



## Activator

# Supplemental Instructions

This booklet contains important information concerning the operation of the inFlow Activator, as well as regulatory and safety information. For best results, please read and keep this booklet.



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## Glossary






Mark	Meaning
	Manufacturer
	Indicates a home use medical device with applied parts rated Type BF
	Do not place defective equipment in the trash. Return to your prescribing physician or to Vesiflo.
	Date of manufacture
<b>REF</b>	Catalog number
<b>SN</b>	Serial number
<b>LOT</b>	Lot number
	Follow Instructions for Use

Table 1. Glossary Meanings

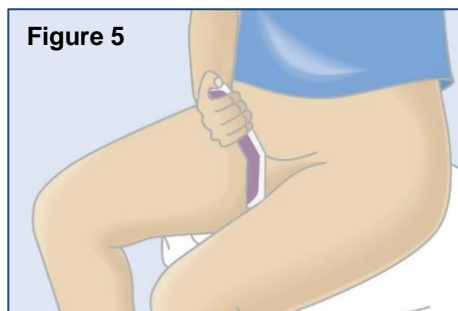
## Notices

- ◆ **WARNING:** No modification of this equipment is allowed.
- ◆ Use only supplied inFlow Charger (Cat. No. 403320). Use of any other charger voids warranty and may result in user hazard.
- ◆ The inFlow Activator and its Base Station are not user-serviceable. Report any problems to your prescribing physician, MTM or Vesiflo.
- ◆ Choose a location for the inFlow Charger or Base Station that makes it easy to disconnect the inFlow Charger from the AC outlet and that makes it unlikely a baby or child could become entangled in the Charger cord, due to the risk of strangulation.
- ◆ Keep the Activator, Base Station and Charger away from children.
- ◆ Not suitable for use in an oxygen-rich environment.
- ◆ Equipment needs to be installed and put into service in accordance with the information provided in this and other accompanying documents

## Using Your Activator

To use your Activator, sit on a toilet/commode (or use a female urinal) and follow these simple instructions:

1. **Hold the Activator as shown** in Figure 4.



2. **Position the Activator as shown** in Figure 5. The bottom (heavy) section should be positioned just above the inserted device and pushed gently into your abdomen. Continue to hold the Activator in this position.
3. **Press the button** to start urinating and continue pressing the button until you no longer hear or feel a urine stream.
4. **Let go of the button when you finish voiding, but continue to hold the Activator in position.** Do not move the Activator away from your body until you hear a loud beep and the light changes from **red** to **green**. This indicates that the device valve has closed, blocking the flow of urine.

If you move the Activator before the device valve closes, you will leak.  
If that happens, do this:

- a. Sit on the toilet/commode again.
- b. Position the Activator so that its bottom section pushes into your body, as described in Step 2 above.
- c. Hold the button down for 10 seconds and then let it go.
- d. **Keep the Activator in position** until you hear a loud beep and see the light change from **red** to **green**.

## Charging Set-up and Use

**To set up the Activator Base Station** (Figure 1), follow this procedure:

1. Find a good location. If the Base Station and inFlow Charger (Figure 2) can be kept away from the sink, a bathroom is usually best. If not, place the Base Station on top of a bureau or similar furniture. *Be sure that the location you choose allows you to easily disconnect the inFlow Charger from the AC outlet.*
2. Insert the inFlow Charger into back of the Base Station (Figure 3). *Note: The inFlow Charger is medical-grade and you should never use a different charger.*
3. Plug the inFlow Charger into an AC outlet.



**To charge the Activator**, insert it into its Base Station (Figure 1). A **red** light on the Activator will blink while it is being charged. When the Activator is fully charged, this light will change to a solid **green**.

You should leave the Activator in its Base Station each night; that way it will always be fully charged to start the day. Always have your Activator close at hand during the day.

Keep in mind that the Activator's magnet can attract metal objects and damage credit cards when it is not in its Base Station.

## Specifications

Activator Operation	Limited to controlling the inFlow device. Operation consists pushing the Activator's (only) button, which when held close to an inserted inFlow device will spin its internal pump and empty the bladder. Releasing the Activator's button when held close to the inserted inFlow device will automatically engage its internal valve and prevent further urine flow.
	The patient (user) or her caregiver is the operator of the Activator.
	Any Activator can control any inFlow device.
	Contact with the inFlow Activator should be limited to intact skin.
Rated Duty Cycle	The Activator duty cycle is 30 seconds on and three hours off based on use 5x times per day, avg. bladder volume of 350cc and nominal inFlow pump output of 12cc/second. Patient-specific variations in this schedule are determined by the prescribing physician.
Applied Parts	The Activator is applied part rating BF. The Activator Base Station and Charger are applied part rating B. The place of the Activator Base Station (bathroom counter, bureau, etc.) is also considered an applied part.
Expected Service Life	Three (3) years normal use based on the estimated life of integral rechargeable battery.
Material	The Activator and Base Station are composed of Chi Mei PC-115P, an ISO 10993-certified material.
Environmental Limitations	No limitations concerning temperature, humidity or atmospheric pressure are anticipated based on use or storage in normal household or commercial office environments or during transport by commercial carriers.
Ingress Protection	The Activator is classified as an IP22 device, which means it is protected against falling drops of water.
	The Activator Base Station is classified as an IP21 device, which means it is protected against vertically falling drops of water or condensation.
Accessories	Activator Base Station, Cat. No. 403310
	inFlow Charger, Cat. No. 403320

