

Instructions for Use



flyte[✦]

Flyte System, MTI-1.5

support@flytetherapy.com | 1-866-735-8482 | www.flytetherapy.com

860 Blue Gentian Rd. Suite 200, Eagan MN 55121

©2024 Pelvital USA, Inc. All rights reserved. Pelvital and Flyte are trademarks of Pelvital USA, Inc.

Table of Contents

Getting Started	3
Thank You for Choosing Flyte	4
Intended Use	4
Indications for Use	4
How Does Flyte Work?	5
What's in the Box?	6
Contraindications	8
Precautions	9
General Safety Information	10
Potential Adverse Events	10
Cleaning	12
How to Clean Flyte	13
Preparing to use Flyte	15
Charge the Controller	16
Gather Materials	17
Visually Inspect	17
Find a Comfortable Position	17
Using Flyte	19
How to Use Flyte	20
End the Day's Session	23
Store and Handle Flyte	23
Support	25
Product Registration & Warranty	26
Warranty Exclusions	26
DME Rental	26
Frequently Asked Questions	27
Troubleshooting	28
Flyte Customer Care	29
Disposing of Flyte	29
Federal Communications Commission (FCC) Power Input	29
Technical Specifications	30
Electromagnetic Compatibility	31
Glossary of Terms	36
Explanation of Symbols	37



Getting Started

Thank You for Choosing Flyte®

Flyte is designed to improve weak pelvic floor muscles. When pelvic floor muscles become weak, actions such as coughing, laughing, and exercising can result in urine leakage, also known as urinary incontinence.

Flyte was designed by physicians who are experts in urogynecology, muscle rehabilitation, and urinary incontinence. Flyte is designed to help strengthen pelvic floor muscles to treat urinary incontinence in women, in the comfort of your home.

Intended Use

The Flyte System is intended for strengthening of the pelvic floor muscles.

Indications for Use

The Flyte System is intended for strengthening of the pelvic floor muscles to treat women with mild, moderate, and severe stress urinary incontinence.

How Does Flyte Work?

Flyte is designed to help women strengthen weak pelvic floor muscles to reduce bladder leaks — both in terms of the frequency of urine leakage and the volume of urine leakage.

Once placed in the vagina and turned on, the Flyte wand delivers a series of mechanical vibrations while the controller guides you through a series of contractions (squeeze and lift) and relaxations of your pelvic floor muscles during a 5-minute per day, six-week treatment. The Flyte System conditions and strengthens the pelvic floor muscles when delivering mechanical vibrations during Kegel contractions. The wand is designed to make optimal contact within the vaginal canal and to deliver vibrations at a specific frequency as directed by the controller. The wand additionally provides a resistive surface against which you can contract your pelvic floor muscles. This treatment is called mechanotherapy.



IMPORTANT: To achieve the best results, it is important that you read these Instructions for Use thoroughly and understand the contraindications, precautions, and directions for use before using Flyte.

What's in the Box?

FLYTE CONSISTS OF THE FOLLOWING COMPONENTS:

- A. Flyte wand:** Measures whether the pelvic floor muscles are contracting, applies load through a mechanical stimulus to amplify the effects of each contraction.
- B. Controller:** A handheld device that controls the delivery of mechanical stimulus by the wand and provides information to guide your pelvic floor muscle contractions.
- C. Charging cable:** Connects the controller to the wall charger.
- D. Charging block:** AC adapter that allows you to plug the controller into a wall outlet for charging.

OTHER ACCESSORIES (NOT INCLUDED WITH FLYTE):

Mild Soap: For cleaning Flyte.

Clean cloths: For wiping the device surfaces.

Water-based vaginal lubricant (optional): Makes insertion of the wand easier.

Lubricated condoms (optional): Makes wand insertion and cleaning easier.

OPTIONAL COMPONENTS (NOT NEEDED FOR USE OF FLYTE):

The Flyte App is a mobile application that provides an optional additional interface to enhance your experience.

