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Scope of delivery:

Point Detector PS3
 Leather case
 firm tip for the acupuncture at the body as well as at the ear (ambilaterally used)
 springy tip
 Volume control
 Battery CR 1/3 N
 Instructions for use
 Instruments book

Permitted Special Accessories:



Safety Connection Cable PS3 / Silberbauer CL- Laser

Permitted device connected to the Point Detector PS3:

Silberbauer Compact Laser of the Series CL plus or CL mini, with connection

1. Intended Use

The Point Detector PS3 is used for the exact search of Acupuncture Points on the body and especially on the ear by medical personnel trained in acupuncture. They must have basic knowledge of hygiene in the medical field.

The PS3 may only be used on uninjured skin!

It may be used on all patients of any age with >2,5kg body weight.

2. Description of the PS 3

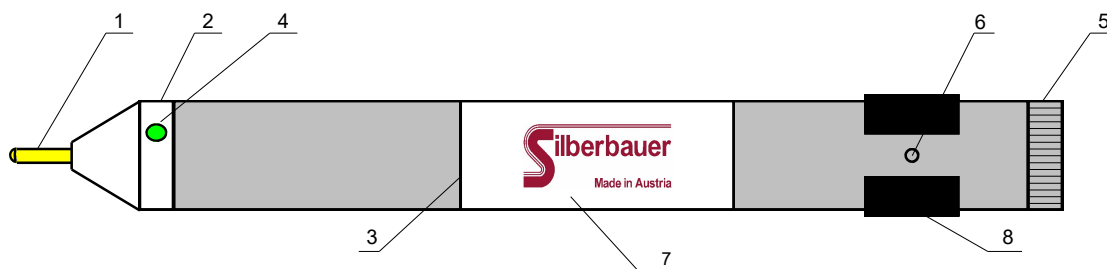
The exact localisation of Acupuncture points at the body and especially on the ear is only possible with a Point Detector.

For this purpose the skin conductance in the range of the probe tip will be detected. This is in fact higher than in the vicinity of these acupuncture points. Depending on the moisture of the skin, the values are very different, but the maximum of the conductivity is always in the middle of the acupuncture point (see also section 6.1).

The PS 3 does not need to be tuned to the skin moisture, because it sets the conductance into the frequency of a tone. So you can easily hear, at which point the highest tone occurs (compared to neighboring areas of the skin): there is exactly the center of the desired acupuncture point!

The PS 3 also does not need to be switched on or off: it is always ready and in readiness it needs so little power that the small battery will last for more than 10 years.

3. Point Detector PS 3: View



1	Tip for Acupuncture at the body and at the ear	5	Battery Lock
2	Plastic Cone	6	Sound Gaps
3	Case, brass, chromed	7	Label PS 3
4	Green Light Emitting Diode	8	Volume Control

4. Safety precautions when using a Point Detector

The corresponding compulsory precautionary measures are to be observed!

Permitted humidity 30 till 95% - the humidity should not be allowed to condense on the apparatus (no droplets)!

Permitted ambient temperature for use, storage and transport: 0 to 50°C

The Point Detector may be used at UNINJURED skin only!



See also chapter 9: Cleaning, Disinfection and Maintenance!

The device may not be modified!

4.1. Contraindications

- To avoid any danger of infection no application to open wounds is allowed.

5. Initiation Procedure

The Silberbauer PS 3 point detector comes with a type CR1/3N battery. To open turn the cap anticlockwise, insert the battery in with the minus pole facing into the case and turn the other way to close shut. The point detector is now ready to use.

The battery can now stay in the point detector for the next years. The minimal wattage allows the battery to hold for more than 10 years.

5.1. Point Detector connected to the Silberbauer Compact Laser:

(Refer to Chapter 7!)

6. Acupuncture Point Detection

6.1. Electric Skin Susceptance at the Acupuncture Points

The physical acupuncture point is identified through the intensity of the skin's electric conductance. Image 2 shows these conductance characteristics at the acupuncture point with respect to its surroundings.

This phenomenon is not only observed through the normal skin properties but in dry and moist skin as well.

This electric characteristic of the acupuncture point can only be put to use through its exact localization.

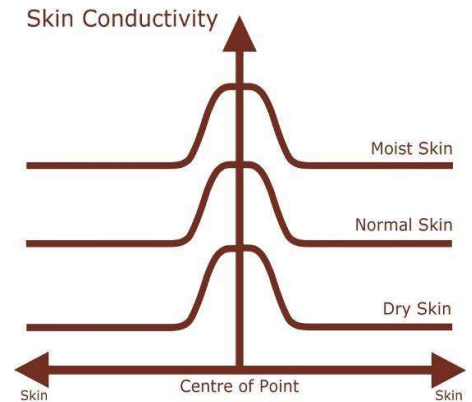


Image 2

The point detector tip can be used ambilaterally and has a semicircular poled brasstip for the acupuncture at the body and a finer tip for points at the ear.

6.2. Identifying Acupuncture Points on the Body



Image 3

With the help of the sophisticated and intricate electronics of its conductive characteristic the PS3 point detector reacts directly proportional to the conductivity i.e. if the electric conductivity or susceptance of the skin increases – the flickering frequency and the intensity in the pitch would increase correspondingly.

While identifying the point place the tip so the semicircular portion (larger radius) as far as it will go facing outside.

The patient should be held with one hand while the other hand is used to maneuver the point detector.

The point detector is then placed near the acupuncture point to be localized, perpendicular to the skin's surface. Assuming the location of the acupuncture point without lifting the probe from the skin it then scans the area. The bearing pressure should be light and consistent at the time.

The spring detector tip provided helps keep the bearing pressure at a constant.

It then follows the direction where the tone gets higher or when the flickering gets more rapid.

Image 4 shows the pitch of the built-in speaker and the flickering frequency of the light diode special built-in as it closes in on the acupuncture point. The blink frequency and the pitch reach their maximum once they arrive at the centre of the acupuncture point.

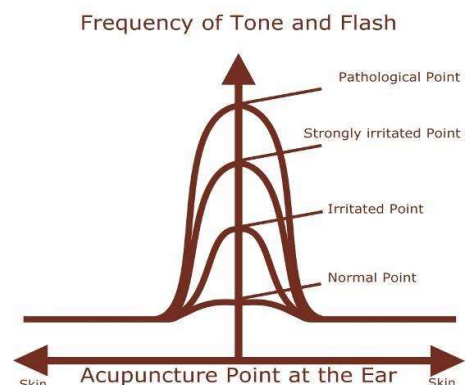


Image 4

It must be observed that not all the points on the body have a high conductivity and some points cannot be localized with the point detector!

6.3. Detecting Points at the Ear and Cranial Acupuncture Points

In contrast with regular physical acupuncture, acupuncture for the ear and the areas near the skull are "silent" according to YAMAMOTO i.e. the electrical skin conductivity is relatively low here in normal cases and it is impossible to find points with any Point Detector.

If there is a disturbance in the organism reflected on the projection zones, the skin conductivity changes at the corresponding acupuncture points and zones.

Image 5 shows the increase in the pitch and the flickering frequency of the acupuncture point detector as the disturbance in those areas increases. This would mean that the point detector not only localizes the irritable points and areas but also determines the rate of disturbance. This can only be conducted through expensive auricular devices. Apart from that there could be the "calibration" of the device to be accounted for.

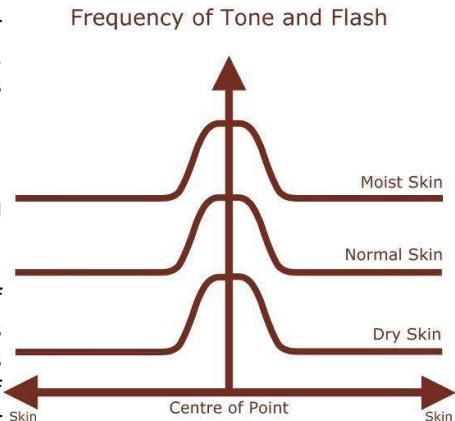


Image 5

Imp.: The patient is to be held with one hand while the other hand must be used to detect puncture points at all times!

6.3.1 Ear - Acupuncture (acc. to Dr. Bucek, Vienna)

The diagnosis of the ear points is very effective by means of point detection.

"Healthy points" have NO tone! Only points or regions corresponding to diseased functions or organs result in a more or less high tone. The highest tone corresponds to the strongest disturbance.

If too many "disturbances" are indicated, the ear is irradiated over a large area for 15 to 30 sec. with a Compact Laser. Then look again with the PS3. Momentary small disorders disappear, pathological points remain.

Now start your laser therapy at the points with the strongest disorders:

- irradiate point or area for 15 sec. (with CL mini at 8 to 30 mW or with CL plus in position Ear Acup.),
- ask your patient whether a spontaneous effect has occurred (e.g. painlessness) (frequently!).
- Then continue searching and continue to irradiate, if other points remain clearly audible.
- repeat therapy after several days.

7. The Acupuncture Point Detector with the Compact - Laser

7.1. Prearranging the configuration

For point search via the laser tip, connect the PS3 / Silberbauer CL- laser safety laser cable to the rear of the laser and the golden socket on the cone of your PS3.

Now the patient gets the point searcher PS3 in the hand. The laser tip now serves the physician as a point search tip. The holes in the spot detector housing must be free to hear the sound!



7.2. The Acupuncture Point Detector on the Body

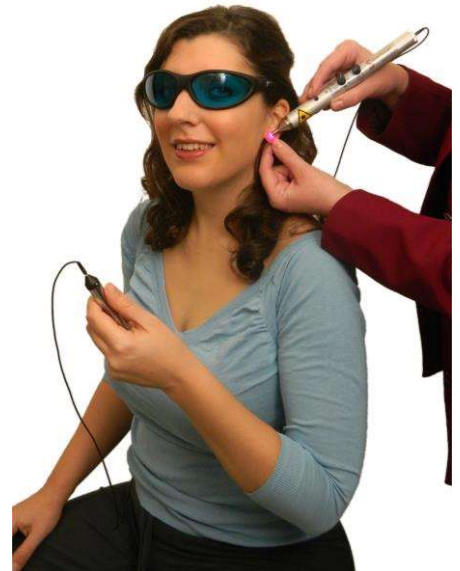
Similar to chapter 5.2 the laser tip – instead of the point detector tip – is then positioned close to the acupuncture point to be localized, slightly oblique to the skin's surface. Then one scans the area in which the acupuncture point is assumed, without lifting the laser tip off the skin. The applied pressure should be light and uniform.

Continue searching in the direction in which the sound becomes higher or the flashing becomes faster. At the center of the acupuncture point, both the pitch and the flash frequency reach their maximum.

The laser button is then pressed at the acupuncture point and the radiation would then begin with an acute focus on the point. The therapy timeline programmed in the compact laser according to every model is optimized for this kind of application.

The patient may hand over the PS 3 during the laser puncture.

It must be observed that not all the points on the body have a high conductivity and some points cannot be localized with the point detector!



7.3. Acupuncture at the ear and Cranial Acupuncture

The laser tip acts as a point detection tip here as well. Refer to section 4.3

8. Possible Dysfunctions with the Point Detector

While transporting the point detector, it must be observed that no conductive connection between the case and the point detector tip. For e.g. if such conductivity exists between the two the tip and the light would keep functioning thereby causing the battery to discharge quicker.

If the PS 3 falls on hard surfaces too often a broken speaker could deem the apparatus "silent".

The following can be availoff our services:

The acupuncture point Di 4 is practically unsuitable to localise point detection since it is poistioned very deep and does not have any exact surface projection. Point detection must hence be practiced with a known point detector.

If the battery is placed in a reverse position the PS 3 will not function. However the battery would not sustain any damage through this.

9. Cleaning, Disinfection and Maintenance

To prevent possible infection risks, the peak point detector must be disinfected before and after each patient.

The housing can be wiped careful with damp cloth using a disinfectant for Medical Devices. It is important to make sure that no liquid reaches into openings.

The point detector tip itself can be wiped either with an alcohol - swab or it can be autoclaved.

There is no additional maintenance of the equipment needed by the operator.

10. Disposal of Point detector, Battery and Accessories



Please observe the regulations of the place of disposal!

The battery must be brought to the next counter for hazardous waste.

Don't dispose like household waste, but give it to the next electrical waste collection point!

11. Quick Test of the Point Detector

The point detector must be checked before every use: while holding it in the hand at the metal case, use the other hand to touch the tip so that the device emits a sound.

12. Shipping of the Point Detector

The point detector can be shipped in its original packing through the post without any problem. Please make sure the casket does not contain anything subject to conductivity so that the point detector refrains from constant humming and flickering – causing the battery to discharge.

Attention! The Instruments Book is a **Document!** Please, send it together with all kinds of inspections or repair together with the device and accessories!

