VIBRASENSE®

Smart Peripheral Neuropathy Screener

Truly Portable

Truly Smart

Rechargeable

70-100 tests per charge

Pocket-friendly

size and price

BETiC
Tech developed at IIT Bombay

ISO 13485:2016

URS ISO 13485

UKAS MANAGEMENT SYSTEMS 0043

CDSCO
MFG/MD/2023/000668

CE EC REP
MARS MEDICAL, GERMANY

FDA Listed

Ayati Devices
Life Saving Innovations

Vibration Perception Threshold - Backed by Research

VIBRASENSE®

Quantifies VPTs at 6 points and provides average VPT for each foot

Vibration perception threshold (VPT) is the lowest vibrational intensity at which a subject perceives vibration stimuli.

VPT is impaired at an early stage in different neuropathies and is widely used for screening for large nerve fibre dysfunction in Diabetes mellitus.

- *Diabetes Care. 2010 Dec;33(12):2635-41.*
- *PLOS ONE, 16(4), e0249461.*

VPT testing is a clinically validated method for screening, early detection and longitudinal evaluation of peripheral neuropathy

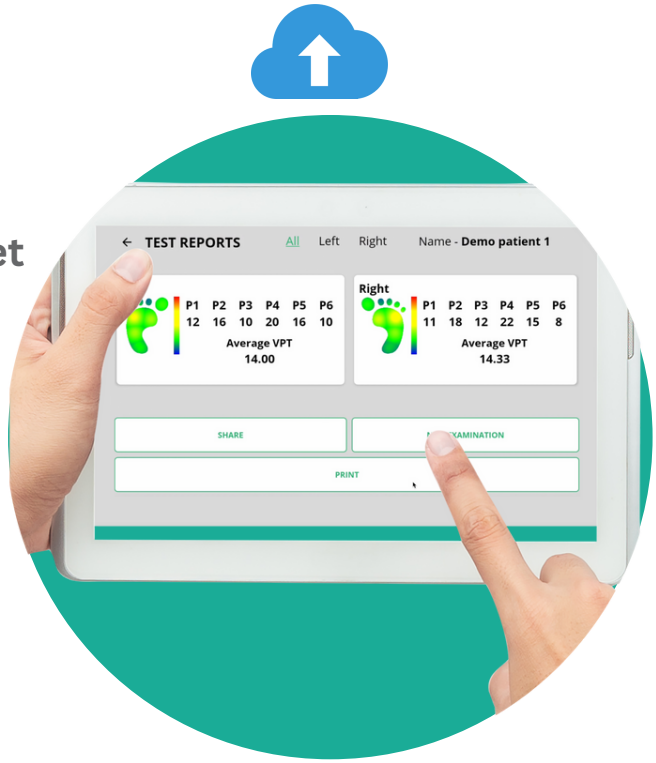
Click of a button - Wireless Digital Reporting

