# *OptiHair2* – Optic fibre based von Frey filaments

## User manual


## 1. Introduction / Intended use

Since their first introduction in 1896 by von Frey [1], von Frey filaments have been used to determine the touch sensibility of humans. Today they are regularly used in pain research [2, 3].

Von Frey originally used human hairs and animal bristles of different lengths that were fixed at a right angle to a thin rod. If such a hair or bristle is pressed with its free end against the skin, the applied force increases until it starts bending, but then remains fairly constant independent of the further bending. Thus, the bending force only depends on the stiffness and length of the hair / bristle and can be easily calibrated. Later, the hairs or bristles have been replaced by synthetic fibres. But this new material has some drawbacks: It shows a plastic deformation so that the force fades during constant pressure. Furthermore, the force is relevantly affected by variations of the room temperature or humidity [4].

Still, some filaments in the market are made from synthetic fibres. They are cut to the appropriate lengths. Therefore, the fibre end varies in diameter and has a sharp edge which may stimulate nociceptors during bending.

In contrast, the “OptiHair2” von Frey filaments are made from optic glass fibres. These are highly elastic and their stiffness is not influenced by normal temperature and humidity fluctuations [5]. Moreover, each fibre tip is coated with a tiny epoxy pearl with a defined diameter of 0.35 to 0.45 mm. In that way a fairly constant contact area is ensured for each fibre diameter. The spherical ending also prevents any undesired stimulation of nociceptors when the fibre is bent.

Unlike other products the “OptiHair2” filaments are longitudinally fixed to an acrylic handle. This enables a simple testing with many filaments as they can be easily placed on the table next to each other and do not have to be put back on a stand. The handles are equipped with a LuerLock coupling. The filament base fits to this coupling. This design allows a quick and simple exchange of broken filaments. The filaments are immediately applicable after removal of the protection cap.

Each “OptiHair2” filament is individually calibrated to a tolerance range of just ± 5 % of the nominal force. The standard set comprises 12 logarithmically calibrated filaments with forces of 0.25 to 512 mN, where the force increases by a factor of 2 from filament to filament.

## Precautions

- “OptiHair2” von Frey filaments are made from optical glass fibres. These glass fibres are highly elastic. Nevertheless they are sensitive to extreme bending and may break if they are bent below their minimal bending radius. The typical value of the minimal bending radius is less than 100x the radius of the glass fibre. The minimal bending radius of the fibres used for “OptiHair2” ranges between 6.5 mm and 37 mm. Down to this radius the filaments can be bent without danger of breaking. However, kinking an optical fibre will inevitably break it.
- If a fibre is broken or the pearl at the tip is missing, please don't use the filament. With an incorrect ending of the fibre you can penetrate and injure skin.
- Do not touch any injured or morbid skin with the von Frey filaments.

## 2. Set components

- 12 “OptiHair2” von-Frey filaments with forces from 0.25 to 512 mN, each with handle and cap
- 8 spare filaments with forces from 0.25 to 32 mN, each with cap (without handle)
- storage box and user manual


*Figure 1: Parts of a von Frey filament: handle, filament and protection cap.*

# 3. Instructions for use

## 3.1. Handling

Each "OptiHair2" consists of a handle, the filament, and a cap that protects the filament (see figure 1). The handles are equipped with a LuerLock connector. The base of the filament fits to this connector and can be simply attached or removed like a needle on a syringe. The coupling mechanism enables a quick and simple exchange of a broken filament.

Each handle is marked with number and force of the filament belonging to it.

In order to remove the filament from the holder, put on the protective cap and turn the cap anticlockwise. If you want to put a new filament on the holder, make sure, that filament and holder belong to each other (e.g. holder 11 = 256 mN and filament no. 11; see also calibration table). Then screw the filament with its protective cap clockwise tightly on the holder.

Be very cautious when you remove or put back the protective cap for the first time. It is safe to get acquainted with the mechanisms of coupling and cap with a thick filament e.g. no. 11 (= 256mN). If a thin filament gets caught between holder and cap it will break. Similarly thin filaments can easily break if the cap is removed without the necessary care (see figures 2 and 3).