The Flyte App enables you to create an account, pair the App with the Controller, and view general Flyte information and instructions. During a treatment session, the Flyte App provides an optional additional interface guiding you through the treatment session. The Flyte App enables you to view treatment history, including dates a treatment session was completed, contraction and relaxation data from those sessions, and the results of two surveys collected from you by the Flyte App at regular intervals.

The Flyte App is not required for use of the Flyte System. Please see page 24 for additional information on installing and securely using the Flyte App.

A. Flyte Wand

B. Controller



C. Charging Cable

D. Charging Block

Contraindications

DO NOT USE FLYTE IF YOU:

- ◆ Are under 21 years of age.
- ◆ Have given birth in the past 6 weeks.
- ◆ Have had genitourinary or pelvic surgery in the past 6 weeks.
- ◆ Have had vaginal surgery within the past 3 months.
- ◆ Have experienced unusual or unexpected vaginal bleeding in the past 6 months.
- ◆ Experience pain or a burning sensation when you urinate, which could indicate a urinary tract infection.
- ◆ Experience vaginal discharge that has an odor, irritation, soreness, or itching, which could indicate a vaginal infection.
- ◆ Have been diagnosed by your doctor with a severely dry (atrophic) vagina.
- ◆ If you have a sensitivity or allergy to silicone.

ASK YOUR DOCTOR BEFORE USING FLYTE IF YOU:

- ◆ Are pregnant.
- ◆ Experience pain during sexual intercourse or when inserting a tampon or tampon-like device.
- ◆ Often have trouble keeping in a tampon or tampon-like device.

DO NOT USE FLYTE:

- ◆ If insertion of the Flyte wand causes excessive discomfort.
- ◆ With a tampon, a tampon-like device, a diaphragm, a pessary, or other intravaginal product.
- ◆ During sexual intercourse.
- ◆ On rare occasions when the wand causes irritation.
- ◆ For any reason other than its intended purpose.

Precautions

- ◆ Flyte is not sterile. Please follow the cleaning instructions prior to use.
- ◆ Use Flyte only as described in this Instructions For Use.
- ◆ Do not disassemble any component of Flyte.
- ◆ Do not use Flyte if any component appears to be damaged.
- ◆ Do not store or use Flyte in excessively hot, cold, or humid environments. Please refer to “Technical Specifications” for approved operating temperature and humidity.
- ◆ Do not share your Flyte with others. It is for individual use only.
- ◆ Do not clean the wand in the dishwasher. The wand is not dishwasher safe.
- ◆ Do not submerge the controller, the charging cable, the charging block, or the wand in water.
- ◆ Let the wand dry before replacing it in the box.
- ◆ No part of Flyte is designed to be repaired or modified by the user. Attempting to repair or modify system components will void any applicable warranty and could lead to injury or further damage to components.

Security Precautions

- ◆ Ensure the Flyte App being downloaded and installed on your mobile device is the same as the one recommended by Pelvital.
- ◆ When using with Flyte App, ensure pairing is only done in the privacy of your home with your trusted mobile device.
- ◆ When connected to the Wi-Fi or cellular data, the Flyte App securely uploads your treatment data to a secure cloud repository for your physician to optionally review.
- ◆ Ensure your mobile device is only connected to reliable/secure Wi-Fi or cellular connection to enable data upload to the cloud.
- ◆ For your security, do not share your mobile device or your Flyte login information with anyone!
- ◆ Please notify Flyte Customer Care if you observe any suspicious behavior with your Flyte device, Flyte App, or Flyte account.

General Safety Information

- ◆ Keep Flyte out of reach of children.

Potential Adverse Events

- ◆ As with all intravaginal devices, a foreign-body response (response of biological tissue to any foreign material in the tissue) may occur.
- ◆ Tissue responses to the wand can include vaginal irritation or discharge, irritation to the urethra or other surrounding tissue, pain, and inflammation. If you experience these responses, you may need to stop using Flyte.
- ◆ Improper placement or use of the wand may cause temporary or permanent injury.

If you suspect that the integrity of any component of Flyte has been compromised, please contact Flyte Customer Care. See page 29 for contact information.



