Medical tuning forks directions for use

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1. Declaration of conformity

The tuning forks meet the requirements of the EC Medical Devices Directive 93/42/EEC and MDR 2017/745 and German national law in the form of the German Medical Devices Act (MPG).

Medical device class I

according to Annex IX MDD Class I (Rule 1)

according to Annex VIII MDR 2017/745 Class I (Rule 1)

2. Basic information

2.1 Instructions for use

The present instructions for use have been developed in accordance with the product-specific and use-related requirements of the MDR.

The instruction manual conveys knowledge of the function, application and variants of the tuning forks.

It shall be ensured that the instructions for use have been read and understood before each use of the tuning forks.

2.2 Intended use/indications

The medical tuning forks are used for full-body examination of patients aged 4 and over.

The tuning forks can be used in various medical areas, e.g. neurological and ear-medical diagnostics:

- Sensitivity tests
- Hearing tests (air and bone conduction)
- further diagnostic tests at the doctor's discretion
- possible fields of application confirmed by studies are:
  - Orthopaedics: Limitation of fractures, identification of stress fractures,
  - Neurology: Nerve compressions, polyneuropathy
  - General medicine: Diabetic foot ulcers, screening of nerve impairment

2.3 Intended use

The tuning forks serve as a sound source of air and bone conduction. The tuning fork shall be placed on the appropriate parts of the body at the end of the stem or on the foot attached to the end. Parts of the body that are free of muscle or adipose tissue are considered suitable.

NOTE

Apply only on healthy skin!

No activation of the tuning fork on a metal surface! or wood

Stop at: Hand bales, thighs, elbows or treatment couch

2.4 Contraindications

No use of nickel-plated tuning forks in a nickel allergy. As an alternative, aluminium tuning forks are possible, depending on the purpose.

Do not use on injured skin.

Exclusion from:

- known lack of vibrations of patients
- Children under 4 years of age
- sensory symptoms, sensory signs including lack of vibration
- a History of Alcohol Abuse
- Use of drugs that may cause polyneuropathy or affect their cooperation
- Persons with a disease that could trigger polyneuropathy

2.5 Side effects

No side effects or concomitant symptoms known.

2.6 User group

Medical or medical professionals with qualification/training for voice application

2.7 Warranty and liability

The manufacturer shall give a two-year warranty when used as intended and appropriately. For further questions or complaints, please contact the manufacturer or your specialist dealer.

Spare parts and accessories can be obtained from the manufacturer or your specialist dealer.

2.8 Contact details

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Fax: +49 (0) 3682/40 09 07
info@stimmgabeln.de www.stimmgabeln.de

3. Precautionary statements and warnings

3.1 Design of precautionary instructions

The safety statements in this document are marked by security symbols and are designed according to the SAFE principle. They contain information on the nature and source of the risk, the possible consequences and the avoidance of the risk.

CAUTION

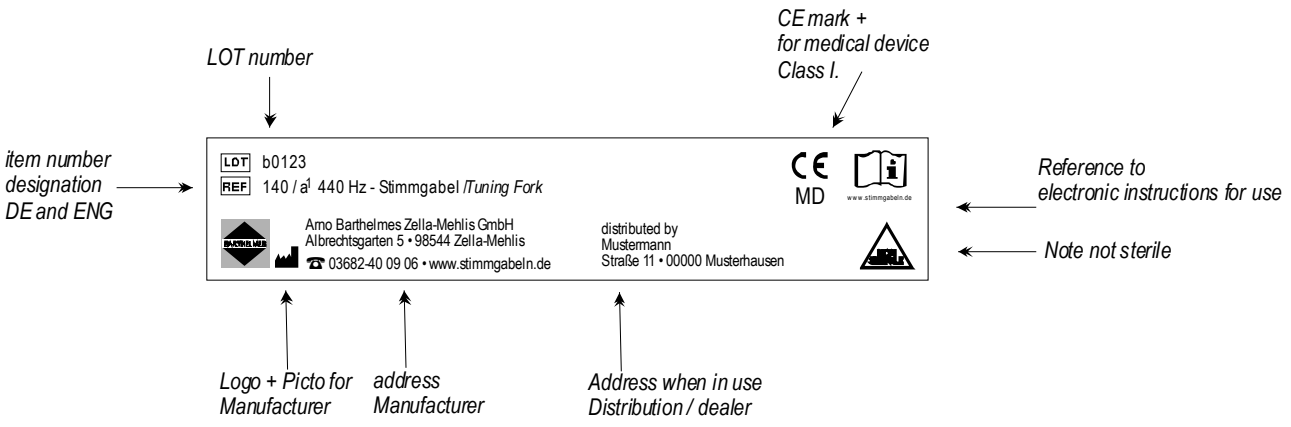
Warns of a risk that can occur if the instructions are not followed.

