



## Toe CPM Hall-U-Sana®

# Instructions for use English



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HA-500.404 Hall-U-Sana User Manual\_EN\_V5  
Article No. HA-500.404



Instruction video



# Toe CPM Hall-U-Sana<sup>®</sup>

## Instructions for use English

Request to the user and/or patient: any serious incident occurring in connection with the device must be reported immediately to the manufacturer and the competent authority of the Member State in which the user and/or patient is located.

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# 1. Introduction

The toe CPM Hall-U-Sana® supports rehabilitation in the post-operative phase after surgery of the 1st ray.

These instructions for use are intended for patients and care personnel.

All serious incidents related to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is located.

- **Read the entire instructions for use carefully before using the toe CPM Hall-U-Sana®.**
- **Only use the toe CPM Hall-U-Sana® for the intended use described in these instructions for use.**
- **Follow the instructions in these instructions for use when adjusting and starting up the toe CPM Hall-U-Sana®.**
- **Contact Lüdi Medical Rehab AG if you need assistance with fitting, commissioning, or cleaning the device.**
- **Only use the toe CPM Hall-U-Sana® in accordance with the instructions from your doctor or nurse.**
- **Advice in these instructions for use does not replace instructions from the doctor providing your care.**
- **Device to be used on prescription only.**

1. For reasons of readability, the masculine form has been chosen in the text; nevertheless, the information refers to members of both genders.

# 1. Introduction

## 1.1 Intended use

The intended use of the Hall-U-Sana® Continuous Passive Motion (CPM) device is the support of post-operative treatment after surgery of the 1st ray through passive movement of the big toe. Passive movement of the toe during post-operative treatment reduces the risk of stiffness and remaining pain and prolonged postoperative swelling after surgery.

## 1.2 Indications

The toe CPM Hall-U-Sana® is suitable for the following areas of application:

- Post-operative treatment after surgery of the 1st ray or any situation in which motion therapy of the MTP-I joint is indicated
- Post-operative treatment after surgery of the 1st ray, such as:
  - Hallux valgus und Hallux rigidus surgeries
  - Surgically treated cartilage defects
  - Surgically treated fractures
  - Joint replacement

# 1. Introduction

## 1.3 Contraindications

The toe CPM Hall-U-Sana® must not be used in the following cases:

- Inflammatory skin changes that could be additionally irritated by the holding apparatus (e.g., toe strap, foot strap) of the device (e.g., atopic eczema or ulcer)
- Thin, vulnerable skin (e.g., after long-term cortisone treatment)
- Unstable fractures
- Acute arthrosis like active arthroses, arthritis or arthropathies (e.g., gout)
- Infection of the metatarsophalangeal joint of the big toe
- Intolerance to mobilization
- Excessive swelling

## 1.4 Side effects

No side effects are known when the toe CPM Hall-U-Sana® is used as intended.

## 1.5 General warnings and cautions

The following warnings and cautions are of a general nature. Other special warnings and cautions appear before the relevant instruction in the instructions for use.

# 1. Introduction

## Warning

- Treatment only if wound healing is advanced, at the earliest 2 weeks after surgery.
- If the pain persists, consult your doctor.
- No modifications may be made to this device.
- The cable can be dangerous for children or pets. Keep the device out of the reach of children - risk of strangulation.
- The cable can be a trip hazard for others. Pay attention to the position of the cable during treatment - risk of tripping.
- The cable can be a tripping hazard if the device is used incorrectly.
- Use the device only in a sitting position - risk of tripping.

## Caution

- The toe CPM Hall-U-Sana® is not intended for use by persons (including children) with impaired physical or mental functions or impaired cognition unless adequate supervision is provided by a person responsible for the patient's safety.
- The toe CPM and control unit must not be subjected to excessive force, dropped or shaken. Do not pull on the cable. Do not stand on the control unit.
- If the operating behaviour of the device changes in an unexplained way, if it makes unusual or unpleasant noises, if you drop the device or if it is handled improperly, stop using it and contact Lüdi Medical Rehab AG (Contact, Section 9).

