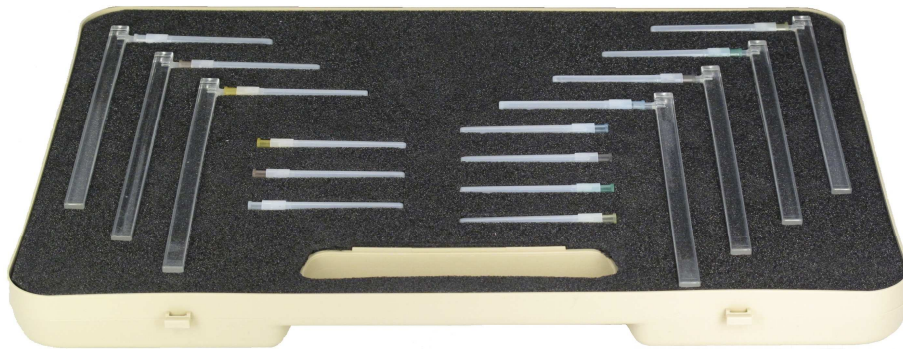




SENSELab AESTHESIOMETER II



Manual
Version 02 EN 2017-03-27

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The SENSELab Aesthesiometer II consists of

- Box for storage
- 7 Handles with monofilaments
- 7 replaceable monofilaments
- Manual (this document)

Introduction

The von Frey hairs are used to investigate cutaneous pin prick sensitivity in humans, by applying to the skin a thin monofilament at a predefined force. For this purpose Somedic has for more than two decades been supplying von Frey hairs, and on request from many customers now developed a von Frey system made with a handle and separate hairs. In this way, the hair can easily be replaced where there is a risk of spreading infections between patients through the contact with the von Frey hair. The hairs are supplied in protective sleeves, much like a syringe needle, and can easily be placed on the handle. The system with a replaceable hair makes it also more economical, as the von Frey hair will wear out over time and it is significantly less expensive to replace a hair, than a complete handle with hair.

Rounded top on the filaments to avoid sharpness sensation

As we have learned throughout the years, even the sharp edges on a very thin filament may disturb the sensitivity. To avoid the sharpness we have formed the new filaments with a rounded top.

Specifications for the Monofilaments

Manufacturing details, diameter, length and nominal force / pressure data for SENSELab monofilament.

Hair (former hair number)	Diameter (mm)	Length (mm)	Nominal force (g)	Nominal force (mN)
Transparent No 5	0,128	40	0,064	0,63
Brown No 7	0,153	40	0,14	1,37
Orange No 8	0,177	42	0,32	3,14
Blue No 11	0,306	42	1,7	16,67
Black No 13	0,403	43	5,1	50,0
Green No 14	0,409	33	8,3	81,4
Yellow No 16	0,508	30	24	235,36

Values given cannot be used as calibration values. They are to be considered as guide lines. The Somedic SenseLab von Frey filament contents of a handle with 1 monofilament insert mounted on the handle, the filament is coloured according to above mentioned table, and we also refer to our previous von Frey set with the numbering (No 5, No 7 etc.)

The monofilament insert is like a syringe needle, the needle is replaced with a nylon filament and has a protective cap. Each set has also 7 filaments for replacement.

Dimension of handle (mm): 8*8*155

Weight of handle: less than 15 g

Comment

By repeating the test 5 times in a designated area of 1 cm² around the intended test site, the reliability of the test can be significantly improved and the test result reported as 5/5 for a subject that responds for every stimuli and 2/5 for someone responding only to 2 of the 5 stimuli (a.s.o.). The rationale behind this comment is that the innervation patterns of the skin mechanoreceptors are irregular, resulting in areas with varying sensitivity to pin prick. If only one stimulus is used, the test may be done at an “insensitive” area and the test result may be reported as “No”. The “statistical” approach, behind the notation of 5/5, matches better the morphology of the mechanoreceptor systems, as well as patterns of possible pathology, than a yes/no response.

