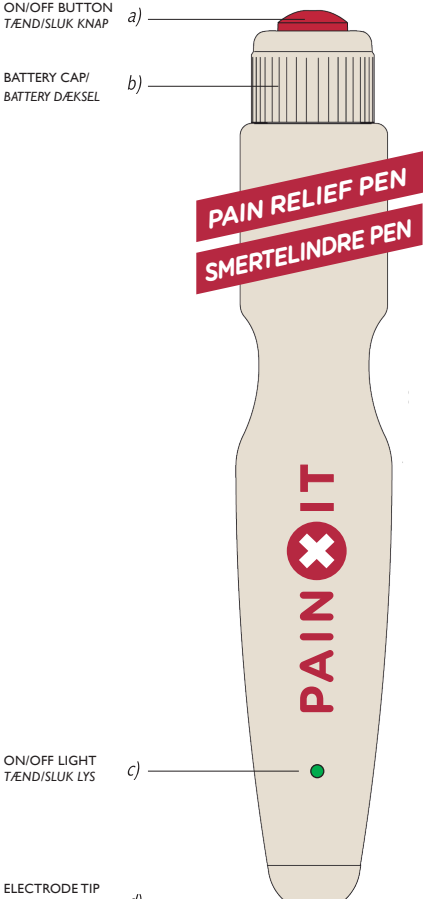
INSTRUCTION BOOKLET
BRUGSANVISNING



01/15

PAIN RELIEVER PEN –
Transcutaneous electro-stimulator

PainXit is a portable non-invasive fast-working, effective, simple and safe medical device designed to relieve both acute and chronic pain. Its efficacy is based on the medical technique called TNS/TENS (Transcutaneous (Electrical) Nerve Stimulation) using low-frequency electrical pulses to activate your body´s own natural defence system against pain - endorphins - to relieve chronic and acute pain through the skin. Drug-free and natural - you can't overdose. NO known side effects.

DESTINATION OF USE:
Clinical purpose: Pain relief (TNS/TENS)
Field of use: Domestic

PACKAGE CONTENT:
PainXit device incl. 1x1,5V AAA battery
1 extra battery +1 x instruction booklet

WARNINGS:
- Do not use the device if you see damages and particularly to the casing and to the electrode tip: please contact the manufacturer as reported in "Assistance" paragraph.
- Avoid the use of the device to people not properly informed by reading the instruction booklet.
- Avoid the use in wet ambience.
- During the treatment, we recommend not wearing metal objects.
- It is forbidden to use the device in such way that the flow of current crosses the cardiac area.
- It is forbidden to use the device on or near injuries or lesions of the skin.
- It is forbidden to use the device on the carotid sinus (carotid), genitals and near the eyes. Keep a minimum distance of 3 cm from the eyeball.
- Do not use the device on patients with an electronic device implanted without consulting the doctor.
- The simultaneous connection of a patient to a HF surgical device can lead burns in corrispondence of the electrodes of the stimulator and the stimulator can be damaged.
- Operate close (p.e. 1 mt) to a shortwave or microwave device for therapy can producing instability in the output of the stimulator.
- The manufacturer is responsible for the performance, reliability and safety of the device if:
  - Eventual additions and/or repairs are performed by authorized personnel
  - The device is used in strict accordance with the instruction of use contained in this instruction booklet

SMERTELINDRE PEN -
Transkutan elektro-stimulator

PainXit er et bærbar hurtigt-virkende, effektiv, enkel og sikker medicinsk apparat designet til at lindre både akutte og kroniske smerter. Dens effektivitet er baseret på en medtode kaldet TNS / TENS – Transkutan (elektrisk) nervestimulation – som ved hjælp af lavfrekvente elektriske impulser gennem huden aktiverer kroppens egen naturlige forsvarssystem mod smerter - endorfiner - og lindrer såvel kroniske som akutte smerter. Du kan ikke overdosere . Ingen kendte bivirkninger.

