

Symbols on Product Labeling

Symbol	Symbol Title	Description
	Date of manufacture + Country of manufacture	Date the device was manufactured. The 2 letters inside the symbol indicate the country code of the country of manufacture
	Use-by date	Date after which the medical device is not to be used.
	Do not reuse	Medical device that is intended for one use, or for use on a single user during a single procedure.
	Batch code	Manufacturer's batch code so that the batch or lot can be identified.
	Catalog number	Manufacturer's catalog number so that the medical device can be identified.
	Manufacturer	Medical device manufacturer
	Importer	The entity importing the medical device into the locale
	Distributor	the entity distributing the medical device into the locale
	EC Representative	The Authorized Representative in the European Community / European Union
	CE Mark	The device has been approved by a Notified Body (NB). The NB is signified by the 4 digits next to the CE Mark symbol
	Do not use if package is damaged	Medical device that should not be used if the package has been damaged or opened.
	Unique Device Identifier	Carrier that contains Unique Device Identifier information.
	Medical device	Item is a medical device
	Refer to Instruction Manual	Instruction manual/booklet must be read
	Degrees of protection provided by enclosures (IP Code)	Protected against solid objects over 12.5mm (e.g a finger) and protected against falling drops of water, if the case is disposed at any angle up to 15 degrees from vertical.
	Keep Dry	Medical device that needs to be protected from moisture
	Type BF applied part	Type BF applied part complying with IEC 60601-1
	RoHS Compliant	Product meets the restrictions on tenhazardous materials suchas lead, mercury, and cadmium
	Temperature	The temperature limits to which the medical device can be safely exposed
	Humidity	The range of humidity to which the medical device can be safely exposed
	Pressure	The range of atmospheric pressure to which the medical device can be safely exposed

Electromagnetic Emissions

Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1 Class B	The in2 patch 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.

Declaration - Electromagnetic Immunity

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance																							
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV 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 commercial or hospital environment.																							
Proximity fields from RF wireless communications EQUIPMENT (Immunity test) IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010	See Table 9 of IEC 60601-1-2: 2014 for the proximity field test levels that were evaluated.	See Table 9 of IEC 60601-1-2: 2014 for the proximity field test levels that were evaluated.	See Table 9 of IEC 60601-1-2: 2014 for the proximity field test levels that were evaluated.																							
Radiated RF IEC 61000-4-3	10V/m	10V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of in2, including cables, than the recommended separation distance calculated from the equations below</p> <p>Recommended separation distance</p> $d = [1.2] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = [2.3] \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ <table border="1"> <thead> <tr> <th rowspan="2">Rated maximum output power of transmitter (W)</th> <th colspan="2">Recommended separation distance according to frequency of transmitter (m)</th> </tr> <tr> <th>80 MHz to 800 MHz</th> <th>800 MHz to 2.7 GHz</th> </tr> </thead> <tbody> <tr> <td></td> <td>$= [1.2] \sqrt{P}$</td> <td>$= [2.3] \sqrt{P}$</td> </tr> <tr> <td>0.01</td> <td>0.12</td> <td>0.23</td> </tr> <tr> <td>0.1</td> <td>0.38</td> <td>0.73</td> </tr> <tr> <td>1</td> <td>1.20</td> <td>2.30</td> </tr> <tr> <td>10</td> <td>3.80</td> <td>7.27</td> </tr> <tr> <td>100</td> <td>12.0</td> <td>23.0</td> </tr> </tbody> </table> <p>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. D Interference may occur in the vicinity of equipment marked with the following symbol: </p>	Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m)		80 MHz to 800 MHz	800 MHz to 2.7 GHz		$= [1.2] \sqrt{P}$	$= [2.3] \sqrt{P}$	0.01	0.12	0.23	0.1	0.38	0.73	1	1.20	2.30	10	3.80	7.27	100	12.0	23.0
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VIRILITY

www.in2patch.com



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Virility Medical
24 Hanagar St.
Hod-hasharon 4527713
Israel
Email: info@in2patch.com
Authorized EU Representative:
Obelis s.a
Blvd. General Wafis, 53
B-1030 Brussels
Belgium
For importer and/or distributor details*, please see the information on the devices' box. *If applicable in your country

in2

in2 User Guide
Management of Premature Ejaculation

Description

The in2 device is a single-use disposable patch designed to manage premature ejaculation. The patch contains electrodes to provide EMS (Electrical Muscle Stimulation) on the perineal muscles to help control ejaculation. The perineum is the area between the legs, between the scrotum (the genitals) and the anus.