**Table 2. Specifications**

## Indicators

Needs charging	When button is pressed, LED will blink red and audio indicator will beep
Charging in process	LED continues to blink red
Charging complete	LED turns green
Device in use (button depressed)	When button is pressed, LED turns green
Use complete, valve engaged	Shortly after button is released, LED turns green and audio indicator beeps

**Table 3. Activator Indicators**

## Electromagnetic Compatibility (EMC) Compliance: Guidance and Manufacturer's Declaration

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The inFlow Activator and accessories comply with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.

The inFlow Activator and accessories have been tested and proven to meet the following requirements for electromagnetic compatibility:

Conducted Emissions	EN 60601-1-2 Group 1 Class B
Radiated Emissions	EN 60601-1-2 Group 1 Class B
Voltage Fluctuations / Flicker Emissions	EN 61000-3-3(2013)
Harmonic Emissions	EN 61000-3-2 (2006) +A1+A2
Electrostatic Discharge	EN 61000-4-2 (2009)
Radiated Immunity	EN 61000-4-3 (2006) +A1+A2
Electrical Fast Transient Burst	EN 61000-4-4 (2012)
Surge	EN 61000-4-5 (2006)
Conducted Immunity	EN 61000-4-6 (2014)
Magnetic Immunity	EN 61000-4-8 (2010)
Voltage Dips and Interruptions	EN 61000-4-11 (2004)

**Table 4. EMC Compliance with Standards**

It is recommended that radio frequency transmitting devices (e.g., cellular phones) not be used in the near vicinity of the inFlow Activator during operation. These may affect medical equipment operation.

The Activator is intended for use in an electromagnetic environment in which radiated radio frequency (RF) disturbances are controlled. The user of the Activator can help prevent electromagnetic interference by maintaining a minimum separation or distance between portable, mobile, or fixed RF communications equipment (transmitters) and the Activator as recommended in Table 5, according to the maximum out power of the communications equipment.


Recommended Separation Distances Between Portable and Mobile RF Communications and the Activator			
Rated maximum output power of transmitter Watts (W)	Separation distance according to frequency of transmitter Meters (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 kHz to 2.7 GHz $d = 2.3 \sqrt{P}$
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 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 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.

**Table 5. Recommended Separation Distances**

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Activator is intended for use in the electromagnetic environment specified below. The customer or the user of the Activator should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 60601-4-2	±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%.
Electrical fast transient/burst IEC 61000-4-4	Not Applicable	Not Applicable	Battery operated equipment
Surge IEC 61000-4-5	Not Applicable	Not Applicable	Battery operated equipment
Voltage Dips, short interruptions and voltage variations on the power supply input lines IEC 61000-4-11	Not Applicable	Not Applicable	Battery operated equipment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should not be greater than levels characteristic of a typical location in a commercial or hospital environment.
Conducted RF IEC61000-4-6	Not Applicable	Not Applicable	Probe does not utilize cables
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Activator than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 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, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

**Table 6. Recommended Electromagnetic Environments**



### Helpful Hints

- ◆ Use the Activator every two (2) to three (3) hours during the day or as discussed with your physician or nurse.
- ◆ Try to drink 36 ounces of fluid daily. This should include at least four 8 oz. glasses of water.
- ◆ Avoid drinking three (3) hours before bedtime and always empty your bladder before sleeping.
- ◆ Keep the inFlow Activator in its powered Base Station when not in use to ensure it will always be fully charged.
- ◆ Read the *Device and Activator Information for Patients and Instructions for Use* that is provided with your inFlow device.

### Problems or Questions?

- ◆ For medical problems, contact your prescribing physician or go to an emergency room.
- ◆ For equipment problems or questions, contact your prescribing physician, your Authorized European Rep or Vesiflo.
- ◆ Always keep an intermittent catheter or other back-up means of bladder drainage with you. If the inFlow does not drain your bladder for any reason, remove the inFlow device and use your back-up.
- ◆ Return defective or unused Activators your prescribing physician, Authorized European Representative or to Vesiflo directly. Do not dispose of locally.