EN

Tremitas

Instructions for Use

for the

Tremipen® Home

CE 1304

Declaration of Conformity

We, the Tremitas GmbH, declare in sole responsibility as the Legal Manufacturer, that the medical device

Tremipen® Home

is in compliance with the Directive MDD 93/42/EEC and the Austrian medical-device-law BGBI. 657/1996.

The CE-label on the device documents the accordance to this.

The full text about the Declaration of Conformity is available on our website: www.tremitas.com

CE 1304

1. Table of Contents

2. General Information

2.1 General Information about the Product

The Tremipen® Home is a class Im medical device used for tremor quantification. The device can be used for monitoring purposes and as an assisting tool for therapeutic processes.

This Instructions for Use (in the following named as "IfU") pertains to the Tremipen® Home (in the following named as Tremipen®), which is delivered to you, the user. Please read the IfU, in particular the safety references, very carefully before using the Tremipen®. Not reading this IfU can lead to the wrong interpretation of measurement results, wrong measurements and safety risks. Not following the IfU will lead to a warranty loss.

2.1.1 Name – Tradename

Tremipen® Home (also Tremipen® Home by Tremitas, Tremipen®).

2.1.2 Reference to Variants

There are different variants of Tremipen® (e.g. Tremipen Home®, Tremipen®.

2.1.3 Reference to allowed Accessories

The Tremipen® does not have accessories within the defined scope of the Medical Device Directive (MDD).

2.1.4 Safekeeping of the IfU

This IfU is based on the standards and rules, which are valid within the European Union. Please note that state-specific guidelines and laws abroad could also apply. Keep the IfU for further use. If you need an additional IfU, please contact your local Tremipen® distributor. If you provide the Tremipen® to third parties, the IfU must also be provided.

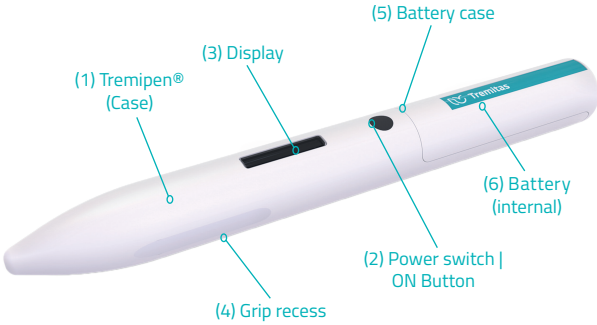
2.1.5 Scope of Delivery | Parts of the Device

The scope of delivery includes the following parts:

1 pc. Tremipen®
1 pc. 1.5 V AAA-battery
see point 4.10 in this IfU
1 pc. Tremipen® Instructions for Use

Tremipen® itself has the following device parts:

1. Tremipen® (Case)
2. Power-switch | ON Button
3. Display
4. Grip recess
5. Battery case
6. Battery



2.2 Legal Manufacturer of the Tremipen®

Tremitas GmbH
Schleppe-Platz 5 | Klagenfurt A-9020 | Austria
www.tremitas.com | office@tremitas.com
+43 660 55 10 380

2.3 Issue Date of the IfU

Date of last revision: Feb 03rd 2020
Version Number: 1.0
Please contact your local Tremipen® distributor if you need details about future versions of the IfU.

3. Intended Use | Purpose

Tremipen® is only allowed to be used for the following purposes:

1. The examination of a physiological process (uncontrollable shaking of upper extremities, hands and fingers)
2. The monitoring of diseases (by measuring the diseases' symptoms on a regular basis), specifically (according to ICD 10-GM-2017):

- G20.- (Primary Parkinson Syndrome)
- G20.0 (Primary Parkinson Syndrome with missing or low-level impairment)
- G20.1 (Primary Parkinson Syndrome with moderate or high-level impairment)
- G25.0 (Essential Tremor)
- G25.2 (Other, not further specified forms of tremor)

3. The monitoring of the symptom tremor (by measuring the symptom on a regular basis)

Tremitas GmbH does not take any responsibilities and liabilities for incidents, accidents, defects and/ or harms and damages, which occur due to a incorrect or improper use of the Tremipen®!

Tremipen® is NOT a toy – keep away from children! Tremipen® must only be used as described in this IfU!

The ON Button of the Tremipen® is a small part, which could be swallowed. Do not remove it or it can become a choking hazard.

