hinscope
Instructions for Use

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WARNING: to properly use this medical device, read and comply with these Instructions for Use.

WARNING: hinscope is intended for use by qualified medical personnel only.

hinscope is not registered for use in private households and may not be disposed of at municipal collection points for waste electrical and electronic equipment. hinlab has authorised a firm to dispose of this device properly. For more detailed information, please contact hinlab.

Indications for use

Hinscope is intended for spot-check vital signs measurement of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities. It is intended to be used by trained healthcare professionals.

Hinscope is intended for spot-check measurements, in adults, of:

- Non-Invasive Blood Pressure (NIBP)
- Pulse rate (PR)
- Oxygen saturation (SpO2)

Hinscope is not intended for use in high-acuity environments, such as intensive care units (ICU) or operating rooms.

Hinscope is not intended for use on acutely ill cardiac patients with the potential to develop life-threatening arrhythmias e.g. very fast atrial fibrillation. These patients should be monitored using a device with continuous electrocardiogram (ECG). Hinscope is not a substitute for an ECG monitor.

Hinscope is not intended for SpO2 and PR measurements in conditions of high motion or low perfusion.

1. Intended Population

hinscope is intended to be used by adult population with arm circumference ranging from 22cm to 32cm (8.66 to 12.6 inches). There are no restrictions related to the user's sex and ethnicity.

Contraindications:

- Do not use the device with patients in critical care settings.
- Do not use the device with patients known to have allergies to adhesives and/or silicon.
- Do not use the device in an MRI environment.
- Do not use the device with patients who have implantable devices (pacemakers, automatic defibrillators, etc.).
- Do not use the device with patients who have localized infection, ulceration, or skin lesions at the device location.
- Do not use the device on tattooed skin, or on moles or freckles.
- Do not use the device with neonatal or pediatric patients.
- Do not use the device with pregnant or breastfeeding women.

*CAUTION**:** Federal law restricts this device to sale by or on the order of a licensed practitioner.*

WARNING: This device has not been evaluated in patients with possible arrhythmias such as Atrial Fibrillation.

2. Documentation Features

2.1 Warnings and cautions

This manual explains how to set up and use hinscope. Important safety information relating to the general use of hinscope appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

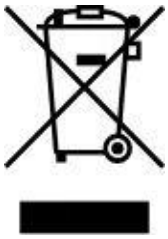
A warning is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.
WARNING: This is an example of a warning statement.

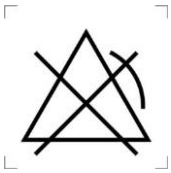
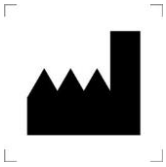
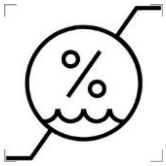
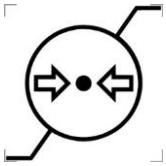
A caution is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.
CAUTION: This is an example of a caution statement.

A note is given when additional general information is applicable.
Note: This is an example of a note.

2.2 Symbol glossary

Symbol	Symbol visual	Symbol definition	Standard title	Symbol title and reference number
Reference		Indicates the manufacturer's catalogue number so that the medical device can be identified	Catalogue number	ISO 7000-2493 2004-01-15
Radio-waves emission		To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	Non-ionizing electromagnetic radiation	IEC 60417-5140 2003-04-04
FCC Logo		The electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission	FCC Logo	47 CFR 2.1074(b)

Disposable		To indicate that separate collection for waste electric and electronic equipment (WEEE) is required.	WEEE; waste electrical and electronic equipment; crossed-out wheeled bin	IEC 60417-6414 2019-08-03
Ingress protection (IP67)	IP67	Code defining the degree of protection provided by the enclosure. IP67 meaning that the equipment is dust-tight, and able to resist to temporary immersion	Degrees of protection provided by enclosures (IP Code)	IEC 60529-IP67
MR Unsafe		An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	MR Unsafe	ASTM F2503 – 13, 7.3.3
Prescription	Rx only	Federal law restricts this device to sale by or on the order of a licensed practitioner	Prescription device	21 CFR 801.109(b)(1)
Manufacturing date		Indicates the date when the medical device was manufactured	Date of manufacture	ISO 7000-2497 2004-01-15
Serial number		Indicates the manufacturer's serial number so that a specific medical device can be identified	Serial number	ISO 7000-2498 2004-01-15
Warning		Caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	Caution	ISO 7000-0434A 2004-01-15

Read instruction for use		To signify that the instruction manual/booklet must be read	Refer to instruction manual/booklet	ISO 7010-M002 2011-05-01
Type BF device		To identify a type BF applied part complying with IEC 60601-1	Type BF applied part	IEC 60417-5333 2002-10-07
No SpO2 alarm		To identify the alarm inhibit on control equipment	Alarm inhibit	IEC 60417-5319 2002-11-03
MD identification		Indicates the item is a medical device	Medical device	ISO 15223-1 Ref 5.7.7
Manufacturer name with address		Indicates the medical device manufacturer	Manufacturer	ISO 7000-3082 2011-10-02
Storage conditions (humidity)		Indicates the range of humidity to which the medical device can be safely exposed	Humidity limitation	ISO 7000-2620 2004-01-15
Storage conditions (temperature)		Indicates the temperature limits to which the medical device can be safely exposed	Temperature limit	ISO 7000-0632 2014-06-04
Storage conditions (pressure)		Indicates the range of atmospheric pressure to which the medical device can be safely exposed	Atmospheric pressure limitation	ISO 7000-2621 2004-01-15

