



Artikel | Item | Article
Artikel | Articolo | Artículo

4507.1.00

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GB **Instruction Manual**
TENS device - «Easy Free» TENS
Please read before using!

CE 0483



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ENGLISH

GB

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1 | Introduction of TENS

1. Theory of therapy

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive technique in which a low-voltage electrical current is delivered through wires from a small power unit to electrodes located on the skin. Electrodes are temporarily attached with paste in various patterns, depending on the specific condition and treatment goals. TENS is often used to treat pain, as an alternative or addition to pain medications. Therapy sessions may last from minutes to hours. The use of electrical stimulus for pain relief was popularized in the 19th century and became widespread in the 1960s and 1970s using battery power.

Transcutaneous electrical nerve stimulation (TENS) was first introduced into current clinical practice following Melzack and Wall's gate control theory of pain in 1965. Davis (1993) and Lewith (1984) explain the gate control theory of pain as follows. An area of the dorsal horn of the spinal cord, known as the substantia gelatinosa, acts as a gate to nociceptive impulses. It receives myelinated nerve fibres, the largest being A fibres, and small non-myelinated nerve fibres (C fibres). If pain impulses pass along fine myelinated fibres and C fibres rather than along A fibres, the gate is opened, and the patient perceives pain. If A fibre transmission of impulses is greater, the gate may be closed.

There is also evidence that the TENS machine enhances the production of the body's own natural pain killing substances: endorphins and enkephalins. Human body produces endorphins and enkephalins, which are opiate-like substances to counter the pain. Low frequency stimulation causes the release of the endorphins and enkephalins.

2. Why consider digital pain relief?

Pain is a warning signal -we need these signals to tell us that something may be wrong with our body. Without it, we may do not know that part of our body might be damaged, thereby damaging them further. However, once we have identified damage, pain serves little purpose. In the case of chronic, regular pain it can significantly interfere with daily activities and the quality of life.

3. How does the Digital Pain Relief (TENS) work?

Digital Pain Relief (TENS) works by passing harmless electrical signals into the body from its pads. This relieves pain in two ways:

1. It blocks the body's pain signals. These are normally transmitted from the area of damage through the nerve fibers to the brain, TENS interrupts these pain signals.

2. TENS stimulates the body's production of endorphins-its own natural painkillers.

2 | General description

2.1 | Contents

- Mainframe
- Wires
- Electrodes (Pads)
- Instruction book
- Batteries

2.2 | Description of the device

(Fig. 1)

- 1 Output plug
- 2 Output cable
- 3 Output plug socket
- 4 LCD Display
- 5 [ON]-Button = Switch on and Intensity (+)
- 6 [OFF]-Button = Switch off and Intensity (-)
- 7 [MODE/STOP]-Button = Function Selection and Stop

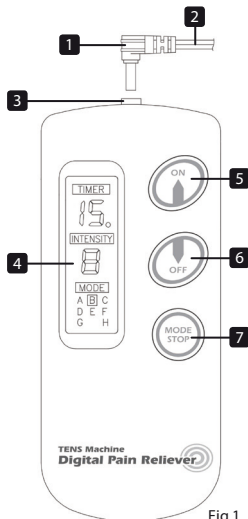


Fig.1

2.3 | Display indicators (Fig. 2)

- 8 Remaining Massage Time Display
- 9 Output Intensity Display
- 10 Function Display
- 11 Timer Display Punkt

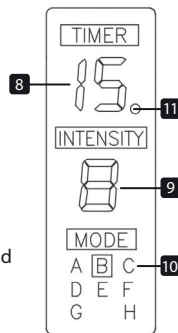


Fig.2

3 | Intended use

Transcutaneous Electrical Nerve Stimulators are intended for temporary relief of pain , including:

- Various chronic pain
- Various acute pain

3.1 | Contraindications

The device is safe for all people, with the following exceptions or the people who are receiving physiotherapy:

- People with acute disease
- Cancer patients
- People with infectious skin wounds
- Women who are in menstrual or expectant mothers
- People with heart disease
- People with high fever
- People with abnormal blood pressure
- People who have no feeling about their skins or people with abnormal skins
- People with abnormal feeling of their body except the above cases

4 | Product description

The AD-2011 is a battery operated pulse generator that sends electrical impulses through electrodes to the body and reaches the underlying nerves and muscle.

- The device is provided with one controllable output channel.
- An electrode pair can be connected to the output channel.