WARNING: Do not use a charging system other than the one provided with Flyte. Use of the wrong charging system can damage Flyte.



WARNING: Do not use Flyte while in the bath, swimming, or otherwise submerged.

This page intentionally left blank.



Cleaning

How to Clean Flyte

We recommend that you clean Flyte before you use it the first time and after each use.

Clean Flyte with mild soap and water. The procedure provided in this Instruction For Use manual explains how to use mild soap and water for cleaning.



WARNING: Note the following warnings when cleaning the wand:

Do not use glass or household cleaners on the wand.

Stop using the wand and contact Flyte Customer Care immediately if you notice any signs of deterioration, such as a change in color, or any indication of damage.

TO CLEAN THE WAND, COMPLETE THE FOLLOWING STEPS:

1. Wash your hands.
2. Use a clean, wet cloth to remove any obvious residue from the wand.

Use only a soft cloth or wipe to clean the wand. Abrasive materials such as scouring pads and steel wool can damage the wand's silicone covering, reducing its reliability and adding to the risk of contamination and infection.

3. Wash with mild soap and warm water for 20 seconds.
4. Rinse the wand thoroughly and dry with a clean dry cloth.



WARNING: Do not submerge the controller, the charging cable, the charging block, or the wand in water.

This page intentionally left blank.



Preparing to Use Flyte

Charge the Controller

Before using Flyte for the first time, you must charge the controller (round unit) for at least 2.5 hours or until the yellow charging light turns off.

Complete the following steps to charge the controller:

We recommend that you recharge the battery weekly or as needed.

1. Plug the black connector end of the charging cable into the controller until you hear a click.
2. Plug the white USB end of the charging cable into the charging block.
3. Plug the wall charging block into an electrical outlet.
4. Allow the controller to charge for at least 2.5 hours, or until the charging light turns off.

The solid yellow charging light on the controller indicates that the device is charging. When this light turns off, the controller is fully charged.

5. When charging is complete, unplug the charging cable from the controller by pressing the tabs on both sides of the connector and gently pulling the cable out.
6. Unplug the charging cable from the charging block.
7. Store the charging cable and charging block in the box for later use. If ready to use, proceed to the next set of instructions.

Gather Materials

Before you start your session, please have the following materials available:

- ◆ A clean cloth for cleaning the wand and controller.
- ◆ Mild soap
- ◆ **Optional.** A water-based vaginal lubricant or a lubricated, non-latex probe cover or condom to make the wand insertion more comfortable.

Visually Inspect

Prior to each use, visually inspect all Flyte components. In particular, make sure that there are no cracks or tears in the silicone cover of the wand or cable that could expose the component's interior wires or electronics.

Find a Comfortable Place and Position

Find a comfortable and private place for your treatment session where you can **concentrate on your treatment** for 5 continuous minutes.

You can use Flyte either lying down, sitting, or standing up. We recommend using Flyte lying on your back when you first begin but choose a position that is comfortable for you.

As you continue with your treatments and gain strength and tone, you may choose to change your position. For the most accurate information on your controller during your session, you should remain in the same position for the full 5 minutes of the treatment session. Feel free to contact our Ask a PT service for options on positions.

This page intentionally left blank.



Using Flyte

How to Use Flyte

Please read steps 1 through 7 before starting your treatment session. Complete the following steps to conduct a treatment session:

- 1** Plug the connector end of the wand's cable into the controller until you hear a click.
- 2** Fully insert the wand into your vagina, with the longer wing facing the front of your body.

If necessary, apply a small amount of water-based vaginal lubricant to the wand or cover the wand with a lubricated, non-latex probe cover or condom.

