This product may be purchased from Connevans Limited secure online store at www.DeafEquipment.co.uk
Introduction

This booklet is a guide to the use and maintenance of the HearCheck Screener, a hearing screening device from Siemens.

You can now screen quickly and easily, determining whether further assessment is indicated (e.g. by a local hearing care professional).
Contents

3 Your HearCheck Screener 4
4 Important hints 5
5 Insert the batteries 6
6 Preparation before use 6
7 How to use 7
8 Reading the results 8
9 Maintenance 9
10 Applicable standards 10
11 Environmental conditions for use 10
12 Technical Data 11
13 Guidance and Manufacturers Declaration 12
14 Siemens Customer Service worldwide 19
**Intended use:**
Playback of acoustic signals with specific volume and in specific order at the push of a button.

**Included in delivery:**
- HearCheck Screener
- Replacement ear cups (25 pcs.)
- User Manual
- 2x AAA batteries
Important hints

- Do not use the HearCheck Screener near mobile phones or equipment emitting radio waves.

- To avoid improper function of the device use only accessories specified by the manufacturer.

- Make sure the battery door is closed before using the device.

- Replace ear cup cover for each patient. Do not reuse covers.

- This device is not an audiometer and should not be used for any purpose other than screening.

- For reliable results you are advised to use the device in environments where background noise does not exceed 50 dB (A).

- For battery replacement, please use only Alcaline Type AAA batteries or NiMH or NiCd rechargeable batteries, type AAA.

- Remove the batteries if equipment is unlikely to be used for some time.

- Do not throw used batteries into household waste. Use locally provided battery recycling systems for environmentally correct disposal.
5 Insert the batteries

6 Preparation before use

Please insert a new ear cup into the ear cover of the device before use. Use a new cup for each patient (or each ear if there is any sign of infection).

Used ear cups can be disposed of in normal waste.

Replacement ear cups (200 pcs.) are available from Siemens Customer Service on 01293 423700. SN 101 74 191
How to use

STEP 1. Gently place the cup of the device over the ear. It’s important that the edges of the cup are in contact with the patient’s head. Move hair out of the way, remove glasses, earrings and hair bands that may prevent achieving adequate contact around the ear.

STEP 2. Press the start button once to initiate the functional test sequence. If working correctly, you will see all 3 lights flash in sequence 3 times. This indicates that the device is ready to use. The test sequence will begin in 3 seconds with three signals at 1000 Hz. (55dBHL, 35dBHL, 20dBHL).

A light will appear when a tone is being played: first red, then yellow, then green. The subject must indicate when a tone is heard by raising a finger.

STEP 3. Count and record the number of times indicated for the first sequence.

STEP 4. The start button must be pushed within 20 seconds of the end of the first sequence (after the green light has appeared) to start the second sequence.

STEP 5. You will see all 3 lights flash in sequence 3x3 times. The test sequence will begin in 3 seconds with three signals at 3000 Hz. (75dBHL, 55dBHL, 35dBHL).
STEP 6. Count and record the number of times the subject has indicated that a tone was heard.

STEP 7. Repeat steps 2 through 6 on the other ear.

**Please note:** button should be pressed within 20 seconds after the first test or the screener will turn off.

### Reading the results

**Please note:** these are screening results and should not be used as audiometric assessment.

The lower the score, the more likely the patient will benefit from a hearing aid. Please see below an example of how the results should be recorded.

<table>
<thead>
<tr>
<th>Left ear</th>
<th>No. of tones heard in the 1000Hz test</th>
<th>No. of tones heard in the 3000Hz test</th>
<th>Total no. of tones heard PER EAR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

**Results**

**If the patient can hear:**

- **All 6 tones**
  - Patient is unlikely to need further hearing assessment.
  - May be discharged after an explanation and advice.

- **3, 4 or 5 tones**
  - Patient is likely to have a hearing difficulty and would benefit from an assessment and fitting of hearing aid product (e.g. open ear tip or instant fit lip).

- **1 or 2 tones**
  - Refer patient for instant fit or for assessment and fitting in two sessions.

- **0 tones**
  - Refer patient for an assessment in a clinic that can appropriately assess severe hearing impairment.

