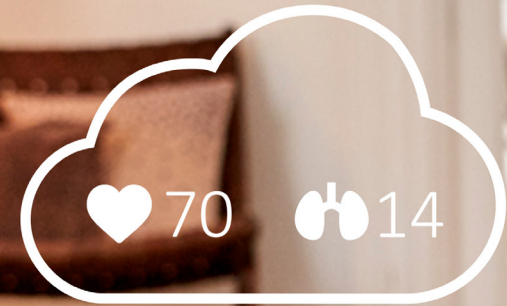


PHILIPS

Connected Care

Healthdot



Looking after patients in-and out-of-hospital

Philips Healthdot is a medical device. It is a wearable biosensor, allowing health care professionals to monitor patients in hospital, but especially for out-of-hospital and during transitional care. It is a single use medical device which is placed on the lower left rib of a patient and continuously captures the patient's heart rate, respiratory rate, posture and activity, all of which are transmitted to the hospital in a secure way.

Philips Healthdot is **one of the world's first biosensors** sending heart and respiratory rates to the hospital without the patient requiring a hub or mobile phone (it uses a built-in LoRa transmitter directly sending data to the cloud). This makes the system easy to use and the sent data reliable.

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 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 left side; Lying on 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 (Biocompatibility)
Applied part	BF
More information	See instructions for use
Release country	The Netherlands

Wireless/Security

Radio	LoRa
Frequency band	868 (band) MHz
RF radiated power output	Maximum 14 dBm (Europe)
Coverage	Anywhere in the Netherlands (without any additional hub or mobile phone needed)
Indoor coverage	Any room with a window
Coverage in practice	In more than 99% of the cases at least one valid data point comes in 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 individually sealed pouch

LoRa gateway

Connection	LoRa to 4G
Installation requirements	Standard power socket, screw 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 webapp accessible with connected devices like mobile phone, tablet or PC

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

HSDP Cloud infrastructure

Name	Philips Health Suite Digital Platform (HSDP)
Location	Within the EU (Ireland)
Security	ISO 27001, 27018, SOC II 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
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