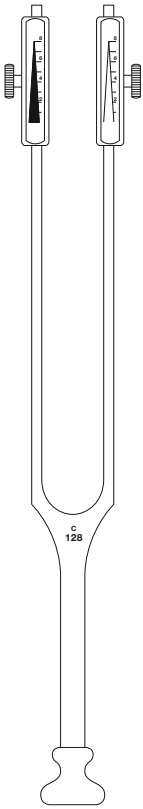
Tuning Fork with Case

Instructions for Use



EN

8030002 | Instructions for Use Tuning Fork | REV 04
Revision status 30.11.2022

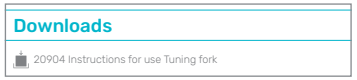
MD

CE

RUCK Tuning fork with case

- Diese Gebrauchsanweisung können Sie in weiteren Sprachen unter nachfolgendem Link herunterladen oder telefonisch anfordern.
- Tämän käyttöohjeen voitte ladata useilla eri kielillä seuraavasta linkistä tai pyytää tietoja puhelimitse.
- Puede descargar este manual en diferentes idiomas en el siguiente enlace o bien solicitarlo por teléfono.
- Instrukcje te mogą być pobierane w innych językach pod poniższym linkiem lub telefonicznie
- Tento návod je také k dispozici v jiných jazycích. Použijte prosím následující odkaz ke stažení návodu nebo si je vyžádejte telefonicky.
- Šo lietošanas instrukciju citās valodās iespējams lejuplādēt zemāk norādītajā saitē vai pieprasīt telefoniski.
- These instructions for use are also available in other languages. Please use the following link to download the instructions or request them on the phone.
- Questo manuale è disponibile anche in altre lingua. Lo si può scaricare utilizzando il seguente link o richiederlo per telefono.
- 此說明書另有提供其他國家語言，請點擊此連結下載檔案，或透過電話詢問下載亦可。
- Navodila za uporabo lahko v številnih jezikih pridobite na sledeči povezavi ali naročite prek telefona
- Acest manual este disponibil si in alte versiuni de limba. Accesati link-ul urmator pentru a descarca manualul sau il puteti solicita telefonic.
- Вы можете загрузить руководства по эксплуатации на других языках кликнув на ссылку или запросив по телефону.
- Τις οδηγίες χρήσεως μπορείτε να τις βρείτε και σε άλλες γλώσσες, πατώντας στο παρακάτω link για να τις κατεβάσετε ή να τις ζητήσετε τηλεφωνικώς.
- U kunt de gebruiksaanwijzing in diverse talen downloaden onder de volgende link. Ook kunt u deze telefonisch aanvragen.
- Ce manuel d'utilisation est disponible aussi en autre langues. Veuillez utiliser le lien suivant pour le télécharger ou demandez-le par téléphone.
- Bu kullanım kılavuzunu farklı dillerdede aşağıdaki bağlantıdan indirebilir yada telefon ile istiyebilirsiniz.
- Atsisiųskite instrukcija lietuvių kalbą paspaudę šią nuorodą, arba paskambinę telefonu.
- A használati útmutatót magyar nyelven a következő linkről tudja tölteni, vagy kérheti telefonon.
- ופלטב תוא שקבל וא אבה קנילב תופסונ תופשב הלעפהב תוארוה תא דירוהל לכות.
- 여러 언어로 된 본 사용설명서를 다음 링크에서 다운로드하시거나 전화로 요청하실 수 있습니다.
- Hægt er að sækja þessar notkunarleiðbeiningar á öðrum tungumálum með eftirfarandi tengli eða panta þær símleiðis
- Ezen kezelési útmutató további nyelveken a következő linken keresztül tölthető le, vagy telefonon megkérhető
- この取扱説明書はその他の言語でも以下のリンクでダウンロードしていただくことが可能です。またはお電 話でお問い合わせいただければご案内申し上げます。
- Denne brugsanvisning kan du downloade på flere sprog på efterfølgende link eller bestille telefonisk
- Denna bruksanvisning på andra språk kan du antingen ladda ned från följande länk eller beställa på telefon
- Цю інструкцію по експлуатації на інших мовах ви можете завантажити за нижчевказаним посиланням на сайт або запросити по телефону

1. hellmut-ruck.de
2. Search term: "2090401"
3. Downloads



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About these instructions

Symbols used

These symbols are used in these instructions or on the product:

Danger to persons. Observe the note marked with this symbol to avoid personal injury.

Endangering the condition or functionality of the product or endangering the environment.

MD Medical product

Manufacturer

LOT Production lot number, batch number

Manufacturing date

CE conformity marking

Refer to the instructions for use

Product description

Declaration of Conformity

The tuning fork fulfils 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 (MDA).

Class I medical device
according to Annex IX MDD Class I (Rule 1)
according to Annex VIII MDR 2017 / 745 Class I (Rule 1)

Intended usage

The medical tuning fork is used to examine the foot area of people from 4 years of age. The prongs of the tuning fork act as a sound conduction source of air and bone conduction. The base of the tuning fork is placed on suitable parts of the body. Healthy areas of the skin, that are free of muscle or fatty tissue, are suitable.

User group

Medical practitioners or healthcare professionals with a qualification or training in the use of medical tuning forks.

Intended use / indications

The tuning fork can be used in various medical fields, such as neurological diagnostics. These include:

- sensitivity tests
- further diagnostic tests at the doctor's own discretion
- Possible fields of application, which have been confirmed by studies, are:
  - Neurology: nerve compression, polyneuropathy
  - General medicine: diabetic foot ulcers, screening examinations for nerve impairment

Contraindications

Do not use on injured skin.

Do not use on the following persons:

- Persons with a nickel allergy. The product contains nickel.
- Children under 4 years of age
- Persons with a known lack of sense of vibration.
- Persons with sensory symptoms, sensory signs including the absence of a sense of vibration
- Persons under the influence of drugs that may cause polyneuropathy or affect their cooperation

Side effects

No side effects or attendant symptoms are known.

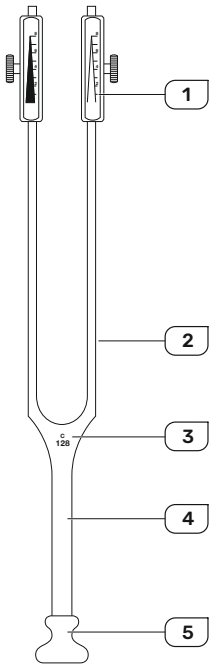
Basic precautions

CAUTION
Examinations, with a medical tuning fork, may only be carried out by doctors or medical professionals and in compliance with the instructions for use.
If the product is damaged, it must not be used for examination as the result of the examination may be incorrect.

Immediately report any serious incidents that have occurred in connection with the product to the manufacturer.

Application basics

The Rydel-Seiffer tuning fork (named after Adam Rydel and Friedrich Wilhelm Seiffer), is a calibrated tuning fork (c 64 Hz and c 128 Hz) that can be used to examine impairments of the peripheral nervous system. The fact that the sensation of vibration (pallaesthesia) is the first to be impaired in the presence of a polyneuropathy (disease of peripheral nerves) is used here.
Causes of polyneuropathies can be, for example, diabetes mellitus, damage to the spinal cord or spinal nerves (e.g., in the case of paraplegia or a slipped disc), vitamin B12 deficiency, alcohol dependence or infections.



1 Removable damper with scale from 0 to 8 with knurled screw for fixation
2 Tines with marking on the side: CE mark, MD symbol, LOT number
3 Frequency indication and logo of the manufacturer
4 Stem
5 Plastic base

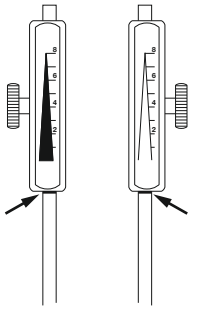
Frequencies

The tuning fork according to Rydel-Seiffer produces vibrations of two different frequencies: With the dampers on, the tone C = 64 Hz (as marked on the dampers) and with the dampers off, the tone c = 128 Hz (as marked on the stem of the tuning fork).
To check for pallaesthesia, the tuning fork is used exclusively with the dampers on.

How to use

Take the tuning fork out of its packaging and check it for damage and signs of wear. Only use the tuning fork if it is not damaged. The smallest damage can influence the vibration frequency and thus produce an incorrect result.
Use: At room temperature.

Checking / adjusting the dampers



The lower edge of the dampers must be in line with the marking lines on the tines.
The dampers can be loosened or tightened using the knurled screws. During use, the knurled screws must be firmly tightened.

Striking the tuning fork

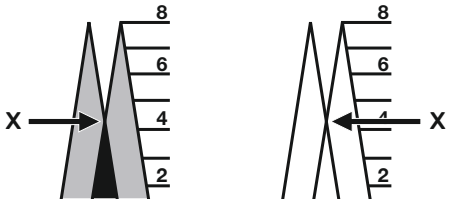
Hold the tuning fork by the black base with one hand. With the other hand, squeeze both vibrating tines together in the area of the dampers and then release the dampers.
Another possibility is to strike the tuning fork with the ball of the hand or a bony spot.
The tuning fork must not be struck against hard objects.

Applying the tuning fork

Immediately after striking the tuning fork, place the base of the tuning fork on areas of the skin under which there are prominent bone points, such as the elbow, the radial head or the inner ankle. The skin must be bare.

Reading the vibration intensity

The dampers are printed with a black and a white triangle with a scale from 2 to 8. Depending on the light conditions, it is easier to observe either the black or the white triangle.
By striking the tuning fork, the tines vibrate and two triangles appear on each damper.
As they fade out, the two triangles slowly slide over each other on a damper. The intersection of the two triangles slowly moves upwards.
This intersection point (X) indicates the vibration strength. Read off the value of the intersection point via the scale. If, for example, a value of "6" is read, one speaks of 6/8 (six eighths).



Practical application

To give the patient a feeling for the tuning fork test, the tuning fork is first placed on points where no disturbance is expected, e.g. elbows or finger joints. Now the vibration sensation in the area of the feet and lower leg can be assessed. The tuning fork is placed on the relevant bone points. The patient has to name the point in time when the slowly fading vibration is no longer noticeable to him/her. This moment is then read off with the help of the scale on one of the dampers.
The test is always carried out at several points and always in a right/left side comparison.

Measuring points

- Tip of the big toe right – left
- Metatarsophalangeal joint right – left
- Inner ankle right – left
- Front edge of shinbone right – left
- Fibula head – left

Normal values

Although the measurement of pallaesthesia is part of the neurological and, e.g., also diabetological routine examination, there is no clear information in the literature on standard values and standardised measurement points.

The following values generally apply as a guide:

- In patients under 60 years of age, readings between 6/8 and 8/8 are normal.
- In patients over 60 years of age, readings between 4/8 and 8/8 are normal.

Lower values should be clarified neurologically.

Cleaning after use

Clean the tuning fork after each use with a dry or slightly greasy cloth. Do not clean the tuning fork in a steriliser.

Disinfect the tuning fork after each use, especially the parts of the tuning fork that come into contact with patients. Use alcohol-based surface disinfectants and follow the manufacturer's instructions for concentration and exposure time.

Packaging, storage, disposal

Packaging

The tuning fork is packed in a cardboard box.

Transport

No special requirements apply to transport.

Storage

The tuning fork must be stored in a dry place and protected from falling.

Disposal

If possible, separate the base from the rest of the tuning fork.
The metal part of the tuning fork must be disposed of at a scrap metal collection point.

Troubleshooting

Problem / Question	Possible cause / measure
Unexpected result	The dampers are not adjusted correctly. Check the position of the dampers, correct if necessary.
	Tuning fork worn or damaged. The tuning fork can no longer be used.
Clanging of the tuning fork while vibrating	The dampers are not fixed. Tighten the knurled screws.
Allergic reaction after skin contact	Use on injured skin. Only use on intact skin
	Nickel allergy. Stem and tines contain nickel.

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