The device wears a Unique Device Identifier (UDI), which can be found on its bottom case. The information encoded contains all the characters written next to the DataMatrix, known as Human Readable Interpretation (HRI), which are:

- GS1 AI 01 : Global Trade Item Number (GTIN)

- GS1 AI 11 : Production Date (YYMMDD)
- GS1 AI 21 : Serial Number

2.3 List of Abbreviations

BP: Blood Pressure

ECG: Electrocardiogram

EMC: Electromagnetic Compatibility

ICU: Intensive Care Unit

LED: Light Emitting Diode

RF: Radio frequency

RPM: Respirations per Minute

SpO2: Peripheral oxygen saturation

WEEE: Waste Electrical and Electronic Equipment

mmHg: Millimetre of mercury, which is a unit of pressure measurement (1 mmHg = 133.322 pascals)

bpm: Beats per minute

3. Safety Considerations

These Instructions for Use assume a working knowledge of vital signs spot checking. To support proper, safe, and accurate operation of equipment, read all operating instructions carefully before using hinscope. hinscope should only be used by trained healthcare professionals.

WARNING: To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use and on equipment labels.

WARNING: No modification of the equipment is allowed. Modification of this equipment may cause interference with other devices, injury to patient and user including electric shock, burns or death.

4. Site of Operation

Only use in areas that meet the environmental requirements outlined in the technical data section.

hinscope is intended to be used in professional healthcare facility environments including physician offices, outpatient facilities, clinics, limited care facilities, and hospital patient rooms.

WARNING: Do not operate the equipment in areas such as: magnetic resonance imaging (MRI) environments, aircraft, ambulance, home or hyperbaric chambers.

WARNING: Do not operate the equipment in close proximity to equipment that emits microwave or other high-frequency emissions since they may interfere with the device's operation.

WARNING: hinscope can not be used in oxygen rich environment.

This equipment is neither approved nor certified for use in areas where oxygen concentrations are greater than 25% or where combustible or explosive gas mixtures are likely to occur.

The device must not be used at the same time as any flammable gas.

5. Maintenance

hinlab equipment will be maintained by hinlab staff only.

The device must undergo regular maintenance inspection every 2 years. If stored for extended periods without being used, make sure prior to operation that the device is in perfect operating condition.

The accuracy of this multifunctional device has been properly tested and its durability has been designed for long-term use. In the context of medical use of the device, technical measurement checks must be carried out with the appropriate means.

The device is not intended to be disassembled or opened except by hinlab for product maintenance. Batteries are intended to be changed only by hinlab service personnel using the appropriate tool. Do not service or maintain hinscope while in use with the patient.

Consult authorized hinlab representative for further information.

Verification of the oximeter's function can be verified with specific test equipment. Consult authorized hinlab representative for further information.

WARNING: Risk of infection. Technical staff can become infected with pathogenic germs. Disinfect and clean the equipment before returning the medical device for repair.

WARNING: Risk of faulty components. Device failure is possible due to wear or material fatigue of the components. To maintain proper operation of all components, this device must undergo inspection every two years (check following manometer mode maintenance procedure for detailed instructions).

WARNING: Repair of the device may only be carried out by the manufacturer otherwise the correct functioning of the device may be compromised.

WARNING: Inspect the cuff on a regular basis and ask hinlab to replace with a new cuff if appropriate.

6. Cleaning and Disinfecting

Cleaning instructions

WARNING: Do not autoclave or sterilize the wearable device or any part of the Hinlab measurement system.

The device is reusable and may be used for more than one patient.

The reusable equipment must be decontaminated following every episode of use and before being sent for service or repair. This is to ensure the safety of both patients and staff.

If any soil is visible on the device, the healthcare provider must remove it before drying with the appropriate wipe (see below). The cleaning of the device occurs as soon as possible when the device is withdrawn from the patient, because soil can dry and get harder to remove.

Inspect equipment surfaces for breaks in integrity that would impair cleaning. Discard the equipment that no longer functions as intended or cannot be properly cleaned.

The device is considered thoroughly clean when:

- There is no visible soil on all surfaces of the device
- The wipe has been wiped over the total surface of the device following the cleaning instructions

The following accessory is needed:

- Wipe with isopropyl alcohol (70–90%), or wipe with other common cleaning agents recommended by CDC guidelines https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

The use of a wipe is the following:

- Rub the device by hand, without undue pressure
- If the wipe is visually contaminated on more than half of its surface, the wipe must be changed

The cleaning of the device must be carried out at room temperature, must be performed manually, and must not take less than 1 minute.

To clean the device, it is imperative to stick to the following instructions, according to the previous measures:

1. Visually check that the device is unbroken
    - if the device is broken, dispose of it
    - if the device is not broken follow the instructions

2. Remove all visible soiling with the appropriate wipe
    - if the wipe is visually contaminated on more than half its surface dispose of it into clinical waste and use a new one

3. Once the device is visually clean, take a new wipe and pass it over the total device surface for at least one minute
    - don’t pass over the same surface twice to avoid any cross-contamination

4. Visually check that the device is clean
    - if the device is still contaminated repeat the cleaning or dispose of the device

Disinfection instructions

The disinfection of the device must be performed after it has been correclty cleaned.

