



CE

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HFE 322

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BASIC INFORMATION



1.0 What do the icons mean?

The safety icons which are displayed in the operating instructions are notes on the proper use of the stimulation glove HFE 322 and for protection of your safety.

The icons represent the following contents:



Read and observe operating instructions!



Warning/danger: In case of improper use, there is a danger of serious injury/damage!



Always comply with these notes!



Warning/danger: The device must not be used by any persons with a pacer!

2.0 Basic information

2.1 What does TENS mean?

TENS: T= transcutaneous (transferred through the skin), E= electrical, N= nerve, S= stimulation.

2.2 Information on the TENS application

A TENS device uses electrical current in the low-frequency range for therapy. The electrical impulses that are generated, their intensity, frequency and frequency width are controlled by the respective application programme. The stimulation glove and the adhesive electrode are used to conduct electrical impulses into the nervous system and the muscles. The current flows from one electrode to the other, depending on impulse type of the device. This procedure influences the pain transfer to the central nervous system when applying TENS therapy. The user no longer perceives pain or perceives it at reduced intensity only. The intensity of the stimulation glove depends on the setting of the respective device. If your TENS device has two channel outputs, one stimulation glove can be connected per channel.

Attention! If two stimulation gloves are used concurrently, they must **not** touch in application. There is the danger of a short circuit and increased current density. This may cause damage, injury and skin burns. **Warning!** Danger of injury!





3.0 Safety notes



3.1 General safety notes

- 3.1.1 In case of a defect, the stimulation glove must not be repaired, used or modified (changed) on your own. Incorrect use may lead to the stimulation current causing pain, injury and burns.
- 3.1.2 If skin changes, pain, pain, swelling, feeling unwell or other irregularities occur during application of the stimulation glove, terminate use at once and consult a doctor!
- 3.1.3 Take off all metallic objects like jewellery, belts, watches and other utensils you are wearing before application to prevent them from getting into contact with the stimulation glove and adhesive electrode.
- 3.1.4 Do not use the stimulation glove and adhesive electrodes when driving a car and do not perform any other work during application.
- 3.1.5 If you have any doubts regarding application of the stimulation glove, consult your doctor beforehand.
- 3.1.6 Do not use the stimulation glove without consulting your doctor or in any locations that are painful without explanation, on swollen muscles or after severe muscle injury. Application of the stimulation glove does not replace medical diagnosis and treatment.
- 3.1.7 Keep these usage instructions for later questions and hand them on along with the stimulation glove if you pass the device on to any third parties. Make the usage instructions available to third parties as well. The usage instructions are part of the stimulation glove.
- 3.1.8 Misuse and non-application-oriented use must be avoided. No other accessories from other devices must be used. Observe the operating instructions of your stimulation device's manufacturer when connecting the stimulation glove to it.
- 3.1.9 Do not place any heavy or sharp-edged objects onto the stimulation glove or adhesive electrodes.
- 3.2.0 Check the stimulation glove for errors before any use. The stimulation glove must not be used if there are any errors or defects.
- 3.2.1 The stimulation glove must rest closely against the hand. There must not be any folds, which would cause a danger of increased current density. Attention: Danger of injury!
- 3.2.2 If there are any irregularities during application, application must be terminated at once.
- 3.2.3 The instructions must be retained during the product's service life.
- 3.2.4 The hand should be slightly moistened with water if the current intensity is not sufficient.
- 3.2.5 <u>Attention!</u> If two stimulation gloves are used concurrently, they must <u>not</u> touch in application! Avoid contact of the stimulation glove with metallic objects during application.

There is the danger of a short circuit and increased current density. This may cause damage, injury and skin burns. **Warning!** Danger of injury!

3.3 For which areas of use/environments is the stimulation glove suitable?

- 3.3.1 Only use the stimulation glove for the intended use for low-frequency applications (max. electrical impulses in the area of up to 120 Hz) and max. 120 mA at the hands of the human body.
- 3.3.2 The stimulation glove is only intended for external use (application via the skin) on humans, specifically for treatment of doubtlessly diagnosed chronic pain.
- 3.3.3 The stimulation glove may be used in case of: acute complaints, for plain therapy, arthritic hand, arthrosis, rheumatic complaints and other chronic pain in the hands.

