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 genitals and the anus.
in2 is available in two intensity levels (High and Low).

Purpose of the patch

The in2 patch is indicated for management of Premature Ejaculation in males who ejaculate after penetration. It is designed to increase the time between erection 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 been diagnosed with, or are receiving treatment for pelvic cancer
- Have an implanted electronic device (e.g., pacemaker, neurostimulator, etc.)
- 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., vasectomy, inguinal hernia)

Warnings and Precautions

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

Potential Adverse Reactions

- 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 from moisture-sealed packaging or remove liner until ready to use
- 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
- Users with past occurrences of ejaculation before penetration
- Men younger than 18 or older than 60
- Men having intercourse with other men

Incidents reporting

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

A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat.

System Components

The in2 is provided in packages containing:

- Four (4) pouches, indicated either High or Low intensity. Each pouch contains one (1) in2 patch
- One (1) User Manual

The Starter Kit contains:

- Two (2) pouches, one indicated High intensity and another indicated Low intensity. Each pouch contains one (1) in2 patch
- One (1) User Manual

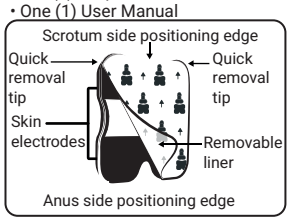


Figure 1
Diagram of skin-side of in2 components

Figure 2
Diagram of cover, Power Button location

Unpacking

1. Select the in2 with suitable intensity (High or Low).

NOTE | If this is your first time using in2, select Low intensity.

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 V-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.

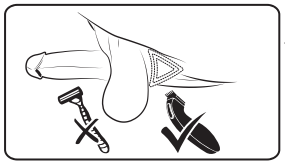


Figure 4
Trim the perineal hair. **DO NOT SHAVE** the perineum.

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)

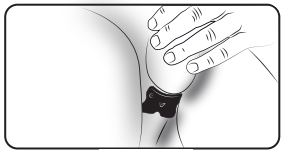


Figure 6
Gently lift the scrotum and apply the patch behind it.

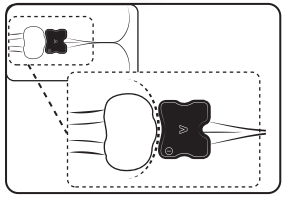
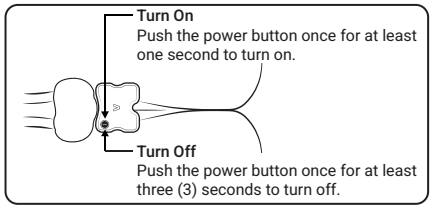


Figure 7
The patch should be closely aligned with the back side of the scrotum.

6.Push the power button once for at least 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, turn off the device immediately. (Hold the power button down for at least three 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.

Product Specifications

Dimensions	W: 42 mm; L: 38 mm; H: 4.8 mm		
Weight	Approximately 6 grams		
Skin-contacting materials	Hydrogel Backing: Polyolefin foam, thermoplastic elastomer (TPE)		
Environmental conditions	Temperature		Humidity
Operational	5ºC to 36ºC	41ºF to 97ºF	5% to 75% RH
Storage	5ºC to 40ºC	41ºF to 104ºF	5% to 75% RH
Transportation	-25ºC to 40ºC	-13ºF to 104ºF	5% to 75% RH
Power Source	LR721 Silver-oxide 2x 1.5VDC non-rechargeable batteries		
No. of Channels	1		
Max Current	HIGH: 14.3mA±10%; LOW: 9.9mA±10%		
Max Voltage	HIGH: 90v±10%; LOW: 60v±10%		
Waveform	Symmetrical Biphasic Pulse		
Pulse Duration	400µs±10%		
Frequency	30Hz±10%		
Electrodes	Hydrogel, minimal size 475mm²		
Range of Impedance	1kΩ-6kΩ±10%		
Current Density	Exceeds 2mA/cm²		

Device package contents

Catalogue 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 pack 4 units
VP44-Lo	Low intensity in2 pack 4 units
VP42	Starter Kit 1 High intensity unit; 1 Low intensity unit

VIRILITY

www.in2patch.com

*If applicable in your country

For importer and/or distributor details*, please see the information on the devices' box.

Belgium
B-1030 Brussels
Blvd. General Wahis, 53
Obelis s.a
Authorized EU Representative:

Virility Medical
24 Hanagar St.
Hod-hasharon 4527713
Israel
Email: info@in2patch.com

in2 User Guide

Management of Premature Ejaculation

Electromagnetic Emissions

Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group1 Class B	The in2 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.

Declaration - Electromagnetic Immunity

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
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 from 80MHz to 2.7GHz	10V/m 10V/m from 80MHz to 2.7GHz	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 **Recommended separation distance** d= [1.2] $\sqrt{p}$ 80 MHz to 800 MHz d= [2.3] $\sqrt{p}$ 800 MHz to 2.7 GHz

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
	d = [1.2] $\sqrt{p}$	d = [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

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:

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.
LOT	Batch code	Manufacturer's batch code so that the batch or lot can be identified.
REF	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 REP	EC Representative	The Authorized Representative in the European Community / European Union
CE	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.
UDI	Unique Device Identifier	Carrier that contains Unique Device Identifier information.
MD	Medical device	Item is a medical device
	Refer to Instruction Manual	Instruction manual/booklet must be read
IP22	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