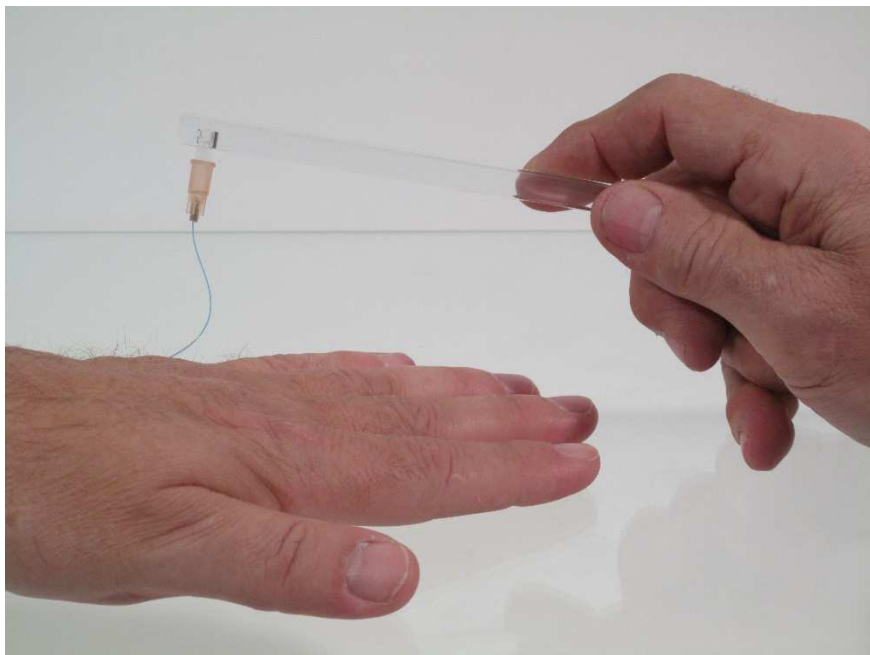
Instructions for use

1. Testing shall be done in a quiet place free from distractions, with the subject to be tested in a comfortable resting position unable to visually follow the investigation procedure.
2. Place the hair on the pin of the handle and take the handle in your hand. Instruct your subject that you will apply the filament when you say “Now” and ask the subject to answer with “Yes” if this gives any tactile sensation, or “No” if nothing is detected.
3. For the testing, you shall hold the handle parallel to the skin and apply the monofilament in a straight angle to the skin. Press the monofilament slowly down until it buckles, hold it steady and then remove it in the same way as it was applied. Say “Now” and then use:

1,5 seconds, from initial touch to buckling

1,5 seconds, held with constant pressure

1,5 seconds, removing



4. Refer to the published literature for more detailed testing protocols and for the interpretation of the results.

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Please note that the von Frey hairs are not intended for use in tests that require absolutely sterile conditions.

Declaration of Conformity

DECLARATION OF CONFORMITY

According to the Medical Device Directive, 93/42/EEC

The undersigned, representing the following manufacturer, established within the EEA

Registered name	Somedic SenseLab AB
Post & visitor address	Norra Mellby 1129 SE-280 10 Sösdala
Country	SWEDEN
Telephone	+46 415 16550
E-Mail	info@somedic.com

hereby declares that the following product is CE-marked 2013

Brand name/Trade mark: SENSELab Aesthesiometer

Type of equipment: SENSELab Aesthesiometer is a non-active, non-invasive medical device classified in Class I. This declaration cover
article no batch no.
10-600-002 101 -
Set with 7 v Frey hairs and 7 monofilaments for replacement

This Declaration of Conformity is given in accordance with Addendum 7, to Directive 93/42/EEC and the Swedish implementation LVFS 2003:11. By signing this document, the undersigned declares as representative for the manufacturer, that the product complies with the requirements of the harmonized standard stated above.

Place of issue:	Sösdala
Date of issue:	March 27 th , 2017
Authorized by:	Bo G. Johansson

Signature:
Title of authority:



CEO, Somedic SenseLab AB