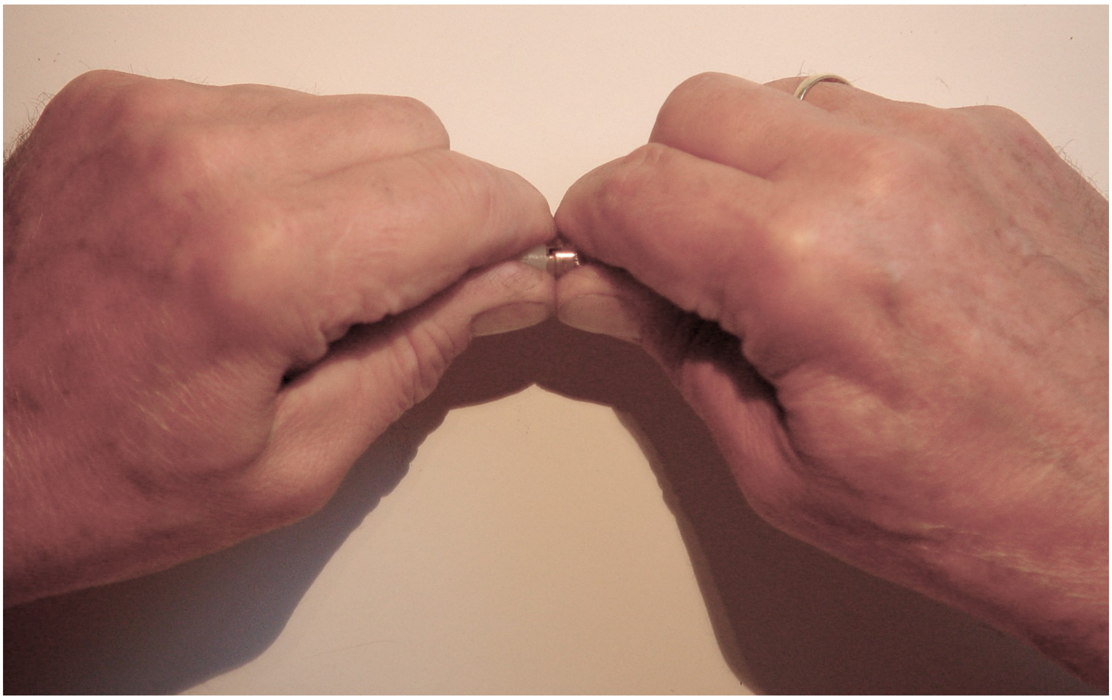

*Figure 2: In order to take off the protective cap, take handle and cap with thumb and index finger of both hands with the fingers touching each other. Then increase the pressure between the fingers and carefully move the cap slightly up and down until it gets loose and can be taken off the holder. The protective cap can only be removed safely, if the filament is connected to the holder.*

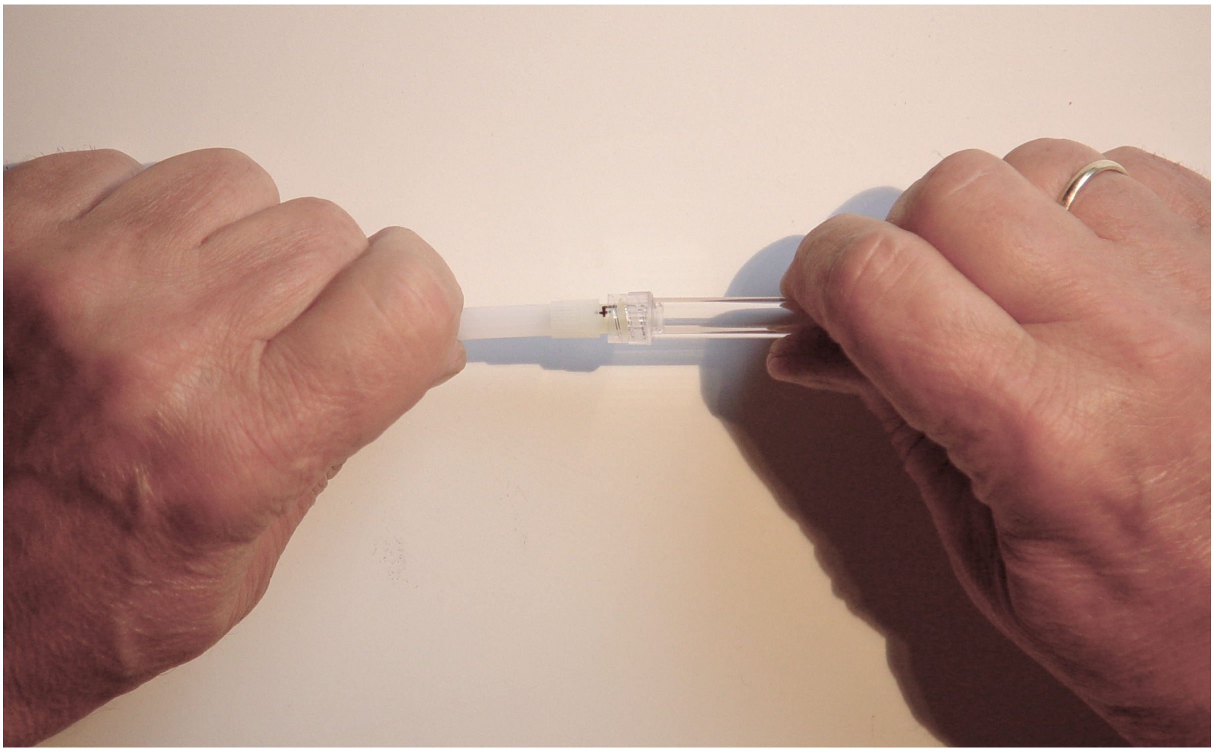

*Figure 3: It is dangerous to pull off the protective cap like this: if the cap gets suddenly loose, the hands will move by reflex against each other and the cap may destroy the glass fibre.*

The filament exerts its nominal force when the fibre begins to bend and there is no sense to go beyond this point. A thin fibre will break if during the examination the holder touches the skin of the patient. Experience has shown that the different types of mishap frequently occur during the first use of new filaments. Later, damage of filaments is rare. It commonly happens, however, if the holder with the unprotected fibre falls off the table or if the filament is by mistake pushed against a hard object. Broken filaments can easily be exchanged. If you want to reorder a filament, quote its number and force.

