Automatically collect vital signs from your patients

Philips Healthdot is a wearable biosensor, allowing health care professionals to monitor and automatically collect vital signs from their patients in the care facility.

It is a single-use medical device placed on the patient's lower left rib and continuously captures the patient's heart rate, respiratory rate, posture, and activity, all securely transmitted every 5 minutes, on average, to the clinical information system. To access the data, Philips Healthdot should be used in combination with a clinical information system allowing health care professionals to check vital signs.

In countries where Healthdot is launched, out-of-hospital monitoring can be enabled by placing LoRa gateways in the out-of-hospital location, for example, in a skilled nursing facility (SNF). For now, home monitoring is only possible in The Netherlands, where there is a Healthdot-compatible LoRa network.

Specifications

Physical

Size (W x H x D)	40 mm x 33 mm x 11 mm
Size of sensor including adhesive (W x H x D)	55 mm x 45 mm x 11 mm (without release liners)
Weight	11.8 g
Battery	2 * Zinc Air PR44 1.45V, non-replaceable
Durability	Survives free fall (1 m drop) per IEC 60601-1
Water ingress protection	IP 55 (IEC 60529:2013), Shower proof
Not manufactured with natural rubber latex	

Use

MRI Safe	No
Single-use	Yes, single-use only
Operational life, data transmission period	Healthdot can be worn for up to 14 days
Required patient actions	Only removal of the device from the skin
Disposable	Yes, as small electronic waste (WEEE)
Serviceable	No

Performance

Respiration rate measurement range	5 – 60 respirations per minute (rpm)
Respiration rate accuracy	±1 rpm
Respiration rate resolution	1 rpm
Respiration rate calculation	5-minute average
Heart rate measurement range	30 – 220 beats per minute (bpm)
Heart rate accuracy	±3% of range or ±1 bpm (whichever is greater)
Heart rate resolution	1 bpm
Heart rate calculation	5-minute average
Activity level	0 = at rest, 1 = minimal activity and 10 = maximum activity
Posture	Supine; Reclined; Upright; Forward leaning; Prone; Upside down; Lying on the left side;Lying on the right side
Data transmission interval	Typically, every 5 minutes

Compliance

Certification	CE-marked – EU MDR 2017/745
Class	Class IIa medical device
In compliance with	IEC 60601-1 :2012 ; IEC 60601-1-11 :2015 ; Regulation EU MDR 2017/745 ISO 10993-1:2018 (Biocompability)
Applied part	BF
More information	See instructions for use
Release countries for use within the care facility	The Netherlands, Belgium, Germany, France, Sweden, Italy
Release countries for use outside the care facility	The Netherlands

Wireless/Security

Radio	LoRa
Frequency band	868 (band) MHz
RF radiated power output	Maximum 14 dBm (Europe)
Coverage (with gateways)	A coverage test will be done in the care facility to place enough LoRa gateways (typically 1-5) to ensure enough coverage in all required areas.
Coverage (without gateways)	Monitoring patients outside of the hospital is currently only available in the Netherlands. More countries will follow in due time.
Indoor coverage	Any room with a window (the Netherlands only)
Coverage in practice (without gateways)	In more than 99% of the cases, at least one valid data point is received within two hours.
Security	Data in rest: AES 128-bit (ECB mode); Data in transit: AES 128-bit (CCM mode), end-to-end data encryption.

Environmental

Operating ambient temperature range	+5°C – +40°C
Operating humidity range	15 – 90% relative humidity limit (non-condensing)
Operating atmospheric pressure range	700 – 1060 hPa
Shipping temperature range	-20°C – +60°C
Shipping relative humidity range	5 – 95% relative humidity (non-condensing)
Shipping atmospheric pressure range	700 – 1060 hPa
Storage temperature range	+5°C – +40°C
Storage humidity range	5 – 95% relative humidity (non-condensing)
Storage atmospheric pressure range	700 – 1060 hPa
Shelf life	12 months in an individually sealed pouch

LoRa gateway

Connection	LoRa to 4G
Installation requirements	Standard power socket, screwed to wall/ceiling
Connected to hospital LAN	No (4G)
Range	Actual range will vary depending on the layout of the building the gateway is used in
Ownership	KPN (return when no longer used)

Pairing website

Dedicated mobile web app accessible with connected devices like mobile phones, tablets, or PC

Minimal system requirements	Android 10 with Chrome web browser (version 81 and higher),
	Screen size 5 inches or larger, resolution minimum 720 x 1280, with a camera of 10 megapixels or more.
	Access to camera allowed (e.g., built-in for mobile, or accessory for PC)

HSDP Cloud infrastructure

Name	Philips HealthSuite Digital Platform (HSDP)
Location	Within the EU (Ireland)
Security	ISO 27001, 27018, SOC 2 Type 2 and HITRUST certification

Product ordering information

Product number (GTIN)	Product description	Quantity
00884838103702	Healthdot 3.1	1
00884838103719	Healthdot Multipack	30 per box

Manufacturer

Philips Electronics Nederland BV Philips CTO Ventures

High Tech Campus 5

5656 AE Eindhoven,

The Netherlands

PHILIPS

CE 0344

Philips Electronics Nederland BV
Philips CTO Ventures
High Tech Campus 5
5656 AE Eindhoven,
The Netherlands