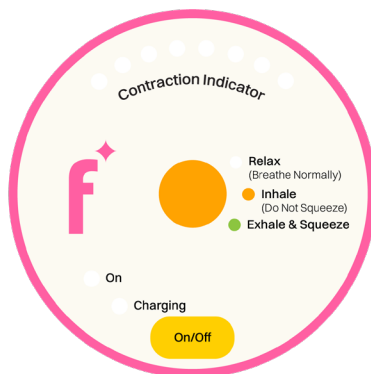
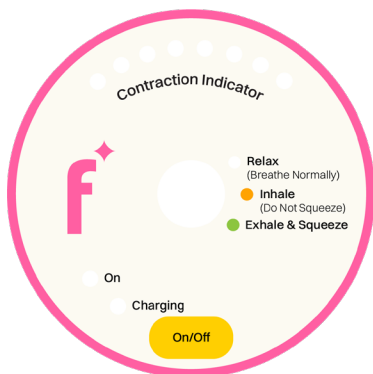
Remove the wand if you encounter excessive discomfort, and then contact Flyte. See "Flyte Customer Care" for contact information.

- 3** On the controller, firmly squeeze the On/Off button for about 1-2 seconds until the device turns on.

The On light on the controller will be solid green. You will also see one blue light blink.

FLYTE WILL NOW START YOUR TREATMENT SESSION!

Relax & breathe normally (8 seconds) Inhale & do not squeeze (2 seconds)



- 4 Flyte starts your treatment with an 8 second rest cycle with NO CENTER LIGHT on. Relax, rest, and breathe normally. Do not squeeze during this rest period.
- 5 The center light will then turn ORANGE for 2 seconds. You will start to feel the vibration of the wand. DO NOT SQUEEZE your pelvic floor during these 2 seconds as Flyte is measuring the resting tone of your pelvic floor muscles. Instead, please continue to relax and take a gentle belly breath in through your nose for these 2 seconds to help further relax your pelvic floor muscles.

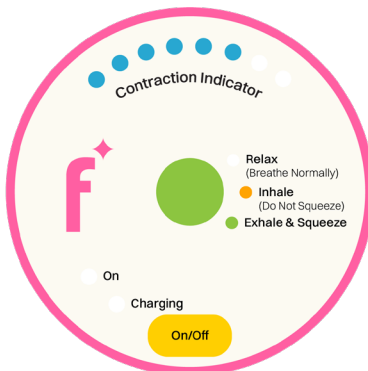
This relaxation awareness will improve the quality of your contraction, improve the information provided on your controller, and help you to feel the location of the muscles you will squeeze during the green light.

DO NOT squeeze your pelvic floor muscles when the orange light is on. Flyte is measuring the resting tone of your pelvic floor muscles. Breathing in and not squeezing during the orange light helps to improve the accuracy of the information provided during the green light (squeeze) phase and reminds you not to squeeze during the orange light phase.

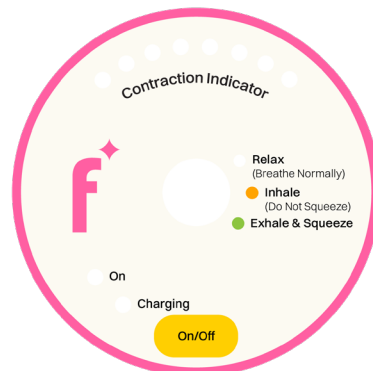
- 6 When the center light turns green, exhale slowly while squeezing and lifting your pelvic floor muscles for 5 seconds until the green center light turns off and the wand stops vibrating.

As you squeeze and lift your pelvic floor muscles, the blue Contraction Indicator lights will light up from left to right. Focus on the timing and coordination of your pelvic floor between the orange light inhale relaxations and the green light exhale squeezes rather than the number of blue lights you can turn on. This will improve the overall function and quality of your pelvic floor response to treatment.

Exhale & Squeeze (5 seconds)



Back to Relax (8 seconds)



How to Use Flyte (continued)

The blue lights indicate how well you can relax and then contract your pelvic floor muscles. It is normal to see variation in the blue lights during a treatment session and from session to session for a variety of reasons. Please contact Flyte Customer Care with any questions.

When the center light turns off and the wand stops vibrating, release and relax your pelvic floor muscles. You will then return to the 8 second rest cycle.

- 7** Repeat steps 4-6 for the full 5-minute session. When the session is done, Flyte automatically turns off. Each session consists of 20 repetitions.

It is important to squeeze your pelvic floor muscles only when the center light on the controller is green.

REMEMBER: Breathing is an important part of any muscle rehabilitation therapy and is also helpful when using Flyte. Inhale and do not squeeze during the 2 second orange phase of the cycle to help relax the pelvic floor, exhale while you squeeze and lift during the green 5 second phase and relax and breathe normally during the 8 second phase when no light is lit on the controller.

End the Day's Session

To end the day's session, complete the following steps:

1. Unplug the wand cable from the controller.
2. Remove the wand from your vagina by grasping the base (by the wings) of the wand.
3. Clean the wand by following the instructions in "Cleaning."
4. Store Flyte in the box until the next session.

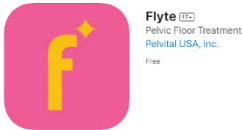
Store and Handle Flyte

- ◆ DO NOT expose Flyte to temperatures below -20°C (-4°F) or above 35°C (95°F), such as ice water, boiling water, or the microwave.
- ◆ Keep away from strong magnetic fields because they can turn Flyte off and on.
- ◆ Store Flyte in the box provided and out of direct sunlight when not in use to avoid device damage and maintain cleanliness.
- ◆ Keep Flyte away from children and pets.
- ◆ Flyte may discolor for various reasons. If discoloration occurs, discontinue using Flyte and contact Flyte Customer Care.

Flyte is not responsible for any damage from improper storage and handling.

Flyte App (optional)

- ✦ For U.S. users, the Flyte App can be downloaded from the Apple or Google Stores. The Flyte App is an optional interface to enhance your experience.
- ✦ Ensure you only download the official Flyte App from the official Apple or Google app store. The official Flyte App appears like this:



- ✦ Once the Flyte App is installed, you must create a Flyte account to pair the App with your Controller and use it
- ✦ Creating the account will require a code provided via email by Flyte Customer Care or your healthcare provider. If you have not received a code, contact Flyte Customer Care at support@flytetherapy.com or 1-866-735-8482.
- ✦ The App will guild you through the available features and a training session before beginning a treatment session.
- ✦ The App connects to the Controller through Bluetooth.

SOUP/COTS Name	Manufacturer (or Supplier)	Product Cybersecurity Information Location	Location within Flyte Device
Gecko SDK	Silicon Labs	https://www.silabs.com/developers/gecko-software-development-kit	Device
BLE stack	Silicon Labs	https://www.silabs.com/developers/bluetooth-low-energy?tab=documentation	Device
MPLAB Code Configurator	Microchip	https://www.microchip.com/en-us/tools-resources/configure/mplab-code-configurator	Device



Support

Product Registration & Warranty

Flyte comes with a 1-year product warranty on the wand and a 3-year product warranty on the controller against manufacturer defect-related problems from normal use of the product. Please register your Flyte by providing us the following information in one of 2 ways:

1. Online at <https://flytetherapy.com/register-your-product/>
2. By calling Flyte Customer Care at 1-866-735-8482 (press 1 when prompted)

Be ready to supply the following information to complete registration:

- ◆ Your name and address
- ◆ Serial number of your Flyte System (located on the back of the box, starts with “S”)
- ◆ Date of Purchase
- ◆ Place of Purchase

Warranty Exclusions

This warranty does not extend to any products (a) that have been subject to misuse, neglect, abuse, improper cleaning, storage, accident, or that have not been properly maintained; (b) that have been modified; or (c) that have been disassembled, serviced, or reassembled by any party other than Pelvital. THE FOREGOING LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES AND EXCEPT FOR ANY EXPRESS WARRANTIES STATED HEREIN, PELVITAL USA EXPRESSLY DISCLAIMS ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF QUALITY, CONDITION, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.

DME Rental

If you have received your Flyte System device under a capped rental arrangement and if applicable, you will receive information about the return process for the Controller from the licensed Durable Medical Equipment (DME) company processing your order. If you have any questions about this, please contact your DME provider or Flyte Customer Care.

Frequently Asked Questions

My wand is slipping out. What do I do?

