Freescan®
the first cuffless blood pressure monitor in the world.

Freescan® is the first monitor able to read blood pressure straight from the pulse. Using the recently developed PulseRead™ technology, pulsewave is combined with a single-lead ECG to deliver precise results in a very short space of time. Data can be sent directly to your smartphone via the integrated Bluetooth transmitter.

Cuffless Blood Pressure Monitoring.
Simple, discreet and painless.

Precise & reliable.
Thanks to the patented PulseRead™ technology.

Small & mobile.
Freescan® is small, portable & fits in any trouser pocket. Measure when and where you want to.

App & Cloud Integration.
The Freescan® app opens up additional features. Your data is always available via the Cloud.

Rechargeable battery.
One battery charge is sufficient for up to 150 measurements. Can be charged simply using the USB cable.

Fast measurement.
Within just 10 seconds, Freescan® provides your current measurement results.

Wireless data transfer.
The Freescan® data can be transferred simply via Bluetooth to your mobile phone.

More than blood pressure measurement.
Along with the blood pressure values, Freescan® also shows your pulse and stress level.

maisense® FREESCAN

Blood Pressure
Model No.
211110

Product Features in General

Classification	Class IIa, Type BF
Device Dimension (L) x (W) x (H)	L 37.6 in x W 14.6 in x H 7.9 in
	L 95.5 mm x W 37 mm x H 20 mm
Weight	60 ±5 g
	2.1 ±0.2 oz
Display	Backlight LCD
LCD Size (L) x (W)	L 32 mm x W 24 mm
Memory	200 measurements
Pulse Sensor	Silicone rubber pressure sensor
ECG Sensor	Metal coated electrodes
Wireless Transmission	Bluetooth
Battery Type	250 mAh rechargeable Li-Polymer battery
Battery Service Life	Approx. 150 measurements
Battery Shelf Life	3 years
Charging Port	DC 5V, 110 mA micro USB connector
Charge Protection	Included
Product Life	3 years
Warranty	1 year

Blood Pressure Measurement

Measurement Method	Pulse Transition Time
Mode of Operation	Non-Continuous
Measurement Site	Radial Artery at the Wrist
Measurement Time	Approximately 10 seconds
Measurement Unit	Millimeters of mercury (mm Hg)
Blood Pressure Range	40 to 230 mm Hg
Blood Pressure Accuracy	±3 mm Hg
Pulse Rate Range	30 to 180 beats/minute
Pulse Rate Accuracy	±5% of the value shown
Irregular Heartbeat Detector	Yes

Environment conditions

Operating Conditions	41° F to 104° F (5° C to 40° C)
	15% to 85% RH (non-condensing)
Storage & Transportation Conditions	-13° F to 158° F (-25° C to 70° C)
	10% to 95% RH (non-condensing)
Environment Pressure (for all)	70 to 106 kPa
Altitude Range	0 to 3000 meters
Water/Dust Protection	IP22

Regulatory Compliance

Performance	IEC 80601-2-30:2013
Electric Safety	EN 60601-1:2006 /
	A11:2011/A1:2013/A12:2014
EMC	EN 60601-1-2:2007+AC:2010
	(IEC 60601-1-2:2007)

Explanation of the material used in the device

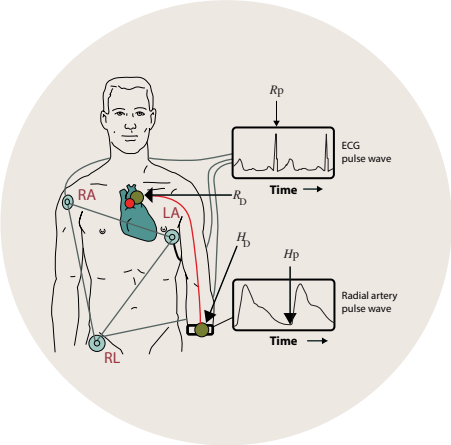
1. ECG electrodes:
   all 3 are gold coated or platinum coated (both are bio-compatible).
2. Pulse sensor:
   pressure sensor encapsulated with silicon rubber, which is also a bio-compatible material.
3. Mechanical:
   It includes a bottom case, a mid-frame, and a top lens.
4. Electronic:
   PCB with active and passive components powered by a rechargeable battery.
5. Display:
   backlight LCD

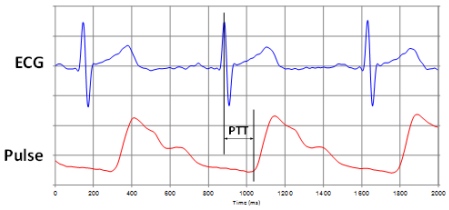
How the device interacts with other device or with the user.

The device can be used standalone as a blood pressure monitor, and it can upload the data to a PC/smartphone via USB/ Bluetooth.

Principles used by the device to generate device output.

The device senses the lead I ECG and radial artery pulse by using 3 electrodes (1 as RA, 1 as LA, 1 as RL) and 1 pressure sensor. With the aforementioned bio-signal, the device may get certain parameters, including pulse transmission time (PTT), and calculates SYS and DIA respectively according to a formula. The devices can also calculate heart rate (HR) and indicates irregular heart beat as well.





Determining blood pressure with pulse transmission time (PTT)

A. Pulse transmission time (PTT) as a measurement for blood pressure

- The transmission speed of a wave is dependent on the distensibility of the media: the lower the distensibility, the faster the wave propagates.
- In the circulatory system, the wall tension of the arteries is a significant influencing factor for the transmission speed of the pulse wave. The higher the wall tension of the artery, the less able is the pulse wave to move to the side and the quicker it propagates along the artery.
- The higher the blood pressure, the higher the wall tension of the arteries and therefore the quicker the pulse wave propagates.

