array of sensors that measure your pressure data. This is the scalloped section that you insert into 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.	<p>A circular inset image shows the top of the pod with a small red circle labeled 'Light' pointing to it.</p>
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 case light indicator 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 drop heavy objects onto the sensor array as this will damage them.
- 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 charging 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.
- 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.
- If there is a tear on the joinery between the pod and the stem, 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 have given birth within the last six weeks.
- 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 use if you are pregnant.
- 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

The only way to display information from your femfit is through the femfit App. Install the App from the appropriate store.

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 and share your pelvic floor information with others, if you wish.

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”.

NOTE: You can use your femfit on multiple devices with the same login account. However, your femfit can only be connected to one smart device at a time.

4.2. Creating an account

To use the femfit App, you must create an account. This is so you can keep track of your progress.

- Open the App on your selected smart device.
- Follow the on-boarding process of the femfit App. For more information see Section 5 of this user guide.

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. It will need to be charged before you use it.

1. Making sure that your femfit is off, place the pod securely in the charger case with the monogram facing upwards.
2. Close the charger case.
3. Plug in the USB charging cable to the charging plug and connect it to a USB power supply. The indicator light on the charger case will blink when it is charging.
4. Let 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 micro USB cable with femfit logo to charge the device. The battery level of your femfit can only be viewed via the femfit App.

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

MN004_E

- 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 button on the pod (where the femfit monogram is located). The pod light indicator beside the femfit monogram should light up. This indicates that your device is ON.

Your femfit will then be advertising its Bluetooth ID for your smart device to detect.

4.5.Connecting and pairing your femfit device

Once your femfit device is ON, open up the femfit App on your smart device.

Connect it to your smart device via the femfit App. See Section 6 for more details.

NOTE: The pod light indicator on your femfit will start blinking once it is connected to the App.

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

- Make sure Bluetooth is enabled on your smart device.
- For Android devices, it is important to enable location services to allow the Bluetooth connection.
- Reset your femfit by turning it OFF (hold button for 1 second) and then turning it ON again.
- Reset the Bluetooth on your smart device, by disabling and re-enabling the Bluetooth function.

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

Tips:

After connecting your femfit for the first time, we recommend you give your device a unique name. This is to avoid confusion with other femfit devices you may encounter.

You can change the name in the App settings.

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 calendar so you don't lose your streak.

5.2.Cleaning your femfit device

Your femfit should be cleaned before and after each use, including its first use, following the procedure below:

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. Rub soap, warm water, sensor and upper stem between your palms for twenty seconds
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 it is returned to its case.

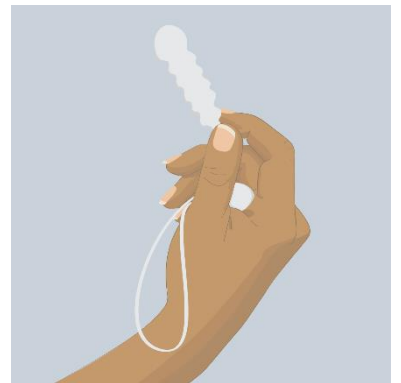
NOTE: If you are post-menopausal and/or are having difficulty inserting the device, you may want to leave the sensor and stem wet for insertion.

NOTE: The pod and charger case should be cleaned with wet wipes, when needed. Do not soak your femfit in any liquid. Immersion for an extended period of time may damage the silicone.

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. A solid light will let you know that it is on and ready to be used.
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.



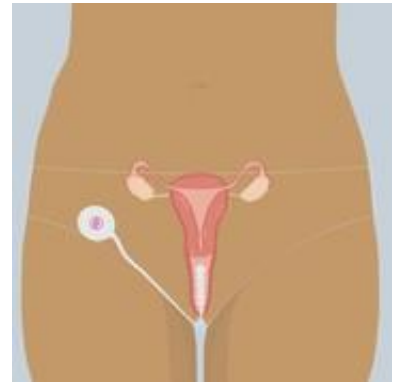
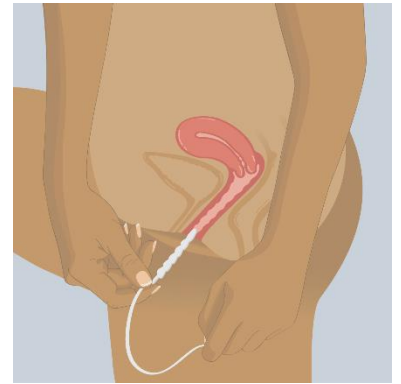
5. During insertion, hold the pod and sensor in one hand. Alternatively, hold the pod in your other hand, as pictured.
6. Ensuring that the dotted side of the sensor is facing towards the back, gently push the sensor inside your vagina. It is similar to inserting a tampon. The sensor must lie flat.
7. 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. Just open the femfit App to start your training exercises. See Section 4 for a walk through of 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 light on the pod will blink 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.Smart device settings

The femfit App requires your smart device 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 Bluetooth connection.