Upload the report to cloud-storage for retrieval from laptop/mobile device later

VIBRASENSE®

Pairs with phone or tablet

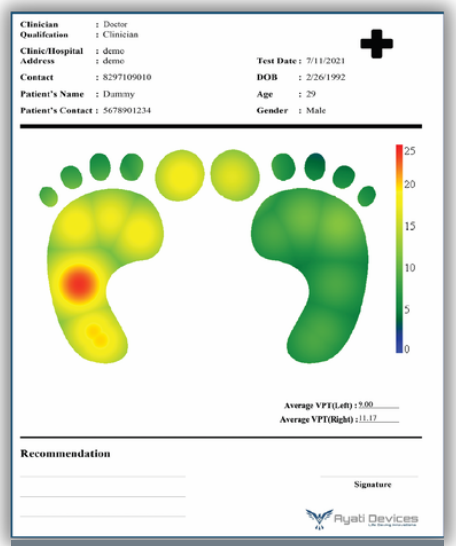
Bluetooth



Printable report generated on your device

Provides Actionable Insights to Clinicians and Patients

Colour-graded report



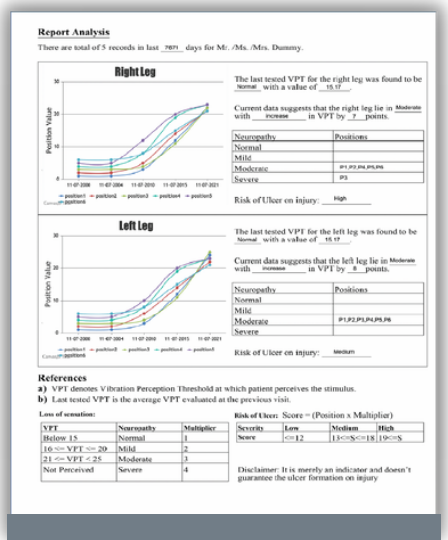
Comparative reporting of Bilateral Vibration Thresholds

Patient-friendly report shows areas of the foot with grades of vibration sensation in different colours

- Normal
- Mild impairment
- Moderate impairment
- Severe impairment

Gives a visual guide to patients about foot areas they should be extra careful about

Longitudinal data capture allows long-term monitoring



Longitudinal monitoring of Vibration Thresholds

VPT evaluation is useful in monitoring disease progression. VPT is an effective predictor of the risk of foot ulceration in diabetes.

They can be used to provide targeted foot-care education to patients who stand to benefit the most.

- *Diabetes Care 1994;17(6):557–560*
- *Diabetes Care. 2019 Jan;42(1):110-118.*
- *Acta Diabetol. 2020 Apr;57(4):433-438.*
- *Diabetes Res Clin Pract. 2008 Apr;80(1):e16-9.*

Provides a visual reference of disease control or progression (A good tool for patient education)

The **American Diabetes Association (ADA)** recommends that all patients should be assessed for diabetic peripheral neuropathy as follows:

- **Type 2: At diagnosis & at least annually thereafter**
- **Type 1: 5 years after the diagnosis & at least annually thereafter**

Diabetes Care 2022;45:S185–S194

Add

VIBRASENSE®

Smart Peripheral Neuropathy Screener

to your Diabetes care paradigm

DETECT NEUROPATHY EARLY
SAVE MORE FEET

Ayati Devices Pvt Ltd

Derbi Foundation,
Dayanda Sagar University,
Kudlu Gate, Bangalore-560068

Ayati Devices
Life Saving Innovations

www.ayatidevices.com

CONTACT US

080 4749 80 80/81

+91 8431845578

info@ayatidevices.com

EU Declaration of Conformity

Legal Manufacturer	***Company Name:*** Ayati Devices Private Limited ***Registered Office Address:*** 507/C, Ecstasy Business Park, City of Joy, ACC Road, Mulund, Mumbai 400080, Maharashtra, India ***Company Address:*** 10, Derbi Foundation, Dayananda Sagar University, Kudlu Gate, Hosur Road, Bangalore 560068, Karnataka, India
Manufacturer SRN	IN-MF-000029603
Website	https://www.ayatidevices.com
Mail ID	nishant.kathpal@ayatidevices.com
Managing Director	Nishant Kathpal
Device Name	VIBRASENSE
Brand Name	VIBRASENSE
Intended Use	A portable device to screen diabetic patients for foot neuropathy at an early stage to prevent foot amputations.
Basic UDI-DI/GMN	8908020434VIBRA93
Catalog No.	AY/M/VIBRA V1.0
Common Specifications	None
Material of Construction	Body: ABS Probe: PTFE
Sterilization	Not Required

Classification of Device	Class I, Rule I and Rule 13 of MDR 2017/745
Conformity Assessment Route	Declaration of Conformity Annex I, Annex II, and Annex III of MDR 2017/745
Notified Body	NA
EC Rep	Mars Medical, Landhausstrasse 46, 70190 Stuttgart, Germany
Authorized Rep SRN	DE-AR-000006312

The device and components utilized in this are complied with RoHs II RL 2011 65 EU. We herewith declare that the above-mentioned product has been designed in compliance with EU MDR 2017/745 and with the regulations listed hereunder:

ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019	Application of risk management to medical devices
IEC 60601-1:2005+AMD1:2012	Medical Electrical Equipment - General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical Electrical Equipment - General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility
IEC 62304:2006+AMD1:2015	Medical device software — Software life cycle processes

All supporting documentation is retained under the premises of the manufacturer. The EU declaration of conformity is issued under the sole responsibility of the Ayati Devices Private Limited.