The disinfection instructions are supposed to follow the same steps as the ones of the “Cleaning instructions”.

The needed accessory to use to disinfect the device is a wipe with isopropyl alcohol (70–90%), or a wipe with other common cleaning agents, as recommended by CDC guidelines for a low-level disinfection.

By following such instructions, the microbicidal process is considered as low-level disinfection.

7. Storage

Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas, and dust, saline or sulphuric air.

Avoid vibration and mechanical shock to the device, even during transport.

Avoid placing the device in an area where chemicals are stored or where there is danger of gas leakage.

The instrument shall be stored in a dry environment and away from sunlight.

8. Defibrillator Precautions

WARNING: hinscope and any other applied device parts should be removed before patient defibrillation.

9. Medical Device Disposal

WARNING: Risk of infection. The device and its components must be disinfected and cleaned before disposal.

When disposing of hinscope, please return to hinlab and observe all applicable laws and regulations.

The return to hinlab will be arranged via the Support Center.

The device is not registered for use in private households, and may not be disposed of at municipal collection points for waste electrical and electronic equipment.

hinlab has authorized a firm to dispose of hinlab equipment in the proper manner. For more detailed information, please contact hinlab.

10. Cybersecurity

hinlab has taken significant steps to protect its system from cyberattacks, but the user has a crucial role in maintaining cybersecurity. The guidelines in this section must be followed.

No protected health information is stored within hinscope, nor transmitted by hinscope. Communications within hinscope different components (device, mobile application) are encrypted to an industry-standard.

The hinscope mobile application can be installed on an Android platform.

10.1 Periodical software updates and patches

On Android, the hinscope mobile application should be updated as soon as a new version becomes available. When a new version does become available, the user will receive an update of the app in-place via an email from hinlab.

To install this new version, the user should uninstall its current version and install the new one.

In case of concern or issue during the update process, contact hinlab's support.

10.2 Dealing with a lost or stolen hinscope

In case a hinscope is lost or stolen, please notify hinlab.

10.3 General guidelines for security

- It is recommended that any mobile device with the hinscope mobile application installed also has a device passcode set.
- Never disclose protected health information within a support message to hinlab. This includes details such as a patient's name or date of birth.

11. Measuring with hinscope

hinlab allows wearable, multi-parameter physiologic measurement in non-critical care environments within professional healthcare facilities, such as general medical-surgical units or skilled nursing facilities.

11.1 System hardware components

Figure 1 hinscope device

11.2 System software components

The system has one application, the hinscope mobile application. This application runs on tablets and smartphones with Android 12 and higher.

The hinscope mobile application provides access to vital signs, such as BP or SpO2, measured by the hinscope device . It can also provide access to battery level and the firmware version of the hinscope device.

12. hinscope Battery Life

The hinscope mobile application allows monitoring of device battery life for devices that are paired to a patient, and actively transmitting data.

WARNING: Batteries are intended to be changed only by hinlab approved personnel using a tool, when incorrect replacement would result in damaging the device and possibly hurt the operator or the patient.

WARNING: The wearable device contains a lithium polymer battery. Do not incinerate the device or place in a trash compactor. Do not puncture the battery.

CAUTION: The battery charge level displayed in the user interface is only accurate if the battery is in normal working condition.

13. Charging

WARNING: To avoid electrical shock, inspect all cables before use. Never use cables that appear cracked, worn or damaged in any way.

WARNING: Worn out or defective batteries can significantly reduce battery capacity or the operating time.

WARNING: Only hinlab approved peripherals should be connected to the device (wireless charger Qi V1.2 compatible).

hinscope is charged wirelessly.

CAUTION: Remove any foreign object between the charging base and hinscope.

hinscope has a battery life of approximately 3 days with an average of 10 measurements per day (with hinscope in deep sleep mode while not measuring).

The LED indicator will flash white until battery level reaches 95%, then it will turn solid white.

When the device is not charging, the LED color indicates battery level:

- Green if battery level is over 20%
- Orange if battery level is below 20%

WARNING: When battery level is below 20%, hinlab cannot guarantee measurement accuracy.

LED color/ LED status	Solid	Flashing
No color	hinscope switched OFF	
White	While charging battery over 95%	While charging battery below 95%
Green	Connected to hinscope mobile application	Ready to connect to hinscope mobile application
Orange	Battery below 20% and connected to hinscope mobile application	Battery below 20% and ready to connect to hinscope mobile application
Blue	hinscope is starting	--
Purple	hinscope in a error mode. Contact support for assistance.	

WARNING: In order to get LED status, if hinscope is switched OFF (no color), switch ON hinscope by pressing ON/OFF button before putting hinscope on an appropriate wireless charger.

WARNING: if hinscope is not switched ON after pressing ON/OFF button, put hinscope on an appropriate wireless charger and wait for the LED status to blink in white.

14. hinscope Setup & Management

CAUTION: Do not apply hinscope on open wounds, sores, or cuts.

CAUTION: If redness appears during use, remove the device.

WARNING: Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.

WARNING: Rest for at least 5 minutes before taking a measurement.

14.1 hinscope

hinscope is worn on the upper arm of the patient using the supplied cuff.

hinscope is re-usable. Please review cleaning and disinfection instructions.

