hallu-sana®

Hall-U-Sana® Toe CPM

Instructions for use

English

CE 0297

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Instruction video

Hall-U-Sana® Toe CPM

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 country in which the user and/or patient is located.

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1. Introduction

The Hall-U-Sana® toe CPM 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 country in which the user and/or the patient is located.

- **Read the entire instructions for use carefully before using the Hall-U-Sana® toe CPM.**
- **Only use the Hall-U-Sana® toe CPM for the intended use described in these instructions for use.**
- **Follow the instructions in these instructions for use when adjusting and starting up the Hall-U-Sana® toe CPM.**
- **Contact your service partner if you need assistance with fitting, commissioning, or cleaning the device.**
- **Only use the Hall-U-Sana® toe CPM 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 to support post-operative treatment following 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, residual pain, and prolonged postoperative swelling following surgery.

1.2 Indications

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

- Post-operative treatment following surgery of the 1st ray or any situation in which motion therapy of the MTP-I joint is indicated

- Post-operative treatment following 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 Hall-U-Sana® toe CPM 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 such as 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 Hall-U-Sana® toe CPM 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 following 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 while seated - risk of tripping.

Caution

- The Hall-U-Sana® toe CPM 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 your service partner (Contact, Section 9.3).

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
	Warning: Observe the warnings in the instructions for use
REF	Article number
SN	Serial number
	Manufacturer
CE	CE marking in accordance with Directive (EU) 2017/745
EC REP	EC Authorized Representative
	Direct current
	Temperature range
	Humidity range
IP21	Protection against access with a finger, protection against solid foreign objects (diameter > 12.5 mm), protection against dripping water
	Do not dispose of product in unsorted household waste
MD	Medical device
	Applied part of type BF
	Keep out of the reach of children
	Non-ionizing radiation. Interference may occur in the vicinity of equipment marked with this symbol
Rx only	Device to be used on prescription only

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 Hall-U-Sana® toe CPM

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

Description

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

2. The Hall-U-Sana® toe CPM

2.1 The user interface of the control unit

Description

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

100% 66% 33% < 15%

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 your service partner in the event of premature discharge. The battery may only be charged by your service partner. The battery may only be replaced by the manufacturer.

3. Adjusting the Hall-U-Sana® toe CPM

The Hall-U-Sana® toe CPM 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 while seated

Warning

- The adjustment as well as the subsequent treatment may only be carried out while seated.
- 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 and, if possible, on a level surface (avoid high-pile carpets).

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

3. Adjusting the Hall-U-Sana® toe CPM

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 rests 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 be in contact here
2. Move foot forward as far as possible
3. Stop at the toe separator

3. Adjusting the Hall-U-Sana® toe CPM

3.3 Securing the foot using the foot strap

The Hall-U-Sana® toe CPM can be used up to men's shoe size 12 (women's size 14).

1

2 Once the foot is pushed all the way forward against the toe separator,

3 The next step is to tighten the foot strap by pulling the strap upwards until the foot is securely fastened to the sole.

Then secure the foot strap with the velcro.

3. Adjusting the Hall-U-Sana® toe CPM

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 will be secured to the toe flap with the strap too far forward. This can lead to the toe not moving correctly at the metatarsophalangeal joint during treatment, but only bending slightly downwards and upwards.

(3) Then secure the big toe firmly on the toe glider with the toe strap. To do this make sure that the big toe is positioned in the loop of the toe strap, tighten the strap by pulling on the end and securing it with the velcro.

4. Switch-on, operation & switch-off

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

The toe CPM is switched on and later switched off again centrally via the control unit. To switch the device 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%), your service partner should be contacted, as the battery charge is no longer sufficient for a complete treatment cycle.

4. Switch-on, operation & switch-off

4.2 Two predefined programs

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 programs with predefined angle groups are sufficient to achieve the desired therapeutic results. In cooperation with leading orthopaedic foot surgeons, the following movement dimensions have been defined for each program:

	Upwards (dorsal) ↑	Downwards (plantar) ↓	Application (recommendation)
Program 1	+20°	-10°	first 4 to 5 days
Program 2	+40°	-20°	after 5th to 30th day

4. Switch-on, operation & switch-off

It is recommended that Program 1 be used first 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: you can then switch to Program 2 (increased angle of 40° upwards and 20° downwards).

If using Program 2 is still painful, we recommend continuing with Program 1 for the time being. After a few days, a new attempt at treatment can be made with Program 2.