The electronics of the AD-2011 Digital create electrical impulses whose Intensity, Pulse Width, Pulse Rate may be altered according to the program. Press buttons are very easy to use and the panel cover prevents changes in the setting.

The AD-2011 corresponds to the below standards:

- IEC 60601-1: 2005/EN 60601-1:2006/AC:2010
(Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance).
- IEC60601-1-2:2007/EN 60601-1-2:2007/AC:2010
(Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests).

4.1 | Technical Data

Produkt name:	TENS Device
Model:	AD-2011 (item 4507)

Number of treatment program:	8
Anzahl Intensities:	8
Range of pulse frequency:	2 ~ 150 Hz
Range of output voltage:	40 V ± 20% (500 Ohm load)
Classification:	Internally powered, Type BF applied part, IPX0, No AP or APG, Continuous operation
Machine size:	approx. 55 x 122 x 19 mm
Weight:	approx. 62 g (exclude batteries)
Power source:	Batteries: 2 x 1.5 V Type AAA
For operation	
Environmental temperature:	5°C - 40°C
Environmental humidity:	< 80%
For storage and transport	
Environmental temperature:	-20°C - 55°C
Environmental humidity:	≤ 95%
Environmental pressure:	80 KPa - 105 KPa
Battery life:	approx. 2 months with alkaline batteries and 30 min. usage per day.

5 | Important safety hints

Retain the manual for further use and forward it to other users!



- Read all of the information in the operation guide and any other literature in the box before operating the unit.

- If there is any uncomfortable during using the device, please stop using it immediately and consult your doctor
- Turn off the power first before alternate the electrode pad to the other channel

- Do not make sharp kinks in the connecting leads or electrodes.
- Do not use the device if you are connected to, or in the vicinity of, high-frequency surgical or industrial equipment. This may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- Observe caution when using the device in the immediate vicinity of cellular phones that are switched on.
- This device is not intended to be used unsupervised by children, individuals with sensory deprivation of any kind or mentally challenged individuals. Any users falling into these categories should be assisted by a responsible adult.
- Please don't use it in the bathroom or other place with high humidity.
- Please do not use it when driving, otherwise, it may lead to incident.
- Please do not use the device while in sleep.
- In the process of stimulating and therapy, please do not allow metal parts of belts, wristwatches or necklaces touch the leaf electrode pads.
- Please don't use it for purposes other than outlined in this manual.
- The device might not meet its performance specifications or may cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
- Pregnant women should not use the device during the first trimester, and should always consult a doctor, midwife or physiotherapist prior to use.
- Simultaneous connection of a PATIENT to a h.f. surgical EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy equipment may produce instability in the device output.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Please do not knock down, repair, and rebuild the device privately.
- Please do not use electrode pads other than those supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
- Please do not share the electrode pads with infective persons to avoid cross-infection.
- The output wave parameters are not be influence by load resistance, except output voltage. When the value of load resistance increased, the output voltage will increase.
- Avoid strong magnetism interference, such as mobile telephone, microwave oven, etc.
- Information regarding potential electromagnetic or other interference between the device used and other devices together with advice regarding

avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION. (p. 90)

- Never stick two adhesive gel pads to each other.
- Keep the adhesive gel pads clean and do not expose to heat or direct sunlight.
- If the gel pads do not attach or are dirty, wipe with a wet cloth or replace with new ones.
- Do not clean the pad or adhesive gels with any chemical. Replacement pads are available from your local distributor.
- Place the electrodes on intact skin only. Do not place on cuts or damaged skin.
- The adhesive pads should be attached around the area of pain before setting the stimulation mode and output intensity

6 | Setup and operating procedures

1. Insert batteries

- a** Open battery cover at the back of the device.
- b** Insert two „AAA“ size batteries. Please pay attention to polarity.
- c** Close the battery cover.



- Rechargeable batteries are not suitable for this device.
- Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage.
- Please do not mix use new and old batteries or different type of batteries.
- Please do not throw battery into fire.
- Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

2. How to place the adhesive gel pads on the electrode?

Each adhesive gel pad is protected by 2 layers of transparent film-one on either side. Remove the layer of film and place that side of the gel pad to skin.

3. Attachment of electrode lead wires

- a** Insert the plug into the electrode socket on the main apparatus.
- b** Connect the snap-fasteners at the other end of the wire to the electrode pads.
- c** Place the electrode on your body as directed by your physician.