NOTE

Important general note

3.2 Symbols used

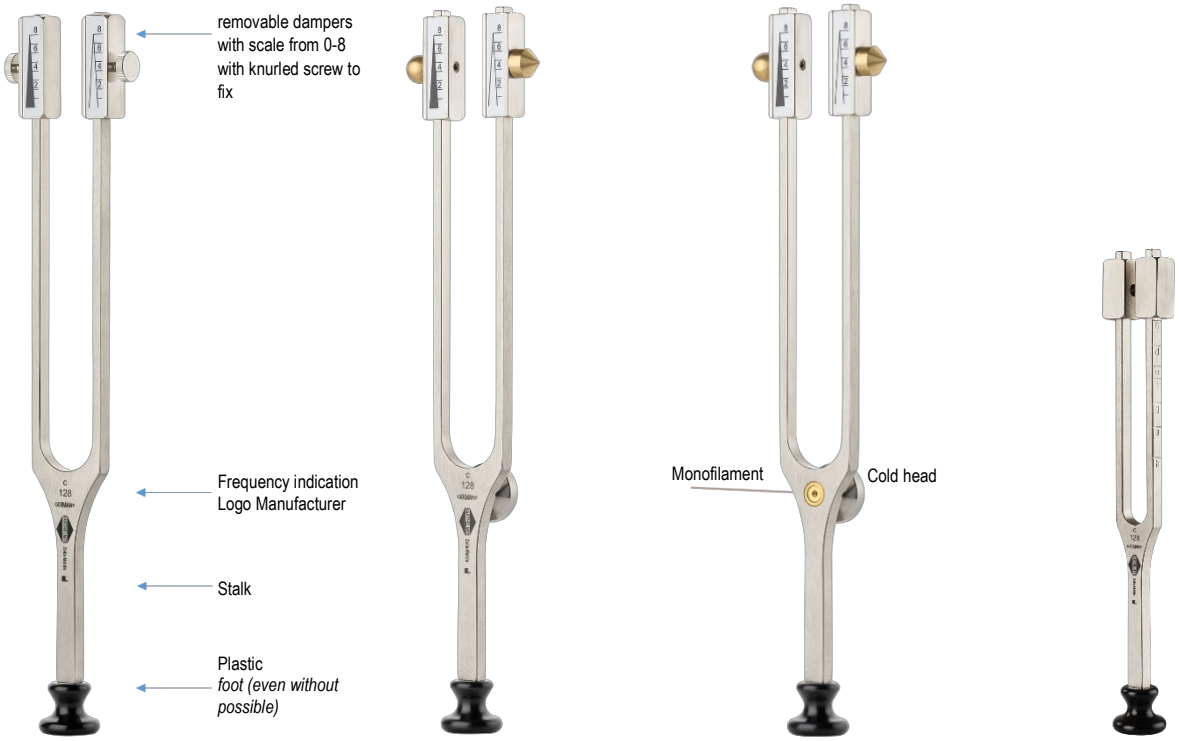
Symbol	Meaning
	Manufacturer
LOT	Batch number, batch
NON STERILE	Not sterile
CE	Communauté Européenne = European Community Authorisation within Europe
REF	Article number
Hinweis auf elFU	electronic instructions for use
MD/MP I	Medical device class I