Various preliminary tests have shown that two 25-minute treatment sessions per day for 30 days is sufficient. However, your doctor may prescribe more than two treatments per day at his or her discretion. They may also advise you to use Program 1 for longer than four to five days.

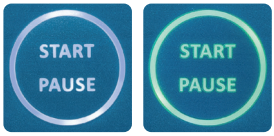
4.3 Selecting the desired program

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

4. Switch-on, operation & switch-off

4.4 Starting the selected program

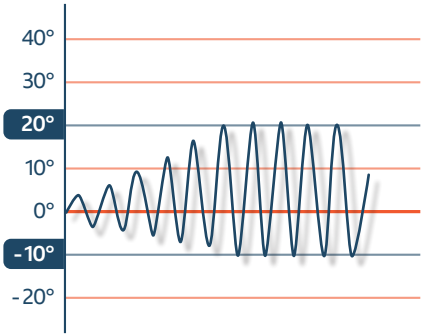
Ensure that the patient is in a comfortable sitting position and that the Hall-U-Sana® toe CPM is lying flat on the floor. The control unit should be held in the hand during treatment, or at least placed within reach, so that it can be operated at any time (e.g. emergency stop in case of pain). The program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



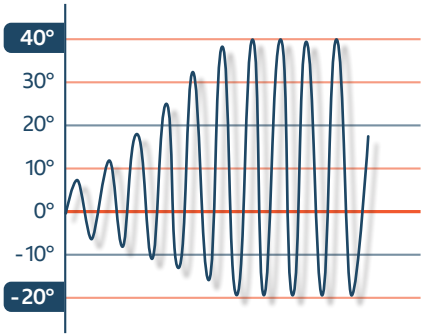
At the same time, the display shows the remaining treatment time in minutes.

In order for the toe being treated to gently get used to the movement, each program 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 Program 1 or +40°/-20° for Program 2.

Warm-up phase, Program 1



Warm-up phase, Program 2

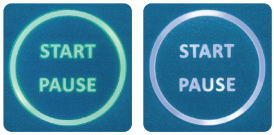


4. Switch-on, operation & switch-off

4.5 Pausing the program

Normally, once a program has been started, it should be completed by the end of the 25-minute treatment period. However, the program may need to be paused 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.



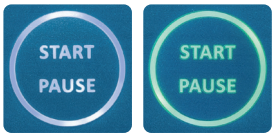
To stop/pause, press the START PAUSE button once. Pressing one of the two program-selection buttons also puts the device into pause mode. The green illuminated LED ring and the writing change to white and the toe flap immediately returns to the horizontal starting position. Depending on the deflection, this can take up to 15 seconds.

During this return time, the display will show a flashing "PAUSE" to alert the user that a pause 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

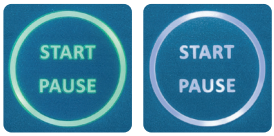


Press the START PAUSE button again to continue the treatment. Accordingly, the LED ring and the writing turn green again.

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 the device off (see Section 4.7). Your service partner must then be contacted immediately.

4.7 Program end & switch-off



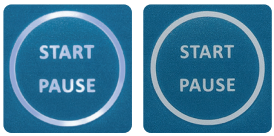
When the planned treatment time of 25 minutes is expired (i.e., the display has counted down from 25 to 0 min), the LED ring and the writing turn white.

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 the device off:

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



2. By keeping the START PAUSE button depressed 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 that the toe CPM always be switched off at the end of the program or in pause mode. If the device is switched off in the middle of a program 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 maximum 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, service & 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, service & environmental information

5.3 Service & 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.
- Do not tamper with or charge the integrated battery.

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, contact your service partner immediately.

After completion of the treatment, contact your service partner immediately to coordinate the return:

Contact details of your service partner, see Section 9.3

Keep the shipping box for the return.

5.4 Environmental information

The toe CPM must be returned to your service partner 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 your service partner.

Error / problem / error message	Action
Device does not switch on	Press and hold the START PAUSE button for 2 seconds. If the device still does not switch on, contact your service partner.
Battery charge low (33% or less)  33% < 15%	The device should have a fully charged battery when received (normal: 100% charge, possibly 66%). However, if the charge is 33% or lower, your service partner 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.
The big toe is not moved up and down properly	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.
The treatment causes very severe pain	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 program and attempt treatment again. If Program 2 (greater range of motion) was selected > select Program 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 your service partner.