Purpose of the patch

The in2 patch is indicated for management of Premature Ejaculation in males who ejaculate after penetration (intromission). It is designed to increase the time between erection (arousal) and ejaculation by delivery of short duration, low-intensity electrical stimulation to the perineal muscles and nerves during intercourse.

Never use in2 if you:

- Have an implanted electronic device (e.g., pacemaker, neurostimulator, etc.)
- Have been diagnosed with, or are receiving treatment for pelvic cancer
- Suffer from skin diseases, irritations, sores or abnormalities in the area between the genitals and the anus
- Have any known allergy or hypersensitivity to any of the patch's materials
- Require any muscle therapy in the area between the genitals and the anus
- Have diabetes with peripheral nerve disease
- Have had surgery in the area of the genitals or anus (e.g., inguinal hernia)

Warnings and Precautions

- Stop stimulation and stop using the patch if pain occurs in the pelvis. Consult a doctor if pain persists
- Do not apply the in2 patch to any area other than the male perineum (the area between the scrotum and the anus)
- The in2 patch is a single-user device (do not transfer between users)
- Stop stimulation and stop using the device if allergic reaction occurs
- Do not use while driving or operating machinery
- Do not shave the perineum (perineal hair) before use

Potential Adverse Reactions

Stop using in2 if you feel:

- Skin irritations and burns
- Discomfort in the pelvis
- Pain in the pelvis
- Allergic reactions

General Usage and Safety Guidelines

Follow these guidelines for safe and effective use of the in2 patch:

- Do not apply any kind of solvents or cleaning agents to the patch
- Do not use while sleeping
- Do not place the patch on other objects
- Keep out of reach of children
- Do not remove the patch from moisture-sealed packaging or remove liner until ready to use
- Do not reuse a patch
- Do not use more than two patches per day

Environmental Conditions that Affect Use

- The patch is intended for home use
- Store in a dry, room temperature environment
- Do not use the patch in water or in a humid environment (such as a jacuzzi, bath, shower, etc.)
- Do not use within 1.5 meters of shortwave or unshielded microwave devices
- Do not use in an oxygen-rich environment
- Do not use near electromagnetic radiation

Disclaimers

The in2 has not been tested on:

- Usage with a pregnant partner
- Men having intercourse with other men
- Users with past occurrences of ejaculation before vaginal penetration
- Men younger than 18 or older than 60

Incidents reporting

NOTE Any serious incident/injury that has occurred in relation to the device should be reported to the manufacturer and/or distributor and/or importer, to the FDA, and the Competent Authority of the Member State in which the user and/or patient is established.

EU

Any incident that directly or indirectly led or might have led to any of the followings:

- (1) the death of a patient, user or other person,
- (2) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- (3) a serious public health threat.

US

Serious injury means an injury or illness that:

- (1) Is life-threatening,
- (2) Results in permanent impairment of a body function or permanent damage to a body structure, or
- (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

System Components

The in2 patch is provided in packages containing:

- Two (2) pouches.
- Each pouch contains one (1) in2 patch
- One (1) User Manual

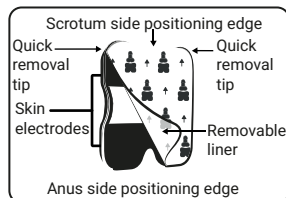


Figure 1
Diagram of skin-side of in2 patch components

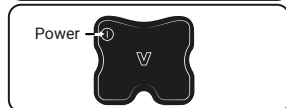


Figure 2
Diagram of cover, Power Button location

Unpacking

1. Open the carton box
2. Take a pouch out of the carton box.
3. Open the pouch as described in Figure 3 and take out the patch.