6.3.The on-boarding process

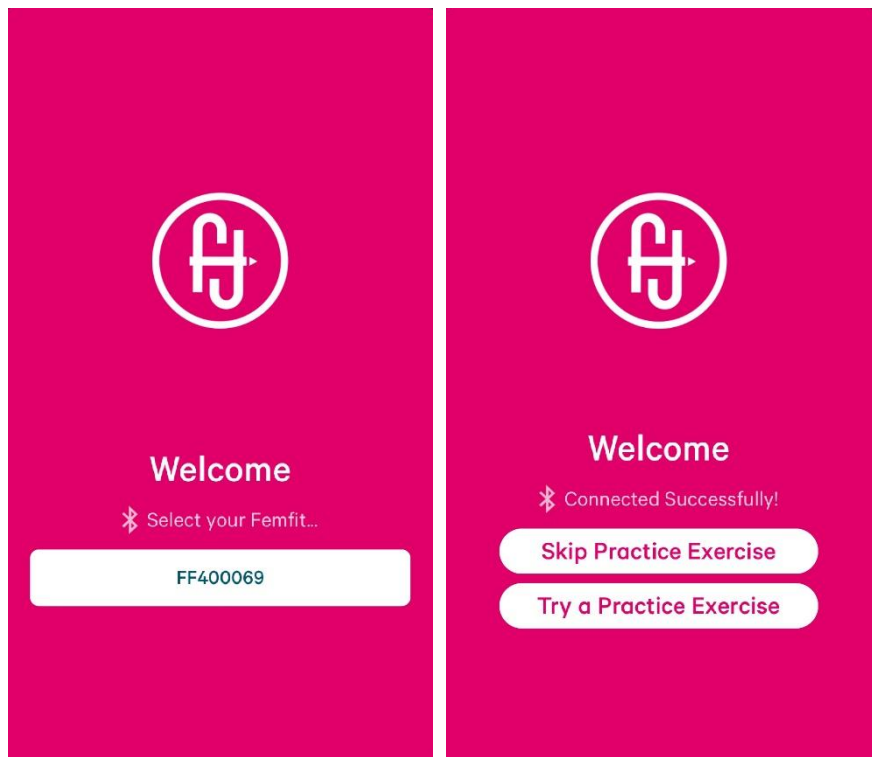
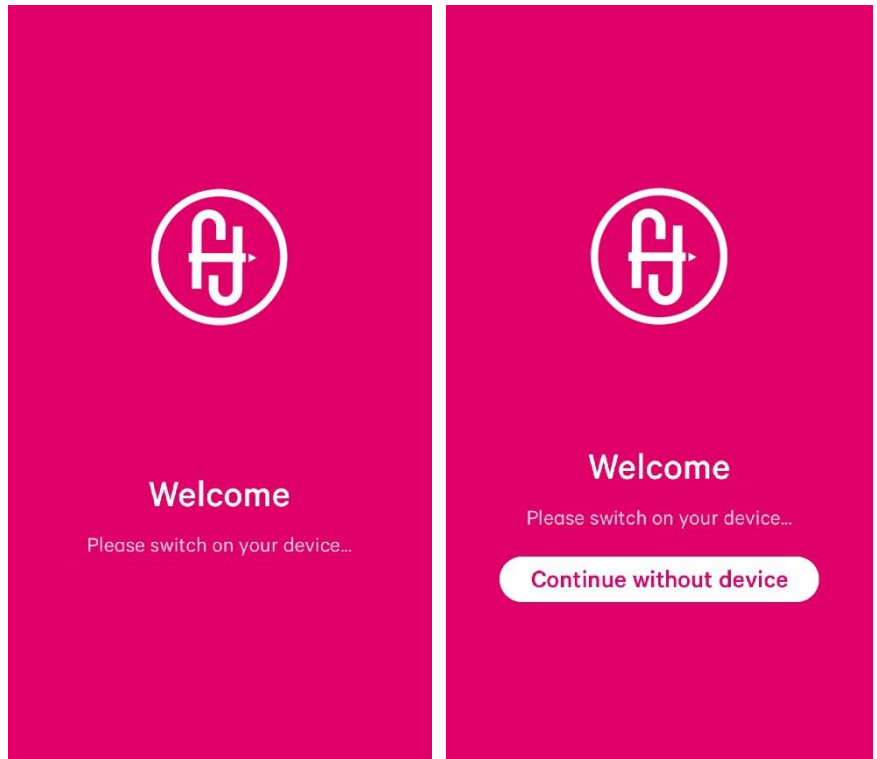
The first time you use open the femfit App, you should see the screen on the top left