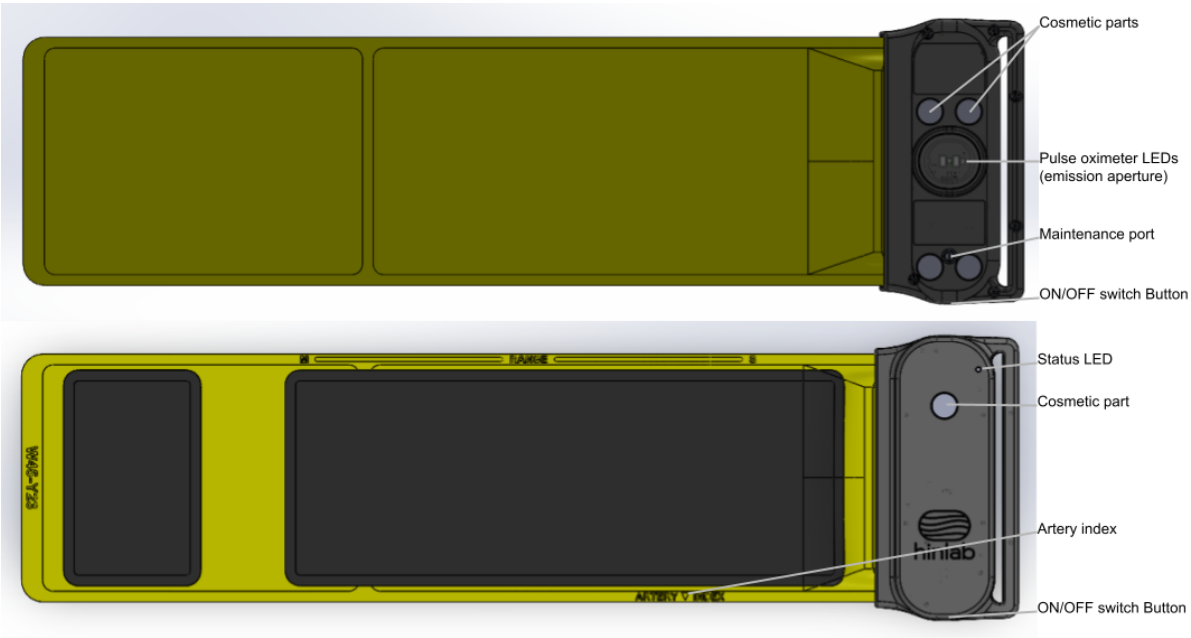


Figure 2 hinscope device front and rear views

14.2 Installing the device

Check that the device is in perfect operating order, without any break on the casing.

Pay extra attention when the instrument is combined with other instruments to avoid misdiagnosis or other problems.

Check that battery level is acceptable and battery condition is good when using the device.

Check that the limb has no wound and that the skin is in good condition.

WARNING: do not apply the cuff over a wound, as this can cause further injury.

Warn the patient that the compression might cause minor irritations in sensitive patients.

Warn the patient that the instrument might cause reactions in patients sensitive to magnetic fields.

14.3 Fitting the device

hinscope is intended to be used by adult population with arm circumference ranging from 22cm to 32cm (about 8.66 to 12.6 inches).

Place hinscope correctly on the arm of the patient before taking a measurement.

1. Remove garments from the upper arm. If the sleeve is rolled up, please ensure that the garment is not too tight so that it does not cause any blood flow constriction.
2. Place the bare arm through the cuff and position the cuff 1/2 inch (1 to 2 cm) above the elbow joint.
3. Place the cuff on the left arm, taking into account the UP and DOWN indications.
4. Align the arrow on the cuff with patient's artery.
5. Tighten the cuff around the arm so that it fits tightly, but with enough space to still insert two fingers between patient's arm and the cuff.

WARNING: Remove tight-fitting, thick clothing from your arm while taking a measurement.

WARNING: ONLY use the arm cuff on persons whose arm circumference is within the specified range of the cuff.

14.4 Starting hinscope

When hinscope is first used new:

- Switch on hinscope by pressing the ON/OFF button. The LED on the device blinks orange or green.
- Put hinscope on the wireless charger. The LED blinks white.
- Wait until the LED turns solid white.

hinscope is ready to use when the LED is solid white. hinscope can be switched on and off by pressing the ON/OFF button.

14.5 Sensor data transmission

WARNING: Removing hinscope from Bluetooth range will prevent transmission of signal data generated from the patient.

Only the hinscope mobile application and hinscope device can communicate with each other.

hinscope transmits physiological signal data over standard BLE (Bluetooth Low Energy).

If hinscope is removed from Bluetooth range, sensor data is lost and measurement is stopped.

14.6 Mobile Application Messages and Symbols

This section lists the messages and the symbols displayed by the user interface to the operator.