- Clean the wires by wiping with a damp cloth.
- Coating them lightly with talcum powder will reduce tangling and prolong life.

4. Finishing the operation

You should hold the plug when pulling it out. Please do not pull the wire.



- Please use clear water to wash or use wet cloth (instead of facial tissue) to gently wipe up the electrodes when cleaning them.
- Wires stay away from babies and children, prevent the winding neck causing suffocation and death.

6.1 | Function and use of buttons

[ON]-button:

- Press this button to turn on the unit and increase the output intensity.
- Each time you press the [ON]-button the intensity of stimulation will increase by one level. (0 - 8, 8 levels in total)



[OFF]-button:

- Press this button to turn off the unit and decrease the output intensity.
- Each time you press the [OFF]-button the intensity of stimulation will decrease by one level (8 - 0, 8 levels in total)
- The output intensity level will be displayed by the number on the LCD display: «1» is the lowest, «8» is highest. The output strength will gradually increase according to the selection of intensity level.
- If the output intensity is at «0», it means that the device is standby status and will automatically shut off in 20 seconds.
- When the output intensity is at 1 - 8, the time setting function starts to work. The black spot on the LCD display will flash once each second.
- The adhesive pads should be attached around the area of pain before setting the stimulation mode and output intensity.



[MODE/STOP]-button:

- To adjust the output function to a suitable level, press the [MODE/STOP]-button
- There are 8 different selections of stimulation settings (form A - H). For detailed descriptions please refer to the following function chart.

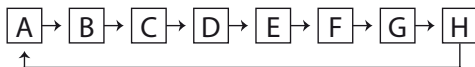


The device has a memory function. Once a particular stimulation setting is chosen it will remain on that setting even when the device is switched off and switched back on. For example, if the device was set to «B» mode before being switched off, when the device is restarted, it will remain in «B» mode until another mode is chosen.

- Press the [MODE/STOP]-button will change the stimulation setting from one mode to another.

7 | Program

The changing process is as follows:



Program		Function
A	Pain Relief	Tapping (Slow)
B	Pain Relief	Tapping (Fast)
C	Pain Relief	Vibrating (Slow)
D	Massage	Kneading (Slow)
E	Massage	Kneading (Fast)
F	Pain Relief/Massage	Vibrating (Fast)
Combined programs		
G	Pain Relief/Massage course: • recommended for shoulder and neck 	15 min. / cycle
H	Pain Relief/Massage course: • recommended for waist and back 	15 min. / cycle

- When the device is turned on, even if the stimulation setting or intensity is changed, it will not affect the timer which will continue to count down the remaining time
- The device will turn off automatically when the set time has elapsed
- The set time of the device is 15 minutes.
- Recommended usage is 1-2 times a day with at least 2-3 hours of rest between each use.
- If you feel any pain or discomfort during use, stop use immediately and consult your doctor.

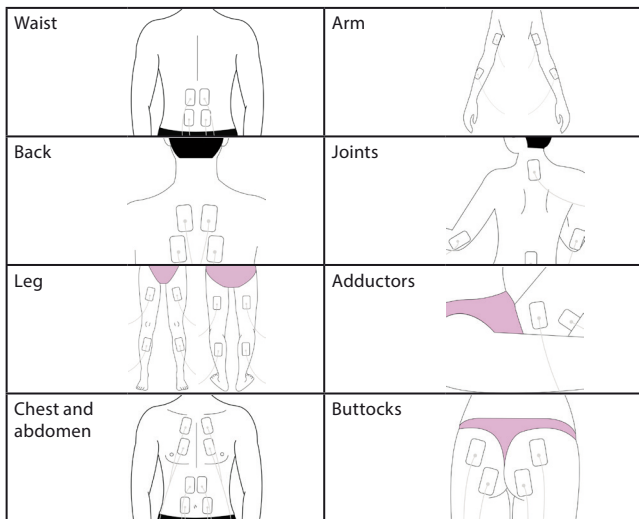
8 | Operating instructions

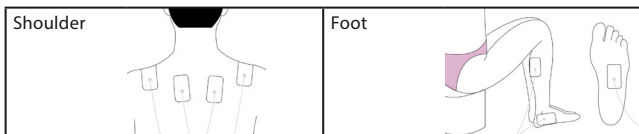
- a** Be sure you know the right points where to place the electrodes and affix them there then, connect the electrodes to Digital Pain Relief with wire.
- b** Switch power on.
- c** After setting mode, intensity and time, you could feel stimulation at electrodes and treatment starts. The time display is enabled and displays the remaining time of application.
- d** Switch power off.
- e** Take electrodes off and clear them as shown in «User Manual»

Clean the electrodes.