# 1. Introduction

## 1.6 Symbols

The following symbols may appear on the product, on the packaging or in the instructions for use.

	Follow instructions for use	<b>IP21</b>	Protection against access with a finger, protection against solid foreign bodies (diameter > 12.5 mm), protection against falling dripping water
	Warning: Observe the warnings in the instructions for use		Do not dispose of in unsorted general waste
	Article number		Medical device
	Serial number		Applied part of type BF
	Manufacturer		Keep out of the reach of children
	CE marking according to the Regulation (EU) 2017/745		Non-ionising radiation. Interference may occur in the vicinity of equipment marked with this symbol
	EC Authorized Representative	<b>Rx only</b>	Device to be used on prescription only
	Direct current		
	Temperature limitation		
	Humidity limitation		

**Attention:** Failure to heed a warning could result in an accident, a medical incident resulting in death or serious injury.

**Attention:** Failure to observe a caution could result in damage to persons or property or impair the function of the device.

## 2. The toe CPM Hall-U-Sana®

The illustrations below show the components of the toe CPM Hall-U-Sana®.



### Description

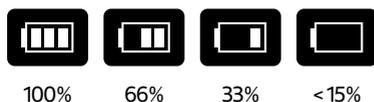
- ① Toe flap
- ② Toe glider
- ③ Toe strap with velcro fastener
- ④ Toe separator
- ⑤ Foot strap with velcro fastener
- ⑥ Soft insole
- ⑦ Slip-resistant sole (on the underside)
- ⑧ Control unit

## 2. The toe CPM Hall-U-Sana®

### 2.1 The user interface of the control unit

#### Description

- ① START PAUSE button: to switch on & off as well as to start and pause a programme
- ② Buttons for the direct selection of programme 1 or programme 2
- ③ Display showing the status and remaining treatment time in minutes
- ④ Display of the charge status of the integrated Li-Ion battery



#### Caution

- The device contains a Li-ion battery. Do not attempt to remove the battery from the device or charge it independently.

The integrated Li-ion battery should be sufficiently charged at the start of therapy to provide power for the duration of treatment of 30 days. Contact Lüdi Medical Rehab AG in the event of premature discharge. The battery may only be charged by Lüdi Medical Rehab AG. The battery may only be replaced by the manufacturer.

### 3. Adjusting the toe CPM Hall-U-Sana®

The toe CPM Hall-U-Sana® has been designed in such a way that only minimal adjustment is required, which can be carried out by the patient himself after a short period of self-study.

#### 3.1 Use only in a sitting position

##### Warning

- The adjustment as well as the subsequent treatment may only be carried out in a sitting position.
- Lying, standing or walking during adjustment or treatment can cause pain, damage to the device, incorrect adjustments and failure to achieve the desired treatment results.
- During adjustment and treatment, the toe CPM must lie flat on the floor, if possible, on a level surface (avoid high-pile carpets).



The toe CPM Hall-U-Sana® itself may only be operated in a resting, horizontal position lying flat on the floor. The patient should be seated.

### 3. Adjusting the toe CPM Hall-U-Sana®

#### 3.2 Correct placement of the foot on the toe CPM

During the treatment, the big toe should be gently moved up and down while attached to the movable toe flap. For this movement to be correct, it is important to position the foot so that the metatarsophalangeal joint of the big toe comes to rest in front of the toe flap's axis of rotation.

The foot must therefore be pushed forward as far as possible until the crease between the big toe and the second toe is firmly positioned against the padded, vertical toe separator. Care should be taken not to build up too much pressure - especially if there are surgical scars in this area.



- ① The crease must have contact here
- ② Move foot forward as far as possible
- ③ Stop at the toe separator

## 3. Adjusting the toe CPM Hall-U-Sana®

### 3.3 Fixation of the foot by means of the foot strap

The toe CPM Hall-U-Sana® can be used up to shoe size 45.



- ① Once the foot is pushed all the way forward against the toe separator,
- ② The next step is to tighten the foot strap by pulling the strap upwards until the foot is securely fastened to the sole.
- ③ Then secure the foot strap with the velcro.

