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भारतीय मानक मसौदा

दृष्टि बाधित व्यक्तियों के लिए यात्रा सहायक इलेक्ट्रॉनिक उपकरण (अल्ट्रासोनिक केन)

Draft Indian Standard

Electronic Travel Aids (Ultrasonic Canes) for Persons with Visual Impairment

Artificial Limbs, Rehabilitation Appliances and Equipment for the Persons with Disability Sectional Committee, MHD 09

Last Date for Comments: **07 October 2024**

FOREWORD

(Formal Clause will be added later)

Cane mountable obstacle detection devices for aiding travel for persons with visual impairment are referred to as Primary Electronic Travel Aids intended to assist a person with visual impairment or blindness in travel. The cane in conjugation with the device with the sensing capabilities is used to detect the obstacles from the ground to head height level of the cane user within a certain area in front of the user. Obstacles which are below knee can be detected by the cane itself whereas obstacles from knee to head height of the user are detected with the sensors on the device and information about them is conveyed to the user through vibrations, beep, or speech to the end user in real time. The intended user population include any person with visual impairment who is a regular user of white cane for his or her mobility needs can use such devices. Target age group is 15-50 years.

Indications:

a. People with complete blindness
b. People with low vision
c. People with deaf blindness

Contra- indications:

a. People who are not experienced to use the white cane.
b. Blindness accompanied with other disabilities (locomotor, intellectual etc.)

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for Rounding Off Numerical Values (second revision)’. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

1 SCOPE

This Indian Standard specifies requirements for a cane mountable proximity sensor-based obstacle detection device. The device aims at detection of obstacles in front of the user with visual impairment while walking with a certain detection range. It aids in obstacle avoidance which makes them perform simple daily tasks without dependence on others. It can be considered as a medical device for compensating the visual disability during travel.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

IS No.	Title
IS 17932 (Part 1): 2023	Biological Evaluation of Medical Devices Part 1 Evaluation and Testing within a Risk Management Process
IS 13276 (Part 1): 2000/ ISO 2631-1: 1997	Mechanical vibration and shock – Evaluation of human exposure to whole body vibration Part 1 General requirements (*first revision*)
IS/ISO 5349-1: 2001	Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration Part 1 General requirements (*first revision*)
IS/ISO 5349-2: 2001	Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration Part 2 Practical guidance for measurement at the workplace (*first revision*)
IS/IEC 60529: 2001	Degrees of protection provided by enclosures (IP Code)

3 TERMS AND DEFINITIONS

3.1 Visual Impairment and Blindness

It is the lack of vision or a loss of vision that cannot be corrected with glasses or contact lenses.

a. Partial blindness means limited vision.
b. Complete blindness, a generally used term, is the complete inability to see anything or any light. (Most people who use the term “blindness” mean complete blindness.)

3.2 Distance vision impairment

a. Mild – visual acuity worse than 6/12 to 6/18

b. Moderate – visual acuity worse than 6/18 to 6/60

c. Severe – visual acuity worse than 6/60 to 3/60

3.3 Near vision impairment:

Near vision impairment is when near visual acuity worse than N6 or M.08 at 40 cm.

A person’s experience of vision impairment varies depending upon many different factors. This includes for example, the availability of prevention and treatment interventions, access to

vision rehabilitation (including assistive products such as glasses or white canes) and whether the person experiences problems with inaccessible buildings, transport and information.

NOTE- According to WHO, the International Classification of Diseases 11 (2018) classifies vision impairment into two groups, distance and near presenting vision impairment.

4 GENERAL REQUIREMENTS

4.1 The cane mountable obstacle detection system must aim at enhancing the capability of the cane rather than replacing it for travel.
4.2 The unit should be light in weight without adding extra weight to the existing cane and at the same time without compromising in terms of strength, particularly impact strength.
4.3 The product can be mounted and detached on the existing white cane easily, without any sighted assistance.
4.4 The unit should be such that it has flexibility to be used by users having different styles of holding and different types of gripping.
4.5 As the angle of inclination of the cane varies from user to user, the product should have flexibility to be used with a wide range of inclination angles.
4.6 The user should be able to use existing white cane mounted with new navigational attachment without application of any additional force or torque.
4.7 The navigational unit needs to be mounted on the white cane in such a manner that obstacle sensing unit always points out in the intended direction without any undesirable rotations leading to missing of signal.
4.8 Whenever an obstacle is sensed, the feedback as a vibratory signal needs to be conveyed to user with an optimum intensity.
4.9 Feedback signal in terms of vibrations should be local and its transmittivity to entire cane and other unintended portions of the navigation unit should be minimized.