- You should hold the plug when pulling it out. Please do not pull the wire.
- Please use clear water to wash or use wet cloth (instead of facial tissue) to gently wipe up the electrodes when cleaning them.
- Do not use brush or fingernail to clean surface of the electrodes to avoid scratching them.

8.1 | Usage diagrams





9 | Troubleshooting

The following table provides information on troubleshooting:

Malfunction	The reason	Countermeasure
You have no feeling of stimulus.	Are the batteries exhausted?	Replace the batteries.
	Are the batteries properly loaded?	Correctly load the batteries.
	Is the wire properly connected?	Firmly connect the wire.
	Have you removed the transparent protection film over the electrode pad?	Remove the transparent protection film over the electrode pad.
Stimulus is weak.	Do the electrode pads firmly stick to the skin?	Firmly stick the electrode pad to the skin.
	Are the electrode pads overlapped?	Separate the electrode pad and stick them to the skin gain.
	Are the electrode pads dirty?	Please clean the electrode pad.
	Is intensity too weak?	Turn the intensity regulation dial to regulate it.
	Are the electrode pads properly positioned?	Change the position of the electrode pad.
The skin becomes red.	Is the therapeutic time too long?	Control it within 10 - 15 minutes a time.
	Do the electrode pads firmly stick to the skin?	Please firmly stick the electrode pad to the skin.
	Are the electrode pads too dry?	Please gently wipe them up with wet cloth and then use them again.
	Are the electrode pads dirty?	Please clean the electrode pad.
	Are the surface of the electrode pads scratched?	Please replace them with new electrode pad.

Power sources cut off in the therapeutic process.	Have the electrode pads come off the skin?	Turn off the power and stick the electrode pad firmly to the skin.
	Are the wires disconnected?	Turn off the power and properly connect the wire.
	Have the batteries been exhausted?	Please replace them with new ones.

10 | Maintenance

- Do not drop this device subject it to strong impact.
- Avoid high temperature and direct sunlight. Do not immerse the device in water.
- If this device is stored near freezing, allow it to acclimate to room temperature before use.
- Do not attempt to disassemble this device.
- If you do not use the device for a long time, please remove the batteries..
- If the device becomes dirty, please clean it with a soft dry cloth. Do not use any abrasive or volatile cleaners.
- No component can be maintained by user in the device.
The circuit diagrams, component part lists, descriptions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated as repairable can be supplied by the manufacturer.
- In order to ensure that the electrodes adhere as long as possible, they should be cleaned carefully with a damp, lint-free cloth.
- After use, stick the electrodes onto the backing film.
- Electrode Pads are designed to be replaceable, so when the electrodes do not adhere firmly, you must replace electrode-pads.

11 | Explanation of symbols



Symbol for «Consult Operation Guide»



Symbol for «WARNING!»



Symbol for «TYPE BF applied parts»



Environment Protection - Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice.



Symbol for «Manufacturer»



Symbol for «Date of manufacture»



Symbol for «Keep dry»

SN Symbol for »Serial number«

CE 0483 Complies with 93/42/EEC requirements

12 | Warranty

The guarantee period is 24 months from the date of purchase and covers all manufacturers' errors in material and quality. This guarantee only applies if the instructions for use have been followed and becomes ineffective if force has been applied to the appliance or it has been used in any but the correct and proper manner, or if it has been serviced by any unauthorised person.

Dear Customer,

In case you product does not function as you expected please do not return immediately. Perhaps our hotline (+49-69-954061-24) can be of assistance. If you are still not satisfied, you have the possibility to return products under 40 € value free of charge within the BRD. We require your address. This you may provide to the above listed telephonic Hotline or by e-mail to: technik@hydass.de. Prepare the package for shipping and include the receipt and description of the problem. Please be aware of the fact that collect packages may not be accepted.