14.6.1 Messages

Displayed messages	Causes	Actions for the operator
"No nearby device detected, re-scan"	• The device is switched off. • The device is already connected to a hinscope application on another mobile device. • The device is too far away from the mobile device. • The bluetooth is not connected with the device where the application is located.	• Turn the device on. • Turn off and then turn on the hinscope device to disconnect it from a mobile device. • Bring the device closer. • Turn on the bluetooth
"hinscope is asking to turn on Bluetooth"	The bluetooth is not turned on in the mobile device.	Click on "Allow".
"Status: Connecting"	The device is connecting to the application.	Wait until the status is "Connected" and the LED of the device is solid.
"Status: Connected"	The device is connected to the application and ready to start a measurement.	Click on "Start Measure" when wanting to launch a measurement.
"Status: Measuring"	The device is currently doing a measurement.	Wait for it to finish or click on "stop measure" if you want to stop the measurement.
"Status: Done"	The device has finished a measurement.	• Take the measurement again if wanted. • Quit the application if wanted.

“Status: Measure stopped”	• The operator clicked on “Stop Measure”, stopping the measurement and the device is deflating. • The measurement last for more than 160 seconds and the device is deflating.	• Take the measurement again if wanted. • Quit the application if wanted.
“SpO2 Relaunch %” or/and “PR Relaunch bpm” or/and “Sys/Dias Relaunch”	The device was unable to measure the vital sign because it detected an element such as movement or low perfusion that prevented the measurement.	Take the measurement again.
Out of range	The device was unable to measure the vital sign because it detected that the measure was outside the range specified in section 21.4	Take the measurement again.

14.6.2 Abbreviations, symbols and warnings

Abbreviations/symbols/warnings	**Definition**
SpO2	Peripheral Oxygen Saturation
PR	Pulse Rate
Sys/Dias	Systolic / Diastolic
mmHg	Millimeter of mercury
bpm	beats per minute
%	percentage
s	seconds
A timer with a value from 0 to 30 seconds appears.	Indicates to the operator how many seconds since the displayed value was calculated.
‘over 30s’ next to PR or Spo2 value.	Indicates to the operator that the displayed pulse rate and SpO2 data is not the current values, or, was calculated more than 30 seconds ago.

15. Admission and Discharge

WARNING: Healthcare professionals should inspect the physical condition of the device before assigning it to a patient.

WARNING: Visually check that the device has been placed securely against the skin. The cuff should be comfortable.

WARNING: Excessive cuff tightness may cause a pressure injury.

The admission process is a step-by-step process that includes mandatory and optional stages dependent on the local operating institution's configuration.

16. Measuring Vital Signs

16.1 Position of the patient and operator

Follow instructions in the manual to install the device: "15.3 Fitting the device".

Then:

1. The operator must be next to the patient during the complete measurement process.
2. The patient shall sit upright with back straight and feet flat on the floor.
3. Patient's hand should be placed palm-side up on a flat surface such as a desk or a table.
4. The middle of the cuff should be placed as the same level as the heart.
5. Arm muscles should be relaxed during measurement.
6. Patient's legs should not be crossed.
7. Patient should stay relaxed and avoid talking.

Figure 3 Position of patient during measurement

Once the device is on the patient’s arm, wait five minutes before starting the measurement so that blood pressure can stabilize.

Stop the operation in case of visible artery occlusion resulting in nerve ischemia.

Do not expose the patient's eyes to the light of the LEDs.

Make sure the patient is not having an allergic reaction to the device.

After measurement, if unexpected readings are obtained, remove the cuff and then put it on the patient again. Relaunch another measurement.

Note: the recommended maximum hinscope application time at a single site is 5 minutes.

Note: Blood pressure readings can be affected by the measurement site, the position of the patient, exercise, or the patient’s physiologic condition.

Note: Not following the above recommendations for the position of the patient or if the patient is talking or moving during the measure can affect the performance of the automated sphygmomanometer and its blood pressure reading.

Note: The performance of the sphygmomanometer can be affected by extremes of temperature, humidity and altitude.

CAUTION: if the cuff is still inflated after 180 seconds or the measurement exceed 180 seconds, the device is making an error, the device shall be removed from the patient arm. It may cause discomfort to the patient's arm.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

CAUTION: hinscope should be protected against unauthorised use.

16.2 Launch a measurement

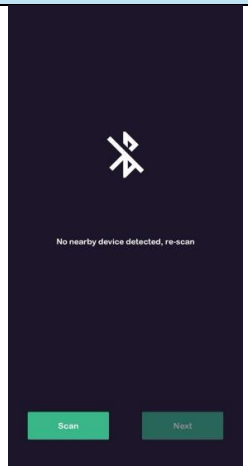
1. To take a reading, the patient shall sit comfortably and rest the arm on a flat surface.
2. Open the application and tap the "Measure" button.
3. Follow the on-screen instructions to begin the reading.
4. Once the reading is complete, results will be displayed on the screen.
5. View readings on the application.

WARNING: Remain still and DO NOT talk while taking a measurement.

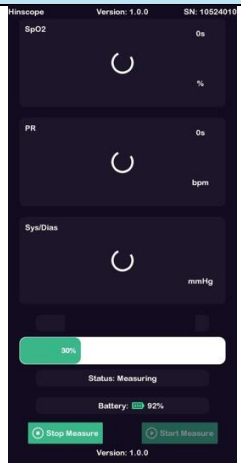
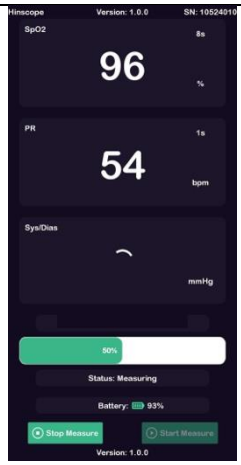
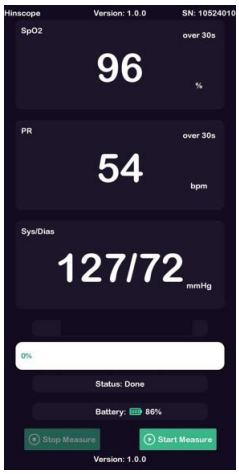
16.3 Mobile application instructions

Make sure Bluetooth and Location on mobile device are enabled before opening the mobile application.