5 FUNCTIONAL REQUIREMENTS

5.1 Cane mountable obstacle detection device should enhance the mobility of people with visual impairment typically people with severe vision loss or blindness.

5.2 Such devices must aim at enhancing the capabilities of normal cane (straight or folding type) by:

a. Increasing the distance of detection of obstacles in the path while walking;
b. Having the capability to detect obstacles which cannot be detected with a normal cane typically the obstacles which do not have footprint on ground like overhanging tree branches, open glass windows, signboards etc.
c. May have additional capability to provide navigation instructions like directions, turns, distance etc.

5.3 Must be usable in indoor, outdoor, and in noisy environments.

5.4 The cane should be made of aluminium (or with materials of similar strength and durability) tubing with about 12 mm of outer diameter to maintain light weight and straight tubing.

5.5 Recommended length of the cane is directly proportional to the height of the user. When the cane is held straight, parallel to the body of the person with the cane tip touching the ground,

it should be at least above the waist level height up to a maximum of sternum bone level. A user can choose an appropriate length within this height range.

5.5.1 Typically, the cane length should be 70 to 90 cm for children, 100 to 120 cm for adults and 120 to 140 cm for tall adults.

a. The white canes should be strong, durable, and light weight to prevent fatigue and withstand certain amount of wear and tear during travel, and its parts should be replaceable.
b. The tubing (e.g. aluminium or graphite) should be 13 mm or smaller outer diameter for the main body of the white cane. The elastic cord used in folding cane should be of good quality to last long.
c. The handle should have rubber grip, and an elastic to hook the cane when not in use. The tip (e.g. Nylon) should have good durability and conductivity.
d. The device should be delivered with fully assembled white cane.
e. The tip should be made of durable (e.g. nylon) material and 2-3 cm thick.
f. The roller tip should be flexible enough to roll in 360 degrees.

5.6 Cane Mountable Device

Cane mountable device or module should fit on the cane and should have all the necessary sensors and the electronic circuitry using which obstacles from knee level to head level height are detected effectively and this information about the presence as well as distance of the nearest obstacle is conveyed to the user in real time.

5.7 Device Mounting and Locking on Cane

The device should have the mechanism to mount and fit on the cane. While walking, device must not become loose or move from its intended fixed position on the cane.

In case, user wants to detach the device from the cane for replacing the damaged or old cane, they must be able it by themselves without dependence on others.

5.8 Holding Part of the Device

The device grip from where the user will hold the device should have adequate texture for preventing slippage. Material should be sweat absorbent. The length of the handle should be less than the length of the top fold of the cane on which it is mounted.

The diameter of the section from where the user will hold the device must be as thin as possible thereby preventing any pain or discomfort in the hands of the user ever after several hours of continuous use. The device grip diameter must be less than 35 mm.

5.9 Sensor Direction

While walking, users should be able to discern whether the sensor is facing forward, which could cause them to lose the sense of direction. To ensure correct sensor orientation while walking, a tactile indicator must be marked on the device gripping area itself. It can be in the form of small depression or embossed marking which enforces the user to hold the device correctly with sensors always facing in the forward direction.

5.10 Sensor Coverage, Tilting and Locking Mechanism

If a single sensor is mounted on the cane, it should be able to detect obstacles from knee level to head height in front of the user throughout the detection range of the device.

The single sensor (receiver and transmitter pair or one transceiver) devices must have an angle tilting mechanism to ensure adequate coverage for:

1. People who will hold the cane inclined using sideways grip.
2. People who will hold the cane straight using fist grip.

Irrespective of the cane holding style of the person, the sensor must be able to detect the obstacles from the knee to head height of the person in the entire range of detection.

Sensor tilting mechanism must not be free to move and it must have fixed discrete positions according to the cane gripping style of the person. Tilling mechanism must support at least 2 discrete positions with a deviation of 20 degrees approximately with the cane axis. It should have proper locking mechanism which ensures that sensor position is not changed accidently while walking or even by accidental touch.

5.11 Orientation of Sensor

5.11.1 The following three parameters shall be considered for deciding the orientation of the directional sensors, whether accurate and reliable:

a. Location of the sensor on the cane (L),
b. Angle at which cane is held by the user (θ) and
c. Angle of the sensor with respect to the unit ($\emptyset$).

Since the location of transducer is fixed on the cane and angle of holding the cane varies from user to user, it is required to adjust the angle of the transducer with cane (**Fig. 1**).