ANVENDELSE:
Klinisk formål: Smertelindring (TNS/TENS)
Anvendelsesområde : Hjemmebrug

PAKKENS INDHOLD:
PainXit apparat incl. 1x1,5V AAA batteri
1 ekstra batteri + 1 x brugsanvisning

ADVARSEL:
- Apparattet må ikke anvendes, hvis det fremstår skadet, både det udvindige og elektroderne nederst: kontakt producenten som anvist i afsnittet "Assistance".
- Undgå brug af apparattet på folk, som ikke er ordentligt informeret via brugsanvisningen.
- Undgå brug i våde omgivelser.
- Under behandlingen, anbefaler vi ikke at bære metalgenstande.
- Det er forbudt, at bruge apparattet på en sådan måde, at strømmen krydser hjerte-området.
- Det er forbudt, at bruge apparattet på eller i nærheden af skader eller læsioner i huden.
- Det er forbudt at bruge apparattet på carotis sinus (carotis), kønsorganer og i nærheden af øjnene. Hold en afstand på mindst 3 cm fra øjeæblet .
- Apparattet må ikke anvendes på patienter med en elektronisk anordning implanteret uden først at konsultere en læge.
- Samtidige tilslutning af en patient til en HF kirurgisk anordning kan føre til forbrændinger i elektroderne i apparattet og det kan blive beskadiget.
- Fabrikanten er ansvarlig for apparattets ydeevne, pålidelighed og sikkerhed når:
- - Eventuelle tilføjelser og /eller reparationer udføres af autoriseret fagfolk
  - Apparattet bruges i nøje overensstemmelse med instruktion, som beskrevet i denne brugsanvisning.

ELECTROMAGNETIC INTERFERENCE

The device does not generate and does not receive interferences from other equipments. However it is appropriate to use the device keeping the applicator at least 3 meters away from televisions, monitors, mobile phones and any other electronic devices.

CONTRAINDICATIONS

Pregnant women first 16 weeks and patients with tuberculosis, juvenile diabetes, viral diseases (acute), mycosis, dermatitis, heart diseases, serious arrhythmias or pacemaker, magnetizable prothesis, acute infections, open injuries, epilepsy (unless different prescriptions) and children.

There aren't any known significant side effects. In some cases on people who are particularly sensitive, redness can occur after the treatment in the treated area and usually disappears within few minutes after the treatment. If the redness persists consult a doctor. In rare cases the evening stimulation can cause delay in falling asleep. In such case avoid the evening treatment.

PainXit works with a battery (1 x AAA 1,5V), wireless, it does not require the use of pads, gel or control unit.
It can be used easily by right or left handed and the ergonomic design has been studied to be easily held at any age. You can use the device directly on your skin and bring it wherever you are; at home, at work, at fitness, on the go or on vacation.

HOW TO USE

(FOR EXTERNAL USE ONLY)

Simply place the electrode tip **(d)** of PainXit on the skin on the painful area for the treatment.
Push the red button **(a)** at the top once to start the treatment, the green light **(c)** will start flashing to confirm the activation.

To stop the treatment push again the red button **(a)** and the green light **(c)** will stop flashing. The recommended duration of the treatment is from 1 to 5 minutes several times a day or as needed. You can´t overdose.

What kind of pain can PainXit relieve?
PainXit can be used for various types of both acute and chronic pain e.g. arthritis, rheumatism and osteoporosis, muscle pain, back and shoulder pain, tennis elbow, knee pain, lumbago, sciatica, sport injuries, phantom-limb pain and chronic neuropathy.

ELEKTROMAGNETISK INTERFERENS

Apparattet genererer ikke og modtager ikke interferens fra andet udstyr. Men det er hensigtsmæssigt at anvende apparattet mindst 3 meter væk fra fjernsyn, skærme, mobiltelefoner og andre elektroniske enheder.