3.4 For which areas of use/environments is the stimulation glove not suitable?



- 3.4.1 The stimulation glove must not be used concurrently with other medical and electrical devices of any kind.
- 3.4.2 Do not use the stimulation glove in the shower, when swimming, in the sauna, when bathing or in any other environment with high humidity. Keep any liquids and metallic objects away during application. Increased stimulation or short circuit may lead to injury and health damage danger to life!
- 3.4.3 Do not use the stimulation glove in bed or when sleeping.
- 3.4.4 Do not use the stimulation glove close to slightly flammable substances and gases or close to explosives.
- 3.4.5 The stimulation glove may interfere with other electrical devices in application or be interfered with by other electrical devices. Therefore, never use the stimulation glove close to other electrical devices.
- 3.4.6 Do not use the stimulation glove at less than 1.5 metres distance to a shortor micro-wave device or a high-frequency HF surgical device, since there is a danger of skin irritation or burns below the electrodes. Do not use the stimulation glove and the stimulator in the mountains at altitudes above 3000 metres.
- 3.4.7 Do not wear any jewellery or any adhesive tattoos in the area of stimulation during application of the stimulation glove.

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3.5 For which areas of application is the stimulation glove suitable?

3.5.1 Treatment with a stimulation device is purely symptomatic. They cannot heal. Contact your doctor if you have any therapeutic questions.

3.6 For which areas of application is the stimulation glove not suitable?

- 3.6.1 Never use the stimulation glove under the following circumstances: a. in case of cardiac diseases and arrhythmia (may cause cardiac arrest), b. directly on wounds, c. if pregnant or in labour, d. in the eye area, e. for patients with a pacer, f. in badly circulated areas of the body, g. for persons with psychological and emotional interferences, h. in persons with a diagnosis of dementia, i. for persons with a low IQ (intelligence quotient).
- 3.6.2 Under the following circumstances, coordinate with your doctor before taking the stimulation glove into operation with a stimulator: a. in case of acute sickness, b. in case of tumours, c. in case of infectious disease, d. in case of fever, e. in case of blood pressure problems, f. in case of skin disease, g. after an accident, h. in case of nausea or vertigo, i. in case of eruption of sickness, j. once irregularities occur, k. in case of pain with unclear cause, l. in case of diabetes, m. in case of seizures, n. during menstruation, o. if parts of the body have no perception of pain, p. for persons with metals in the body.
- 3.6.3 Treatment with the stimulation glove and a stimulator is ineffective for unspecified pain.
- 3.6.4 Do not use the stimulation glove if sudden scare may cause you to injure yourself.
- 3.6.5 The stimulation glove and adhesive electrodes must not be placed on open wounds, sensitive skin areas and fresh scars.
- 3.6.6 The following persons should not use the stimulation glove: Children, helpless persons, persons suffering from allergies, persons with weak immune systems, persons with pain from unclear causes, cardiovascular problems or diabetes, persons with circulation problems of the outer arteries and tissue or severe cardiovascular disease; ask your doctor in doubt.
- 3.6.7 If a person cannot perceive electrical stimulation current properly, this stimulation glove must not be applied. Children are more sensitive to stimulating current! Frail and disabled persons may not be able to make clear when the stimulation current device reaches too high an intensity.





3.7 Use by children and teens

- 3.7.1 Never treat any children with this stimulation glove!
- 3.7.2 The stimulation glove must be kept inaccessible for children and teens below 18 years!

3.8 Use of the stimulation glove

- 3.8.1 The stimulation glove must only be connected to stimulators with a 2 mm plug. Please ensure that the device/stimulator is switched off during application or removal of the stimulation glove.
- 3.8.2 If you want to re-position the stimulation glove during application, switch off the device/stimulator first.
- 3.8.3 Use of the stimulation glove may cause skin irritation. In case of skin irritation, e.g. reddening, blistering or itching, no longer use the stimulation glove. Do not use the stimulation glove permanently at the same place of the body because this may lead to skin irritation.
- 3.8.4 Before application, clean and dry off the skin regions intended for the stimulation glove thoroughly. The skin areas should be grease-free and clean.
- 3.8.5 The cables and stimulation glove must only be connected when the stimulation device (TENS device) is switched off.
- 3.8.6 To avoid cable damage, avoid direct pulling at the cables when removing the plug connections from the stimulation glove. Only pull or push the plugs to connect or remove the stimulation glove.
- 3.8.7 Plugging the stimulation glove in and out to and from the TENS device is possible by the plug connection to the electrical cable.
- 3.8.8 Every person reacts differently to electrical nerve stimulation. If application is not successful, coordinate with your doctor.
- 3.8.9 Do not pull on the cable to disconnect the plug connections of the stimulation glove.
- 3.9.0 The stimulation glove must not be used on body areas with skin inflammation, open and fresh wounds.
- 3.9.1 Only apply the stimulation glove to the intended body area of the hands.
- 3.9.2 If not ordered differently by the doctor, we recommend an average treatment duration of 30 minutes up to three times per day.
- 3.9.3 Intensity perception does depend on the day-to-day condition and may be adjusted by the user according to individual needs by adjusting the stimulator intensity.

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4.0 Where must the stimulation glove not be used?

- 4.0.1 The stimulation glove must not be attached to body areas with skin inflammation, open and fresh wounds.
- 4.0.2 Only apply the stimulation glove to the intended body area of the hand and observe the application notes.

4.1 Storage/maintenance of the stimulation glove

- 4.1.1 The stimulation glove is maintenance-free.
- 4.1.2 Clean the stimulation glove after each application. Do not disassemble or repair the stimulation glove, because this may cause technical or physical accidents.
- 4.1.3 The connection lines and adhesive electrodes must not be bent sharply.
- 4.1.4 For commercial or economic use of the stimulation glove, safety-technical inspection is required every 24 months according to § 6 MPBetreibV. The safety-technical inspections must be performed by a specialist for medical products. For more information, contact our service centre (see page 12).

4.2 Cleaning and care of the stimulation glove

- 4.2.1 The stimulation glove must not be exposed to direct sunlight. Do not place the stimulation glove on hot surfaces!
- 4.2.2 Clean the surfaces of the stimulation glove carefully with a moist cloth or manually at max. 30 °C. The stimulation glove must not be connected to the device/stimulator for this. Then let the stimulation glove dry off well. Do not put it into the drier.
- 4.2.3 For hygienic reasons, every user should use his own stimulation glove.
- 4.2.4 The TENS device/stimulator must not be switched on or be connected to the stimulation glove during cleaning and care.
- 4.2.5 A suitable commercial disinfectant can be used for disinfection. Then let the stimulation glove dry off well.
- 4.2.6 Let the stimulation glove dry off well after each cleaning! Check that the insides of the stimulation glove are dried well as well.
- 4.2.7 Observe the washing icons on the inside area of the stimulation glove.

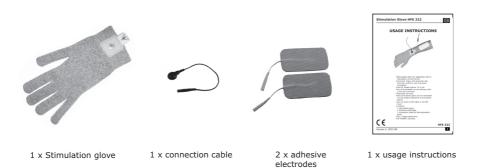
4.3 Disposal of the stimulation glove

4.3.1 If the stimulation glove is to be recycled at some point, disposal must be performed according to the statutory provisions. Ask your town or a disposal company about this. Dispose of the stimulation glove according to the EC directive on waste electrical and electronic equipment 2002/96/EC-WEEE.

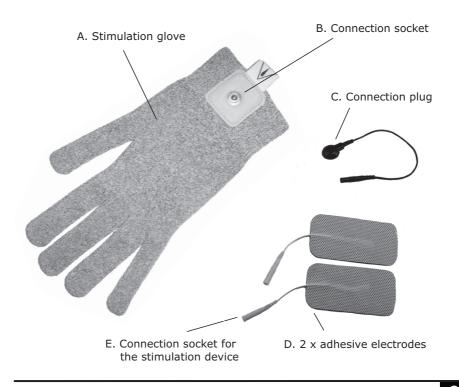
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4.4 Scope of delivery/packaging content



4.5 Setup of the stimulation glove





5.0

APPLICATION

Putting on and application of the stimulation glove D. Adhesive Application with a stimulation device (TENS) electrode Step 1: For TENS application, first slightly moisten the hand to be treated with water. preferably using a moistened cloth. Step 2: When tightening and applying the stimulation glove, observe that there are no folds and that the glove is tight against the hand. Push the finger tops of the glove completely onto the fingers.(see figure 1). E. Connection sockets for Step 3: the stimula-Now push the connection plug (C) tor device onto the connection socket (B) of the stimulation glove. Observe C. Connection that the plug latches correctly. plua Step 4: Now remove the B. Connection adhesive electrode (D) socket from the carrier film (see and attach it to the page 9) forearm according to (figure 1). Step 5: Connect the two connection sockets of Figure 1 A. Stimulation glove the adhesive electrode and the stimulation glove to the connection cables of

the stimulation device now. Observe that the stimulation device (TENS) is switched off when connecting it. After the connection is established, you may start TENS application. Observe the usage instructions of the stimulation device. The impulses flow from the stimulation glove to the adhesive electrode and vice versa when applied (bipolar impulse).

Step 6:

If you want to terminate the application, the stimulation device must be switched off first. Then loosen the two plug connections (B), take off the stimulation glove and remove the adhesive electrodes.

Attention! If two stimulation gloves are used concurrently, they must **not** touch in application. Avoid contact of the stimulation glove with metallic objects during use. There is the danger of a short circuit and increased current density. This may cause damage, injury and skin burns. **Warning!** Danger of injury!

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TECHNICAL DATA/ICONS



6.0 Technical data, icons:

Model type: Stimulation Glove HFE 322 Size M, length approx. 21.5 cm, +/- 1 cm Size: Max. impulse voltage (V): Up to 130 volt at a load of 500 Ohm per channel Up to max. 120 Hz (Hz=oscillations per second) Max. frequency (HZ): Max. impulse strength Up to max. 120 mA at 1000 Ohm load, direct current (mA=milliampere, Ohm=electrical resistance (mA): 5 °C - 40 °C (degrees Celsius) Ambience temperature: 30% - 80% (percent) Max. humidity at regular work: 50°C Storage/transport temperature 5 °C - 50 °C (degrees Celsius) 80% Max. humidity at storage/transport 10% - 80% (percent) Approx. 20 g without adhesive electrode and Weight/socks: connection cables Material: Metals, plastics The stimulation glove is compliant with EU-directive 93/42 EEC for medical products. LOT Batch designation LOT V4612HFE322 Manufacturer: Handelshaus Dittmann GmbH, Kissinger Straße 68, D-97727 Fuchsstadt/Germany M 2012-11 Production date: 2012-11 (year-month) Type label: Stimulation Glove HFE 322 Material: 71,8% Polyester, Handelshaus Dittmann GmbH 21,2% Spandex, 3,7% Polyurethane Kissingerstraße 68 Dittmann. 3,3% Metals. D-97727 Fuchsstadt/Germany Applicable on the right and left hand LOT V4612HFE322 Size M, Length ca. 21,5 cm i



Meaning of the icon on the product, packaging or the usage instruction: Electrical devices are valuable resources and must not be disposed of in household waste at the end of their lifetime! Help us in environmental protection and resource protection and submit this device to the corresponding collection point. The organisation responsible for waste disposal can answer any questions you may have. Dispose of the stimulation glove according to the EC directive on waste electrical and electronic equipment 2002/96/EC-WEEE.





7.0 Warranty

The stimulation glove purchased by you was developed and produced with great care.

The statutory warranty period is 24 months from the date of the purchase regarding material and fabrication defects of the product. Please keep the receipt as proof of purchase of the stimulation glove to assert any warranty claims.

The following are excluded from warranty:

- Damage from improper use
- Defects that were already known to the customer at purchase
- Wear parts
- Damage from unauthorised manipulation and due to the customer's own fault

After the end of the warranty period, you may send the defective stimulation glove to the address below for repair. Repairs after the warranty period are subject to charges.

For technical problems, questions and warranty claims regarding this stimulation glove, contact us as follows:

NOTES: If you have any complaints regarding the stimulation glove, contact the service centre first! If required, the service centre will initiate return of the device. <u>Packages sent POSTAGE UNPAID are not accepted by the service</u> centre!

Handelshaus Dittmann GmbH Abteilung Service-Center Kissinger Straße 68 D-97727 Fuchsstadt/Germany Email: hotline@servicecenter.tv Phone hotline: 0180-5012678 (0.14 € / min from German landlines; up to 0.42 € per minute from mobile phones) www.dittmann-gmbh.com

With kind regards

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Manufacturer:

Handelshaus Dittmann GmbH Kissinger Straße 68 D-97727 Fuchsstadt/Germany



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