4. How to use the Tremipen® safely

4.1 Handling of the Tremipen® – How to make Measurements

1. Push the ON Button on the Tremipen®.

2. Take the Tremipen® into your hand and hold it just like a regular pen; a strong grip is not necessary, only a loose grip (this is necessary so that the tremor is not overlapped by a physiological tremor) — see chapter 4.1.1 for further information.
(Measurements can be made for the right hand, the left hand or even both with two measurements; this depends on your dominant side and which side is more interesting for you and/or your physician for assessments and evaluations.)

3. Choose one of the standardized positions to make a tremor measurement. The Tremipen® provides you a 5 second countdown. See chapter 4.1.1 for further information. *(These positions can be the rest tremor position, the postural tremor position, the wing-beating tremor position etc.).*

4. After 5 seconds a beep tone sounds, the progress bar appears and the measurement begins. For the next 30 seconds, remain still in the chosen position; no writing or moving activities are required.

5. After 30 seconds, another beep tone sounds, and the measurement is over. The display shows the measurement results; these results are also stored within the Tremipen®.
6. After 30 seconds, the Tremipen® automatically turns off and is ready for another measurement.
7. The Tremipen® can be manually shut down by continuously pressing the ON button for 3 seconds (this can be done during or after a measurement)

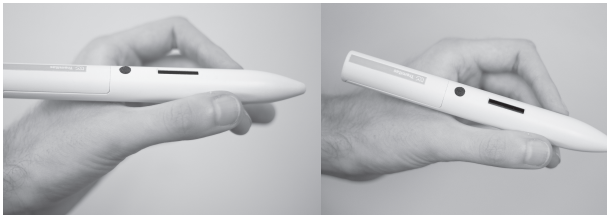
The Tremipen® must only be used with a closed battery case!

For further information and instruction videos please visit our website www.tremitas.com.

4.1.1 Measurement Positions (Examples)

The following rules apply for all measurement positions:

1. The Tremipen® must be held with a loose grip, just like a regular pen, so that no physiological tremor can influence the actual tremor.
2. The thumb and index finger are positioned on the grip recess, the middle finger supports the Tremipen® from below.
3. The Tremipen®'s end with the battery case has to rest on the back of the hand.
4. The measurement position must be identical for all measurements if results need to be compared.
5. Throughout the whole measurement process, you shall not move the hand deliberately



How to hold the Tremipen® during a measurement

Measurement Position for Rest Tremor (e.g. for Parkinson's Disease)

1. Hold the Tremipen® as described above.
2. Place your arms in a relaxed position onto your upper legs or onto armrests of a chair, as seen in the picture above.
3. Remain in this position during the whole measurement process.

Measurement Position for Postural Tremor (e.g. for Essential Tremor)

1. Hold the Tremipen® as described above.
2. Extend your arms horizontally / forward in a 90° angle with straightend and lowered shoulders as seen in the picture above.

3. The fingers on the hand, which does not hold the Tremipen®, should be spread out. Additionally, the ring finger and the little finger of the hand, which is holding the Tremipen®, should be spread away from the palm as far as possible.
4. Remain in this position during the whole measurement process

Wing-Beating Position (e.g. for Essential Tremor)

1. Hold the Tremipen® as described above.
2. For the wing-beating position, the arms are positioned just like wings as seen in the picture above.
3. The hands are held in front of the upper body, slightly below the chest, the fingertips of both hands should be close to each other.
4. Remain in this position during the whole measurement process.

4.1.2 Interpretation of Measurement Results

The Tremipen® determines the following measurement parameter:

1. The tremor's amplitude (intensity of shaking) – measured in mG (milli-G)

After a measurement, the tremor's intensity is shown on the display in mG.

The following symbol is shown for all measurement results below 10mG and 3Hz (underflow):

The following symbol is shown for all measurement results over 1750mG (overflow):

All measurement results are beyond the measurement range of the Tremipen® if they are below 10mG and above 1750mG.