Technical description

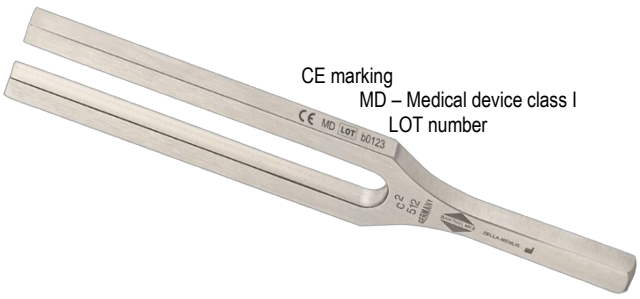
3.3 Variants of medical tuning forks

3.3.1 Tuning forks made of steel with damper and foot

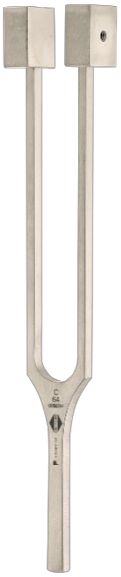


REF **125** to Rydel-Seiffer	REF **NE2** Multifunctional voice fork Neuropathies according to ZellaMed	Ref **NE3 Multifunctional** fork Neuropathies according to ZellaMed	REF **131** after Lucae
C 64 Hz/c 128 Hz with removable dampers	C 64 Hz with fixed dampers	C 64 Hz with fixed dampers	With adjustable dampers from c – h
Length approx. 24 cm, material: Steel, nickel plated, approx. 6 mm thick	Length approx. 24 cm, material: Steel, nickel plated, approx. 6 mm thick	Length approx. 24 cm, material: Steel, nickel plated, approx. 6 mm thick	Length approx. 17 cm, material: Steel, nickel plated, approx. 6 mm thick

Marking on tines, laterally:



3.3.2 Tuning forks with dampers



REF **2** according to Hartmann	REF **3** according to Hartmann	REF **4** according to Hartmann	REF **5** according to Hartmann
C_{-1} 32 Hz with fixed dampers	C 64 Hz with fixed dampers	C 128 Hz with fixed dampers	$C^{1}256$ Hz with fixed dampers
Length approx. 30 cm, material steel, nickel plated, approx. 6 mm thick	Length approx. 24 cm, material steel, nickel plated, approx. 6 mm thick	Length approx. 17 cm, material steel, nickel plated, approx. 6 mm thick	Length approx. 15 cm, material steel, nickel plated, approx. 6 mm thick

REF **140** For Weber Rinne Test
$A^{1}440$ Hz with foot
Length approx. 17 cm, material steel, nickel plated, approx. 7.5 mm thick

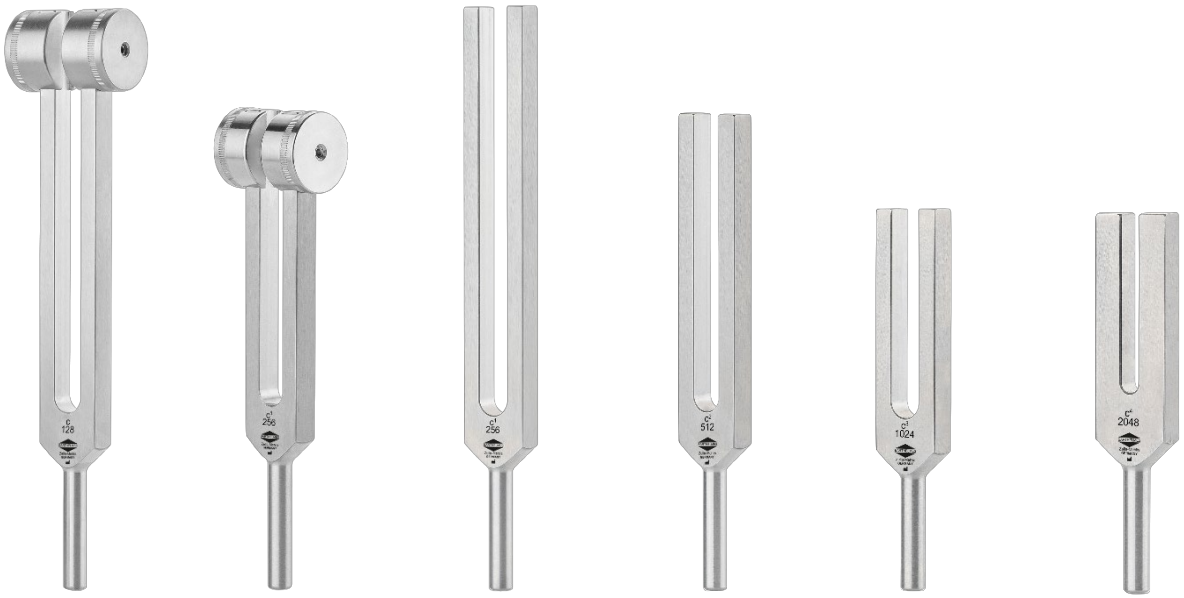
3.3.3 Tuning forks with foot without damper