KONTRAINDIKATIONER

Gravide i de første 16 uger, patienter med tuberkulose, type 1 diabetes, virussygdomme (akut), mycosis, dermatitis, hjertesygdomme, alvorlige arytmier eller pacemaker, børn, magnetiserbar protese, akutte infektioner, åbne sår, epilepsi (medmindre lægen anbefaler andet) og børn.

Der er ikke nogen kendte betydelige bivirkninger. I nogle tilfælde for mennesker, der er særligt følsomme, kan rødme forekomme efter behandlingen i det behandlede område,der som regel forsvinder inden for få minutter efter behandlingen. Hvis rødme vedvarer konsulter en læge. I sjældne tilfælde kan sen aftenbehandling forårsage forsinkelse i at falde i søvn. I sådanne tilfælde undgå aftenbehandling.

PainXit bruger ét batteri (1 x AAA 1,5V), – ingen brug af ledninger, pads, gel eller andet. Anvendes nemt ved både højre eller venstre hånd, og det ergonomiske design er funktionelt for alle alderstrin. Du kan bruge PainXit direkte på huden og have den med dig uanset, hvor du er; i hjemmet, på arbejdet, i fitness center, på farten eller på ferie.

HVORDAN BEHANDLER MAN?

(TIL UDVORTES BRUG KUN)

Du skal blot placere spidsen med elektroderne **(d)** af PainXit på huden på det smertefulde område, der skal behandles. Tryk én gang på den røde knap øverst **(a)** for, at starte behandlingen, det grønne lys **(c)** vil begynde at blinke for at bekræfte aktiveringen.

Tryk igen én gang på den røde knap øverst **(a)** for at stoppe behandlingen. Det grønne lys **(c)** stopper også med at blinke. Den anbefalede varighed af behandlingen er fra 1 til 5 minutter, gerne flere gange om dagen eller efter behov. Du kan ikke overdoserer.

Hvilken slags smerte kan PainXit lindre? PainXit kan bruges til både akutte og kroniske smerter ved f.eks. gigt, osteoporose, tennisalbue, lumbago, iskias, sportsskader, kronisk neuropati samt ved muskel-, ryg- og skulder smerter og fantomsmerter.

WHEN NOT TO USE PAINXIT

- If you have a pacemaker
- In the first 16 weeks of pregnancy
- On and around eyes
- On damp or wet skin
- Close to metal prosthesis
- Close to oxygen or flammable liquids
- If you suffer from epilepsy
- On open injuries
- On aortic arteries, on the muscles of larynx and pharynx
- On the heart
- While driving any vehicle

CAUTIONS

Carefully read this instruction manual before use. Keep out of reach of children; small parts can be removed and swallowed.
These guidelines do not intend to give any medical advice, when in doubt, before using the product and if you are using medications such as steroids, warfarin, etc. you need to consult your doctor.
The use of PainXit is forbidden for children under the age of 12 years without adult supervision.

INSTRUCTIONS FOR CLEANING

Use a damp cloth. For the electrode tip use a damp cloth or non-aggressive detergents.

IMPORTANT

If you suffer from from pain or other symptoms that you don't know the origin of, consult your doctor. PainXit can relieve pain, but in no case can avoid doctor's diagnosis or replace a treatment without consulting a doctor.

BATTERY CHANGE (1 x AAA 1,5 V)

Change the battery in case the device does not work.
1. Unscrew the battery cover **(b)**
2. Remove the old battery and put in the new battery AAA (1,5V)
3. Screw the battery cover **(b)** to close

PainXit has 2 years warranty (with replacement) against any manufacturing defect, with regular and proper use of the device.
The warranty decays in case of tampering and in case of intervention on the device performed by non-authorized personnel by the manufacturer or by the authorized retailer.