13. Warning and Information Signs:

The manufacturer shall be considered responsible for the effects on the safety, reliability and performance of the apparatus only if

- Changes or repairs are carried out by persons authorised by him,
- the device is used in accordance with the operating instructions.

The device should not be exposed to inflammable gases or steam or narcotics.

Image symbols used:



Permitted ambient temperature



Manufacturer



Follow the instructions!



Year of manufacture

SN

Serial number

MD

Medical Device

IP20 means: protected against solid foreign objects with diameter $\geq 12,5$ mm and against opening with a tool, no protection against water

Label at the device:



Label at the case:



Label at the packaging of the standard tip:




Label at the packaging of the springy tip:



14. Specifications

PS3 Point Detector

Manufacturing and Marketing:	Dipl.Ing. Gerhard Silberbauer Medical and Physical Electronics Hiessgasse 15, 1030 Vienna, Austria, Europa; office@silberbauer.at
Usage in compliance with the law:	Acupuncture point search
Quality Mark:	VA f.Radiotechnik at TGM, Vienna, Protocol no. TGM-VA EE 38008 EMC
Accessories:	refer to instruction manual page 2
Internal Power Source:	replaceable battery, remains in device
Battery permitted:	CR1/3N
Classification:	internal power source
-Degree of protection against electric shock:	 Application part type BF
-IP- Code:	IP20
-Degree of protection in during use in the presence of explosive anasthetic mixtures with oxygen or helium:	The device is not to be put into function around explosive surroundings or with explosive anasthetic mixtures with oxygen or helium.
-Mode of operation:	Longterm usage
-acc. MDR2017/745:	Ila
Battery current:	max. 0,03 A
Weight with battery:	60 g
Dimensions:	15 x 138 mm (D x L incl. tip)
Expected life time:	20 years min.

EMC (Reference required in accordance with EN 60601-1-2:2015):

The Silberbauer Point Detector PS3 is tested according to the standard EN 60601-1-2:2015.

Result:

Emission: the limit values according to limit class B have not been exceeded!

EU – Declaration of Conformity

The Company

DI. Gerhard Silberbauer
Hiessgasse 15, 1030 Wien, Austria, EC,

declares its sole responsibility in development, production and sales of the medical product:

Point Detector, Model: PS 3,
Medical Product Class II A, for the detection of acupuncture points

according to the EC- Medical Product Guideline 93 / 42 / EWG of the council of European Community from June 14th, 1993, annex II (without 4).

This product meets all the requirements of the regulations in 93 / 42 / EWG annex I.

Involved Notified Body:

TÜV NORD CERT GmbH
Langemarckstraße 20
45141 Essen
Deutschland (Germany)
Notified Body No. 0044, Certification Authority for Medical Products.

This Declaration of Conformity is valid for all Point Detectors PS3 produced until 2024-05-26.

Vienna, 2019-07-09



Dipl.Ing. Gerhard Silberbauer
CEO and QM Manager



Berlin Cert GmbH · Dovestraße 6 · 10587 Berlin

Dipl. Ing. Gerhard Silberbauer-Medizinische
Elektronik
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1030 Vienna
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Berlin, 14.08.2024

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices

Reference number: 24-116-S

To whom it may concern,

This letter confirms that, Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0633 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the manufacturer listed above.

The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR by the 20 Mar 2023 for the relevant devices.

Berlin Cert
Prüf- und Zertifizierstelle
für Medizinprodukte GmbH
Geschäftsführer
Johannes Lieback
Prof. Dr.-Ing. Jan Uwe Lieback
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Gesellschaft mit beschränkter
Haftung, Sitz Berlin
Registergericht Berlin
HRB 78249 B
USt-IdNr. DE814899384

Commerzbank AG
IBAN DE43 1008 0000 0944 4403 00
BIC DRESDEFF100
Postbank Berlin
IBAN DE18 1001 0010 0647 2431 07
BIC PBNKDEFF

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



Digital unterschrieben
von Martin Tettke
Datum: 2024.08.15
11:10:17 +02'00'

Dipl. Ing. Martin Tettke

Head of Certification Body and Notified Body

Tabelle 1: devices covered by this letter

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Punktsucher PS3	Class IIa	Punktsucher PS3	442321806247 NB Identification: 0044
Compact Laser CL plus/mini	Class IIa	Compact Laser CL plus/mini	442321806247 NB Identification: 0044

Tabelle 2: revision history

Date	action
14.08.2024	Initial Issue

