

# INSTRUCTION MANUAL

## BIOTHESIOMETER



## MODEL: ABM-100

Read these instructions carefully before using your Ultrasound Therapy Unit and keep it carefully for future reference.

For more information visit us at [www.sunmedisys.com](http://www.sunmedisys.com)

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An ISO 13985:2012 Certified Products

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## INTRODUCTION

Diabetes mellitus (DM) is a heterogeneous group of disease, characterized by a state of chronic hyperglycaemia, resulting from a diversity of etiologies, genetic, and environmental factors acting jointly. The underlying cause of diabetes is the impaired production or action of insulin, a hormone that controls glucose, fat, and amino acids metabolism. Two broad categories of diabetes are designated as type 1 and type 2 DM. Type 1 diabetes is the result of complete or near total insulin deficiency. Type 2 DM is a heterogeneous group of disorder characterized by a variable degree of insulin resistance, impaired insulin secretion and increased glucose production, and abnormal fat metabolism. Type 2 DM is more common than type 1 DM. The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. [1] The global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014. Diabetes prevalence has been rising more rapidly in the middle- and low-income countries. The number of people with type 2 DM is increasing in every country.

The WHO predicts that developing countries will bear the burden of this epidemic in the 21st century. India is called the diabetic capital of the world. Type 2 DM in Indians is being increasingly seen in younger and less obese persons than in western countries. The WHO projects that diabetes will be the 7th leading cause of death in 2030.

DM is a multisystem disorder; the nervous system is most frequently affected. Diabetic polyneuropathy is one of the most common long-term complications of diabetes affecting 50% of all diabetic people. Diabetes affects both myelinated and unmyelinated nerve fibres. Clinical symptom varies widely in peripheral neuropathy due to diabetes. In majority of cases, sensory symptoms predominate. Distal symmetrical neuropathy is the most common accounting for 75% of diabetic peripheral neuropathy (DPN).

The International Neuropathy Guidelines define DPN as the presence of symptoms and/or signs of peripheral nerve dysfunction in patients with diabetes after exclusion of other causes. This condition affects 30-50% of the patient population with diabetes, and this prevalence tends to increase proportionally with the duration of diabetes. Neuropathy often presents with a loss of protective sensation, defined as a level of sensory deficit, where a patient can sustain an injury without recognizing any inciting trauma. The progression from minor injury into ulceration, and ultimately evolution into a non-healing wound with underlying infection has been documented as the most common series of events preceding lower extremity amputation.

Invariably, diabetic neuropathy is a critical independent risk factor for foot ulceration and lower extremity amputation. Results from the diabetes control and complications trial showed that strict glucose control reduces the development of neuropathy in patients with type 1 diabetes. Vibration perception threshold (VPT) has added much too early diagnosis of peripheral neuropathy. The previous studies showed that, in mild-to-moderate diabetic neuropathy, VPT serves as excellent tool. VPT evaluates affection of peripheral nerve in a quantifiable manner. VPT testing had been done by many authors.

VPT can be measured with a biothesiometer. The biothesiometer probe, which vibrates at amplitude proportional to the square of the applied voltage, was applied perpendicular to the test site with a constant and firm pressure. The study was carried out as per Saha et al., at an average 6 points in both feet great toe, 1st metatarsal, 3rd metatarsal, 3rd and 5th metatarsal, instep, and

heel. The first probe was applied to patients hand to explain the feel of vibration early. Then patient is asked to concentrate on feet and to tell as soon as he starts feeling the vibration, and the value is noted. During recording, the voltage was increased from 0 to 50 V.