ANVEND IKKE PAINXIT

- Hvis du har en pacemaker
- I de første 16 uger af graviditeten
- På og omkring øjnene
- På fugtig eller våd hud
- Tæt på metal protese
- Tæt på ilt eller brændbare væsker
- Hvis du lider af epilepsi
- På åbne sår og skader
- På aorta arterier og svælg/strubehoved
- Over hjertet
- Under kørsel af ethvert køretøj

FORSIGTIG

Læs omhyggeligt denne brugsanvisning før brug. Opbevares utilgængeligt for børn; små dele kan fjernes og indtages.
Disse retningslinjer har ikke til hensigt at give nogen lægelig rådgivning, ved tvivl om før ibrugtagning og hvis du bruger medicin såsom steroider, warfarin el.lign. skal du kontakte din læge.
Brugen af PainXit er forbudt for børn under 12 år uden hjælp fra en voksen.

ANVISNINGER OM RENGØRING

Brug en fugtig klud. For elektrodespidsen brug en fugtig klud eller et mildt rengøringsmiddel .

VIGTIGT

Hvis du lider af smerter eller har andre symptomer, som du ikke kender grunden, kontakt din læge. PainXit kan lindre smerter, men kan aldrig erstatte en lægens diagnose eller erstatte en behandling uden at konsultere en læge.

BATTERISKIFT (1 x AAA 1,5 V)

Det er tid til at udskifte batteriet, hvis enheden ikke fungerer.
1. Skru batteridækslet af **(b)**
2. Fjern det gamle batteri og indsæt et nyt batteri AAA (1,5V)
3. Skru batteridækslet **(b)** på igen

PainXit har 2 års garanti (med udskiftning) for enhver fabrikationsfejl ved regelmæssig og korrekt brug af apparattet.
Garantien bortfalder for fabrikanten eller en autoriseret forhandler i tilfælde af manipulation og i tilfælde af reparation eller vedligeholdelse, der er udført af en ikke-autoriseret part.

CAUTIONS FOR STORAGE

The equipment is protected up to the following environmental conditions:
Without the supplied package ambient temperature: from +5 to +40°C
relative humidity: from 30 to 80%
pressure: from 500 to 1060 hPa.
With the supplied package ambient temperature: from –10 to +50°C
Relative humidity: from 10 to 90%
Pressure: from 500 to 1060 hPa.

INFORMATION FOR DISPOSAL

The product is subject to the WEEE regulation (presence of the symbol on the label) on recycling: for the disposal of the product, please use the specific equipped areas for the collection of electronic material or contact the manufacturer.

MAINTENANCE AND PROBLEM SOLVING

If the device is used according to what indicated in this manual, no particular routine maintenance is required. If you encounter malfunctions or problems in the use of PainXit, check the following:

· *It does not turn on*. Check if the the battery is inserted correctly and eventually replace it (see chapter "Battery change"). If the problem continues contact the manufacturer.

· *It does not transmit electrical impulses.* Check that you have inserted the battery properly and verify that the green light **(c)** is on. If the problem continues contact the manufacturer.

· *PainXit turns off during operation.* We recommend to replace the battery and start again the treatment. If the problem continues contact the manufacturer.

ASSISTANCE

The manufacturer has exclusive rights for technical intervention on the equipment. For any technical assistance, please contact:

Xit-International, Denmark
www.painxit.com
ask@painxit.com

Eventual technical documentation concerning repairable parts can be provided but only upon company authorization and only after giving adequate instructions to the intervention personnel.

FORHOLDSREGLER VED OPBEVARING

Apparatet er beskyttet under følgende forhold: Uden den medfølgende pakke omgivelsestemperatur: fra +5 til +40°C Relativ luftfugtighed: fra 30 til 80% pres : 500-1060 hPa.
Med den medfølgende pakke omgivelsestemperatur: fra -10 til +50°C
Relativ fugtighed: fra 10 til 90%
Tryk: 500-1060 hPa.

INFORMATION TIL BORTSKAFFELSE

Produktet er omfattet af WEEE -forordningen (tilstedeværelse af symbolet på etiketten) på genbrug: for bortskaffelse af produktet skal du bruge de specifikke dertil indrettede områder til indsamling af elektronisk materiale eller kontakt producenten.