Score the right ear in exactly the same way.
Maintenance

Note:
- The device requires very little maintenance except for daily wiping with a clean, dry or damp cloth. Use water or lukewarm, diluted solution of water and household detergent to wet the cloth. Do not use alcohol or other solvents, and never immerse in water.
- The device has been factory calibrated and should be returned for recalibration three years after the manufacturing date labelled inside the ear cover. If you need to return the device, please contact Siemens Customer Service on 01293 423700.
- To determine proper functionality and adequate calibration, an operator with normal hearing (or a person who can hear all 6 signals) should perform a hearing test on his own ear at least once a day or before the device is used for another person.
Applicable standards

- EN 980/2006:
  Symbols for use in the labelling of medical device
- EN 60601-1:
  Medical electrical equipment - Part 1: General requirements for safety
- EN 60601-1-2:
  Medical electrical equipment - Part 1: General requirements for safety. Collateral standard.
  Electromagnetic compatibility

Environmental conditions for use

In the operation
- Temperature range: +10°C to +40°C
- Relative humidity: 30% to 75%, non condensing
- Air pressure: 70 kPa to 106 kPa

During transportation
- Temperature range: -20°C to +60°C
- Relative humidity: 10% to 90%, non condensing
- Air pressure: 70 kPa to 106 kPa
Technical Data

General Classifications

Medical devices class: 2 a
Protection class: II
Applied parts: Type BF
IP protection class according to IEC 60529: IPX0
AP or APG classification: Not applicable
Operating mode: Continuous operation
Power: Internally powered equipment
Sterilisation / disinfection: See manual chapter 9
Accuracy of measurement: 3 dB
Test frequencies: 1000 Hz, 3000 Hz
Tolerance of frequencies: +/- 5%
Total Harmonic Distortion (THD): < 10%
Test levels: 20, 35, 55, 75 dBHL
Power save function: Automatic power off after 20 sec.
Battery Size: AAA (1,5 V)
Number of batteries: 2
Battery Lifetime: 1000 measurements
The device fulfills EN 60601-1-2 and requires special precautions regarding EMC. It must be installed and put into service according to EMC information provided in this document. Please take into account, that portable and mobile RF communications equipment can affect medical electrical equipment.

**Warning:**
- The device or system should not be used adjacent or stacked with other equipment.
- The use of accessories, transducers and cables other than those specified, with the exception of parts for internal components, may result in increased emission or decreased immunity of the equipment or system.
**Guidance and manufacturer's declaration - electromagnetic emissions**

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

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The HearCheck Screener 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The HearCheck Screener is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
Guidance and manufacturer's declaration - electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>± 8 kV air</td>
<td>± 8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>± 2 kV for power supply lines</td>
<td>Not applicable</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>± 1 kV for input/output lines</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV differential mode</td>
<td>Not applicable</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>± 2 kV</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
## Immunity test

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>$&lt;5% , U_r$ ($&gt;95%$ dip in $U_r$) for 0.5 cycle $40% , U_r$ ($60%$ dip in $U_r$) for 5 cycles $70% , U_r$ ($30%$ dip in $U_r$) for 25 cycles $&lt;5% , U_r$ ($&gt;95%$ dip in $U_r$) for 5 sec.</td>
<td>Not applicable</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the HearCheck Screener requires continued operation during power mains interruptions, it is recommended that the HearCheck Screener is powered from an uninterruptible power supply or a battery.</td>
</tr>
</tbody>
</table>

### Power frequency (50/60 Hz) magnetic field

| IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

**Note:** $U_r$ is the a.c. mains voltage prior to application of the test level.
### Guidance and manufacturer's declaration - electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable and mobile RF communications Equipment should be used no closer to any part of the HearCheck Screener, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conducted RF</th>
<th>3 Vrms</th>
<th>150 kHz to 80 MHz</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
</tr>
</tbody>
</table>

**Recommended separation distance**

- Not applicable
- \( d = 1.2 \sqrt{P} \) (80 MHz to 800 MHz)
- \( d = 2.3 \sqrt{P} \) (800 MHz to 2.5 GHz)

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:
<table>
<thead>
<tr>
<th>Note 1:</th>
<th>At 80 MHz and 800 MHz, the higher frequency range applies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note 2:</td>
<td>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td>
</tr>
</tbody>
</table>

| a               | Field strengths from fixed transmitters, such as base stations for radio (mobile/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 HearCheck Screener is used exceeds the applicable RF compliance level above, the HearCheck Screener should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HearCheck Screener. |
| b               | Over the frequency range 150 kHz to 80 MHz, field strengths |
**Recommended separation distances between portable and mobile RF communications equipment and the HearCheck Screener**

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter ( W )</th>
<th>Separation distance according to frequency of transmitter ( m )</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz ( d = 1.2 \sqrt{P} )</td>
<td>80 MHz to 800 MHz ( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>Not applicable</td>
</tr>
<tr>
<td>0.1</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1</td>
<td>Not applicable</td>
</tr>
<tr>
<td>10</td>
<td>Not applicable</td>
</tr>
<tr>
<td>100</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in meters \( (m) \) can be estimated 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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