Your Hydass customer service team

Warranty and service:

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EMC TABELLE - ELEKTROMAGNETISCHE KOMPATIBILITÄT

Leitlinien und Herstellererklärung zur elektromagnetischen Strahlung		
Der Artikel 4508 ist für die Verwendung in einer Umgebung mit den nachstehend definierten elektromagnetischen Eigenschaften vorgesehen. Der Kunde oder der Benutzer des Artikels hat sich zu vergewissern, dass er in einer solchen Umgebung eingesetzt wird.		
Emissionstest	Konformität	Elektromagnetische Umgebung - Anleitung
RF - Emissionen CISPR 11	Gruppe 1	Das 4508 verwendet RF-Energie ausschließlich für den internen Betrieb. Folglich sind seine RF-Emissionen sehr schwach und es besteht keine Gefahr, dass sie Interferenzen mit einem danebenstehenden Elektrogerät erzeugen.
RF Emissionen CISPR 11	Klasse B	Artikel 4508 ist für den Einsatz in allen Räumlichkeiten geeignet, inkl. Privaträumen und an Orten, wo er direkt an das öffentliche Niederspannungs-Stromversorgungsnetz, das Wohngebäude versorgt, angeschlossen wird.
Überschwingungsströme IEC 61000-3-2	Nicht zutreffend	
Spannungsänderungen/ Spannungsschwankungen IEC 61000-3-3	Nicht zutreffend	


Für alle ME EQUIPMENT und ME SYSTEME

Leitlinien und Herstellererklärung zur elektromagnetischen Störfestigkeit			
Der Artikel 4508 ist für die Verwendung in einer Umgebung mit den nachstehend definierten elektromagnetischen Eigenschaften vorgesehen. Der Kunde oder der Benutzer des Artikels hat sich zu vergewissern, dass er in einer solchen Umgebung eingesetzt wird.			
Funktstörfestigkeitstest	Leistungstest IEC 60601	Compliance level	Elektromagnetische Umgebung - Empfehlungen
Entladung statistischer Elektrizität (ESD) IEC 61000-4-2	± 6 kV Kontakt ± 8 kV Luftentladung	± 6 kV Kontakt ± 8 kV Luftentladung	Die Böden müssen aus Holz, Beton oder Keramikfliesen sein. Falls die Böden mit synthetischem Material ausgelegt sind, muss die relative Feuchtigkeit bei einem Minimum von 30% liegen.
Störfestigkeit gegen schnelle transiente elektrische Störgrößen IEC 61000-4-4	± 2 kV für Stromversorgungsleitungen	Nicht zutreffend - batteriebetriebenes Gerät	Nicht zutreffend

Stoßspannungen IEC 61000-4-5	$\pm 1 \text{ kV line(s) to line(s)}$	Nicht zutreffend	Nicht zutreffend
Spannungseinbrüche, Kurzzeitunterbrechungen und Spannungsschwankungen bei ankommenden Stromversorgungsleitungen IEC 61000-4-11	$< 5\% U_T$ (Spannungseinbruch $> 95\% U_T$) in 0.5 Zyklus $< 40\% U_T$ (Spannungseinbruch $> 60\% U_T$) in 5 Zyklen $< 70\% U_T$ (Spannungseinbruch $> 30\% U_T$) in 25 Zyklen $< 5\% U_T$ (Spannungseinbruch $> 95\% U_T$) in 5 Sekunden	Nicht zutreffend	Nicht zutreffend
Magnetfeld mit energietechnischen Frequenzen (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Die elektromagnetischen Felder mit der Spannung des Stromnetzes müssen die Pegeleigenschaften eines durchschnittlichen Ortes in einer typischen Büro- oder Krankenhausumgebung haben.
MERKE: U_T ist die Spannung des Wechselstromnetzes vor Anwendung des Leistungstests.			

Leitlinien und Herstellererklärung zur elektromagnetischen Strahlung

Der Artikel 4508 ist für die Verwendung in einer Umgebung mit den nachstehend definierten elektromagnetischen Eigenschaften vorgesehen. Der Kunde oder der Benutzer des Artikels hat sich zu vergewissern, dass er in einer solchen Umgebung eingesetzt wird.