Screen	Display on Screen
Home screen (wait two seconds) The version of the mobile application is visible on this screen.	
Device connection screen 1. Click on ‘Scan’.	

Screen	Display on Screen
2. Click on your device's name. MAC addresses are also displayed. If your device is not available in the list (see Section 14.6.1 for more details). 3. After selecting the device, click on "Next". Only one hinscope device can be selected and connected at a time. The device integrated software version is visible for each detected device in the list.	 *Connection screen when no device is found*  *List of available devices* 

Screen	Display on Screen
	 *The device is selected*
Measurement screen 1. Wait until the Status tab indicates 'Connected' (see Section 14.6.1 for more information on the different statuses). 2. The device LED should be solid green or solid orange (no longer flashing). 3. Click on 'Start Measure' to start a measurement. At the bottom, next to the word “Battery”, a battery symbol is present. Each bar of the symbol represents 20% and the percentage indicates the device's battery level. At the top left, is the name of the device connected to the application. At top right, is the MAC address of the device connected to the application. The version of the mobile application is also visible on this screen.	 *Waiting for a measure*
Measurement screen During a measurement: 1. Several rotating circles indicate that a measurement is in progress.	

Screen	Display on Screen
2. The progress bar, in percentage, is increasing. 3. The 'Start Measure' button is no longer clickable (grayed out). 4. The 'Stop Measure' button is clickable (green) if you need to stop a measurement in progress. In case of an emergency, click on the "Stop Measure" button to immediately stop the measurement.	 *The measurement has started*
Measurement screen After one minute, a SpO2 value and a PR value appear. When a vital sign value appears, a time delay starts up to 30 seconds (see Section 14.6.1 to find out more info on the time delay). When these values are displayed, the device inflates more to calculate blood pressure. Once the progress bar reaches 100%, systolic and diastolic values are displayed. The device deflates. When the measurement is stopped (due to the end of the measurement or intentionally by clicking on 'Stop Measure'), the 'Start Measure' button can be clicked to repeat the measurement. You can also go back to the previous screen to select another device.	 *SpO2 and PR values have been received*  *Blood pressure values have been received*

17. Troubleshooting

If hinscope fails to connect to the application, ensure that Bluetooth is enabled on the mobile device and that hincope is within range.

If the LED turns to flashing purple, please contact support for assistance.

If there are any other issues with the application or device, please contact support for assistance.

18. Overall spot-check measurement sequence

The spot-check measurement takes place in two steps:

1. First, the SpO2 and PR vital signs are measured for a maximum duration of 50 seconds.
2. Second, the BP measure is automatically launched after the SpO2 and PR values are displayed. The cuff will start inflating until reaching an adequate pressure above the systolic. Once the measure is completed, the cuff will automatically deflate and the systolic (Sys) and diastolic (Dias) blood pressures will be displayed.

19. Pulse Rate and Pulse Oximetry

WARNING: The device should not be placed over a tattoo - doing so may prevent calculation of an accurate pulse rate or SpO2.

WARNING: hinscope should not be used as an apnea monitor.

WARNING: SpO2 measurements are particularly sensitive to the pulsations in the artery and the arteriole. Measurements may not be accurate if the patient is experiencing shock, hypothermia, anemia or has received certain medications that reduce the blood flow in the arteries.

WARNING: Movement, ambient light and low perfusion may affect SpO2 and pulse rate calculation and accuracy. hinlab is not intended for use in calculating accurate SpO2 during periods of high motion, high ambient light and low perfusion conditions.

19.1 Principle of Operation

Pulse oximetry is a continuous and non-invasive method for measuring the arterial oxygen saturation level in the blood. Oxygen (O2) is transported in the blood in two forms: dissolved in plasma or bound to hemoglobin. The majority of oxygen is carried by hemoglobin. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) have different absorption properties for red and infrared light, as depicted in the graph below.

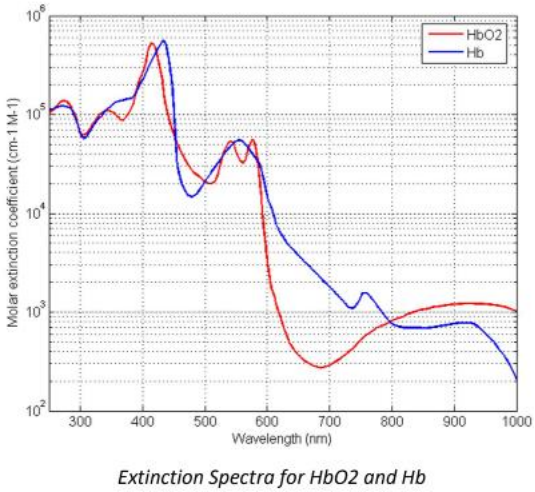


Figure 4 Extinction Spectra for HbO2 and Hb

hinlab utilizes an optical pulse oximeter sensor that emits both red and infrared light onto the skin of the upper arm to distinguish between oxygenated and deoxygenated blood. The sensor detects the reflection of red and infrared light that has not been absorbed by the blood and other tissues. This leads to the photoplethysmography (PPG) signal, from which the SpO2 and PR are derived.