If you have not done so already, turn ON your device by pressing the button on the pod. The white light on the POD should now be on. The App should find your femfit after a few seconds.

If the screen on the top right appears, check your phone settings to ensure that your Bluetooth is turned on. Once Bluetooth is enabled, turn your device off and then on again.

If you are a first time user, please follow the instructions on your device screen to set up your femfit on the App.

NOTE: After your device has been paired to the femfit App, you will be able to rename your femfit from its serial number to a name of your choice if you wish under settings in the App.



Select your femfit: You should see the screen on the bottom right if you have successfully connected using Bluetooth.

You may also choose to continue into the App without a device. You can now “Try a Practice Exercise” or “Skip Practice Exercise”.

“Try a Practice Exercise”

You will be guided through the insertion of your femfit and shown how the App displays feedback about your pelvic floor muscles.

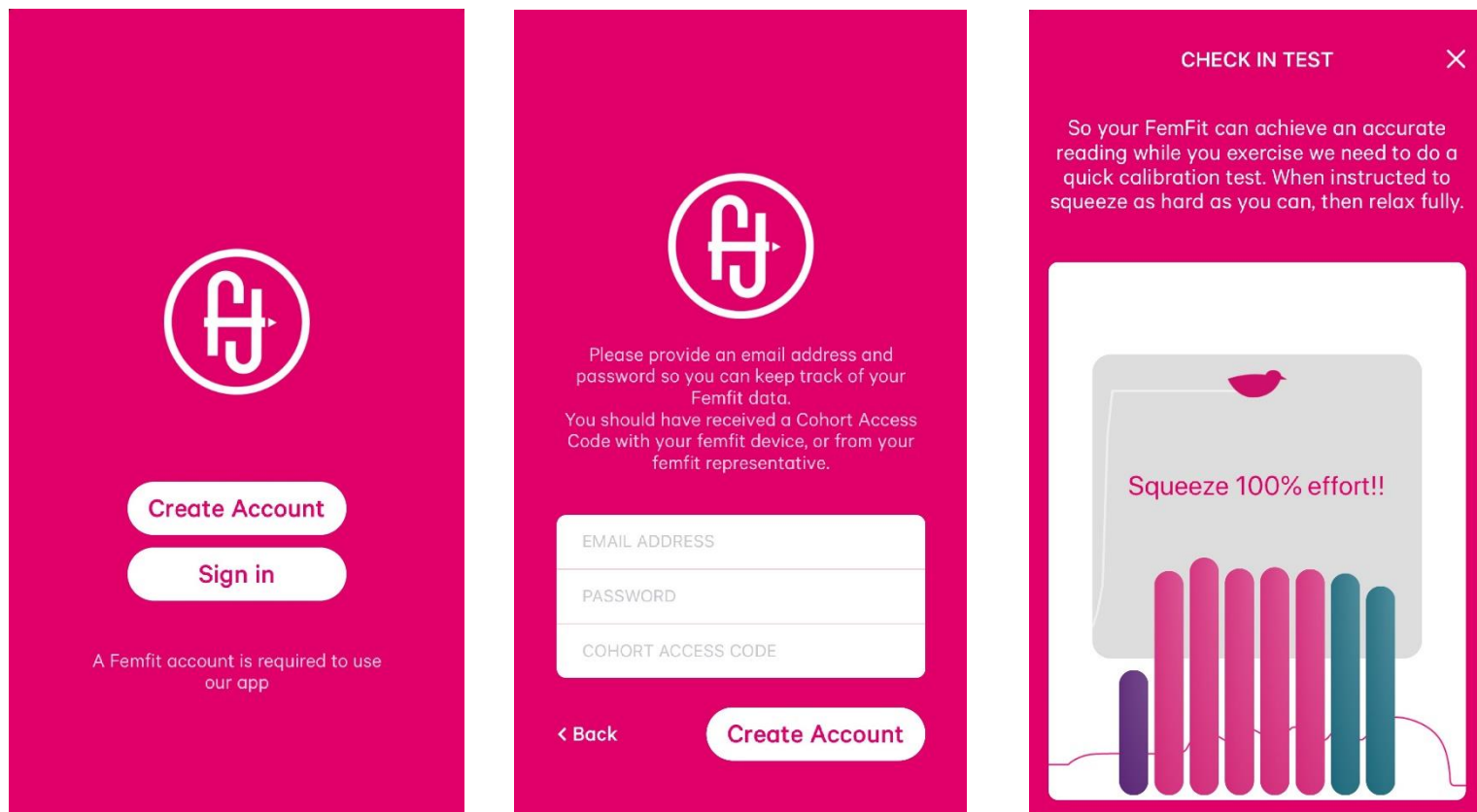
“Skip Practice Exercise” or finishing “Try a Practice Exercise”