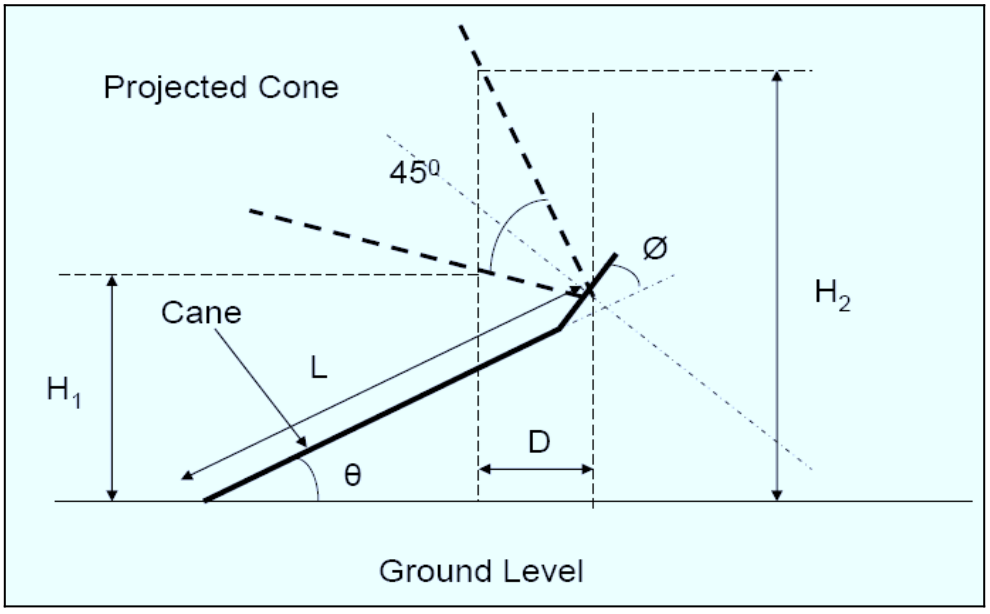

FIG. 1 ORIENTATION OF SENSOR

The following calculations give the correlation between $\emptyset$ and θ.

From Fig. 1:

$$\theta + \emptyset = ((1/\sqrt{2} - \sqrt{2} * D)/(H2 - H1)$$

Assuming for an average θ value of 55° based on standard style of holding the cane in an inclined manner, the angle $\emptyset$ can range from $0° \; to \; 30°$.

NOTE This flexibility and adjustability feature in the design will allow the user to correctly orient the detection cone of the sensor to cover obstacles from knee to head height of the person.

Alternatively, the cane should have more than one sensor, one for detecting obstacles in front of the user and the other for obstacles from shoulder to head height of the end-users.

Obstacles below the knee level height may not be considered for detection by the device as they are effectively detected with the cane itself.

5.11.2 The sensor coverage should not be too wide in horizontal direction. If a sensor detection cone is about 45° then the horizontal coverage of a distance of 3 m should be around 1.38 meters ± 10% as shown in **Fig. 2**.

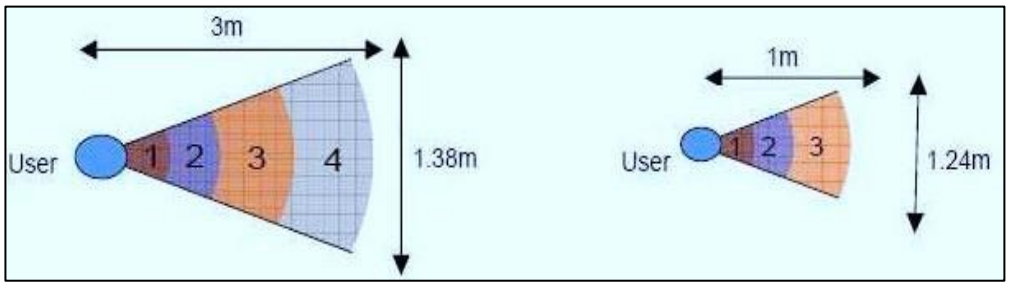

FIGURE 2 SENSOR COVERAGE

NOTE If the horizontal coverage is more than the recommended value, then walking through narrow coordinates or identifying open doors will become extremely difficult as a device will start detecting sidewalls as obstacles and the user will think there is an obstacle in front though in reality it will be a false positive from the sidewalls.

5.11.3 The vertical coverage of the sensor should be such that the obstacles appearing between the knee to height region in front of the user are reliably detected. As shown in **Fig. 3**, given a sensor with a detection cone of 45 degrees, at 2m, sensors should be able to detect the obstacles with the vertical height of 1.74 meters above the knee level. Obstacles from ground level to knee level height typically 0.64 m can still be detected with the normal cane.