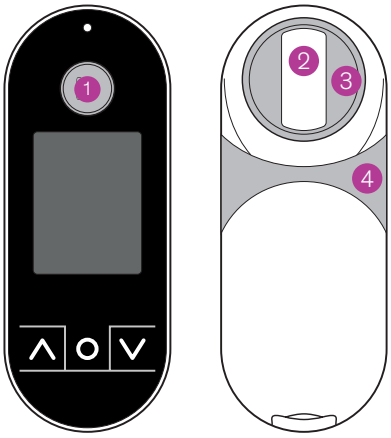
B. Determining the transmission speed

The transmission speed of the pulse wave is determined by measuring the time it takes for the wave to move from the heart to the radial artery. In this way, we take the R wave in the ECG to be the start of the wave propagation with the blood output from the left heart. The arrival of the wave at the radial artery is measured mechanically with a pressure sensor.

C. Patient profile needed when using indirect measuring methods

Blood pressure is measured directly in the artery in only the rarest cases. The usual measurement with the blood-pressure cuff is an indirect method, as is measurement by pulse wave transmission time. To be able to deduce the actual blood pressure from the measured parameters, i.e. the pressure value in the cuff or the transmission speed of the pulse wave, some body constitution parameters must be taken into account. The usual measurement with the blood-pressure cuff is the upper arm circumference. To correctly determine the blood pressure with the pulse wave transmission speed, the distance between the heart and the measuring point on the left wrist is needed, as in order to determine the speed, the distance covered is needed, along with the time. As the proportions of most people are very similar, the distance sought can be deduced from body height and weight, without having to measure them directly. Moreover, over the course of a lifetime, the elasticity of the vascular wall changes. Data is also available for normal ageing, so the elasticity can be deduced from age and gender. Body height, weight, age and gender are therefore recorded in the device's profile.

If a person has an atypical constitution, e.g. disproportionately long arms for his or her body height, it is also possible to calibrate the device with a reference blood pressure value for individual patients.



Front and rear view

1. RA Electrode & Button
2. Pulse Sensor
3. LA Electrode
4. RL Electrode

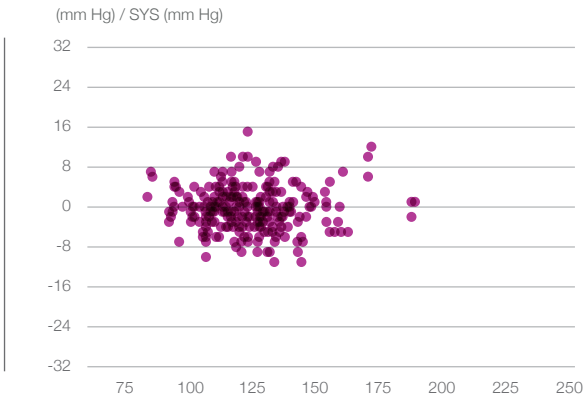
Validation data

Freescan is validated in accordance with ISO 81060-2:2013 (Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type) and bears the CE mark for medical devices. The validation was carried out with 300 measurements on 100 patients. Each measurement with Freescan was compared to independent control measurements carried out by two nurses with the mercury sphygmomanometer, whereby neither control measurement was allowed to differ from the other by more than 4 mm Hg.

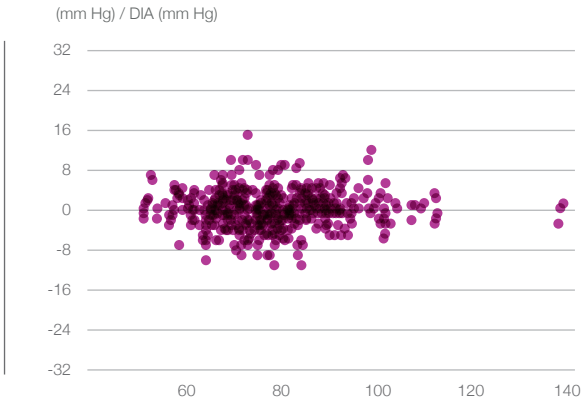
The age of the patients was between 28 and 70, the weight between 40 kg and 105 kg, and the body height between 142 cm and 180 cm. 34% of the patients were female, while 66% were male. The systolic blood pressure values were between 86 mm Hg and 198 mm Hg, while the diastolic values were between 50 mm Hg and 139 mm Hg.

In the analysis, there was an average deviation in the systolic (SYS) values of -1.39 mm Hg, and 0.32 mm Hg in the diastolic (DIA) values, relative to the reference values. This fulfills the requirements of the standard, which permits average deviations of up to +/- 5 mm Hg. The standard deviation of SYS deviations was 4.2 mm Hg and the standard deviation of DIA deviations was 2.52 mm Hg. This is also fully compliant with the standard, as a standard deviation of SYS/DIA deviations of up to 8 mm Hg is permitted.

SYS deviations



DIA deviations



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Intended use of the device.

- The device is used to monitor the blood pressure and is helpful to those with hypertension disease. It may be applied to the population from age 30 to age 70, for both male and female.
- Since the device has to sense the radial artery pulse, it must be applied to left wrist with handheld by right hand.
- The device can be measured anytime the users intend to do so, as long as the device is operated correctly.
- The measurement result (SYS/DIA/HR) is for reference only and cannot be used as diagnosis basis. Users have to consult doctors for further interpretation and treatment.
- The device will be sold over the counter with no prescription required.

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