VEDLIGEHOLDELSE OG PROBLEMER

Hvis apparattet anvendes i overensstemmelse med det, angivet i denne brugsanvisning, kræves der ikke nogen vedligeholdelse i øvrigt. Hvis du støder på fejl eller problemer i brugen af PainXit skal du kontrollere følgende:

· *Den tænder ikke*. Tjek om batteriet er isat korrekt og evt. udskifte dette (se kapitlet "Battery ændringer"). Hvis problemet fortsætter skal du kontakte producenten .

· *Det sender ikke elektriske impulser.* Kontroller, at batteriet er isat korrekt, og kontroller, at det grønne lys **(c)** lyser. Kontakt producenten, hvis problemet fortsætter.

· *PainXit slukker under brug.* Vi anbefaler, at udskifte batteriet og starte behandlingen igen. Kontakt producenten, hvis problemet fortsætter.

ASSISTANCE

Producenten har eksklusivt ret til at foretå tekniske indgreb på apparettet. For enhver teknisk assistance kontakt:

Xit-International, Denmark
www.painxit.com
ask@painxit.com

Eventuel teknisk dokumentation vedrørende reservedele kan udleveres, men kun efter virksomhedstilladelse og først efter at have givet fyldestgørende instrukser til fagpersonalet..

Emissions		
Emission test	**Conformity**	**Electromagnetic Environment - guidance**
RF Emissions Cispr 11	Group 1	The appliance use 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	The appliance is suitable for use in all establishments included than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Immunity aspects at r.f.

The appliance is intended for use in the electromagnetic environment specified below. The customer or the user of the navigator should assure that it is used in such an electromagnetic environment.

Immunity test	Test level EN 60601-1-2	Compliance Level	Electromagnetic environment - guide
RF radiated EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	

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:

Immunity aspects

The appliance is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	Test level EN 60601-1-2	Compliance Level	Electromagnetic environment - guide
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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 magnetic field EN 61000-4-8	3 A/m	3 A/m	Magnetic power frequency fields should be that of a typical commercial or hospital environment..

Recommended separation distances between portable and mobile RF communications equipment and the appliance

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of the transmitter (m)		
	From 150kHz to 80MHz $d = 1.2 \sqrt{P}$	From 80MHz to 800MHz $d = 1.2 \sqrt{P}$	From 800MHz to 2GHz $d = 2.3 \sqrt{P}$
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 metres (m) can be determined 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.

Notes:
(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

TECHNICAL SPECIFICATIONS

Description:
Portable electronic stimulator

Classification:
Class IIa medical devices

Product dimensions:
130 x Ø26 mm

Energy:
0.4 mJ at 1000 Ω

Operating temperature:
0° C - 40° C. R.H.< 90%

Storage temperature:
-20° C - +50° C

Average product life:
2 years

SYMBOLS / *SYMBOLER*

The product is subject to the WEEE regulation (presence of the symbol

Manufacturer/*Producent*

LOT: Batch/*Batch*

50
−20

Temperature limits/
Temperatur grænser

Follow instructions for use/
Følg brugsanvisningen

Warning/*Advarsel*

WEEE Directive Warning:
Old electrical appliances are valuable materials and should not be disposed of with domestic refuse! Customers are urged to help protect the environment and natural resources by taking the appliance to a special waste collection centre when it is no longer in use.

WEEE direktiv Advarsel:
Gamle elektriske apparater er værdifuldt materiale og må ikke bortskaffes med almindeligt husholdningsaffald ! Forbrugerne opfordres til at hjælpe med at beskytte miljøet og de naturlige ressourcer ved at bortskaffe apparatet via et center for særligt affald, når det ikke længere er i brug.

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Conforms to ECC Directive 93/42 /
Opfylder EU direktiv 93/42

Type BF applied part/ *Type BF anvendt del*

Use in a dry place and away from water/ *Anvendes et tørt sted og væk fra vand*

IT INTERNATIONAL
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WWW.PAINXIT.COM
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PATENTED
CLASS IIA MEDICAL DEVICES