If you find your Flyte wand is being pushed out during your treatment, it is likely that you are not using your pelvic floor muscles properly or using the right muscles. Please visit our website www.flytetherapy.com under Using Flyte FAQs and Videos. You can also contact Flyte Customer Care for support.

What is the wand made of?

The wand's outer cover is made of medical-grade silicone. Electronic components located inside the inner casing deliver the mechanical vibrations.

Can I use Flyte during my period?

Yes, you can use Flyte during your period. However, be sure that you have removed any tampons or other intravaginal devices prior to use.

Can I sterilize the wand?

The wand should not be sterilized. It is intended to be cleaned according to the instructions included in this Instructions For Use. Do not boil the wand or clean it using any agents or methods other than those listed in this Instructions For Use.

What should I do if the wand is uncomfortable to use?

Some discomfort may occur when using Flyte. Some women have experienced discomfort for the first few days as they begin exercising their pelvic floor muscles, similar to the discomfort you feel in any muscle when you begin a new training program. If the discomfort is excessive, consider discontinuing use of Flyte and calling Flyte Customer Care.

How often should I recharge the device's battery?

It is recommended that you recharge the battery weekly or as needed. When the battery reaches a low level, the green On light on the controller blinks on and off. If the charging light does not turn on when plugged in, Flyte does not need to be charged. Continue to use.

Can I share Flyte with someone else?

No. Flyte is a single-user product.

Troubleshooting

Refer to the below table if you have problems with any component of Flyte.

Problem	Probable Cause and Solution
The controller does not turn on when I press the On/Off button.	The most likely cause is a depleted battery. Try charging the controller for at least 2.5 hours before attempting to turn the device on again.
The controller turns on, but the wand does not vibrate.	Make sure that the wand cable is securely plugged into the controller until you hear a click.
The wand or controller behaves in a manner that is inconsistent with the directions for use.	Turn the controller off, unplug the wand, plug back in, and then turn the controller back on. If this does not resolve the issue, contact Flyte Customer Care.
Yellow charging light not turning on	Be sure your charging cable is fully plugged in until you hear a click. Or the battery is already fully or nearly fully charged and does not need to be charged. Continue to use as directed.
The Bluetooth connection is lost between the controller and the Flyte App during a therapy session.	The therapy session is still safe and effective. After the session, attempt to re-pair the device. If it is unsuccessful contact Flyte Customer Care. If you suspect that there is interference with your device Bluetooth connection (from a TV, Microwave, etc.), move away or to a room where such disturbances are not present.

Flyte Customer Care

If problems persist, please contact Flyte:

- ◆ Email: support@flytetherapy.com
- ◆ Web: www.flytetherapy.com
- ◆ Phone: 1-866-735-8482 (Press 1 when prompted)

Flyte Customer Care is staffed by Doctors of Physical Therapy that specialize in pelvic floor physical therapy. You can be confident in connecting with us that we can help answer your questions and guide you towards success.

ABOUT PELVITAL USA, INC.

For more information about Pelvital, please visit our website at www.flytetherapy.com.

Disposing of Flyte

Flyte contains a rechargeable lithium-ion battery. The battery may contain hazardous substances that could affect health and the environment if not properly disposed of. To avoid the dissemination of those substances in our environment and to diminish the pressure on natural resources, Pelvital encourages you to use the appropriate systems for product disposal. Consult your local council for advice on the location of such facilities. Note that the lithium battery in the controller poses a fire hazard and may explode if incinerated.



Federal Communications Commission (FCC) Power Input

This device complies with Part 15 of the FCC Rules of Operation and 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 §21 by the FCC as follows: Interference which endangers the functioning of a radionavigation 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.