Ayati Devices
Life Saving Innovations

Date: 24-06-2022
Place: Bangalore

Nishant Kathpal
CEO & Director, Ayati Devices

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Amendment History				
Rev. No.	**Issue No.**	**Amendment Description**	**Authority**	**Effective Date**
00	01	Issue Draft	MD / CEO	24-06-2022
01	01	Added SRN Details & Basic UDI-DI / GMN	MD / CEO	20-10-2022

Ayati Devices
Life Saving Innovations

Date: 24-06-2022
Place: Bangalore

Nishant Kathpal
CEO & Director, Ayati Devices

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FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

New Search Back To Search Results

Proprietary Name:	VIBRASENSE
Classification Name:	DEVICE, VIBRATION THRESHOLD MEASUREMENT
Product Code:	LLN[6]
Device Class:	1
Regulation Number:	882.1200[7]
Medical Specialty:	Neurology
Registered Establishment Name:	AYATI DEVICES PRIVATE LIMITED[8]
Registered Establishment Number:	3027307766
Owner/Operator:	AYATI DEVICES PRIVATE LIMITED[9]
Owner/Operator Number:	10087928
Establishment Operations:	Manufacturer

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Page Last Updated: 07/31/2023

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सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2023/000668

1. M/s Ayati Devices Private Limited, 507/C, ECSTASY Business Park, City Of Joy, ACC Road, Mulund, Mumbai 400080Mumbai, Mumbai City, Maharashtra (India) - 400080 Telephone No.: 8297109010 FAX: 8297109010 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Ayati Devices Pvt. Ltd., Block 1, Second Floor, DERBI Foundation, Dayananda Sagar University, Kudlu Gate, Hongasandra Village, Hosur Road, Bengaluru, Karnataka, 560068, India, Bengaluru (Bangalore) Rural, Karnataka (India) - 560068 Telephone No.: 8297109010 FAX: 8297109010

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Diabetic Foot Screener Model No.:VIBRASENSE - Vibration Frequency 120 Intended Use:VIBRASENSE is screening device to be utilized by clinicians for screening diabetic patients for foot neuropathy at an early stage to prevent foot amputations Class of medical device:Class A Material of construction:Casing material ABS Polyurethane, PTFE Teflon Probe Dimension(if any):210 X54X42 mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):VIBRASENSE

Place:

Date:06-Jul-23

BHAGOJI TAYAPPA KHANAPURE

Digitally signed by BHAGOJI TAYAPPA KHANAPURE
Date: 2023.07.06 18:20:54 +05'30'

State Licensing Authority

VIBRASENSE vs OTHER STANDARD METHODS OF NEUROPATHY SCREENING

Study title: A clinical investigation evaluating the risk of occurrence, presence and severity of Diabetic foot neuropathy using VIBRASENSE

Investigators
Dr Srihari Sharma K N, Dr Anil Kumar H

Approvals
Ethics Committee - CDSIMER

Study site
Chandramma Dayananda Sagar institute of Medical Education and Research (CDSIMER) - Kanakapura, Karnataka

CTRI registration
CTRI/2022/11/047002

Introduction

VIBRASENSE (Ayati Devices Private Limited) is a portable and quick screening tool for peripheral neuropathy. It works by quantifying the vibration perception threshold (VPT) that is impaired at an early stage in different neuropathies and is widely used for screening for large nerve fibre dysfunction in Diabetes mellitus.