### 3. Adjusting the toe CPM Hall-U-Sana®

#### 3.4 Securing the big toe to the toe flap

 **Caution**

- For effective treatment, pull the slider as far back as possible before tightening the toe strap.



- 1 The big toe must rest loosely in the open toe strap on the toe glider (slider).
- 2 Then pull the movable toe glider (slider) as far back as possible. Otherwise, the big toe is secured to the toe flap with the strap too far forward. This can lead to the toe not moving correctly around the metatarsophalangeal joint during treatment, but only bending slightly downwards and upwards within itself.
- 3 Then secure the big toe firmly on the toe glider with the toe strap. For this make sure that the big toe lies in the loop of the toe strap, tighten the strap by pulling on the end and fixing it with the velcro.

## 4. Switch-on, operation & switch-off

### 4.1 Switching on the toe CPM Hall-U-Sana®



The toe CPM is switched on and later switched off again centrally via the control unit. To switch on, press and hold the START PAUSE button for 2 seconds. The device switches on. During start-up, the Hall-U-Sana® "U" logo is displayed briefly. The device immediately enters standby mode.

This is indicated in two ways:

- The LED ring of the START PAUSE button and the labelling of the button light up white.
- "READY" appears on the display.

The current charge status of the Li-ion battery is shown in the top right-hand corner of the display. If there is only 1 bar (33%), Lüdi Medical Rehab AG should be contacted, as the battery charge is then no longer sufficient for a complete treatment cycle.

## 4. Switch-on, operation & switch-off

### 4.2 Two predefined programmes

The treatment is carried out by slowly moving the movable toe flap with the big toe secured to it (at 3 degrees per second) upwards (dorsal) and downwards (plantar) by a motor:



- ① Starting position
- ② Upwards (dorsal)
- ③ Downwards (plantar)

Based on many years of trials, it has been shown that two fixed programmes with predefined angle groups are sufficient to achieve the desired therapeutic success. In cooperation with leading orthopaedic foot surgeons, the following movement dimensions have been defined for each programme:

	Upwards (dorsal) ↗ ↘	Downwards (plantar) ↙ ↚	Application (recommendation)
Programme 1	+20°	-10°	first 4 to 5 days
Programme 2	+40°	-20°	after 5th to 30st day

## 4. Switch-on, operation & switch-off

It is recommended to first use programme 1 for 4 to 5 days so that the metatarsophalangeal joint of the big toe has been prepared and an increased range of motion has been achieved: then you can switch to programme 2 (larger angle of +40° upwards and -20° downwards).

If pain still occurs when using programme 2, we recommend continuing with programme 1 for the time being. After a few days, a new attempt at treatment can be made with programme 2.

Various preliminary tests have shown that a treatment of 2 x 25 minutes per day for 30 days is sufficient. However, the doctor looking after you may prescribe more than two treatments per day at his or her discretion. They may also advise you to use programme 1 for longer than four to five days.

### 4.3 Selection of the desired programme



When the toe CPM Hall-U-Sana® is switched on, programme 1 is preselected by default. The green-illuminated "1" indicates that programme 1 is selected. By pressing key "2", programme 2 can be selected: accordingly, the digit "2" lights up green.

## 4. Switch-on, operation & switch-off

### 4.4 Starting the selected programme

Ensure that the patient is in a comfortable sitting position and that the toe CPM Hall-U-Sana® is lying flat on the floor. The control unit should be held in the hand during treatment or at least placed within reach so that it can be operated at any time (e.g. emergency stop in case of pain). The programme can now be started by pressing the START PAUSE button once. The LED ring around the key, which has been white until this point, and the "START" and "PAUSE" lettering, now light up green.

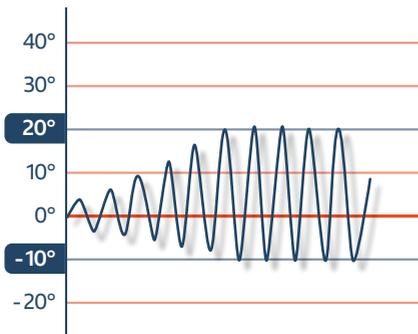


At the same time, the display shows the remaining treatment time in minutes.

