



Synapsys Vestibular Vibrator

Multi-frequency vibrator

DESCRIPTION

Synapsys Vestibular Vibrator is a multi-frequency vibrator, designed to favour detection of vibration-induced nystagmus (VIN), to help finding unilateral vestibular dysfunctions and especially compensated deficits.

It can be used in conjunction with systems that allow nystagmus observation, or nystagmus analysis and video recording.

VIBRATION FREQUENCIES

Three possible vibration frequencies, set from device's control box:

- 30 Hz
- 60 Hz
- 100 Hz

DEVICE FEATURES

- Vibration induced by continuous pressure of handpiece button
- Control box equipped with support for handpiece placement
- Vibration head protected by replaceable and biocompatible foam cover

POWER SUPPLY

Power supply: 24 V DC – 1.25 A, through an external medical grade 100–240 V, 0.8–0.4 A, 47/63 Hz power

MECHANICS

Device size (WxDxH): 15 x 21 x 6 cm / 5.9 x 8.3 x 2.4 in.

Weight:

- Handpiece: 0.6 kg / 1.3 lb
- Control box + handpiece: 1.5 kg / 3.3 lb

Handpiece cable length: 3 m / 118.1 in.

FREIGHT PACKING

Size (WxDxH): 31 x 10 x 29 cm / 12.2 x 3.9 x 11.4 in.

Gross weight: approx. 2.2 kg / 4.8 lb

APPLICABLE STANDARDS

Electrical safety: IEC 60601-1

EMC: IEC 60601-1-2

Biocompatibility: ISO 10993-1

Risk management: EN ISO 14971/A11, ISO TR 24971

Usability: IEC 62366-1, IEC 60601-1-6

Processing: ISO 17664-2

Environmental testing: IEC 60068-2-31

INCLUDED PARTS

- Vestibular Vibrator handpiece
- Control box
- Power supply with power plugs
- 10 replaceable foam covers for vibrator head
- User manual

MDR CLASSIFICATION

Class IIa [Classification rule: 10, (Annex VIII, MDR 2017/745)]

Notified body: TÜV SÜD Product Service GmbH (0123)

PRODUCT CODES

10741: Multi-frequency vibrator (30, 60, 100 Hz)

DISPOSABLES AND CONSUMABLES

11845: Replacement foam for vibrator (pack of 20)

Synapsys Vestibular Vibrator is manufactured by:

INVENTIS S.r.l.

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