## Vibra-Med Biothesiometer

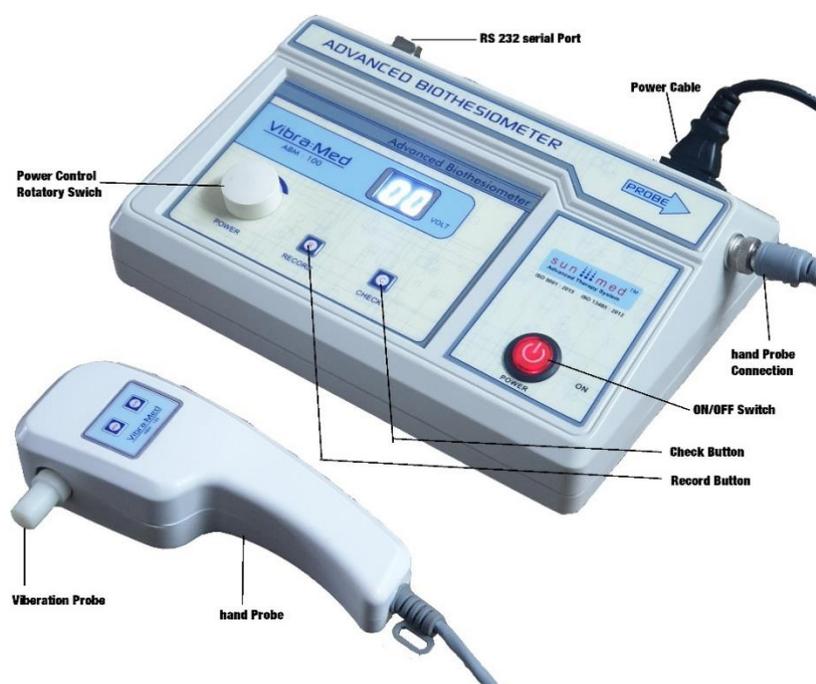
Vibra-med is a state-of-the-art and easy-to-operate Digital biothesiometer. It is designed keeping in view operator ease, accuracy in reading, and patient safety.

Loss of sensation due to neuropathy is the major cause of painless injuries to the feet. Such injuries result in chronic ulcerations and further complications leading to large amputations. Hence early and accurate detection of sensation loss due to neuropathy is the best way to protect the feet from amputation.

The vibratory perception threshold at various sites on the plantar foot quantifies the loss of sensation. An increase in VPT means diminished sensation and increasing risk. Vibra-med is designed as a digital electronic system with complete mains isolation. Vibra-med does not use mains supply directly to generate the oscillations. The frequency and amplitude dependency on the AC power supply of a common biothesiometer is totally eliminated. The generation of vibration is very stable and does not vary from place to place and time to time. Being digital, it gives very accurate readings. It is a device for measuring the threshold of perception of vibration sense (VPT), which is of use when assessing peripheral neuropathies, as seen in diabetics.

## QUICK START GUIDE

- ❖ Check all the accessories with Main unit, Probe and power cable.
- ❖ Now connect the power cable with Unit as well as at mains power plug.
- ❖ Connect hand piece probe to the main unit's output socket.
- ❖ Press Power button which will glow in red colour when power on.
- ❖ Place the hand piece at the desired point.
- ❖ Rotate the Intensity knob clockwise to increase the intensity.
- ❖ Set desire intensity to record the reading either by pressing the record button on the unit or at the hand piece.
- ❖ You can stop the output by pressing the check button on the unit or at the hand piece.



## METHOD OF APPLICATION

1. Clean the skin by tissue paper or cotton, preferably wet cotton.
2. Position the patient in such a way that the application area is well visualized and patient can sit or lay down during the treatment. The ease of patient is of utmost importance.
3. Bring the machine near the patient.
4. Switch on the machine and set the desktop/Laptop software to record the readings.
5. Put the hand probe vibration point at the desired foot point and increase the power in Volts.
6. Ask the patient when he/she start feeling the vibrations and press the check button to confirm it.
7. Once confirmed, record the reading.
8. Do the same procedure at all the points and record the readings.

## About the Software

First you log on by your User ID and Password. Then the following screen will appear.

The screenshot shows a software window titled 'Patient Details' for 'GUPTA HOSPITAL'. It displays the date '02-02-22' and time '18:23:27'. The 'Patient Information' section includes fields for Name (Mr. Venut), Patient ID (23), Patient Type (Out Patient), Mobile No. (919130457), Email ID (abc@mail.com), Consultant (Dr. Aail), Specialization (Medicine), Referral Dr., and Technician (Ravi). There are 'SEARCH' and 'CLEAR' buttons. The 'Patient BMI' section shows Height (158 cm) and Weight (60 Kg), resulting in a BMI of 24.03 Kg/m<sup>2</sup>. A 'Habbits and Other Info.' section is also present. A 'VibraTest' button is visible at the bottom right.

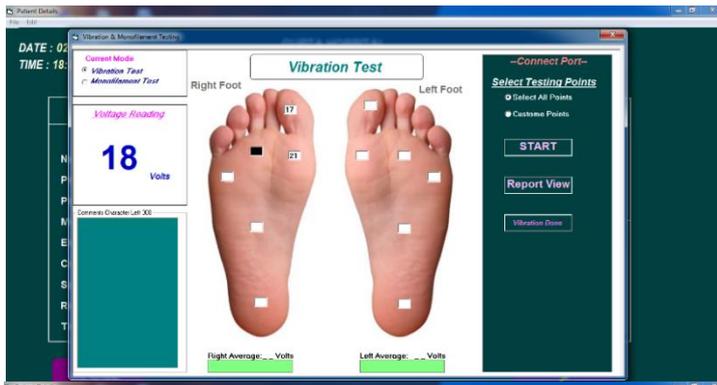
Add the Patient Name, Mobile no. ID and Date etc. and press the Vibra Test.

The screenshot shows the 'Vibration Test' interface. It features two foot diagrams labeled 'Right Foot' and 'Left Foot' with several 'X' marks indicating testing points. A large digital display shows '0 Volts'. On the right, there are 'Connect Port', 'Select Testing Points', 'START', 'Report View', and 'Vibration Done' buttons. The 'Current Mode' is set to 'Vibration Test'.

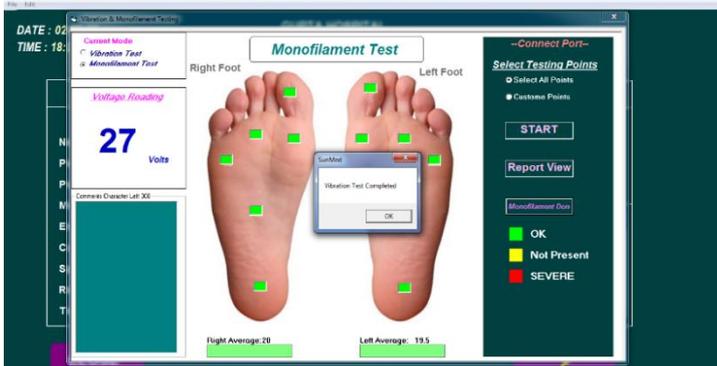
Keep the vibration point at the first point and start the test.

The screenshot shows the 'Vibration Test' interface with the digital display now showing '17 Volts'. The foot diagrams and control buttons remain the same as in the previous screenshot.

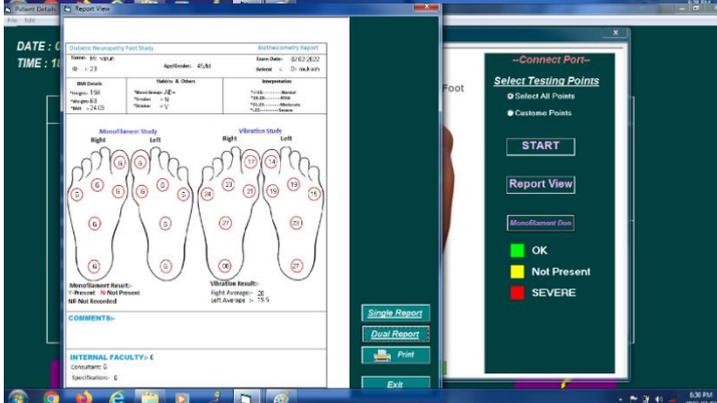
Increase the power and when patient feels it record the reading by pressing the record switch either at the unit or hand probe.



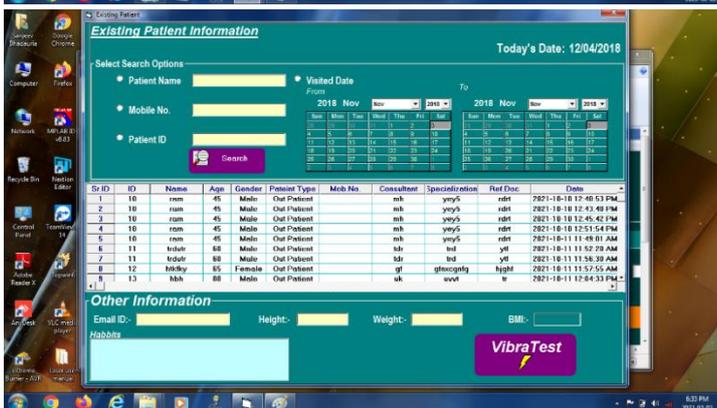
It will record the reading and then repeat the same step on all the points and record the readings.



Once it is done, it will show the screen with Vibration test completed.



Now you can see the result on the screen and Print out can be obtained by pressing the Print button.



Now you can see the patient record of all his visits.

## STANDARD ACCESSORIES

The Biothesiometer Unit will be supplied with the following accessories:

1. Main Unit: 1 No.
2. Applicator (Hand Probe): 1 No.
3. USB connector: 1 No.
4. USB cable: 1 No.
5. Software to be installed on your system: 1 No.
6. Mains Cable: 1 No.
7. User's Manual: 1 No.

## TECHNICAL SPECIFICATIONS

Mains Voltage	100-230v AC 50/60 Hz +-10% SMPS Supply
Maximum Power Consumption	40 VA
Output Intensity	0-50 V.
Emission Frequency	50 Hz ±10%
Port	RS 232 Port for USB converter
Fuse	1 Amp. (within AC Socket)
Weight	2.0 kg. (Approx.)
Dimensions (L x B x H) in.	8.5 x 7.5 x 3 in.

## MAINTENANCE

There is very little maintenance required for this Unit.

If the ON/OFF switch lamp is not glowing steadily when the switch is put on, the problem could be due to blown fuse. To replace a burnt out fuse, remove it from the fuse holder and replace it only with a 1A/250V Fuse. DISCONNECT THE POWER TO THE INSTRUMENT BEFORE REMOVING THE FUSE FROM THE HOLDER.

There are no other user serviceable parts inside the instrument. Refer all problems to the nearest dealer or write to us at our email: [sunmedisys@gmail.com](mailto:sunmedisys@gmail.com) , you can Also Visit us and write your Query at [sunmedisys.com](http://sunmedisys.com)

### *Replacement of Fuse:*

There is one mains fuse and one extra fuse in the within the mains fuse socket, to replace the mains fuse peel out the fuse socket with a finger nail and replace the fuse with the extra fuse - push the fuse back into the socket until you hear a click.

## WARNING

- ❖ Before using the equipment, the user should read carefully the instructions contained in this manual.
- ❖ Before treating a patient, the user should familiarize himself with the operating modes and have clear knowledge of indications & contraindications for the use of apparatus.
- ❖ Please insure this manual is readily available at all times to the personnel authorized to use the apparatus.
- ❖ For safety purpose, the power cord has been fitted with an earthed plug.
- ❖ ONLY USE AN EARTHED POWER SUPPLY SOCKET.
- ❖ The unit must be connected to approve power supply system.
- ❖ Do not use the apparatus close to SWD or MWD devices, may cause instability in output and functioning in program.
- ❖ Never leave the patient unattended during the treatment.
- ❖ The apparatus may not be used in so called “wet rooms” (hydro therapy rooms).
- ❖ Sun Medisys will not be responsible for Therapy Effects resulting from an improper use of the apparatus.

## WARRANTY CERTIFICATE

Customer Name - \_\_\_\_\_

Address - \_\_\_\_\_

Equipment Name - \_\_\_\_\_

Serial No. - \_\_\_\_\_

Warranty - From: \_\_\_\_\_ To: \_\_\_\_\_

The Instrument is under warrantee by the manufacturer for one year from the date of purchase and during this period, the defective parts shall be replaced or repaired, free of charges, if it is due to faulty material or workmanship, subject to the following Terms and Conditions.

- ❖ The Instrument should be used properly in accordance with the instructions as given in the instruction manual.
- ❖ The warranty does not cover the Instrument attended by others excepting our authorised service centre/dealer.
- ❖ Replacement of parts made of Rubber Electrodes, Laser Probe, Laser Diode, enclosure and carry bag are not covered within this Warranty.
- ❖ The cost incurred bringing the machine to our dealer's premises or service centre and back are to be borne by the customer.
- ❖ The Warranty does not cover the Instrument operated outside the range of stipulated Electric Supply.
- ❖ The decision of the manufacturer is final in all cases of warranty claims.

### HEREBY CERTIFIED

Yours's truly,

For Sun Medisys Inc.

**OUR OTHER PRODUCTS**



2 Channel TENS



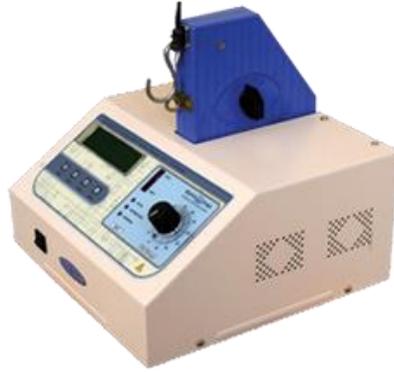
IFT/MST



4 Channel TENS PWM



Digital Traction



LCD Traction



Longwave



LASER



4 Channel LCD TENS



4 Channel TENS with battery backup



1 MHz Ultrasound



LCD Ultrasound



TENS/MST

For More Information, Visit us at [www.sunmedisys.com](http://www.sunmedisys.com), you can write any queries there or directly buy from us.

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