This will take you to the login screen where you can “Create Account” or “Sign in”. You need to have a femfit account to use the App.

NOTE: Once your account is set up, and you have connected your femfit device once, 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.Login screen

Once you have created your femfit account, each subsequent visit to the App will take you to the home screen on the left. Please sign in. Once your femfit is successfully connected to the App, the pod light indicator will start blinking.



6.5.Check-in test

Each time you use your femfit device, you will need to perform a check-in test to calibrate your femfit for the exercise session. It is important to have your device in place and to be in the correct posture (e.g. lying down) **before** you start check-in. Once you are comfortable and ready, proceed to follow the on-screen instructions.

NOTE: Keep your smart device and femfit less than 1 meter apart to ensure a strong and stable connection.

6.6.My day

Once you have completed the check-in test, you will see the “My Day” tab in the App. This screen gives you a summary of all your activities, any training sessions scheduled, and the battery and connection status of your femfit.

There is a bar at the bottom of your screen which allows you to access the various functions in the App.

From here, you can choose to access the following:

Help

This will take you through the on-boarding 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

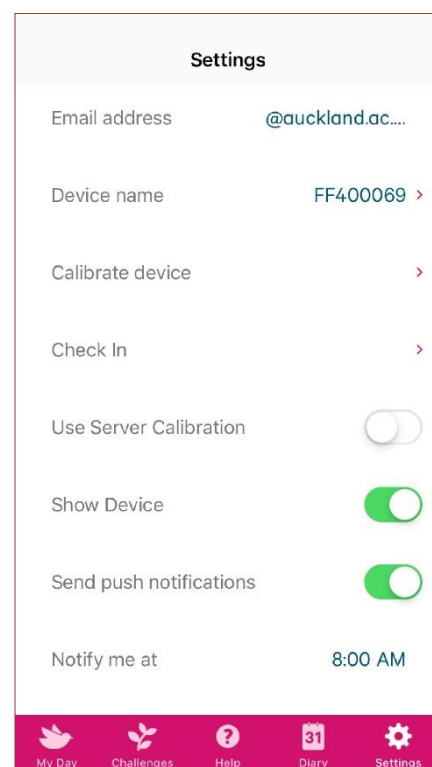
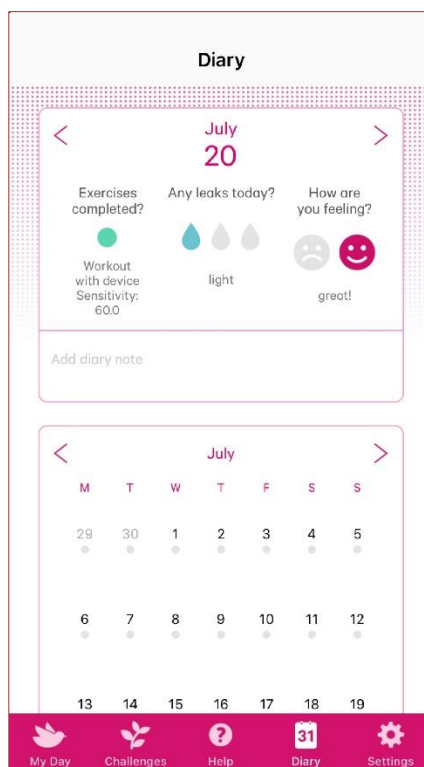
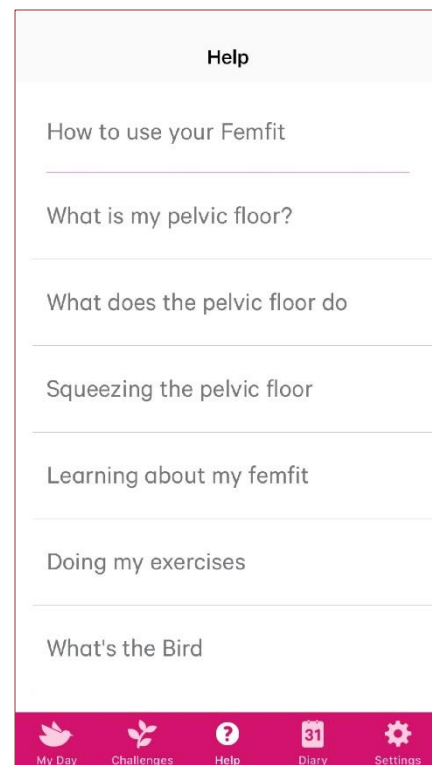
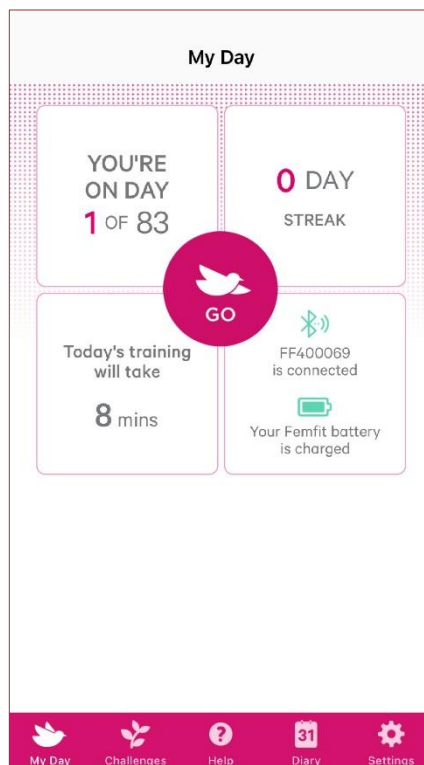
Here you can see your current training plan and record any events such as leaks, your mood, problems, etc. The current day will automatically be selected but you can select and edit other days on the calendar.

Programmes

Here you select a training programme. The Starter programme introduces the 4 types of exercises that are typically used in exercise programmes.

Strength builder 12-week programme: 12 weeks of progressive exercises. The intensity and repetition of the exercises increases every 4 weeks. Position to do the exercises changes from lying to supported standing, to standing.

Post-surgery programme: A 12 week programme designed to help with strength building and co-ordination.



Settings

Here you can manage your account information and see your femfit information. You can also forget your current device if you would like to connect to another femfit device.

GO

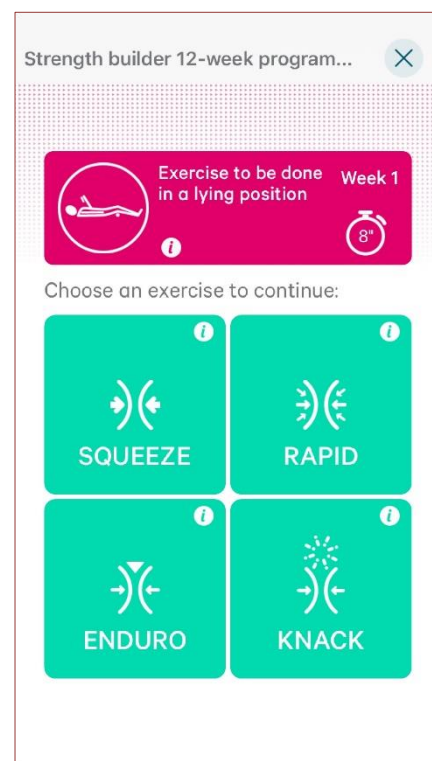
When you are all set, tap on GO to load your training programme for today.

