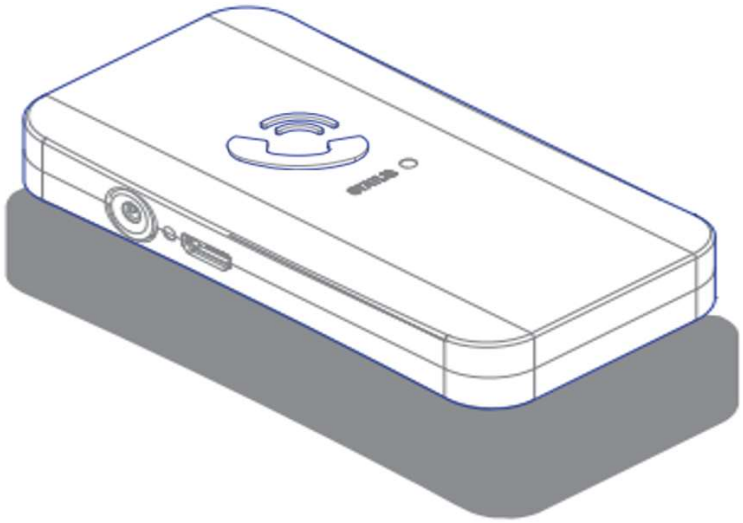
Smart Pulz

Instruction for use for

Smart Pulz Device



CONTENT

INSTRUCTION TO USER

Dear user, thank you very much for purchasing the Mediot 's SmartPulz.
This manual describes, in accordance with the SmartPulz 's features and requirement, main structure, functions, specifications, correct methods of transportation, installation, usage, repair, operation, maintenance and storage, etc., as well as the safety procedures to protect both the user and the equipment. Please refer to the respective chapter for details. Please read the user manual carefully before using this product. The user manual describing the operating procedures should be followed strictly. Failure to follow the user manual may cause measuring abnormally, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to user's negligence of operation.

SAFETY

- **Warnings**

1. DO NOT charge the device while being used on patient.
2. DO NOT use SmartPulz while the patient is being scanned by MRI.
3. DO NOT use SmartPulz with patient with abnormal movement (e.g. Parkinson, delirium tremens, etc.).
4. DO NOT use SmartPulz in operating room.
5. DO NOT use SmartPulz in neonate or infant.
6. DO NOT use SmartPulz in patient who allergy to metal or plastic.
7. DO NOT use SmartPulz in critical patient (ICU, Operating patient). SmartPulz is for non-critical patient or healthy individual only.
8. SmartPulz should not be used with patient with heart disease.
9. It is recommended that the SmartPulz should be inspected before use, when there is obvious damage, stop using the device.
10. Discomfort or pain may appear if using the device for extended period, especially for patients with thin skin. It is recommended that skin at the applied site should be inspected regularly. If allergy is suspected, stop using the device.
11. SmartPulz is only one of the clinical auxiliary equipment other than means of clinical diagnosis. The clinical response factors determining the patient's condition must be consolidated under the guidance of a doctor.
12. Prevent children from swallowing the device or its accessories. Children must be accompanied by adult guardian while using the product.
13. Please follow local ordinances and recycling instruction regarding disposal or recycling of the device and batteries.
14. Both device and monitor must be placed near a SmartPulz compatible Wi-Fi router to operate properly. (Not more than 5 meters)

Cautions
A. The equipment is designed to measure the heart rate, respiratory rate, skin temperature and body position. Factors that may degrade SmartPulz performance or affect the accuracy of the measurement include the following:

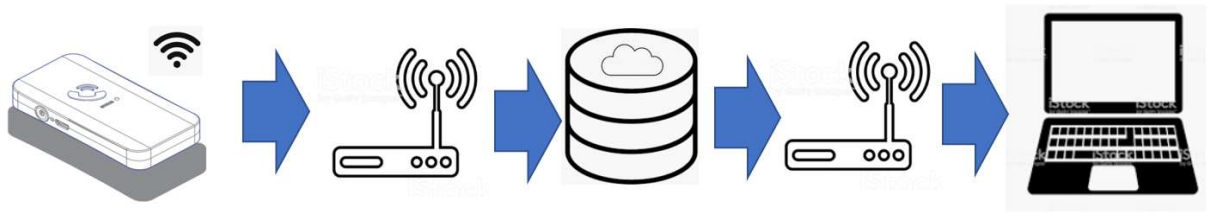
- Extreme room temperature lessens skin temperature measurement accuracy.
- Skin temperature reading should be done after applying SmartPulz to patient for 10 minute or longer.
- Any kind of movement will render heart rate and respiratory rate unreliable and should not be interpreted at those moment.
    - Cause by user (e.g. walking, shaking body, changing body position, etc.)
    - Equipment that produce vibration (e.g. air bed pump, suction, etc.)
    - Some disease with abnormal movement (e.g. Parkinson, Delirium tremens, etc.)

- Activities that involve respiratory muscle (e.g. talking, eating, swallow, etc.) will make respiratory rate unreliable.
- Patient that have varies respiratory rate (e.g. Kussmaul breathing, Panic attack, etc.), the result will vary greatly between minute to minute.
- Patient with varies heart rate (e.g. Bigemini PVC, Paroxysmal AF, etc.) the result will vary greatly between minute to minute.

B. Please read the measure value when the waveform on screen is equably and steady-going, the measure value is optima value and the waveform at the moment is the standard one.

THE BASIC

Principle of the SmartPulz is as follows: A group of sensors measure movement/ vibration/ position/ temperature on the patient's chest, sampling the data and sent to the internet and store on cloud. The algorithm then processes the data into vital sign and sent to the user.



Introduction

Intended Usage

For use in hospital by adult patient of non-critical health condition. Measuring and recording of heart rate, respiratory rate, posture of user, and skin temperature through the attachment of device at the upper chest to aid in monitoring of vital signals and posture. Report the collected data to the nurse and alert when the data is out of acceptable set range to prevent occurrence of pressure ulcer or undetected deteriorate in vital sign.

- **Warnings**

This SmartPulz is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.

Cautions

- The SmartPulz is intended for use in hospital, clinical institution, healthcare community.
- The SmartPulz is not designed for newborn and infant.
- The SmartPulz is not designed for critically ill patient.

Components

The SmartPulz system consists of SmartPulz device, SmartPulz UI software, SmartPulz service.

- SmartPulz device consist of electronic circuit and sensor, temperature probe, battery and plastic enclosure.
- SmartPulz UI software is a web base application.
- SmartPulz service includes installation, setup of the devices and scheduled maintenance.

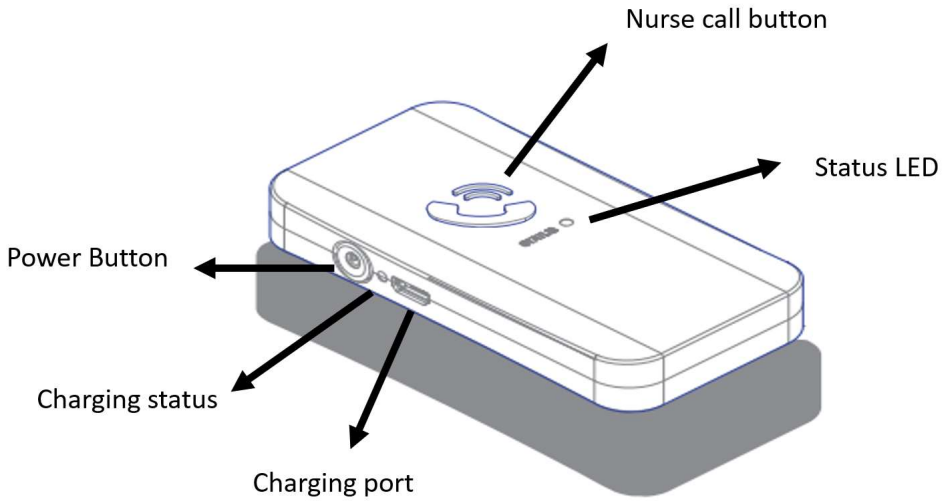
Notes

*The temperature probe is the stainless metallic icon in the middle of the equipment to which contact to patient's chest skin.
*The probe is the applied part of the equipment.
*The enclosure includes plastic front lid, plastic back lid, silicone power button and silicone seal.

Features

- Low volume, light weight and easy to carry.
- Low in power consumption.
- Auto reconnect to Wi-Fi if disconnected.
- Nurse call button at the front lid.

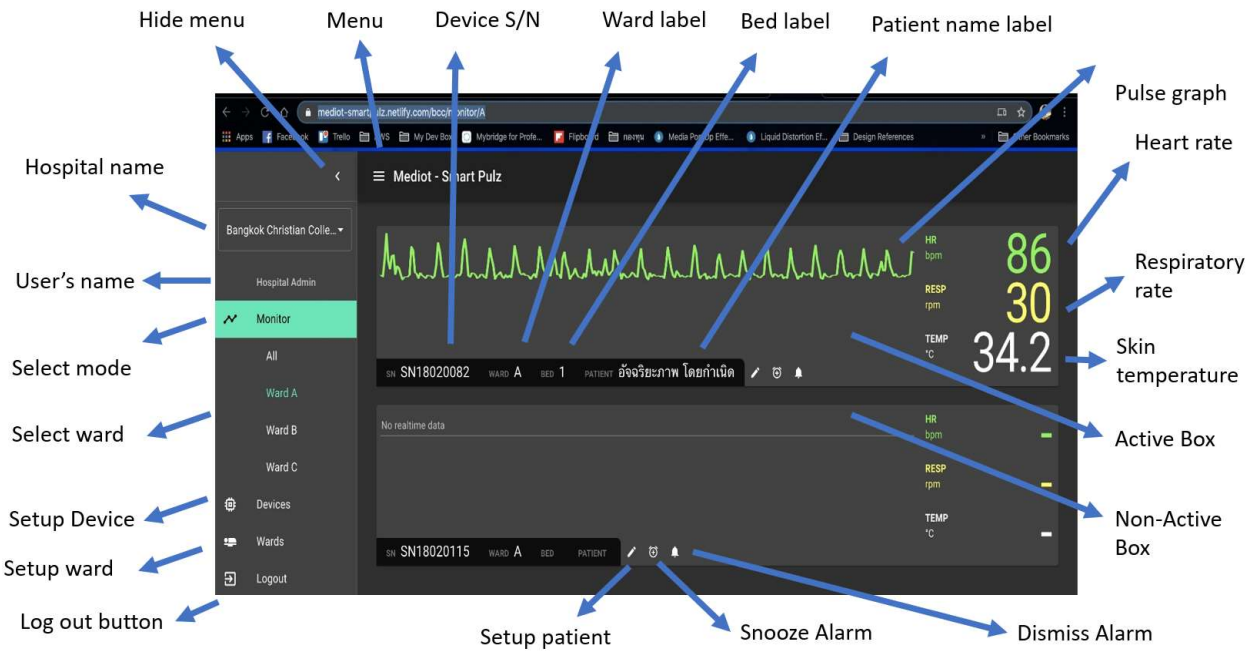
Front view (Device)



Function (Device)

• Pulse rate measurement • Respiratory rate measurement • Temperature measurement • Body position measurement	• Nurse Call button • Display connection status LED • Charging status LED

Front view (Web Application):



Function (Web application)

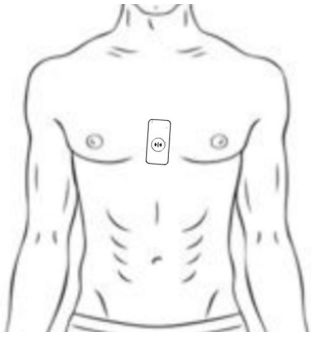
• Monitor multiple patient in real time • Display pulse graph for each patient • Display heart rate, respiratory rate, temperature for each patient • Identify by serial number, ward, bed, and patient's name	• Alarm setup window • Alarm notification as condition set • Convenient snooze or dismiss alarm • Easy setup ward, device • Easy login and logout