4.1.3 Symbols on the Tremipen® Display

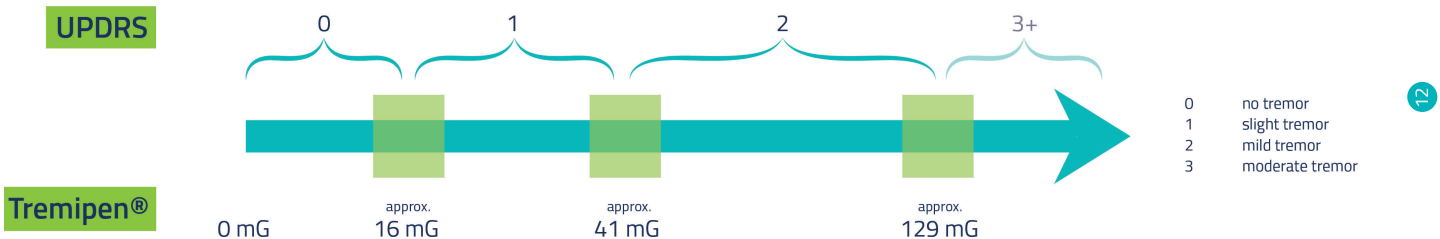
	The preperation time was started, the display shows a countdown (5, 4, 3, 2, 1)
	The Tremipen® is in measurement mode, this is shown with a progress bar
	The tremor amplitude is shown; it consists of a two- to four-digit number, followed by the unit (mG)
	The tremor amplitude was too low
	The tremor amplitude was too high
	The tremor frquency was too low
	The battery is almost depleted / the battery needs to be changed
	The technical self-diagnosis function was trigggered
	The Tremipen® is in Bluetooth® mode
	A system error occurred

4.1.4 Tremor Amplitude (Power of Main Peak)

The tremor amplitude is a relevant parameter to define how strong and intense tremor manifests. The tremor amplitude was historically measured in milli-Volt or mV, but the more accurate physical unit for this purpose is milli-G or mG. 1G equals the acceleration or gravity of earth and since the accelerometer inside the Tremipen® measures accelerations, mG is currently used more often than mV. (Nevertheless, it is possible to convert the values).

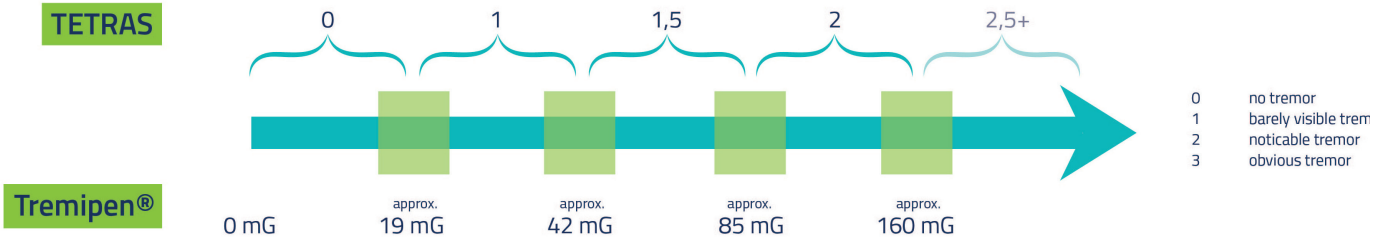
To better understand the relations between the mG unit and the tremor amplitude, the Tremitas GmbH has used available clinical data from own clinical trials to create a comparison between the amplitudes defined in the "Unified Parkinson's Disease Rating Scale" (UPDRS) and the "The Essential Tremor Rating Assessment Scale" (TETRAS). These scales are only for information purposes and shall not to be used as exact scales.
(go to page 12 & 13)

Tremipen® vs. UPDRS Assessment*



*Note: Comparison was calculated with combinatoric analysis. The used data was collected during a clinical trial in partnership with the Medical University of Graz. The thresholds of the categories shall be interpreted as orientation ranges and not as absolute values. Sample number n = 208. The results are only valid for measurements acquired from Tremitas systems and algorithms

Tremipen® vs. TETRAS Assessment*



*Note: Comparison was calculated with combinatoric analysis. The used data was collected during a clinical trial in partnership with the Medical University of Graz. The thresholds of the categories shall be interpreted as orientation ranges and not as absolute values. Sample number n = 208. The results are only valid for measurements acquired from Tremitas systems and algorithms

4.1.5 Medical Decisions based on Tremipen®

The measurement results generated by the Tremipen® are clinical measurement results that can be be used within the intended purpose. Nevertheless, the results and the use of the Tremipen® are NOT meant to be used for diagnostic or therapeutic purposes by users, who are not medical experts. This applies for the following, but not exclusive list of situations:

- Self-diagnosis without a medical expert
- Self-adjustment of medications without a medical expert
- Self-decided changes in medication without consulting a medical expert

4.2 User (Training, Knowledge)

The Tremipen® is intended to be used by the patients themselves (lay person), since the intended functioning requires the patient to hold the object.
Medical experts and professionals can assist during the preparation or the implementation of the intended operation.
The Tremipen® itself does not require special training and knowledge, but the IfU must be understood and complied with.