6.7.Live training

The live training screen will guide you through your exercises for the day. Each session has 4 types of exercises. For the first month, these exercises will take around 8 minutes to complete. In the second month, this will step up to 12 minutes. In your third and final month, the exercises extend to 16 minutes. The exercises are “Squeeze”, “Rapid”, “Enduro”, and “Knack”. When you begin your program, you will be instructed to perform your exercises lying down. As your muscles improve, the App will instruct you to graduate to a supported standing position and later to standing unsupported. If you are ever unsure of the position you should exercise in, you can check the box at the top of the screen when you select ‘GO’ (pictured to the right). 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.

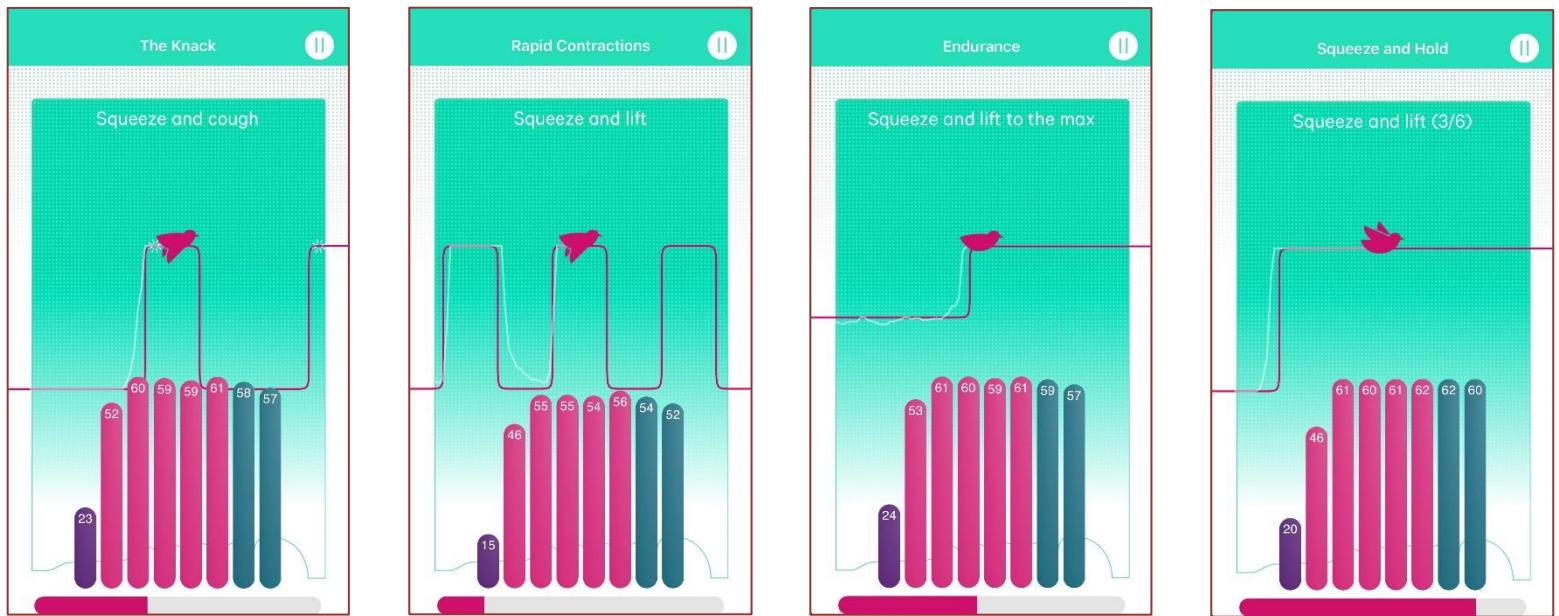
The App will guide you on the number and timing for each exercise. By clicking on the ‘i’ you will get more information about each of the exercises. Once your exercise session starts, your femfit will send live feedback to the App about how effective your muscle contractions are.

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 <i>Increasing muscle strength</i>	Rapid <i>Improving coordination and endurance</i>
<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 pink 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 pink bars as they represent your internal pelvic floor muscles.</p>	<p>For this exercise, you will squeeze and lift your pelvic floor muscles rapidly, release and relax, and then repeat.</p> <p>The pink 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 pink bars as these represent your internal pelvic floor muscles.</p>
Enduro <i>Endurance and control - the ‘Podium’</i>	Knack <i>Coordination</i>
<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 pink 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 pink 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 pink 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 pink 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 exercise session:








When you have finished, the App will record your performance for the day.