REF **41** after Lucae	REF **42** after Lucae	REF **43** after Lucae	REF **44** after Lucae	REF **45** after Lucae	REF **46** after Lucae
C 128 Hz	$C^1$256 Hz	$C^2$512 Hz	$C^3$1024 Hz	$C^4$2048 Hz	$C^5$4096 Hz
Length approx. 26 cm, material steel, nickel-plated, approx. 9 mm thick	Length approx. 20 cm, material steel, nickel-plated, approx. 9 mm thick	Length approx. 16 cm, material steel, nickel-plated, approx. 9 mm thick	Length approx. 13 cm, material steel, nickel-plated, approx. 9 mm thick	Length approx. 12 cm, material steel, nickel-plated, approx. 9 mm thick	Length approx. 11 cm, material steel, nickel-plated, approx. 9 mm thick

3.3.4 Tuning fork without foot without damper

REF **31** according to Hartmann	REF **32** according to Hartmann	REF **33** according to Hartmann	REF **34** according to Hartmann	REF **35** according to Hartmann	REF **37** according to Hartmann
C 128 Hz	$C^1$256 Hz	$C^2$512 Hz	$C^3$1024 Hz	$C^4$2048 Hz	$C^5$4096 Hz
Length approx. 26 cm, material steel, nickel-plated, approx.6 mm thick	Length approx. 20 cm, material steel, nickel-plated, approx. 8 mm thick	Length approx. 16 cm, material steel, nickel-plated, approx. 8 mm thick	Length approx. 13 cm, material steel, nickel-plated, approx. 8 mm thick	Length approx. 12 cm, material steel, nickel-plated, approx. 9 mm thick	Length approx. 11 cm, material steel, nickel-plated, approx. 9 mm thick

3.3.5 Tuning forks made of aluminium alloy



REF **20**	REF **21**	REF **22**	REF **23**	REF **24**	REF **25**
c 128 Hz	c^1 256 Hz	c^1 256 Hz	c^2 256 Hz	c^3 1024 Hz	c^4 2048 Hz
Length approx. 26 cm, material aluminium, approx. 10 mm thick	Length approx. 20 cm, material aluminium, approx. 10 mm thick	Length approx. 16 cm, material aluminium, approx. 10 mm thick	Length approx. 13 cm, material aluminium, approx. 10 mm thick	Length approx. 12 cm, material aluminium, approx. 10 mm thick	Length approx. 11 cm, material aluminium, approx. 10 mm thick

Reduced representati

REF **29**	REF **26**	REF **27**	REF **28** ..
C_{-1} 32 Hz	C 64 Hz	c 128 Hz	c^5 4096 Hz
Length approx. 37.5 cm, material aluminium, approx. 10 mm thick	Length approx. 28 cm, material aluminium, approx. 10 mm thick	Length approx. 28 cm, material aluminium, approx. 10 mm thick	Length approx. 11 cm, material aluminium, approx. 10 mm thick approx. 10 mm thick

4. Areas of application

4.1 General

CAUTION

Medical tuning forks shall be examined only by medical or healthcare professionals and in accordance with the instructions for use.

CAUTION

For the patient's known nickel allergy, use only tuning forks made of aluminium alloys.

CAUTION

Slight damage to the tuning fork can lead to an influence of the oscillation frequency.

CAUTION

Displacement of the dampers can lead to an influence of the oscillation frequency. These are mounted on the manufacturer's side.

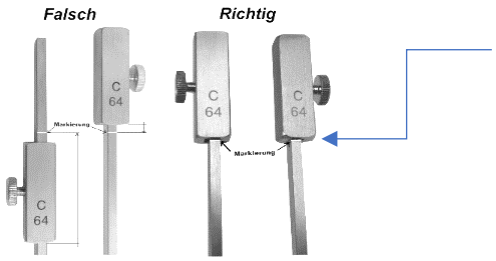
NOTE

In case of damage, the product must not be used to examine patients!

NOTE

All serious incidents related to the product shall be reported to the manufacturer without delay.

1. Remove the tuning fork from your packaging and check it for damage and possibly for the smoothness of the moving parts (damps), see picture for exact position.



Marking lines on both tines — visible below the dampers

detachable dampers REF:125 PE

It is up to the doctor to choose the appropriate frequency depending on the specific purpose of use. Hit the tuning fork at the hand bale or bony spot, in no case on hard objects (e.g. steel, wood or stone). Make sure that the stroke is short and springy, i.e. the tuning fork is touched only very briefly. The duration of the vibration of the tone reaches a maximum time span due to this short stop. The tone should not be heard.

2. Now carry out the desired investigations. Positioning of the tuning fork takes place depending on the application location. In case of ear disease: Place tuning fork in about 3-4 cm next to the outer ear canal.
3. In neurological studies, the place of application varies from head to toe.
4. If the tuning fork used has fixed weights, do not unscrew them. The frequency changes by moving the weights and a precise adjustment can only be made by the manufacturer.
5. Do not clean the tuning fork in sterilisers after use. For cleaning, use a dry or slightly greasy cloth.
6. Disinfect the tuning fork after use.

4.2 Hearing test

The hearing test is performed by testing the air line (voice fork vibration in front of the ear) or by bone conduction (setting the tuning fork on the skull bones).

Differences between sound sensation disorder and sound line interference

Sound sensation disorder

The basis is, for example, diseases of the inner ear or damage to the cochlearis nerve. The perception of sound waves is deteriorated both via the air line and over the bone line. Sounds are therefore perceived quieter on the affected side than on the healthy side.

Noise conduction disorder

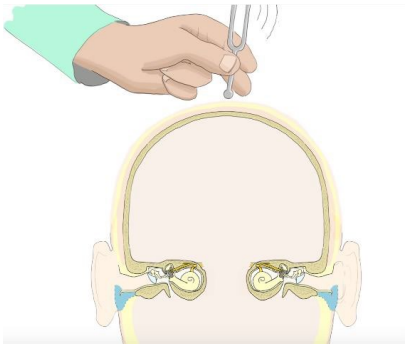
On the other hand, the basis of sound conduction disorders are diseases of the middle ear, such as otosclerosis or otitis media. A displacement of the external auditory canal, such as the cerumen obturans, can also lead to a sound conduction disorder. In this case, sound waves can only be transmitted to the inner ear to a limited extent via the middle ear. As a result, the airline is deteriorated, but the bone line is still intact. Sounds are even perceived louder by this way on the affected side.

Tuning forks with low (from 16 Hz) and medium (5 kHz) frequency are particularly suitable for testing. Despite electroacoustic audiometers for immediate diagnosis and clinical follow-up observations, manual tuning fork testing still prevails. For screening tests under difficult conditions, such as noise for the hearing test in school, the application is still carried out depending on the doctor. The Rinne Voice Fork
Test is a very effective instrument for detecting sound conductivity difficulty. The gutter test is most sensitive when performed by an experienced tester. The type of hearing loss is diagnosed with the Weber test, where the tuning fork is placed in the middle of the patient's forehead, upper head, nose back or upper central incisors (with a rubber glove above the handle). In the case of sound conductivity, the sound in the affected ear shall be heard; The differentiation of a sound sensation from
a sound conduction disorder is achieved only in the summary of the findings of the gutter and Weber test.

4.2.1 Belonged to Weber

In Weber test, the bone conduction of both sides is compared.