4.3 Medical Indications

The Tremipen® shall only be used for the following symptoms or diseases (according to ICD-10-GM-2017):

- G20.- (Primary Parkinson Syndrome)
- G20.- (Primary Parkinson Syndrome)
- G20.0 (Primary Parkinson Syndrome with missing or low-level impairment)
- G20.1 (Primary Parkinson Syndrome with moderate or high-level impairment)
- G25.0 (Essential Tremor)
- G25.2 (Other, not further specified forms of tremor)
- Additionally, tremor as a symptom.

4.4 Where, how long and how often should the Tremipen® be used?

- The Tremipen® can be used in clinical environments, such as hospitals and doctors' offices, and in home environments.
- The Tremipen® is NOT meant to be used outdoors.
- The measurement process of the Tremipen® takes approximately 30 seconds.
- Including the activation and other usability features, the typical duration of use is still below 60 seconds.
- The Tremipen® is intended for multiple applications.

4.5 Contraindications

Currently, no contraindications are known regarding the use of the Tremipen®.

4.6 Exclaimers

Exclaimers for incorrect use of the Tremipen®

The Tremipen® must NOT be used by users, who are not able – in case of physical and/or mental impairments – to implement a correct measurement. In this case, the measurement must be supervised by qualified personnel or professionals. Otherwise it could lead to wrong measurement results.

4.7 Application Environment

Attention: The Tremipen® must only be used under the following environmental conditions. Otherwise it could damage the device or lead to wrong measurement results.

4.7.1 Temperature

10°C to 35°C

4.7.2 Humidity

20% to 80%

4.7.3 Brightness

Keep away from heat and direct sunlight!

4.7.4 Electromagnetic Compatibility | Radiation

See chapter 4.14. Do not use the Tremipen® in close proximity to devices, which generate strong electromagnetic fields such as magnetic resonance imaging devices or HF surgical equipment.

4.7.5 Pressure

700 hPa to 1060 hPa

4.7.6 Heights above the Sea Level

Heights above the sea level are bound to the pressure described in chapter 4.7.5

4.8 Storage | Safekeeping | Transport

- If you do not use the Tremipen® for a longer time, keep it safe within the provided packaging.
- Clean the Tremipen® before storage as described in chapter 4.20. This is especially important if the Tremipen® is used by multiple users.
- Protect the Tremipen® against direct sunlight and other sources of heat and put it into the provided and specially designed packaging.
- Keep the Tremipen® away from children.
- The Tremipen® must only be transported within the provided packaging.
- If the Tremipen® is not stored within the recommended environmental conditions described within this IfU (heat and coldness), let it cool down or warm up for at least an hour at room temperature (approx. 20°C) before using it again.

Protect the Tremipen® against rain, wetness and humidity to prevent damages to the device or wrong measurement results.

4.9 Time until Retesting

The Tremipen® is produced for an overall operating period of 2 years until it has to be retested. This operating period only be guaranteed if rthe Tremipen® is properly used.

4.10 Installation | Battery Usage | Battery Changing

The following steps must be implemented before the first use of the Tremipen®!

4.10.1 Installation

1. Take the Tremipen® out of the packaging.
2. Open the battery case.
3. Insert the enclosed battery correctly and carefully; pay attention to polarity. The positive pole of the battery must face to the display:

4. Close the battery case. Attention, do not bruise your fingers!
5. Press the ON Button on the Tremipen® and check if the device turns on and performs a measurement.

For the Tremipen®, only the following battery or a battery with at least equal specifications is recommended. Using a different type could lead to wrong measurement results.

Brand:	Varta®
Model:	Industrial
Type:	AAA Battery (1.5V)

All performance characteristics and functionalities of the Tremipen® were only tested with this type of battery! The Tremitas GmbH is not liable for improper functioning or malfunctions of the Tremipen® due to the use of other battery types. If alternative batteries are used, they have to have at least equal specifications.

4.10.2 Battery Usage and Changing

1. Open the battery case of the Tremipen®.
2. **Optional:** Carefully extract the old and/or empty battery if available!
3. Carefully insert the new battery – pay attention to polarity!
4. Close the battery case; take care not to bruise your fingers!