For a correct use of von Frey filaments it is necessary that you can always see the fibre, which is difficult for the smallest diameters. Therefore, use a good illumination during the examination and wear magnifying spectacles with a working distance of 40-50cm.

## 3.2. Examination of touch thresholds

Touch thresholds should be examined on a relaxed and recumbent patient who has the eyes closed. Move the filament vertically against the skin until it starts bending, and let the patient report the detection of the touch sensation. The bending force of each filament is given in mN in the calibration table and on the handle. Start with a certainly supra-threshold force and stepwise decrease it until the patient fails to feel the touch of the filament. Note down its force and then increase the force until the patient feels the touch again. Note down also that force. Then, for two additional runs, decrease the force until sensation disappears and increase it until it reappears. Note down the respective force values. Calculate the final threshold as the mean of the three infra-threshold and the three supra-threshold force values. If during the examination an obviously incorrect force value has been obtained (e.g. by a disturbance) discard the respective value pair and repeat that measurement. Dummy stimuli (i.e. movement of the filament holder without touching the skin) should occasionally be added to check the patient's reliability.

## 4. Technical data

| | |
|---|---|
| forces | 0.25, 0.5, 1, 2, 4, 8, 16, 32, 64, 128, 256, 512 mN, tolerance: ± 5 %<br>All forces have been checked before delivery by means of force sensors. |
| material | optical glass fibre<br>spherical epoxy ending, diameter: 0.35 – 0.45 mm |
| handle | acrylic handle with LuerLock coupling |

| FILAMENT | FORCE (mN) | *Calibration (g)* | Length (mm) | Diameter (µm) |
|---|---|---|---|---|
| 1 | 0,25 | 0,025 | 49,5 | 65 |
| 2 | 0,50 | 0,051 | 35 | 65 |
| 3 | 1,0 | 0,102 | 57,5 | 100 |
| 4 | 2,0 | 0,204 | 40,5 | 100 |
| 5 | 4,0 | 0,408 | 50 | 125 |
| 6 | 8,0 | 0,815 | 49 | 155 |
| 7 | 16,0 | 1,63 | 34,5 | 155 |
| 8 | 32,0 | 3,26 | 41 | 195 |
| 9 | 64,0 | 6,52 | 49,5 | 240 |
| 10 | 128 | 13,0 | 35 | 240 |
| 11 | 256 | 26,1 | 56,5 | 370 |
| 12 | 512 | 52,2 | 40 | 370 |

*Table 1: Calibration table of filament numbers and forces*

## 5. Sterilization / Disinfection

After having tested touch thresholds on infected skin or on mucous membranes, von Frey filaments must be sterilized or disinfected. As the handle is made of acryl and macrolone and as the filament base is made of other thermolabile plastics, heat sterilization is not possible. The best method for sterilization of von Frey filaments is *PLASMA STERILIZATION*. Alternatively, wipe disinfection of the handle and the filament with an alcohol-free solution, and ethylene oxide sterilization of the filament are possible. All other cold sterilization methods have drawbacks and are not recommended for more than one cycle. Table 2 gives an overview on applicable methods for handle and filament. For further questions consult your hygiene department.

| | **Method** | **Drawbacks** |
|---|---|---|
| ***Handle*** | Ethylene oxide | May get small cracks. Label may fade |
| | Gamma radiation | May become yellow and brittle. Label may fade |
| | Wipe disinfection | *Possible* without solvents. Alcohol may cause cracks. |
| ***Filament*** | Ethylene oxide | *Possible* |
| | Gamma radiation | *Plastic parts may become brittle over several cycles.* |
| | Bath disinfection (without alcohol) | Numbers may fade.<br>*Not safe.* |
| | Wipe disinfection with solvent-free wipes (e.g. mikrozid® sensitive wipes) | *Possible*. Pull filament through the moist wipe taking great care not to tear off the spherical end. |

*Table 2: Drawbacks of cold sterilization and disinfection methods.*

## 6. Labelling

The "OptiHair2" filaments are class 1 medical devices and are produced and checked according to our quality management system. They left our company in a faultless state. In order to maintain this state you should always store them in the delivered storage box in dry environments.

Each filament is labelled with a number which corresponds to a specific bending force. The force is given in mN in the calibration table and on the handle. The CE mark for the whole set is noted on the storage box. Each set has an individual serial number.

## 7. Literature


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## 8. Contact


MRC Systems GmbH, Hans-Bunte-Str. 10, D-69123 Heidelberg, Germany
Phone: +49-6221-13803-00, Fax: +49-6221-13803-01, E-mail: info@mrc-systems.de