Tap the handle of the tuning fork against the hand to trigger a slight vibration. Hold the foot of the swinging tuning fork with thumb and index finger of the dominant hand and place the tuning fork on the centre of the patient's forehead or on the vertex of the head.



The sound transmits itself via bone conduction – physiologically it can be heard median in the area of the apex or forehead. Ask the patient to determine whether the sound on one side is better and longer than on the other side.

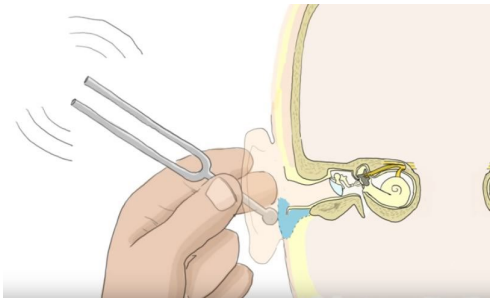
If the sound on one side is perceived louder, one speaks of a "lateralisation". This can have two reasons: If there is a one-sided sound sensation disorder, the sound lateralises to the side with the healthy sound sensation. For example, in case of an inner ear damage on the right, the sound is heard louder on the left. If there is a one-sided sound conduction

disorder, the sound lateralises on the affected side, since in this case a louder hearing impression is created in the bone conduction. For example, in the case of a middle ear damage to the right, the sound is heard louder.

4.2.2 Belonged to Rinne

The Rinne test compares one's own hearing through bone conduction to the hearing through air conduction to determine whether a hearing deficiency, when detected, is conductive or sensorineural. The test makes use of the fact that the sound is transmitted physiologically better via the airline than via the bone line.

Tap the handle of the tuning fork against the hand to trigger a slight vibration. Let the patient cover the ear not to be tested by moving a finger into the ear canal of that ear. Hold the foot of the swinging tuning fork with thumb and index finger of the dominant hand and place it on the mastoid in the patient's ear.

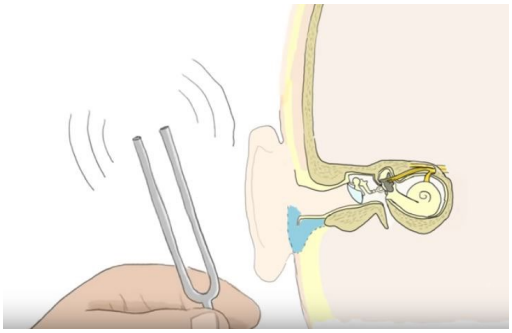


The sound waves are transmitted to the inner ear via bone conduction. As soon as the patient indicates that he can no longer hear the sound, the examiner holds the tuning fork directly in front of the patient's ear. The sound waves are now transmitted by air to the inner ear.

A patient with a shawl conduction disorder can no longer perceive this tone, as the air conduction is severely restricted = finding "Rinne negative".

However, in the case of a healthy person – but also in a patient with sound sensation disorder – the airline is always better than the bone conduction. Tone of the tuning fork is still heard = finding "Rinne positive".

Alternatively, the test can also be performed faster by placing the tuning fork on the mastoid and holding it directly in front of the equilateral ear after a short hearing impression.



If the sound is perceived louder, the test result is positive and the airline is intact. If the sound is not perceived louder, the channel test is negative and there is a suspicion of a sound conduction disturbance.

4.3 Sensitivity test

The patient's sense of vibration can make diagnoses about diseases and their stages.

The swinging tuning fork is placed on bony body places.

In the case of pathologically reduced vibration perception, pallanaesthesia is referred to.

Depending on the location of the patient, the doctor may draw conclusions on the patient's underlying illnesses if there is a reduced perception of vibration. For example, a decrease in the perception of vibration can be a result of diabetes or a fracture.

The doctor is free to use it at his own discretion.

4.3.1 Sensitivity test with tuning fork according to Rydel-Seiffer REF 125 PE/NE2/NE3

NOTE

It is a subjective method of investigation; as a result, patient-related deviations are possible.