4.10.3 Typical Battery Lifespan

The battery has a lifespan of approximately 3-4 months if the Tremipen® is used twice per day. This only applies to the battery type described within this IfU.

4.10.4 Controlling the Battery Status

The status of the battery can be controlled in the following way:

- Push the ON Button on the Tremipen®.
- If a measurement process is starting, the battery is okay.
- If the battery symbol is shown or the display stays dark, the battery needs to be replaced.

4.11 Connections with and to Main Power Supplies

The Tremipen® is not intended to be connected to cables, sockets or main power supplies. This is strictly forbidden, because it can cause damages or destroy the Tremipen®. Furthermore, this could result in increased electromagnetic emissions or decreased electromagnetic immunity and lead to improper operation (Mortal Danger)!

4.12 Combination | Compatibility with other Products and Devices

The Tremipen® is a stand-alone device and is not intended to be used in combination with other products and/or devices. If such use is necessary, the Tremipen® and other devices should be observed to verify that they are operating properly.

Future combinations and compatibilities with other products and devices will be announced on www.tremitas.com

4.13 Distance to RF Communications Equipment

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm to any part of the Tremipen®. Otherwise this could result in the degradation of the performance of the Tremipen®.

4.14 Electromagnetic Compatibility (EMC)

Pay attention to the following information about the electromagnetic compatibility of the Tremipen®. Otherwise not paying attention could lead to wrong measurement results and health impairments. Please ensure that the Tremipen® is only used within the tested boundaries that are described in the following tables.

4.14.1 Electromagnetic Classification of the Tremipen®

The Tremipen® is classified as Group 1 (CISPR 11):
It uses HF energy for internal functions only. Consequently, it is improbable that the Tremipen's emissions will cause damages to nearby electronic devices.

The Tremipen® is classified as Class B (CISPR 11):
It can be used in all establishments. This also includes domestic establishments and establishments that are directly connected to a low voltage power supply network for private purposes.

4.14.2 Summary of Electromagnetic Emissions

Test	**Frequency Ranges**
EN 55032 B RF Interference field	30 - 1000 MHz
EN 55032 B RF Interference field	1 - 6 GHz

4.14.3 Summary of Electromagnetic Immunity

Test	**Parameter**
EN 61000-4-2: Electrostatic discharge	± 4 kV ± 8 kV indirect contact discharge ± 2 kV ± 4kV | ± 8 kV ± 15 kV Air
EN 61000-4-3: Electromagnetic field	80 MHz - 2.7 GHz at 10 V/m 2.7 GHz - 6 GHz at 3 V/m
EN 61000-4-8: Power frequency magnetic fields	50Hz / 60Hz at 30A/m

4.14.4 RF Properties

The Tremipen® uses a Bluetooth® RF transmitter with the following properties:

Property	Value
Frequency bands of transmission	2.4GHz band from 2402-2480 MHz (40 channels)
Frequency modulation properties	GFSK-Modulation
Effective radiated power (3m)	approx. 87dBµV/m

The Tremipen® was tested following the valid and applicable EMC guidelines. The test report with No.: PB19G599 from 17.09.2019 was issued by: Accredited Test Laboratory No. 185.

For further information please contact the Tremitas GmbH or your local Tremipen® distributor.

4.15 Accessories

The Tremipen® does not have any accessories.

4.16 Service

The user must not implement service activities. Contact the local distributor in case of malfunction.

4.17 Repair

Repairing the Tremipen® is not intended to be done by the user. Contact the local distributor if assistance is needed.

4.18 Retesting

Retesting is required if the Tremipen® Home is dropped or damaged. Contact the local distributor if assistance is needed.

4.19 Inspection | Reevaluation

The Tremipen®, being a medical device, must be inspected/reevaluated every 2 years after the first activation. If this inspection/reevaluation is not done, NO warranty and liability concerning to functionality and correctness of measurements of the Tremipen® is guaranteed by Tremitas GmbH. Inspection/reevaluation of the device is carried out by Tremitas GmbH – for further information visit our website www.tremitas.com or contact your local Tremipen® distributor.