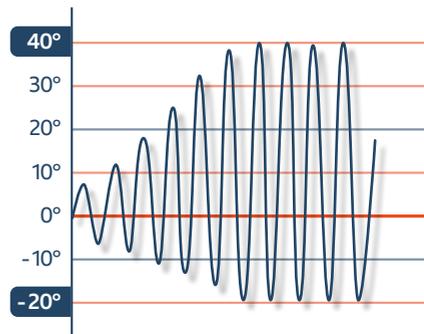


In order for the operated toe to gently get used to the movement, each programme begins with a warm-up phase. With each up and down movement, the angle is increased by 5° until the maximum deflection angle is reached: +20°/-10° for programme 1 or +40°/-20° for programme 2.

#### Warm-up phase programme 1



#### Warm-up phase programme 2



## 4. Switch-on, operation & switch-off

### 4.5 Interruption du programme

Normally, once a programme has been started, it should be completed by the end of the 25-minute treatment period. However, it may happen that the programme must be interrupted if, for example:

- one of the straps has not been tightened properly,
- the foot has not been correctly advanced against the toe separator and is thus too far back,
- the toe glider has not been pulled back enough before securing the big toe to it, so that the toe does not move up and down correctly,
- persistent pain occurs.



Pa stop/pause, press the START PAUSE button once. Pressing one of the two programme selection buttons also puts the device into pause mode. The green illuminated LED ring and the writing change to white and the toe flap immediately returns to

the horizontal starting position. Depending on the deflection, this can take up to 15 seconds.

During this return time, the display will show a flashing "PAUSE" to alert the user that pausing has been initiated.



When the toe flap has reached the horizontal position, "PAUSE" stops flashing on the display. The treatment is paused. The problem can now be resolved (possible adjustment/correction of the fastening, etc.). During the pause, the treatment time counter stops.



## 4. Switch-on, operation & switch-off

### 4.6 Continuing treatment



Press the START PAUSE button again to continue the treatment. Accordingly, the LED ring and the writing turn green again.

At the same time, the remaining treatment time is displayed.



If the above problems persist or the pain continues, pause the treatment again and switch off the device (see Section 4.7). Lüdi Medical Rehab AG must then be contacted immediately.

### 4.7 Programme end & switch off



When the planned treatment time of 25 minutes is reached (i.e., the display has counted down from 25 to 0 min), the LED ring and the writing turn white.

A flashing "END" is also shown in the display while the toe flap moves to the horizontal starting position. When the horizontal position is reached, only "END" is displayed (the flashing stops).



## 4. Switch-on, operation & switch-off

There are two ways to switch off:

- ① After 5 minutes of inactivity, the toe CPM switches off automatically.



- ② By keeping the START PAUSE button pressed for 2 seconds, the toe CPM can be switched off immediately.

Before the device switches off, the "Power Off" symbol appears briefly on the display



### 4.8 Forced switch-off

It is recommended to always switch off the toe CPM at the end of the programme or in pause mode. If the device is switched off in the middle of a programme sequence (press and hold the START PAUSE button for 2 seconds), the toe flap must first return to the horizontal starting position. If the flap is in the outermost deflection, this process can take up to 15 seconds.

During this time, the "Power Off" symbol flashes to signal the user that the flap is returning to the horizontal position and the switch-off process has been initiated.



When the toe flap has reached the horizontal position, the "Power Off" symbol stops flashing, and the device switches off.

## 5. Cleaning, storage, servicing & environmental information

### 5.1 Cleaning

#### Warning

- Do not clean under running water or with chemicals - the device is not waterproof (IP21). No liquid must get into the toe CPM or the control unit.
- Do not use abrasive or corrosive cleaning agents.

If necessary, the toe CPM and the control unit can be wiped clean with a damp, soft cloth. Make sure that the device is switched off.