This model is used to diagnose nerve diseases that manifest in a reduced vibration sensitivity. The following cases have the following symptoms:

• Metabolic disorders such as diabetes

• Toxic nerve damage such as alcoholism

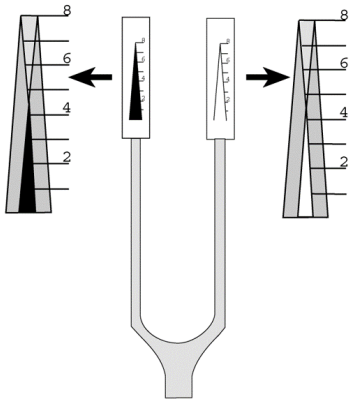
• Bacterial nerve inflammation

Disturbances in certain spinal cord pathways can also lead to reduced vibration sensitivity. The tuning fork REF:125 PE (c 128 Hz/C 64 Hz) has two removable dampers with scaling. The scaling consists of one arrow (full or contour arrow) with cross division in eight steps. Two adjustment screws are used to fix the dampers, it is necessary to ensure exact adjustment of the dampers. To trigger the vibration, hold the tuning fork to your handle and hit it on an adjusting screw on the hand bale. The oscillation of the tines blurs the arrows into two triangles, which, depending on the vibration strength, form a point of intersection running upwards (comparative value). The Rydel-Seiffer tuning fork, with a scale classification, allows the readable values to be compared to healthy persons. The standard limit for healthy persons is comparable to the deviation from these values, so that a change in hearing can be derived. The fine perception of vibrations of a patient is first examined either on the forearm or better on the temporal bone. The patient is asked to indicate the time from which he no longer feels the vibration. The examiner observes the dampers and evaluates the height of the overlapping triangle based on the lateral values/scale.

Normal values are between 6/8 and 8/8 in people under 60 years of age. If the patient is over 60 years old, he should experience a vibration over 4/8. An overview of the normal values can be found in the table below.

Upper extremities		Lower extremities	
Age	Value	Age	Value
40	≥ 6,5	≤ 40	≥ 4,5
41-85	≥ 6,0	41-60	≥ 4,0
>85	≥ 5,5	61-85	≥ 3,5
		>85	≥ 3,0

Now the depth sensitivity outside of the lower extremities is checked (outside ankles, inner ankles, heads of the middle foot bone and big toe tip). In the case of a typical diabetes-related nerve disease, the sensation of vibration in the outer areas, especially in the prose, decreases equally strongly on both sides. The extent of nerve damage can be determined more precisely by attaching the tuning fork along the shin front edge.



1.Put the tuning fork with the plastic base on the body to be examined.

2. Ask the patient for information when the vibration has resolved after his or her sensation

3.Now read the value of the intersection point on the transverse scale.

If the vibration perception is missing or weakened
(e.g. 4/8), there is suspicion of neuropathy.

For a long-term control, create findings at the same body places and document the comparison values.

4.4 Warm/cold test with multifunctional fork NE2/NE3

The foot of the tuning fork is made of a plastic (warm). The button in the middle of the tuning fork is made in the same diameter of the foot and is made of stainless steel (cold). These two elements are reciprocally used for the warm/cold test. The use of the two selected materials makes it ideal to assess the warm/cold feeling. It is advisable to perform this test 2-3x, only after that an assessment of the patient (with eyes closed) can be carried out.

4.5 Blunt/peak test with multifunctional fork NE2/NE3

The gold-coloured stump/tip test elements are a ball and a pointed cone, with which one can test the perception (with closed eyes) by gently attaching to the skin of the patient. It is helpful to pull the fork 1 to 2 cm above the patient, thus significantly simplifying the perception for the patient.

4.6 Monofilament test with multifunctional fork NE3

1. By pulling the cold test button, move the monofilament from the protective groove.
2. Turn the button in a desired direction until it snaps in noticeably in the final position. Now the filament is ready for use.
3. Run the test under the sole of the foot. Note that you only test in uninjured and uncorrupted areas.
4. Place the nylon thread vertically on the skin surface and apply a pressure for about 3 seconds until the thread bends.
5. Perform the test at least 3 times. Break between the tests for about 30 seconds.
6. If your patient does not feel pressure even in case of repetition, there is an increased risk of developing foot damage in the context of diabetic neuropathy.