4.20 Cleaning and Disinfection

Clean the Tremipen® only as advised. Improper cleaning of the Tremipen® may cause damages to the medical device or possible infections

For cleaning, use only a lint-free cloth, which is free of dust and use only the recommended cleaning/disinfection agents:

- Keep the Tremipen® away from dust, fuzz, pets, vermins and children to prevent staining.
- Use non-aggressive surfactant based cleaning agents (e.g. soap or detergents). Do not use bleach or similar substances
- Medicinal alcohol such as Isopropanol (max. 70%)
- Do NOT use aggressive cleaning agents, brushes with metal or nylon bristles or sharp or metallic cleaning articles, such as knifes, hard spattles etc. They can damage the surface.
- Avoid that the Tremipen® comes into contact with running water.
- Do NOT put the Tremipen® into the dishwasher.
- Wipe-off the Tremipen® with a slightly moistened cloth. Wipe it dry afterwards.
- For disinfection, take a cloth and moisten it a little with one of the recommended agents. Wipe the Tremipen® immediately dry disinfection, to prevent liquids from entering the Tremipen®.

- Do NOT dip the Tremipen® into cleaning agents!
- If the Tremipen® is used by more than one user, it must be disinfected before every new user.

4.21 Decommissioning Lifecycle of the Tremipen®

If the Tremipen® is decommissioned, the following steps must be implemented. Otherwise not following the steps could lead to environmental harm.

1. Remove the battery from the battery case and decommission it properly!
2. Decommisson the Tremipen® only as electronic waste!
3. Decommisson the IfU and packaging as waste paper!
4. Decommisson the foam inside the packaging as plastic waste!

4.22 Correct Waste Disposal

4.22.1 Disposal of Packaging Waste

Recycle the packaging as waste paper. Otherwise not recycling could lead to environmental harm.

4.22.2 Disposal of the Tremipen®

As per „Directive 2012/19/EU of the European Parliament and of the Council of July 4th 2012 on waste electrical and electronic equipment“ and per country specific rules and guidelines, the following rules apply:

Electronic waste (used devices) must NOT be decommissioned as residual waste. Otherwise such a decommissioning could lead to environmental harm.

This symbol points out, that the Tremipen® must not be decommissioned as residual waste. This is required by the guideline for electrical and electronic equipment (2012/19/ EU) and by national laws about residual waste. The Tremipen® must be given to a suitable waste collection center. Inappropriate handling of used medical devices may have negative effects on the environment and human health. This can happen due to potentially dangerous materials, which are used in electrical and electronic waste materials. By appropriately decommissioning the Tremipen®, you contribute to an effective use of natural resources.
You will receive information about suitable waste collection centers from your local municipality, from public disposal carriers or from your local waste disposal plant.

Do NOT decommission batteries as residual waste. Otherwise this could lead to environmental harm.

As a consumer, you are legally obliged to collect all used batteries and to recycle them properly. Regardless of whether they contain harmful substances or not.
Examples for such substances are lead (Pb) or mercury (Hg).

5. Performance and Technical Data

Type	Tremipen®
Model	Home
Lot Number	See label on the packaging and the Tremipen®
Power Supply	1.5V ⎓ (1 × 1.5 V Battery - Type AAA, Varta)
IP Protection Category	IP42
Weight	approx. 30g including the battery
Dimensions	approx. (L × Diameter): 165mm × 18mm
Data Storage	150 measurements (if more are made, then the oldest ones are over-written)
Measurement Range	
Tremor frequency	3 - 20Hz
Tremor amplitude	10 - 1750mG
Tolerance Ranges	
Tremor frequency	± 10 % absolute tolerance or a maximum of ± 2Hz
Tremor amplitude	± 10% absolute tolerance or a maximum of ± 100mG

5.1 Changes of Technical Data

Changes of technical data without informing the user is possible, due to future technical updates.

5.2 Rules, Laws and Standards applicable for the Tremipen®

For a full list of applicable rules, laws and standards see the Declaration of Conformity within this IfU (page 1).

6. Adverse Effects and Residual Risks

(MDD, Attachment I, Chapter 2)

Adverse Effects: Based on previous clinical evaluations NO adverse effects were identified!

Residual Risks: Based on previous clinical evaluations NO critical residual risks were identified! Residual risks concerning the use are defined in chapter 7.