Figure 3
Pouch opening by tearing the top part using one of the tear-notches

Directions for Use

Applying the Patch

For best results, follow these directions:

1. Trim perineal hair to 2–4 mm length with hand-held electric clippers.

CAUTION

Do not shave the perineum area; shaved skin may encourage skin irritations.

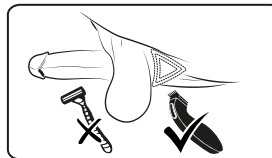


Figure 4
Trim the perineal hair.
DO NOT SHAVE the perineum.

2. Wash and clean the skin to remove any oils. Dry thoroughly.
3. Make sure that there are no cuts, abrasions, or sores in the area.
4. Remove the liner and gently bend the patch in a U-shape.



Figure 5
Remove the liner before applying the patch.

5. Gently lift the scrotum to expose the perineum. Apply the patch to the center of the perineum. The Scrotal Positioning Edge should be closely aligned with the back side of the scrotum (see Figures 6 & 7)

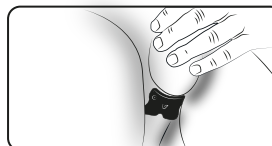


Figure 6
Gently lift the scrotum and apply the patch behind it.

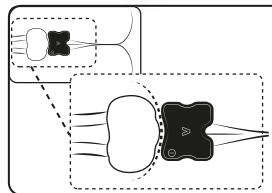
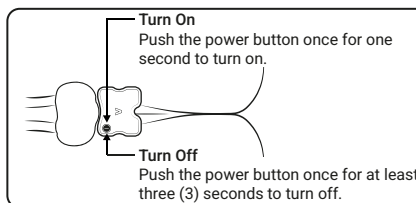


Figure 7
The patch should be closely aligned with the back side of the scrotum.

6. Push the power button once for one second to turn on. The stimulation begins and reaches the configured intensity level within a few seconds.

The in2 patch operates between 12 and 15 minutes (continuously or cumulatively).



CAUTION

if you experience discomfort or pain, stop the stimulation (turn off the device) immediately. (Hold the power button down for at least three (3) seconds.)



Removal and disposal of the patch

After usage, turn OFF the device and remove the patch as follows:

1. Hold down the power button for at least three (3) seconds to stop stimulation.

CAUTION



Do NOT remove the patch while it is still ON as it may result in pain and discomfort from the electrical output generated by the patch.

2. Grasp the non-stick tips to gently peel the patch away.
3. Return the patch to its packaging and dispose of in regular (non-recycled) waste.

References

Product Specifications

Dimensions	W: 42 mm; L: 38 mm; H: 4.8 mm		
	W: 1.65 in; L: 1.5 in; H: 0.19 in		
Weight	Approximately 6 grams (0.21 oz)		
Skin-contacting materials	Hydrogel Backing; Polyolefin foam, thermoplastic elastomer (TPE)		
Environmental conditions	Temperature		Humidity
	Operational	5°C to 36°C / 41°F to 97°F	5% to 75% RH
Storage	5°C to 40°C / 41°F to 104°F	5% to 75% RH	
Transportation	-25°C to 40°C / -13°F to 104°F	5% to 75% RH	
Power Source	LR721 Silver-oxide 2x 1.5VDC Non-rechargeable batteries		
No. of Channels	1		
Max Current	14.3mA±10%		
Max Voltage	90v±10%		
Waveform	Symmetrical Biphasic Pulse		
Pulse Duration	400µs±10%		
Frequency	30Hz±10%		
Electrodes	Hydrogel, minimal size 475mm ²		
Range of Impedance	1kΩ-6kΩ±10%		
Current Density	Exceeds 2mA/cm ²		

Device package contents (Bill of Materials)

Catalogue (Part) Number	Description
VP40-Hi	High intensity in2 patch Single unit (patch in pouch)
VP40-Lo	Low intensity in2 patch Single unit (patch in pouch)
VP44-Hi	High intensity in2 patch 4 units
VP44-Lo	Low intensity in2 patch 4 units
VP42	Starter Kit 1 High intensity unit; 1 Low intensity unit