### 5.2 Storage

#### Caution

- Use the device only in environments with an ambient temperature between 10°C and 35°C (50°F and 95°F).
- Use the device only in environments with 15% - 80% relative humidity, non-condensing.
- Store or transport the device only in an environment with 15% - 90% relative humidity, non-condensing.
- Store or transport the device only in environments with an ambient temperature between -20°C and 50°C (-4°F and 122°F).
- Always store the device in the locked transportation case between treatments.

## 5. Cleaning, storage, servicing & environmental information

### 5.3 Servicing & returns



#### Caution

- Repairs and service work may only be carried out by a specialist authorised by U-Sana Medical AG.
- Do not open the toe CPM or the control unit and do not remove the toe flap.
- The integrated battery must not be tampered with or charged.

No service work needs to be carried out by the patient. This is the sole responsibility of the service technician. In the event of malfunctions or a discharged battery, Lüdi Medical Rehab AG must be contacted immediately.

**After completion of the treatment, Lüdi Medical Rehab AG must be contacted immediately to coordinate the return:**

**Lüdi Medical Rehab AG**  
Hans Huber-Strasse 38  
4502 Solothurn, Switzerland

Tel. +41 32 626 3090  
E-mail: [service@luedimedical.ch](mailto:service@luedimedical.ch)  
[www.luedimedical.ch](http://www.luedimedical.ch)

Keep the shipping box for the return.

### 5.4 Environmental information

The toe CPM must be returned to Lüdi Medical Rehab AG after completion of treatment or in the event of a defect. Irreparable parts are professionally dismantled and sorted according to type and sent to the appropriate recycling collection points.

## 6. Troubleshooting

The following problems can be remedied independently by the patient if necessary. If the problem persists, contact Lüdi Medical Rehab AG.

Error / problem / error message	Action
<p>Device does not switch on</p>	<p>Press and hold the START PAUSE button for 2 seconds. If the device still does not switch on, contact Lüdi Medical Rehab AG.</p>
<p>Battery charge low (33% or less)</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>33%</p> </div> <div style="text-align: center;">  <p>&lt; 15%</p> </div> </div>	<p>The device should have a fully charged battery when received (normal: 100% charge, possibly 66%). However, if the charge is 33% or lower, Lüdi Medical Rehab AG must be contacted immediately to order a replacement device (as the battery charge is no longer sufficient for the intended duration of treatment). The same must be done if the charge drops to 33% or lower during the treatment period and at least half of the treatment still has to be completed. In this case, the charge is not sufficient.</p>
<p>The big toe is not moved up and down properly</p>	<p>Make sure that the foot is pushed all the way forward (the crease between the big toe and the second toe must fit snugly against the toe separator).            Make sure that the toe glider (slider) is pulled back as far as possible.            Ensure that the toe and foot straps are well tightened.</p>
<p>The treatment causes very severe pain</p>	<p>Immediately press the START PAUSE button: the toe flap immediately moves to the horizontal starting position and the device goes into "PAUSE" mode.            After a pause of 15 to 20 minutes, start the programme and attempt treatment again.            If programme 2 (greater range of motion) was selected &gt; select programme 1 again (smaller range of motion).            If the pain persists: Switch the device off (hold down the START PAUSE button for at least two seconds) and contact Lüdi Medical Rehab AG.</p>

## 6. Troubleshooting

Error / problem / error message	Action
<p>The toe flap remains in an oblique position</p>	<p>Press and hold the START PAUSE button for at least 2 seconds to switch off the device &gt; when the device is switched on again, the toe flap automatically returns to the horizontal starting position.</p>
<p>If too much force/ resistance is applied, the toe flap immediately moves to the horizontal position for safety and the "Overload" symbol is displayed:</p> 	<p>Make sure that the toe flap is no longer blocked (e.g. by objects trapped in the side). Check that the foot or big toe is correctly positioned and secured in place. Acknowledge the error message by pressing the START PAUSE button. "PAUSE" appears in the display. Then press the START PAUSE button again to continue the programme.</p> <p>If the problem persists, contact the Lüdi Medical Rehab AG.</p>
<p>In exceptional cases, this error symbol may be displayed: the toe flap moves to the horizontal position and pauses. The device cannot be operated any further:</p> 	<p>In these situations, switch off the toe CPM by holding down the START PAUSE button. After 10 minutes, switch the device back on. If the same error message appears again, switch the device off again and switch it on again after 30 minutes. If the problem persists, switch the device off and contact Lüdi Medical Rehab AG immediately, stating the two-digit error code, which begins with "E" (shown as "12" in the picture).</p>