19.2 Averaging

hinlab utilizes averaging in order to smooth pulse rate data and prevent inappropriate and transient artifacts from affecting stability of results. The data update period is provided in the technical data.

The time that a pulse rate was calculated is displayed on the user interface.

19.3 Calibration of pulse oximeter sensor

hinscope's pulse oximeter sensor was calibrated in a controlled hypoxia study on a diverse population of healthy adults. hinscope has an RMS of 1.2 bpm on the range 30bpm to 200bpm.

A functional tester cannot be used to assess the accuracy of the pulse oxymeter sensor.

hinscope will be maintained by the manufacturer. When in need of assistance or to report unexepected event, please contact hinlab for further information.

To verify operation of pulse oximeter, hinscope utilizes a reflective oximeter sensor on te bottom surface of the casing. hinscope will be verified and maintained by an person designated by the responsible organization (hinlab) using a model AECG100 (software version 1.0.7.3) test system (WhaleTeq, Taipei City, Taiwan).

19.4 Clinical accuracy

A controlled hypoxia desaturation study was performed on 12 healthy subjects to validate the SpO2 and PR accuracy of hinscope over the range of 70-100%, compared to arterial blood samples assessed by CO-Oximetry. The clinical validation protocol followed the guidelines defined in ISO 80601-2-61:2017.

The demographics of subjects in the study included five males and seven females (age: 23-47 yrs, BMI: 19.1-28.9, arm contour: 23-32.5 cm). The skin pigmentation/tones ranged from light to dark (Fitzpatrick I-VI), with five lightly pigmented, four medium pigmented and three darkly pigmented.

The following table shows the bias and accuracy per decade of SaO2 (and over the entire range).

SaO2 range (%)	70-80	80-90	90-100	70-100 (overall)
# data pairs	89	94	100	283
Bias	0.60	-1.43	-1.74	-0.90
Arms	2.04	2.34	2.40	**2.27**

The following tables show the bias and accuracy by skin pigmentation and by gender.

Skin Pigmentation (Fitzpatrick)	**Light (I-II)**	**Medium (III-IV)**	**Dark (V-VI)**	**Overall**
# data pairs	122	94	67	283
Bias	-0.77	-0.66	-1.48	-0.90
Arms	1.88	1.99	3.13	2.27

Gender	**Female**	**Male**	**Overall**
# data pairs	168	115	283
Bias	-0.54	-1.42	-0.90
Arms	2.21	2.35	2.27

20. Blood Pressure

This product uses the oscillometric measuring method to detect blood pressure. Before every measurement, the device establishes a “zero pressure” equivalent to the atmospheric pressure. With inflation of the arm cuff, the unit detects pressure oscillations generated by the brachial artery pulsatility, which are used to determine the systolic and diastolic pressure.

hinlab has validated the accuracy of the blood pressure measurement in a clinical validation study following ISO 81060-2:2018.

CAUTION: Do not apply hinscope and its pressurization on the arm on the side of a mastectomy or lymph node clearance.

WARNING: Pressurization of the inflatable part can temporarily cause loss of function of simultaneously used monitoring medical equipments on the same limb.

WARNING: Too frequent measurements can cause injury to the patient due to blood flow interference.

WARNING: Do not apply the cuff and its pressurisation on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because this could temporarily cause blood flow interference and could result in injury to the patient.

21. Technical Data

This section contains technical specifications for the physical and functional aspects of hinscope. These specifications apply to adult patients.

21.1 Manometer mode (maintenance)

This test verifies that the pressure sensor outputs a correct value of raw pressure in the cuff.

- Plug a tubing from the simulator to the maintenance port
- Using the app in test mode, activate the mode of the device where the valve is closed and the device sends raw pressure readings via BLE.
- Set up the BP simulator to a static value of pressure.
- Once the pressure value displayed by the simulator is stabilized, check that the value output on the app is the same

To test exhaustively the pressure sensor one can do this test on several pressure values on the range from 40 to 230 mmHg.

21.2 EMC Warnings & Precautions

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of hinscope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

During electromagnetic disturbances, the operator should not expect any unacceptable loss of performance or data.

Compliance level for emissions tests:

Emissions Test	Test Standard	Emissions Class and Group
Terminal disturbance voltages	CISPR 11:2015+A1:2016+A2:2019	Group 1 Class B
Radiation disturbance	CISPR 11:2015+A1:2016+A2:2019	Group 1 Class B
Harmonics current emission	IEC 61000-3-2:2005 +A1:2008 +A2:2009	Class A
Mains voltage fluctuations and flicker	IEC 61000-3-3:2013	--

Compliance level for immunity tests:

Immunity Test	Test Standard	Immunity Test Level
Electrostatic discharge	IEC 61000-4-2:2008	Air discharges: ±2 kV, ±4 kV, ±8 kV, ±15 kV Contact Discharges: ±4 kV, ±8 kV
Radiated RF EM fields	IEC 61000-4-3:2006 +A1:2007 +A2:2010	80 – 1000 MHz: 10V/m 1000 – 2700 MHz: 10V/m
Proximity fields From RF wireless communications equipment	IEC 61000-4-3:2006 +A1:2007 +A2:2010	385 MHz: 27V/m 450 MHz: 28V/m 710, 745, 780 MHz: 9V/m 810, 870, 930 MHz: 28V/m 1720, 1845, 1970 MHz: 28V/m 2450 MHz: 28V/m 5240, 5500, 5785: 9V/m
Electrical fast transients/bursts	IEC 61000-4-4:2012	AC input-output power: ±2000 V

Immunity Test	Test Standard	Immunity Test Level			
Surges	IEC 61000-4-5:2014+A1:2017	AC input-output power: Line to Line: ± 0,5 kV, 1 kV Line to Earth: ± 0,5 kV, 1 kV, 2 kV AC mains input power: ±0,5, ±1 kV			
Conducted disturbances induced by RF fields	IEC 61000-4-6:2013	AC input-output power: 3V, 6V			
RATED power frequency magnetic fields	IEC 61000-4-8:2009	Single coil dimensions: 1m x 1m X-axis: 30A/m, 50Hz and 60Hz, 10s Y-axis: 30A/m, 50Hz and 60Hz, 10s Z-axis: 30A/m, 50Hz and 60Hz, 10s			
Voltage dips	IEC 61000-4-11:2004 + A1:2017	UNOM [VAC]	Frequency [Hz]	Test level [% UNOM]	Duration [cycles]
		100	60	0	0.5
		100	60	0	1
		100	60	70	30
		100	60	0	300
		240	50	0	0.5
		240	50	0	1
		240	50	70	25
		240	50	0	250
Iimmunity to proximity fields from RF wireless communications equipment and immunity to proximity magnetic fields	IEC 60601-1-2:2014 Table 9 and IEC 61000-4-39:2017	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m			

No deviations or allowances to IEC 60601-1-2 were necessary. The measurement result is considered in conformance with the requirement if it is within the prescribed limit. It is not necessary to calculate the uncertainty associated with the measurement result.

hinscope should be periodically tested for electrical safety.

21.3 System Hardware Components

Physical Attributes	
Size (HxWxD)	133 * 67 * 24 mm
Weight	175g

hinscope mobile application

Title	hinscope
Version	v1.0.0
Compatible hardware	Android 8 minimum

Battery Specifications

Rating Voltage	3.7V
Capacity (for a new battery)	1150mA.h
Operating Time	3 days (10 measurements per day)
Charge Time	5 hours (full recharge)

Environmental Specifications

Temperature Range	0° C - 40° C
Relative Humidity	10 - 95%
Atmospheric Pressure	80-106kPa
Protection Against Ingress of Water	IP67
Maximum Altitude	2000 meters
Applied parts (type BF)	Enclosure and cuff

Storage

Data Storage	64MB Flash 5MB RAM
Embedded Software Version	v1.0.0

Network Specifications

Transmission Protocol	Bluetooth Low Energy (BLE)
Quality of service	Data integrity: > 90% Throughput: > 1KBps Data latency: < 300ms
Frequency	2.402 – 2.480 GHz

Power	Transmit: +8 to -20 dBm Receive: -96 dBm (1 Mbps), -103 dBm (125 kbps)
Transmission range	10 meters without obstacles
Security	Anonymous data

Pulse oximeter LED specifications

Power	2.41 mW (Green) 1.98 mW (Red) 1.38 mW (Infra-Red)
Nominal Wavelength	529 nm (Green) 660 nm (Red) 950 nm (Infra-Red)
Pulse Frequency Period	25 Hz for a single LED (period of 40 ms)
Pulse Duration	0.14 ms
Irradiance (at 10mm)	20 W/m² (Green) 17.90 W/m² (Red) 8 W/m² (Infra-Red)
Short Wavelength Boundary	515 nm (Green) 650 nm (Red) 930 nm (Infra-Red)

Each pulse cycle is configured to:

- switch on the Green LED for 0.14ms,
- then a pause of 0.325ms,
- switch on the Infra-Red LED for 0.14ms,
- a pause of 0.325ms,
- switch on the Red LED for 0.14ms.

After 40ms, the cycle starts again.

21.4 Measuring Specifications

21.4.1 Pulse Rate

Sensing Method	PPG (Photoplethysmogram)
Measurement Range	30-200bpm
Resolution	1bpm
Accuracy	3bpm
Data Update Period	spotcheck measurement (more than 1 minute)

21.4.2 Pulse Oximetry (SpO2)

Sensing Method	PPG (Photoplethysmogram)

Measurement Range	70% - 100%
Resolution	1%
Accuracy	3.5%
Data Update Period	Spotcheck measurement (more than 1 minute)

21.4.3 Blood Pressure

Method	Oscillometry during inflation
Measurement Range	Diastolic: 40-130 mmHg Systolic: 60-230 mmHg
Resolution	1mmHg
Accuracy	5mmHg ± 8mmHg
Rated Range of Cuff Pressure	0mmHg - 299mmHg

21.5 Certifications

FCC ID	2BF3K13EA2BF3K
IC Model	--
FDA	--

The FCC ID can also be found on hinscope's labels.

WARNING: This device complies with FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

WARNING: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Compliance Statement
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection

against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.