Warnings:

1. Always make sure the Wi-Fi compatible with Mediot SmartPulz is available and internet connection is stable.
2. Connect and turn on appropriate speaker on the computer using SmartPulz web application. Low volume may result in notification failure.
3. Make sure that at least one notifying personal is available at the SmartPulz computer station.

OPERATING GUIDE

1) Charge the device before use (read the battery charging instruction)
2) Make sure the appropriate Wi-Fi signal is available
3) Turn power on by gently push the power button and hold for 8 second.
4) Wait for the LED to change from blink red (waiting for Wi-Fi) to intermittent green blink (ready).
5) Attach the device to patient at middle chest (see picture below) and secure with tape.



6) Open web browser on the work station computer and login to SmartPulz website.
7) Choose the correct hospital, ward and choose monitoring module.
8) Assign the device to patient bed on SmartPulz web application.
9) Setup alarm setting, patient name, bed and ward in SmartPulz web application.
10) The system will continuously monitor the vital sign (heart rate, respiratory rate, skin temperature), position and SmartPulz web application will notify if the alarm condition is met.
11) Click snooze alarm or dismiss alarm to hold or discontinue notification.
12) To stop using device, click at setup patient and choose discharge patient.
13) Disconnect device from patient.
14) To turn off device, gently press and hold the power button for 8 second.

Attention for operation

A. Before use, check and confirm the patient and condition is compatible with SmartPulz device.
   a) DO NOT use in infant and neonate
   b) DO NOT use in patient who allergy to plastic and metal.
   c) DO NOT use in patient with heart disease.
   d) DO NOT use in critically ill patient who need intensive monitoring.
   e) DO NOT use in patient with movement disorder.

B. Before use, check and confirm the environment should be non-combustible material as well as avoid high or low temperature and humidity.

C. The device must place at a proper site and make adjustment as necessary to maximize accuracy.
D. The tape used to secure SmartPulz device must be medical grade and does not cause allergy to patient.
E. The equipment may not work normally on some patient (especially obese patient), re-position the equipment could improve the measurement.
F. Don't shake the body and try to keep the patient still during the measurement.
G. The user should not moveout from Wi-Fi range.
H. The enclosure of the device is seal by glue, DO NOT try to open the enclosure.
I. Clean the device and let dry before use (Read Cleaning section below).
J. DO NOT use the device under water.
K. Stop using the equipment if the liquid flows into the inside of the equipment and wait for the machine to dry.

Battery charging instruction

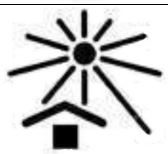
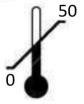
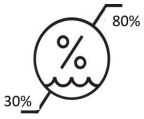
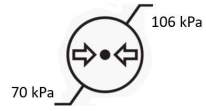
A. Disconnect the device from patient and turn off the device.
B. Put micro-USB charging cable into the charging port.
C. Connect micro-USB cable to power adaptor (INPUT: 5V ⎓ 0.5A)
D. The charging status LED will turn red.
E. Let the battery charge until charging LED status turn green (Indicate fully charge).

F. Disconnect device/power cord from power adaptor.

Warnings:

- DO NOT recharge the battery beyond 3 years expiratory date (500 times).
- DO NOT use higher voltage or ampere power adaptor.
- Always disconnect the device from patient when charging.

LABEL AND INFORMATION

	Manufacturer: MEDIOT Partnership 38/92 Bangcherknung Talingchan BKK, Thailand		Do not use if package is damaged
	Manufacturing date: YYYY-MM		Keep away from sunlight
	Serial number: 1802XXXX		Temperature limit from 0 to 50 degree Celsius
	Non-Sterile		Humidity limitation 30 to 80%
	Follow instruction for use		Atmospheric pressure limitation 70-106 kPa
	Medical device Class II		Type B applied part
	INPUT: 5V ⎓ 0.5A		DO NOT dispose it with domestic waste, Dispose it to electrical and electronic equipment disposal.