## 7. Technical data

<b>Weight:</b>	Toe CPM (incl. Li-ion battery) and control unit: 1.014 kg
<b>Dimensions (mm):</b>	<ul style="list-style-type: none"><li>• Toe CPM (shoe): 299 x 138 x 69</li><li>• Control unit: 115 x 47 x 18</li></ul>
<b>Max. load on the toe CPM:</b>	20 kg (even load distribution)
<b>Range of use:</b>	Shoe size 36 to 45, left and right foot
<b>Materials:</b>	All parts in contact with the body, such as the insole, fastening straps, toe separator, etc., are made of bio-compatible materials
<b>Power supply:</b>	Direct current 7.2V (integrated Li-Ion battery, 10.05 Ah)
<b>Current consumption:</b>	2.5 A
<b>Conforms to:</b>	IEC 60601-1:2005 (Third Edition)+A1:2012 EN 60601-1:2006+Cor.: 2010+A1:2013
<b>EMC (electromagnetic compatibility):</b>	IEC 60601-1-2:2014 EN 60601-1-2:2015
<b>Operating conditions:</b>	<ul style="list-style-type: none"><li>• 10° to +35°C ambient temperature</li><li>• Max. 80% relative humidity without condensation</li></ul>
<b>Storage conditions:</b>	<ul style="list-style-type: none"><li>• -20°C to 50°C storage temperature</li><li>• Max. 90% relative humidity without condensation</li></ul>
<b>Protection class:</b>	IP21

## 8. IEC 60601-1-2: 2014

### 8.1 Electromagnetic emissions

The toe CPM Hall-U-Sana® is intended for operation in the electromagnetic environment described below. The user of the toe CPM Hall-U-Sana® should ensure that it is used in such an environment.

#### Guidelines and manufacturer's declaration - Electromagnetic emissions

Emission measurements	Compliance	Electromagnetic environment - Guidelines
RF emissions according to CISPR 11	Group 1	The toe CPM Hall-U-Sana® uses RF energy exclusively for internal functions. Therefore, RF emissions are very low and are unlikely to interfere with adjacent electronic equipment.
RF emissions according to CISPR 11	Class B	The toe CPM Hall-U-Sana® is intended for use in all facilities including those in residential areas and those directly connected to a public supply network which also supplies buildings used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	Class A	
Emission of voltage fluctuations according to IEC 61000-3-3	Satisfied	

## 8. IEC 60601-1-2: 2014

### 8.2 Electromagnetic immunity to interference

The toe CPM Hall-U-Sana® is intended for operation in the electromagnetic environment described below. The user of the toe CPM Hall-U-Sana® should ensure that it is used in such an environment.

#### Guidelines and manufacturer's declaration - Electromagnetic immunity to interference

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Electrical static discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood or concrete or have ceramic tiles. If the floor is covered with synthetic material, the rel. humidity must be at least 30%.
Fast transient electrical disturbances/bursts according to IEC 61000-4-4	±2 kV for the feed-in ±1 kV for input/output		Not applicable, as no power supply unit
Shock waves according to IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV between lines ± 0.5 kV, ± 1 kV, ±2 kV between line and earth		Not applicable, as no power supply unit
Voltage interruptions according to IEC 61000-4-11	<5% $U_T$ (>95% reduction of $U_T$ ) Duration: 5 seconds.	<5% $U_T$ (>95% reduction of $U_T$ ) Duration: 5 seconds.	After reinitialisation, continue the programme by pressing the START PAUSE button.