Technical Specifications

Model: MTI-1.5	Main power: Lithium-ion rechargeable battery, 680-710mAh nominal capacity
Electrical class: Internally powered	Operational frequency: 30 Hz
USB input power: 5 V direct current (DC), 485 mA (455 mA for charging and 30 mA for electronics)	Training cycle: 5 minutes
Modes: Training mode, Charging mode	Ingress protection: IP22*
Weight: <ul style="list-style-type: none">◆ Controller: 69 g ± 2 g◆ Wand: 89 g ± 1 g	Dimensions: <ul style="list-style-type: none">◆ Controller: 80 mm (diameter) x 16 mm (height)◆ Wand: 29 mm (diameter) x 100 mm (length)
Power requirement: Internally powered 5 V DC	Temperature: <ul style="list-style-type: none">◆ Operating: 5°C (41°F) to 35°C (95°F)◆ Storage: -20°C (-4°F) to 35°C (95°F)
Atmospheric pressure: 700 hPa to 1060 hPa	Relative humidity: <ul style="list-style-type: none">◆ Operating: 10 - 90%, non-condensing◆ Storage: 10 - 85%, non-condensing
Safety certifications: IEC/EN 60601-1; IEC/ EN 60601-1-2; IEC/EN 60601-1-11	Charging time before first use: Approximately 2.5 hours

*Protected from touch by fingers and objects > 12mm. Protected from water spray < 15 degrees from vertical.

EXPECTED SERVICE LIFE

When proper care is taken, and maintenance instructions are followed, the expected service life of Flyte is 1 year for the wand and 3 years for the controller.

Electromagnetic Compatibility

Flyte requires special precautions for electromagnetic compatibility (EMC) and should be used according to the EMC information provided in this Instructions For Use.

For electromagnetic (EM) compliance, it is important to use only accessories that meet the specifications recommended by Pelvital. (Please refer to the “What’s in the Box?” section.)


The following recommendation is for actions to ensure that Flyte remains safe with regard to EM disturbances:

- ◆ If Flyte is used in a location near (for example, less than 1.5 km [1 m] from) AM, FM, or TV broadcast antennas, it may be necessary to take preventative actions to reduce the EM interference level (for example, by physically moving to a different location).

Guidance and Manufacturer’s Declaration — Electromagnetic Emissions

Flyte is intended for use in the electromagnetic environment specified below. The customer or user of Flyte should ensure that it is used in such an environment. When Flyte is exposed to EM disturbances, the system may show abnormal behavior.

Emissions test	Compliance	Electromagnetic environment: Guidance
Radiated Emissions: EN55011	Group 1 Class B	Flyte uses radio-frequency (RF) energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
Conducted Emissions: EN55011	Group 1 Class B	
Harmonic emissions: IEC 61000-3-2	Not applicable	Flyte is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions: IEC 61000-3-3	Not applicable	

Guidance and Manufacturer’s Declaration — Electromagnetic Immunity			
Flyte is intended for use in the electromagnetic environment specified below. The customer or user of Flyte should ensure that it is used in such an environment. When Flyte is exposed to EM disturbances, the system may show abnormal behavior.			
Immunity test	IEC 60601 test Level	Compliance level	Electromagnetic environment: Guidance
Electrostatic discharge: EN61000-4-2	±2, ±4, ±6, ±8 kV contact ±2, ±4, ±8, ±15 kV air	A	
Radiated RF immunity: EN61000-4-3	10 V/m 80 MHz to 2.7 GHz	A	<p>Portable and mobile RF communications Equipment should be used no closer to any part of Flyte than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance d = 1.17√P 80 MHz to 800 MHz d = 2.33√P 800 MHz to 6 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).</p> <p>Flyte is fairly sensitive to radiated RF. Disturbances in data transfer are possible at and below the specified test level. It may be necessary to move away from interfering equipment. 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:</p> 
	28 V/m 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz	A	
	27 V/m 385 MHz	A	
	9 V/m 710, 745, 780, 5240, 5500, 5785 MHz		
Electrical Fast Transient/ Burst: EN61000-4-4	+/-2 kV AC Power +/-1 kV Signal and I/O Cables	AA	