6.8. Your femfit information

No personal identifying data is stored by the App on JUNOFEM's servers. Only encrypted pressure data is stored and linked to your account. For more information please refer to JUNOFEM's privacy statement and cyber-security statement.

6.9.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

7.1.Introduction

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

7.2.Ending your exercise session

Once you have completed your daily exercises and put in all the notes you would like recorded in the diary, you can close the App by pressing the home button on your smart device (or any other way you close an App on your smart device). You do not need to disconnect your femfit before you close the App.

7.3.Turning OFF and removing your femfit device

After your training session, please follow the steps below:

Turning OFF your femfit device

To turn OFF your femfit, hold down the button on the pod for 1 second. If you do this while connected to the App you will see the “Lost Connection” screen.

If your femfit is not connected to the App, it will automatically turn off after 20 minutes.

If your femfit is connected to the App, it will automatically turn off when the battery voltage runs flat.

Removing the femfit device

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.

7.4.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. If you wish to, 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.

NOTE: Refer to Section 11 for environmental storage conditions.



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 area's local waste management requirements.

9. Troubleshooting

9.1.Introduction

These troubleshooting sections are organized by their function or system component. The solutions are shortened, and some information has been left out. You can find more detailed answers and preventative measures in the specified sections indicated by 'according to Section #. #.'

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 should 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.

9.3.femfit device

Problem	Solution
Device is not turning ON	Charge your femfit according to section 4.3 to ensure that there is enough charge. Press the button located underneath the femfit monogram on the pod. The pod light indicator (located next to the logo) should light up.
Device won't turn OFF	Hold down the button on the pod for 1 second until the light has stopped blinking.
Unsure what LED indicator status means	Light on – device is on Light off – device is off Light is blinking – device is connected to the App

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.

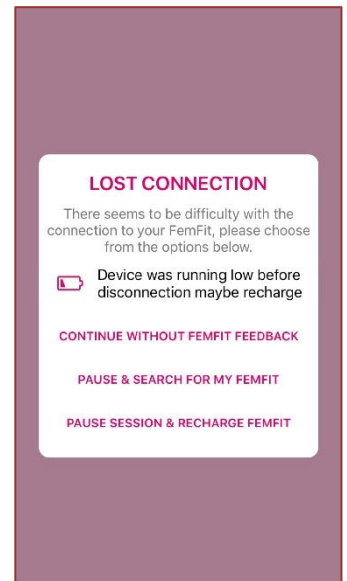
App cannot detect device

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
MN004_E



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

Disconnect and reconnect your femfit. Close and reopen the femfit App.

10. Glossary

Abdominal muscles	The stomach or core muscles. Their pressure is indicated by the top two sensors (7 and 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 (pink bars) and abdominal muscles (blue bars) .
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 indicator light	LED on pod that is 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.

<i>Stem upper</i>	The half of the narrow extension of the sensor on the half closest to the sensor.
<i>Stem lower</i>	The half of the narrow extension of the sensor on the half closest to the pod.
<i>‘Squeeze’</i>	Squeeze, lift, and hold maximum contraction; trying to hold this for a specified duration.
<i>Starter program</i>	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.
<i>Training program</i>	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.
<i>Urinary incontinence</i>	Any involuntary leakage of urine. Stress incontinence is leakage during stress or load on the body such as a sneeze or cough.
<i>USB charging cable</i>	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 array	IP67
Power box	IP22
Case	IP21

Operating environmental conditions

Parameter	Min	Max
Temperature	5°C	40°C
Humidity	15%	90%
Pressure	700hPa	1060hPa

Transport environmental conditions

Parameter	Min	Max
Temperature	-20°C	60°C
Humidity	0%	90%
Altitude	0m	12,800m

Charger case electrical specifications

USB type connection	Micro USB
Max. peak current	TBD (~600mA)
Average current	TBD (~150mA)

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	

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.
Pod and Charger case	Biocompatible acrylonitrile-butadiene-styrene (ABS) plastic. Meets the requirements of ISO10993-1. Nature of contact: skin. Duration of contact: <60minutes.