PRINCIPLE OF MEASUREMENT

1. Heart rate measurement method - Seismocardiography (SCG)

Thoracic vibrations are produced by the heart's contraction and the ejection of blood from the ventricles into the vascular tree. SCG is a measurement of local vibration of the chest wall in response to the heartbeat. The SCG was first observed by Bozhenko in 1961 and was first applied in clinical studies 30 years later in 1991. SCG can be detected by placing a low-noise accelerometer on the chest. If a tri-axial accelerometer is used, SCG components are present in all three axes with a specific pattern. Since it is a measure of local vibrations, the precise location of the sensor on the chest impacts the measured signal. A widely used placement has been on the sternum. SCG provides accelerometer derived respiratory data and accurate information about quiescent phases within cardiac cycle according to the chest wall movement and mechanical states of the heart. SCG can

be used to assess the mechanical activity of the heart by detecting aortic opening (AO) and aortic closure (AC) events.

SCG has two components were dominant.
1) a large low-frequency (sub-Hz) element due to movement of the chest wall caused by expansion and contraction of the lungs during the test
2) a component with sharper amplitudes and upper frequency (>5 Hz) contents caused by pulsations of the chest wall due mainly to acoustic waves produced by the heart valves

Although SCG in general has not been deployed in the clinical environment (2014), some promising applications have been suggested.
1) Assessing the timing of different events in cardiac cycle.
2) Computing heart rate variability.
3) Computing respiratory information.

2. Respiratory rate measurement method
Accelerometer derived respiratory (ADR)
ADR is the low frequency signal which can be derived from SCG signal.

3. Body temperature measurement method
Semiconductor Thermometers
Semiconductor thermometers are made by semiconductor diodes which have voltage-current characteristics that are temperature sensitive. Semiconductor thermometers have small temperature measurement ranges compared to thermocouples and RTDs but they can be accurate, inexpensive, and easy to interface with.

SPECIFICATIONS

Classification:
Type of protection against electric shock ----------II (Internally powered equipment)
Degree of protection against electric shock----------Type B-applied part
Degree of protection against hazard of explosion----------Ordinary equipment: not protected
Equipment type----------Monitoring system, Physiologic UMND:12636

Measurement specifications:
Heart rate declared accuracy
Range----------50-250 bpm
Tolerance----------10 bpm

Respiratory rate declared accuracy
Range----------5-45 rpm
Tolerance----------5 rpm

Skin temperature declared accuracy
Range----------25-45 degree Celsius
Tolerance----------1 degree Celsius

*Note: accurate measurement requires the patient to stay still

Product design:
Dimensions (W x L x H) ----------80x40x11 mm
Shape & Color---------- Rounded rectangular, white

Status LED ----------2x Bicolor (for connection and power status)
Button ---------- power switch, nurse calling button
Charge port----------micro USB
Dustproof and waterproof rating----------IP43

Power requirements:
Specification of batteries----------rechargeable lithium-polymer
Operating current----------less than 250mA
Rated DC voltage---------- 3.3 V

Environmental specifications:
Temperature Storage ---------- 0₀ to 50℃
Temperature Operating ----------0₀ to 50℃
Humidity Storage & Operating----------30-80%
Atmosphere pressure Storage & Operating ----------70-106kPa

Connection:
Signal usage ----------Wi-Fi 2.4GHz 802.11b/g/n
Working range---------- within Wi-Fi router range
Update interval: ----------15s

Safety standard

IEC 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
IEC 60601-1:2005 + A1:2012	General requirements for basic safety and essential performance
IEC 60601-1-2 ETSI EN 300 328 , FCC ETSI EN 301 489	Electromagnetic compatibility
IEC 60601-1-6	General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62304: 2016	Medical device software -- Software life cycle processes
IEC 60601-1-8:2006	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 80601-2-56:2017	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
IEC 80601-2-49:2018	Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

Note: Specifications are subject to change without notice.