4.7 Orthopaedics: Limitation of fractures/incrimination of athletes

(1) Fractures of the femur neck, thigh shaft and shin – tuning fork of 128 Hz [1]

Alternatively, the tuning fork can be placed over the middle joint head of the thigh bone. For differentiation of fractures of the neck from those of the thigh shaft, the hopper of the stethoscope can be placed over the larger trochanter and the tuning fork over the kneecap as before. In the case of fractures of the shin, the stethoscope was placed over the tibia

1Misurya, R. K.;Khare, A.;Mallick, A.;Sural, A.;Vishwakarma, G. K. (1987):Use of tuning fork in diagnostic Auscultation of fractures.In:Injury 18 (1), pp. 63-64.DOI:10.1016/0020-1383(87)90391-3.

nodules (Tibial tu-bercle) and the tuning fork over the inner ankle. The conductive sound was compared to that of the uninjured part of the body. Compared to the healthy part of the body, the sound line was not present or only limited in the event of a fracture.
The tuning fork of 128 Hz was chosen because waves of this frequency are not transmitted as easily by the fraction as waves of higher frequencies.

(2) acute compartment syndrome of the forearm [2] — tuning fork with 256 Hz
The variance analysis showed significantly that 256-Hz vibration is the most reliable and earliest sensory method at a pressure of 35 to 40 mmHg. At an increased compartment pressure, this showed a reduced or missing vibration perception when using a 256 HZ tuning fork. So that one can say in reverse that a reduced vibration perception indicates an increased compartment pressure in the forearm.

(3) Stress fractures (load fractures) [3]— tuning fork with 256 Hz
Runners with symptoms of stress fractures were tested with a 256 Hz to detect a stress fracture. A 3-pain assessment is highly predictive of the presence of a stress fracture.

5. Cleaning/disinfection

Manual cleaning: for cleaning use a dry or slightly greasy cloth.: After use, the tuning fork must not be cleaned in sterilisers.

Disinfect the tuning forks after each application, in particular the parts of the tuning forks that come into contact with patients. Use surface disinfectant on an alcoholic basis and observe the manufacturer's information on concentration and exposure time.

7. Packaging/transport/storage/disposal

Packaging

A standard packaging is used. The tuning fork REF:125 PE is packed in a cardboard box. All other tuning forks are individually packaged in standard polyethylene bags.

Transport

There are no special requirements for transport.

Storage

The tuning forks shall be kept dry and sturdy.

Use/application

At room temperature. Perform a visual check for damage and signs of wear before use.

Disposal

The tuning forks shall be disposed of via the scrap metal collection site.

2Phillips, J. H.;MacKinnon, S.E.;Beatty, S.E.;Dellon, A. L.;O'Brien, J. P. (1987):Vibratory sensory testing in acute compartment syndromes.A clinical and experimental study.In:Plastic and reconstructive surgery 79 (5), pp. 796-801.DOI:10.1097/00006534-198705000-00020.
3Wilder, Robert P.;Vincent, Heather K.;Stewart, Jonathan;Pack, Candace;Vincent, Kevin R. (2009):Clinical Use of Tuning Forks to Identify Running-Related Stress Fractures.In:Athletic Training & Sports Health Care 1 (1), pp. 12-18.DOI:10.3928/19425864-20090101-10.

8. Sources of error

Error/symptom	Reason – action
Result unexpected	• Displacement of dampers – frequency change – adjustment by manufacturer • Displacement of dampers – Frequency change – Adjustment to marker on the back (only for REF:125 PE) • Material removal – frequency change – unusable tuning fork
Tuning fork hints bent	• Tuning fork unusable
Rust on the tuning fork	• Alloy defective – Use only in dry areas – Submission to manufacturer
Damper lost	• Ordering spare parts possible, if possible, to be replaced by manufacturer
Screw lost	• Spare parts order possible, user assembly possible
Plastic foot lost	• Spare parts order possible, user assembly possible
Allergic reaction after skin contact	• Tuning fork are nickel plated – exclusion for nickel allergy • Application to injured skin – to be applied only to intact skin
Cluttering of the tuning fork when swinging	• Dampers are not firm, tightening the screws

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