Surface temperature

Surface temperature of pod or charger case insert	Surface temperature may get up to 60 degrees Celsius 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
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	charger.
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Accuracy

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

Service life

<i>Shelf life</i>	36 months
<i>Service life after first use</i>	12 months

Essential Performance:

femfit is a pelvic floor training tool which measures a pressure profile in the vagina to track pelvic floor strength during a training program. femfit records the pressures accurately across 8 sensors which respond independently to the vaginal pressure.

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 saturating, 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 Ltd or the local distributor.

12. Electromagnetic immunity and emissions declaration and guidance

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by JUNOFEM Ltd as replacement parts for internal components (if any), may result in increased emissions or decreased immunity of your femfit.

Guidance and manufacturer's declaration — femfit

12.1. Electromagnetic emissions specifications


Immunity test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	Your femfit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Your femfit is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

12.2. Electromagnetic immunity specifications

Your femfit is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Transmitter compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 IEC 60601-1-11	0% UT for 1 cycle 0% UT for 0.5 cycle at 8 phase angles 70% UT (30% dip in UT) for 25 cycles 0% UT for 250 cycles	Not applicable	Main power quality should be that of a typical commercial or hospital environment.

NOTE: Your femfit is wirelessly powered by its charger case.

Immunity test	IEC 60601 test level	Transmitter compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 (Receiver only)	3 Vrms 150 kHz to 80 MHz	3 Vrms	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Recommended Separation Distance $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	10 V/m	

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the G6 is used exceeds the applicable RF compliance level above, the G6 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the femfit.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

12.3. Recommended separation distances between portable and mobile RF communications equipment and the femfit

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of your femfit including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Your femfit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the receiver as recommended in the next table, according to the maximum output power of the

communications equipment.

Portable and mobile RF equipment includes baby monitors, Bluetooth wireless headsets, wireless routers, microwave ovens, laptops with internal Wi-Fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

12.4. Minimum recommended distance between other RF transmitters and the Dexcom transmitter/receiver

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz d = $1.2P^{1/2}$	80MHz to 800MHz d = $1.2P^{1/2}$	800MHz to 2.5GHz d = $2.3P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in feet can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12.5. 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.

Guidance and manufacturer's declaration — charger case

12.6. Electromagnetic emissions specifications


Immunity test	Compliance	Electromagnetic environment guidance
<i>RF emissions CISPR 11</i>	Group 2	The charger case uses RF energy to perform its function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
<i>RF emissions CISPR 11</i>	Class B	The femfit is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

12.7. Charger case electromagnetic immunity specifications

The charger case is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Transmitter compliance level	Electromagnetic environmental guidance
<i>Electrostatic discharge (ESD) IEC 61000-4-2</i>	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
<i>Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8</i>	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.
<i>Electrical Fast Transient/Burst IEC 61000-4-4</i>	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
<i>Surge IEC 61000-4-5</i>	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
<i>Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11 IEC 60601-1-11</i>	0% UT for 1 cycle 0% UT for 0.5 cycle at 8 phase angles 70% UT (30% dip in UT) for 25 cycles 0% UT for 250 cycles	0% UT for 1 cycle 0% UT for 0.5 cycle at 8 phase angles 70% UT (30% dip in UT) for 25 cycles 0% UT for 250 cycles	Main power quality should be that of a typical commercial or hospital environment.

NOTE: UT is the AC main voltage prior to application of the test level.

Immunity test	IEC 60601 test level	Transmitter compliance level	Electromagnetic environmental guidance
Conducted RF IEC 61000-4-6 <i>(Receiver only)</i>	3 Vrms 150 kHz to 80 MHz	3 Vrms	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Recommended Separation Distance $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the G6 is used exceeds the applicable RF compliance level above, the G6 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the femfit.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

12.8. 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.

INDUSTRY CANADA STATEMENT








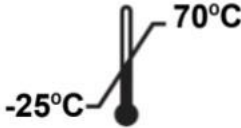




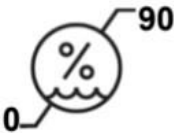

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

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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.

13. Label symbols

The symbols found on the charge case of the femfit tell you about the proper and safe use of the femfit system. Below is an explanation of what each symbol means.

	C-Tick: Compliance with applicable EMC standard	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
	CE marking		RF transmitter
	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		

14. Need help?

More information can be found at thefemfit.com

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

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