HANDLING, TRANSPORTATION

Unpack
First, check the carton or other packaging to see any damaged signs of product. Please inform the transporter or local dealer if any sign took placed.

- Take out all covered plastic from the carton.
- Remove any plastic materials from the carton.
- Check to see any sign of damages in the SmartPulz device, such as scratches and dents.
- Connect to SmartPulz web application and test all modules

Storage

Keep the SmartPulz in the place of damp proof and non-corrosion environment

Transportation

Be transferred by common transporting tools: ship, plane, train, truck.
SmartPulz can be manually handled.
No throwing or dropping during transshipment.

MAINTENANCE, CLEANING, DISINFECTION

Maintenance

The equipment's designed life expectancy is 3 years, keep your equipment and accessories free of dust and dirt, and follow these rules:

A. Please clean the equipment before use according to chapter Cleaning.
B. Recharge the batteries in time when the battery indication is less than 10%.
C. It is recommended that the equipment should be kept in a dry environment with no corrosive gases and good ventilation anytime. The moisture and high-light environments will affect its lifetime and even damage the equipment.
D. It is best to preserve the product in a place where the temperature is between 0 to 50℃ and the relative humidity is less than 80%.
E. The packed equipment can be transported by ordinary conveyance. The equipment can not be transported together with toxic harmful corrosive materials.

Cleaning

The equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment. Recommended cleaning agents are: Ethanol(75%) To clean your equipment, follow these rules:

a) Shut down the SmartPulz device.
b) Clean the exterior surface of the equipment and probe using a soft cloth dampened with the cleaner.
c) Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
d) Dry the equipment in a ventilated, cool place.

To avoid damage to the equipment, follow these rules:
Cautions

- Always dilute according to the manufacturer's instruction or use lowest possible concentration
- Do not immerse part of the equipment in the liquid
- Do not pour liquid onto the equipment or accessories
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners)
- If spilling liquid onto the equipment, contact us or your service personnel.

Disinfection

Disinfection by EO or autoclave may cause damage to the equipment. It is not recommended unless otherwise indicated in your hospital's service schedule.

Disposal

When discarding the SmartPulz, comply with local rules or regulations. Batteries should never be thrown away or incinerated but disposed of in accordance with the local regulations concerning battery disposal.

Accessories

1. One SmartPulz device
2. One user manual.

LED SIGNAL MEANING

	Power LED	Signal LED
Initial (Start)	Red: Battery ran out Green for 5sec: Normal	
During use	Red: Battery ran out	Slow Green Toggle: Normal Fast Red Toggle: Fail to send data
Charging	Red	
Fully charge	Green	

TROUBLESHOOTING

- Warning

Necessary maintenance must be performed by qualified service personal ONLY.
Users are NOT permitted to maintain the equipment by themselves.
There are NO replaceable components in the equipment.

Trouble	Possible reason	Solution
The device cannot be turn on	The battery is drained away or almost drained away.	Charge the battery.
	The malfunction of the device.	Please contact the local service center.
The device cannot connect to Wi-Fi (Red blink after turn on)	No Wi-Fi	Set-up compatible Wi-Fi router that connect to internet
	No SmartPulz compatible Wi-Fi router	Change SSID and password of the router to match SmartPulz requirement.
	No internet from the compatible router	Check the router weather internet is available by other means.
The heart rate or respiratory rate are not displayed.	The device is taken off the patient and placed on table.	Put device back on the patient
	Device position is poor	Adjust device position as shown in operating guide.
Poor respiratory rate accuracy	Signal is too low to detect. (The device is far from abdomen)	Re-adjust device position downward.
The respiratory rate and pulse rate are not displayed stably (Graph doesn't look normal)	Patient is moving.	Normal
Temperature reading is below normal	The device is attached to patient less than 10 minutes	Wait for 10 minutes