7. Safety Warnings and Risks

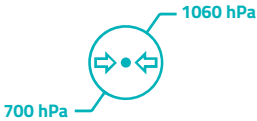
	The Tremipen® must NEVER be used for self-diagnosis or self-therapy or for changes to the medication without a medical professional.
	Contact your attending doctor if you receive unexpected results, which are not caused by technical or usability errors.
	The Tremipen® must only be used as described in this IfU! Do NOT manipulate your tremor to get lower and/or higher measurement results.
	If you have an allergic reaction or skin irritation while touching the Tremipen®, do NOT touch the device anymore and contact the Legal Manufacturer!
	The Tremipen® must only be used within the environmental conditions described in this IfU! Otherwise this could lead to wrong measurement results.
	The Tremipen® is NOT a toy! Keep it away from children due to swallowable parts.

	The Tremipen® is a sensitive electronic medical device. Avoid situations, which can damage the case and / or the electronics/ the sensor. Especially avoid strong mechanical impacts, such as falls from heights above one meter or throwing or stepping onto the Tremipen® etc. This could lead to wrong measurements results.
	Do NOT use the Tremipen® anymore if visible damages occur or are seen (e.g. cracks on the case; electronics do not work correctly and as described within the IfU). This could lead to wrong measurement results. In such a case, contact the Legal Manufacturer or the local distributor.
	The case of the Tremipen® may be a breeding ground for bacteria, viruses and other microorganisms. Disinfect the case of the Tremipen® regularly and appropriately as described within the IfU to avoid infections.
	If the Tremipen® breaks due to mechanical impacts, pay attention to sharp edges. In such a case, touch the electronics, the battery and the case ONLY with gloves to avoid injuries.
	Only clean and disinfect the Tremipen® as described within the IfU! Too much or a wrong cleaning agent may damage the case and/or the electronics.
	If the Tremipen® overheats, has a possible short circuit, and if the acoustic signal becomes too loud or other suspicious situations occur, do NOT use the Tremipen® anymore to avoid injuries. Contact the Legal Manufacturer or the local distributor!
	Do NOT remove the label on the Tremipen®! If the label is removed or lost, please follow the information within the IfU, on the packaging or online via www.tremitas.com. Otherwise, this could lead to a wrong use.

	While changing the battery, take care of the correct polarity and of using the correct battery type with the correct voltage, as it is described within this IfU. Wrong battery types or too high or low voltages may cause a wrong measurement result and/or damages to the device.
	While changing the battery, pay attention to possible liquids leaking from the battery. In this case, do NOT touch the device and/or the battery without gloves to avoid injuries.
	Pay attention while changing the battery. Do NOT clamp and bruise your fingers with the battery case, this could result in an injury.
	The Tremipen® is a medical device, which must be inspected/reevaluated every 2 years after its first use. An inspection/reevaluation is necessary due to aging components and possible inaccuracies of the sensor. This could lead to wrong measurement results.
	Do NOT try to change and/or manipulate the source code of the Tremipen®! This is strictly forbidden because this could lead to wrong measurement results.
	Do NOT remove the ON Button of the Tremipen®. The ON Button could become loose due to aging (button becomes porous) or mechanical or environmental factors. (Danger of swallowing!).
	Take care of static discharges. This can damage or destroy the electronics. Do NOT touch the Tremipen® if you are statically charged.
	Never use the Tremipen® in an environment that can lead to ignitions or explosions (e.g. due to sparks). This could lead to injuries.
	Recycle the Tremipen® only as described within this IfU. Otherwise this could cause environmental harm.

8. Definition of Symbols

	This list of symbols applies to the IfU, the packaging and the labeling on the Tremipen®.
	Pay special attention / Use special caution.
	Situations or events are strictly forbidden / prohibited.
	This symbol provides information about the Legal Manufacturer.
	This symbol provides information about the current batch/lot number.
	This symbol informs that it is nescessary and required to read and to store the Instructions for Use (IfU).
	This symbol informs to pay attention to the polarity of the battery.
	This symbol provides information about the protection against electric shocks. This symbol defines type BF (body float).
CE 1304	This symbol is the CE-label which guarantees, that the medical device complies with the applicable regulations for medical devices.

	This symbol describes that the device must not be decommissioned as residual waste. (Disposal of electronic equipment / electric waste)
	This symbol describes that the battery must not be decommissioned as residual waste.
	This symbol provides information about how to properly decommission and recycle the packaging materials.
	This symbol provides information about the operating temperature.
	This symbol provides information about the operating humidity.
	This symbol provides information about the storage temperature.
	This symbol provides information about the storage humidity.
	This symbol provides information about the operating pressure.
	This symbol informs that the device must be protected from direct sunlight and heat.