The device is portable, hand-held, battery-powered, and can screen up to 70+ patients with a single charge. In this study, VIBRASENSE was compared against other standard methods of neuropathy screening

Study Subjects

Sample size: 562

Inclusion Criteria:
- Adult patients with Type 2 Diabetes mellitus
- Consented to participate as study volunteers

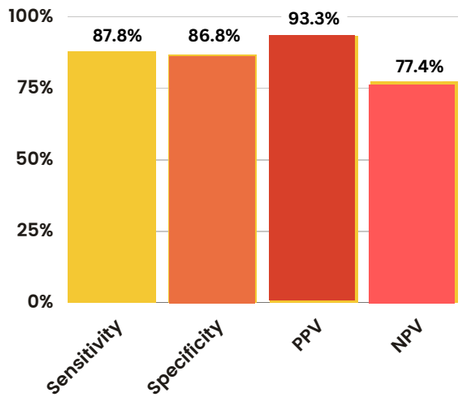
Exclusion Criteria:
Patients with:
- Active foot ulceration
- Visual evidence of recently healed foot ulceration
- Lower Limb amputation of any kind
- Diagnosed PN of any origin other than diabetes
- Alcoholic neuropathy

Methodology

Diabetic patients visiting the hospital OPD and those who participated in diabetic camps of the hospital and fulfilling the study criteria were invited to participate in the study. After informed consent, a structured assessment form was used to record the preliminary details of the participant. Recruited patients (N=562) underwent evaluation for neuropathy that included clinical examination, and vibration perception threshold (VPT) assessments with VIBRASENSE (test device) and a standard BIOTHESIOMETER (Kodys Biothezi VPT - standard device). Those with VPT ≥15 V were noted to have peripheral neuropathy. Diagnosis made with VIBRASENSE (test device) was compared with BIOTHESIOMETER (standard device) and sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) evaluations were performed. A small subset of patients (N=61) underwent nerve conduction study (NCS) as per standard of care assessment.

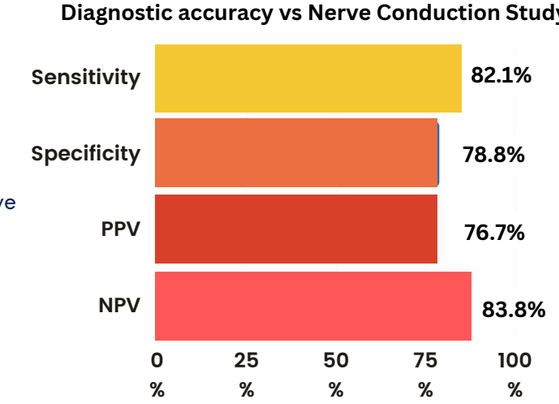
Comparisons

Diagnostic accuracy vs standard BIOTHESIOMETER



VIBRASENSE demonstrated good sensitivity (87.8%) and Specificity (86.8%) against the standard BIOTHESIOMETER.

Diagnostic accuracy vs Nerve Conduction Study

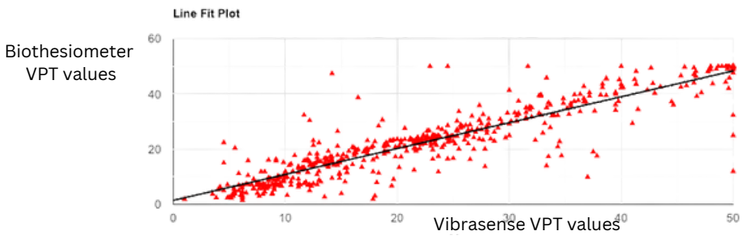


VIBRASENSE when compared against the gold standard (Nerve conduction study), showed good sensitivity (82.1%) and specificity (78.8%).

Results/Findings

CORRELATION WITH BIOTHESIOMETER

VPT values recorded by VIBRASENSE showed a very strong positive correlation (Spearman's correlation rs = 0.891, P < 0.001) with average VPT values recorded with standard Biothesiometer (Figure 1).



Conclusion

VIBRASENSE demonstrated high sensitivity and specificity in diagnosing peripheral neuropathy against the standard BIOTHESIOMETER and against abnormal nerve conduction which is considered as the gold standard.

VIBRASENSE - can be a useful screening tool for peripheral neuropathy in diabetes patients in routine clinial practice settings.