## 8. IEC 60601-1-2: 2014

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields with mains frequency have the same characteristics as the magnetic fields in a hospital or business environment.
Conducted RF disturbance variables according to 61000-4-6	3 V <sub>Effective value</sub> 150 kHz to 80 MHz		Not applicable, as no power supply unit
Radiated RF disturbance variables according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	The field strength of fixed radio transmitters should be less than the compliance level <sup>a)</sup> at all frequencies according to an on-site investigation <sup>b)</sup> . Interference may occur in the vicinity of equipment marked with the following symbol. 

**Note 1:** At 80 MHz and 800 MHz, the higher value applies.

**Note 2:** These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is influenced by absorptions and reflections of buildings, objects, and people.

- a) Across the frequency range from 150 kHz to 80 MHz, the field strength is less than 3 V/m.
- b) The field strength of fixed transmitters, such as base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot be predicted theoretically with accuracy. To determine the electromagnetic environment due to fixed RF transmitters, a site survey is recommended. If the determined field strength at the location of the toe CPM Hall-U-Sana<sup>®</sup> exceeds the compliance level specified above, the toe CPM Hall-U-Sana<sup>®</sup> must be observed with regard to its normal operation at each place of use. If unusual performance characteristics are observed, it may be necessary to take additional measures, such as reorientation or repositioning of the toe CPM Hall-U-Sana<sup>®</sup>.

## 8. IEC 60601-1-2: 2014

### 8.3 Recommended protective distances

The toe CPM Hall-U-Sana® is intended for operation in the electromagnetic environment specified below in which radiated RF disturbance parameters are controlled. The user of the toe CPM Hall-U-Sana® can help prevent electromagnetic interference by maintaining minimum distances between portable and mobile RF communication devices (transmitters) and the toe CPM Hall-U-Sana® as recommended below according to the maximum output power of the communication device.

#### Recommended protective distances between portable and mobile RF communication devices and the toe CPM Hall-U-Sana®

Nominal power of the transmitter W	Protective distance according to transmission frequency 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 $d = 1,2 \sqrt{P}$
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, whose nominal power is not given in the table above, the distance can be determined using the equation belonging to the respective column where P is the nominal power of the transmitter in watts (W) according to the specifications of the transmitter's manufacturer.

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**Note 1:** An additional factor of 10/3 was used to calculate the recommended protective distance of transmitters in the frequency range from 80 MHz to 2.5 GHz to reduce the likelihood that a mobile/portable communication device inadvertently introduced into the patient area would cause interference.

**Note 2:** These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is influenced by absorptions and reflections of buildings, objects and people.

## 9. Contact

### 9.1 Legal manufacturer



**Effectum Medical AG**  
Kirchgasse 11  
4600 Olten, Switzerland

[www.effectummedical.com](http://www.effectummedical.com)  
E-mail: [info@effectummedical.com](mailto:info@effectummedical.com)

### 9.2 For product queries and complaints

**U-Sana Medical AG**  
Hohlegasse 4  
4104 Oberwil, Switzerland

[www.usanamedical.com](http://www.usanamedical.com)  
E-mail: [info@usanamedical.com](mailto:info@usanamedical.com)

### 9.3 For service, support and distribution

**Lüdi Medical Rehab AG**  
Hans Huber-Strasse 38  
4502 Solothurn, Switzerland

[www.luedimedical.ch](http://www.luedimedical.ch)  
Tel. +41 32 626 3090  
E-mail: [service@luedimedical.ch](mailto:service@luedimedical.ch)

### 9.4 EC Authorized Representative



**MED-RAS GmbH**  
Eichenallee 8H  
21521 Wohltorf, Germany

[www.medras.de](http://www.medras.de)  
Tel. +49 4104 994444 – 0  
E-mail: [info@medras.de](mailto:info@medras.de)

### 9.5 Warranty

2 years (mechanical parts)  
2 years (electronics)



**usana**medical

[www.usamedical.com](http://www.usamedical.com)

Legal Manufacturer: Effectum Medical AG, Kirchgasse 11, 4600 Olten, Switzerland, [www.effectummedical.com](http://www.effectummedical.com)