6. Troubleshooting

Error / problem / error message	Action
The toe flap remains in an oblique position	Press and hold the START PAUSE button for at least 2 seconds to switch off the device > when the device is switched on again, the toe flap automatically returns to the horizontal starting position.
If too much force/ resistance is applied, the toe flap immediately moves to the horizontal position for safety and the "Overload" symbol is displayed: 	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 on the display. Then press the START PAUSE button again to continue the program. If the problem persists, contact your service partner.
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: 	In these situations, switch off the toe CPM by pressing and holding the START PAUSE button. Wait 10 minutes, then 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 your service partner immediately, stating the two-digit error code, which begins with "E" (shown as "12" in the figure).

7. Technical data

Weight:	Toe CPM (incl. Li-ion battery) and control unit: 1.2 kg
Dimensions (mm):	• Toe CPM (shoe): 299 x 138 x 69 • Control unit: 115 x 47 x 18
Max. load on the toe CPM:	20 kg (even load distribution)
Range of use:	US men's shoe size 4 to 12 (women's size 6 to 14), left and right foot
Materials:	All parts in contact with the body, such as the insole, fastening straps, toe separator, etc., are made of biocompatible materials.
Power supply:	Direct current 7.2 V (integrated Li-ion battery, 10.05 Ah)
Current consumption:	3.0 A
Conforms to:	IEC 60601-1, EN 60601-1 IEC 60601-1-11, EN 60601-1-11
EMC (electromagnetic compatibility):	IEC 60601-1-2 EN 60601-1-2
Operating conditions:	• 10°C to 35°C (50°F to 95°F) ambient temperature • 15% to 80% rel. humidity, non-condensing
Storage conditions:	• -20°C to 50°C (-4°F to 122°F) storage temperature • 15% to 90% rel. humidity, non-condensing
Protection class:	IP21

8. IEC 60601-1-2

8.1 Electromagnetic emissions

The Hall-U-Sana® toe CPM is intended for operation in the electromagnetic environment described below. The user of the Hall-U-Sana® toe CPM 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 Hall-U-Sana® toe CPM 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 Hall-U-Sana® toe CPM is intended for use in all facilities including those in residential areas and those directly connected to a public low-voltage power grid 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

8.2 Immunity to electromagnetic interference

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

Guidelines and manufacturer's declaration - Immunity to electromagnetic interference

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±2, ±4, ±8 & ±15 kV air discharge	± 8 kV contact discharge ±2, ±4, ±8 & ±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%.
Quick transient electrical disturbances / bursts according to IEC 61000-4-4	±2 kV for the feed-in ±1 kV for input/output		Not applicable, as there is 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 ground		Not applicable, as there is 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.	Not applicable, as there is no power supply unit.

8. IEC 60601-1-2

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Magnetic field at the mains frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m		Not applicable, as there are no parts sensitive to magnetic fields in the Hall-U-Sana®.
Conducted RF disturbance variables according to 61000-4-6	10 $V_{Effective\ value}$ 150 kHz to 80 MHz		Not applicable, as there is no power supply unit.
Radiated RF disturbance variables according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 6.0 GHz	The field strength of fixed radio transmitters should be less than the compliance level[a)] at all frequencies according to an on-site investigation[b)]. 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 Hall-U-Sana® toe CPM exceeds the compliance level specified above, the Hall-U-Sana® toe CPM 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 Hall-U-Sana® toe CPM.

8. IEC 60601-1-2

8.3 Recommended protective distances

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

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 in the respective column where P is the nominal power of the transmitter in watts (W) according to the specifications of the transmitter's manufacturer.

8. IEC 60601-1-2

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
E-mail: info@effectummedical.com

9.2 For product queries and complaints

U-Sana Medical AG
Hohlegasse 4
4104 Oberwil, Switzerland

www.usanamedical.com
E-mail: info@usanamedical.com

9.3 For service, support and distribution

Contact details, see back of this IFU

9.4 EC Authorized Representative

MED-RAS GmbH
Eichenallee 8H
21521 Wohltorf, Germany

www.medras.de
Tel. +49 4104 994444 – 0
E-mail: info@medras.de

9.5 Warranty

2 years (mechanical parts)
2 years (electronics)

Service, support and sales

Place address sticker here

www.usanamedical.com

Effectum Medical AG, Kirchgasse 11, 4600 Olten, Switzerland, www.effectummedical.com