Funktörfestigkeitstest	Leistungstest IEC 60601	Richtwerte	Elektromagnetische Umgebung - Empfehlungen
Abgestrahlte RF-Energie IEC 61000-4-3	3 V/m 80 MHz bis 2.5 GHz	3 V/m	<p>Tragbare und mobile RF-Kommunikationsgeräte dürfen nur in einem Abstand zum Gerät und seinem Zubehör benutzt werden, der mindestens dem empfohlenen und mit der Formel für die Senderfrequenz berechneten Abstand entspricht.</p> <p>Empfohlener Abstand:</p> $d = 1.2 \cdot \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \cdot \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>Wonach P der Leistungspegel der Maximalspannung des Senders in Watt (W) ist, der in den technischen Spezifikationen des Herstellers angegeben ist, und demzufolge d der empfohlene Abstand in Metern (m). Die Feldstärke der festen RF-Sender, wie durch eine elektromagnetische Untersuchung^a festgelegt, muss unter dem Richtwert liegen, der in jeder Frequenzbandbreite^b liegt.</p> <p>Störsignale können in der Nähe jedes Gerätes mit dem folgenden Symbol auftreten: </p>

ANMERKUNG 1: Von 80 MHz bis 800 MHz wird die Hochfrequenzamplitude verwendet.

ANMERKUNG 2: Diese Richtwerte können in bestimmten Situationen nicht angemessen sein. Die elektromagnetische Ausbreitung wird durch Absorption und Reflexion von Gebäuden, Gegenständen und Menschen beeinflusst.

^a: Die Feldstärken der Signale aus festen Sendern, wie Basisstationen eines Funktelefons (Mobil-oder schnurloses Telefon) und eines mobilen Radios, Amateurfunkradios,

AM- und FM-Radio- und TV-Signalen, sind nicht exakt vorherzubestimmen. Eine Analyse der elektromagnetischen Umgebung des Ortes ist zu erwägen, um die elektromagnetische Umgebung, die von festen RF-Sendern ausgeht, berechnen zu können. Wenn die Stärke des in der Umgebung des Compex Performance gemessenen Feldes den oben angegebenen RF-Richtwert überschreitet, ist die korrekte Funktionsweise des Compex Performance zu überprüfen.

^b: Oberhalb der Frequenzamplitude von 150 kHz bis 80 MHz muss die Feldstärke weniger als 3 V/m betragen.

Empfohlener Abstand zwischen einem tragbaren und mobilen RF Telekommunikationsgerät und dem 4508.

Das 4508 wurde für eine elektromagnetische Umgebung entwickelt, in der ausgestrahlte RF-Turbulenzen kontrolliert werden. Käufer oder Benutzer des 4508 können zur Verhütung elektromagnetischer Störsignale beitragen, indem sie den in der nachfolgenden Tabelle mit den empfohlenen Richtwerten angegebenen Mindestabstand zwischen den tragbaren und mobilen RF-Kommunikationsgeräten (Sender) und dem 4508 und die maximale elektrische Leistung des Telekommunikationsgeräts berücksichtigen.

Max. elektrische Leistung des Senders W	Abstand gemäß Frequenz des Senders mCISPR 11		
	150 kHz bis 80 MHz $d = 1,2\sqrt{P}$	80 MHz bis 800 MHz $d = 1,2\sqrt{P}$	800 MHz bis 2,5 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

Falls die maximale elektrische Leistung eines Senders nicht in der nachstehenden Tabelle aufgeführt ist, kann der empfohlene Mindestabstand in Metern (m) mit der Formel für die Senderfrequenz berechnet werden. wonach P dem vom Hersteller angegebenen maximalen elektronischen Leistungspegel des Senders in Watt (W) entspricht.

ANMERKUNG 1: Von 80 MHz bis 800 MHz wird die Hochfrequenzamplitude verwendet.

ANMERKUNG 2: Diese Richtwerte können in bestimmten Situationen nicht angemessen sein. Die elektromagnetische Übertragung wird durch Absorption und Reflexion von Gebäuden, Gegenständen und Personen verändert.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The 4508 is intended for use in the electromagnetic environment specified below. The customer or the user of the 4508 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The 4508 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
RF emissions CISPR 11	Class B	The 4508 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

For all ME EQUIPMENT and ME SYSTEMS


Guidance and manufacturer's declaration - electromagnetic immunity			
The 4508 is intended for use in the electromagnetic environment specified below. The customer or the user of the 4508 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	±2 kV for power supply lines	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)

Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Voltage dips, short inter- ruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels cha- racteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity

The 4508 is intended for use in the electromagnetic environment specified below. The customer or the user of the 4508 should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the 4508, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:</p> $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <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,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment. Marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, 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.

^a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast

and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 4508 is used exceeds the applicable RF compliance level above, the 4508 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 4508.

^b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the 4508

The 4508 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 4508 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 4508 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 transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 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 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.

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.



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