	This symbol informs about Bluetooth® or other wireless transmissions.
	This symbol informs that a direct current is used.
	This symbol informs that the Tremipen® must be protected against moisture and humidity.
IP42	This symbol informs about the protection against solid matters (e.g. dust) and liquids (e.g. water) 4 means that the device is protected against solid matters above 1mm in size. 2 means that the device is protected against dripping water if the device is inclined up to 15°.
	The Regulatory Compliance Mark (RCM) shows that a product is safe to supply to the Australian market.

9. Technical Self Diagnosis Function

The Tremipen® has a built-in technical self-diagnosis function to check, whether the product was delivered safely to the user.

If the Tremipen® is damaged or the sensor is not working correctly, then the technical self-diagnosis function is triggered. In this case, the Tremipen® is not working properly after inserting the battery, but showing the following symbol on the display:

Additionally, a beep sound is heard repeatedly.
If your Tremipen® is having an activated technical self-diagnosis mode, do not use it. Instead, contact your local Tremipen® distributor.

10. Technical Bluetooth® Interface

The device has a deactivated Bluetooth® interface, which can be activated for technical purposes.

The Tremipen® has a built-in Bluetooth® module and Bluetooth® interface, which is used for technical maintenance by the Legal Manufacturer.

If the ON Button of the Tremipen® is continuously pressed for at least 3 seconds, then the Bluetooth® mode is activated. This is indicated by the following symbol on the display:

Once activated, the device will try to connect to compatible apps or other systems. Nevertheless, the Tremipen® turns off after 30 seconds, just like after a normal measurement. From now on, the device will try to connect with compatible systems via Bluetooth® after each measurement.

the Bluetooth mode can be completely deactivated. Quickly press the ON button three times in a row if the following symbol can be seen:

For more information about future apps and connecting devices visit www.tremitas.com.

11. Possible Error Causes and Solutions

Error	Possible Causes of Error	Solutions
The Tremipen® can not be switched on	No battery inserted	Insert a new battery
	Empty battery inserted	Insert a new battery
	Battery inserted wrongly	Pay attention to polarity!
	The device is damaged/defect	Contact the Legal Manufacturer
The Tremipen® shows unexpected results	Device is incorrectly used	Read about the correct use as described within the IfU
	Device is damaged/ defect	Contact the Legal Manufacturer
	Measurements are correct	Contact a doctor!
The Tremipen® cannot be activated after a battery change	Empty battery inserted	Insert a new battery
	Battery inserted wrongly	Pay attention to polarity!
	Device did not receive enough power	Insert a newbattery
The Tremipen® often shows a frequency underflow	Too much movement during a measurement	Do not rotate the device during a measurement
	Measurements are correct	Consult a medical expert!
Bluetooth® transmission issues	Too many Bluetooth® devices within the proximity	Deactivate other BT devices if possible
	Data transfer was interrupted by accident	Press the ON button for 3 seconds and restart the transmission

12. Definition of Color Coding and Identifying Colors

No special identifying colors or color codings are used for the Tremipen®.

13. Special Exclusions

Tremipen® is NOT A STERILE medical device!
Tremipen® is NOT intended for single use!
Tremipen® is NOT a custom made product!

14. Information about Safety Reports

A safety report and a safety and risk analysis are available for the Tremipen®. For more information about these documents, which are part of the product development file, please contact the Tremitas GmbH or your local Tremipen® distributor.

15. Reference to Clinical Performance

A Clinical Evaluation for the Clinical Performance is available for the Tremipen®.
For more information about these documents, which are part of the product development file, please contact the Tremitas GmbH or your local Tremipen® distributor.

16. Allowed Languages for this IfU

Regarding the allowed languages, national laws relating to the *"Medical Devices Directive 93/42/EEC – Part: Mandatory Language Requirements for Medical Devices",* apply.

This IfU is available in the following reference languages (Feb. 03rd 2020):

- GERMAN
- ENGLISH

Further and new languages will be announced on: www.tremitas.com.

17. CE-Label

Please see page 1 of this IfU.

18. Warranty and Contact

For information about warranty conditions and services, please contact the local distributor for Tremipen products.

Hotline	+ 43 660 55 10 380
Website	www.tremitas.com

19. Local Tremitas Partner

For warranty claims, please contact the following organization:

Notes

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Tremitas GmbH
Schleppe-Platz 5
A - 9020 Klagenfurt

www.tremitas.com

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