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

Flyte is intended for use in the electromagnetic environment specified below. The customer or user of Flyte should ensure that it is used in such an environment. When Flyte is exposed to EM disturbances, the system may show abnormal behavior.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment: Guidance
Surge Immunity: EN61000-4-5	+/-2 kV Line 1 to Earth Neutral to Earth	A	
	+/-1 kV Line 1 to Neutral	A	
Conducted Immunity: EN61000-4-6:	3 Vrms 0.15 MHz to 80 MHz 6 Vrms 1.9, 3.75, 5.35, 6.798825, 7.15, 10.125, 13.56, 14.1, 18.12, 21.2, 24.94, 27.12, 28.82, 40.68, 52 MHz	A	
Power frequency magnetic field: EN61000-4-8	30 A/m	A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips and Interruptions: EN61000-4-11	100% reduction for 0.5 cycles	A	
	100% reduction for 1 cycles	A	
	30% reduction for 25/30 cycles	C	
	100% reduction for 250/300 cycles		

Guidance and Manufacturer’s Declaration — Electromagnetic Immunity

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 Flyte is used exceeds the applicable RF compliance level above, Flyte should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and Flyte

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

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 a part of Flyte. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of the transmitter, W	Separation distance according to the frequency of the transmitter, m		
	150 kHz to 80 Hz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 6 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and Flyte

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

NOTE: At 80 MHz and 800 MHz, the separation distance for 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.

Glossary of Terms

Atrophic vaginitis:

Thinning, drying, and inflammation of the vaginal walls caused by a reduction in estrogen

Intravaginal:

Inside the vagina

Pelvic floor exercises:

Exercises designed to improve the function of pelvic floor muscles

Pelvic floor muscles:

Layers of muscles that play a role in sphincter control, organ support, lymphatic drainage, stability, and sexual function

Pelvic floor physical therapist:

A physical therapist who specializes in treating the pelvic floor muscles as well as musculoskeletal causes of various pelvic disorders

Stress urinary incontinence:

Complaint of involuntary loss of urine on effort or physical exertion including sporting activities, or on sneezing or coughing

Urinary incontinence:







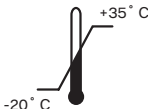
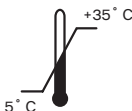
Complaint of involuntary loss of urine

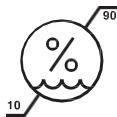
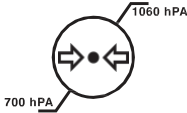
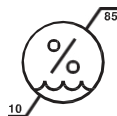





Urogynecologist:

A doctor who specializes in disorders of the pelvic floor, such as incontinence

Vagina:

The passage leading from the uterus to the outside of the female body

Explanation of Symbols	
	Indicates the medical device manufacturer.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Refer to instruction manual/booklet.
	DO NOT THROW IN TRASH.
	Indicates the need for the user to consult the Instructions For Use for important information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Indicates a medical device that needs to be protected from moisture.
	Only store and transport system components in places where the temperature ranges between -20°C (-4°F) and 35°C (95°F).
	Only use this system when the room temperature is between 5°C (41°F) and 35°C (95°F).

Explanation of Symbols	
	Only use this device with relative humidity between 10% and 90%, non-condensing (that is, no water is forming on the device because of condensation).
	Only use this device when the atmospheric pressure is between 700 hPa and 1060 hPa. Except in extraordinary circumstances, the weather in most parts of the world has an atmospheric pressure well within the 700-hPa to 1060-hPa range.
	Only store and transport this system with relative humidity between 10% and 85%, non-condensing (that is, no water is forming on the device because of condensation).
	Indicates the date when the medical device was manufactured.
	Do not expose to sunlight.
	Indicates the manufacturer's catalogue number so the medical device can be identified.
	Type BF Applied Part.
	Indicates that the device is enabled with Bluetooth® capability. The device leverages Bluetooth Low Energy version 5.2.

This page intentionally left blank.

Instructions for Use



OTC IFU Part #: LBL-027-04

©2024 Pelvital USA, Inc. All rights reserved.
Pelvital and Flyte are trademarks of Pelvital
USA, Inc.

Reproduction, adaptation, or translation
of this Instructions For Use is prohibited
without prior written permission of Pelvital,
except as allowed under copyright laws.

PELVITAL

Pelvital USA, Inc.
860 Blue Gentian Rd.
Suite 200
Eagan, MN 55121
USA
www.flytetherapy.com