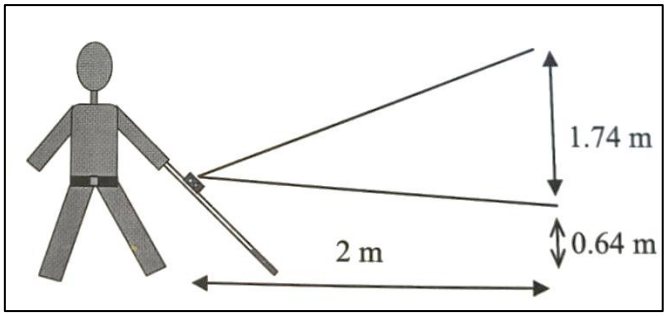

Fig. 3 Side view illustrating the vertical coverage of the detection zone at a distance of 2m from the user.

5.12 Detection Range

The system must provide an option for user adjustable detection range or modes depending on the type of environment in which the device is used, e.g. short range (less than or equal to 1.5 m) which may be used for travel in crowded places or indoor areas whereas long range (less than equal to 3.0 m) may be used for travel in open spaces like corridors, halls, or outdoor areas.

The detection range can further be subdivided into sub ranges and each sub range to be associated with unique vibratory pattern. User can infer the obstacle distance using this vibratory pattern.

5.13 Weight of the Device

The overall weight of the device must be within 500 mg and should be evenly distributed along the shaft on which it is to be mounted.

5.14 Indoor and Outdoor Use

The device should work effectively in indoor as well as outdoor environments. The specifications of the sensor technology used in the device must conform that it is designed for use in outdoor environments. Moreover, the information conveyed by the device should be usable, loud and strong enough to be understood in both the environments irrespective of the surrounding noise.

5.15 Materials

Materials that come in contact with the human body shall be assessed for biocompatibility using the guidance in IS 17932 (Part 1). The result of assessment shall be incorporated in the risk analysis and management.

5.16 Battery and Charge Level Indication

Safety of the person using the device depends on proper functioning of battery. There should means to indicate the user regarding the charge level/state of charge of the power supply, and must be provided.

At the time of indicating the critical charge, sufficient reserve charge of the internal power supply shall be available to allow timely reaction.

A timely reaction can be either recharging or replacing the power supply without interruption of the availability of the power, till the recharge of the internal power supply can be done.

Either the exact charge level be conveyed to the user or at least the approximate charge level be conveyed to the user.

5.16.1 High-Capacity Rechargeable Battery

Mobility requires continuous use without the need of recharging. The capacity of the device battery should be chosen in such a way that it should provide 6 to 8 hours of continuous use (considering worst case scenario of maximum power dissipation) without the need of recharging the device.

5.16.2 Charging Port

The device should have a symmetrical charging port (like Type-C USB) so that user can insert the charging connector from any side without damaging the port. If the port is asymmetrical (like micro-USB), then there should be a tactile (embossed, textured, or depressed) indicator around the port to indicate the correct orientation for inserting the charging connector.

5.16.3 Accessible Battery Level Indicators

The device should provide battery level information to the user at the time of powering ON. The user must also be able to check the battery status as per its own preference.

Battery level indication may be provided through simple beeps and vibrations patterns like:

a) Three beeps with 3 short vibrations for FULL battery
b) Two beeps with 2 short vibrations for 50% battery
c) One beep with 1 short vibration for 30% battery
d) Periodic beep and vibration for low battery
e) A distinct and easily recognizable alarm when battery is completely discharged.

In case of a device that supports Bluetooth connectivity, the battery information can be conveyed accurately on a smartphone application. The application may also generate appropriate notifications, such as, if the battery charging is complete or low battery, prompting the user to take the corrective action.

5.17 Noise and Vibration

Manufacturers must evaluate the noise and vibration from the powered canes in the intended environment(s) of use.

Noise should be reduced as much as possible at the source. Noise levels should be related to the circumstances in which an assistive product is used. The effects of vibration should be checked as per the following:

a. IS 13276 (Part 1);
b. IS/ISO 5349-1;
c. IS/ISO 5349-2.

Alternatively, manufacturers should determine what appropriate methods of test are available in other standards and supplement these with a panel consisting of users with a disability, career and appropriate professionals to assess the acceptability of noise and vibration.

5.17.1 Option to Control Vibration Intensity

The device should allow the user to control the intensity of vibrations used to convey distance and/or related information to the user. The vibration feedback options should be limited to no more than four intensity levels. Too many options might hinder with the user adaptation by presenting an overload of intensity levels.

5.18 Ingress of Liquid

In case of any liquid that can come into an enclosure unintentionally, there shall be a way for the liquid to be removed from the enclosure or render the liquid as harmless.

The device that is not in contact with water during normal use of reasonably foreseeable misuse (e.g. during the cleaning process) shall at least be protected as per IPX2 of IS/IEC 60529.

5.19 Portability

A portable device or any of its parts, that is portable, shall withstand the stress caused by a free fall from the height onto a hard surface.

Mass (m) of portable assistive device or its parts (Kgs)	**Drop Height (cm)**
$m < 0.2$	100
$0.2 < m < 1$	20
$1 < m < 10$	5
$10 < m < 50$	3
$m > 50$	2

The sample to be tested, with the maximum load in place, is lifted to a height above a thick hardwood board that lies flat on a concrete floor or a similar rigid base. The dimensions of the board shall be at least those of the footprint of the sample being tested. The sample is dropped three times from each orientation in which it may be placed during the intended use.

After the test, any damage sustained which results in an unacceptable risk is determined by inspection of the risk management file and inspection of the assistive product parts that are portable, constitutes a failure.

5.20 Accessible User Interface

5.20.1 Buttons

The buttons provided on the device for controlling its operation (power button, range adjustment button etc.) must be easily identifiable, distinguishable, and usable by the persons with visual impairment and blindness.

For easy identification, distinction and accessibility, buttons should either have distinct shape or textures or embossed symbols around them or Braille labels.

Operating a button should be intuitive for the end users. They can be clickable or a slider or toggle. At the same time, the design of the buttons should be such that accidental change of state while using or storing the device should not occur.

5.20.2 Device Output

5.20.2.1 Output information from the device must be conveyed to the end-user through vibrations and/or beeps.

5.20.2.2 The patterns of vibrations and beeps must be intuitive, distinct, and usable in real time while the device is under use.

5.20.2.3 The device must also convey information about the failure of the key components like sensor and vibrator to ensure that the user is not misguided by malfunctioning of the device which may result in collision or even injury.

5.20.2.4 In case, speech is also used for conveying the information then the speech rate must be adjustable so that users can set it according to their own preferences while travelling with the device.

5.21 Applicable Standards

The cane mountable obstacle detection device is used for assisting persons with visual impairment during travel which makes them perform simple daily tasks without depending on others. As it is considered as a medical device for compensating the disability, it must conform to the standards for important aspects, as applicable to a medical device, given at **Table 1** of **Annex-A**.

6 REQUIREMENTS OF INFORMATION SUPPLIED BY THE MANUFACTURER

6.1 General

6.1.1 The manufacturer shall provide the information comprising of all data in the instructions for use. All information shall be in accessible formats.

6.1.2 The information shall take in to account the intended users, the conditions of use and any issues specific to individual assistive product type that are necessary for the safe and effective use of the product.

6.1.3 Special attention shall be paid to accessibility of the user information, particularly the instructions for use and the design of labels and the design and presentation of warnings.

6.1.4 Instructions for use

The manufacturer should provide the information in the format appropriate for use by persons with visual impairment and blindness. It should be categorized in into pre-sale information, user information and service information. Information must be accessible and meet the needs of the individual users.

7 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*,

2016 and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.

8 PACKAGING

8.1 The design of the packaging should be such that end user should be able to unpack the device from the package on their own without any need of help from others. The information about the device on the package should be accessible to the end-user.

8.2 All the necessary accessories and spare parts should be included in the package. If any special tools are required, it should be included with the delivery. Each white cane should be delivered in an individual package with a label clearly stating the details of the product. The package should withstand handling during transportation.

ANNEX-A

(Clause 5.21)

Table 1 Applicable Standards

S. No	Standard	Title
QUALITY MANAGEMENT SYSTEM		
1.	IS/ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
RISK MANAGEMENT		
2.	IS/ISO 14971: 2019	Medical devices – Application of risk management to medical devices
SAFETY / APPLICABILITY		
3.	IS 13450 (Part 1): 2024	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
4.	IS 13450 (Part 1/Sec 11): 2024	Medical Electrical Equipment Part 1 General requirements for basic safety and essential performance Section 11 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
5.	IS/ISO 62304: 2015	Medical device software – Software life-cycle processes
USABILITY REQUIREMENTS		
6.	IS 13450 (Part 1/Sec 6): 2024	Medical electrical equipment Part 1 General requirements for basic safety and essential performance Section 6 Usability
INFORMATIONAL (LABEL & IFU) STANDARDS		
7.	IS/ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1 General requirements
8.	IS/ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer