



## New Product Information Sheet

Specifications subject to change  
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Model (code):  
WheezeScan (HWZ-1000T-E)

***Product description: Wheeze Detector***  
***Product category: Wheeze Detectors***  
***Model (code): WheezeScan (HWZ-1000T-E)***



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## General description

WheezeScan uses innovative listening technology to identify “wheeze” or “no wheeze” quickly and accurately. WheezeScan is a convenient tool to help parents to manage their children’s asthmatic symptoms at home.

**Packaging content** (use info from the IM –technical specs chart)

1. Device
2. Storage case
3. 2 “AAA” alkaline batteries
4. Instruction manual
5. Quick reference guide

## Purpose

The OMRON WheezeScan is intended to detect the presence of wheezing in infants, toddlers and children from 4 months to 7 years of age.

## Application field

This product is intended for use in home and clinic.

## Intended user

Parents who are advised by a physician, caregivers, school nurses and physicians are allowed to use this device. DO NOT let patient use this device on his/her own.

## Indications for use

Medical product’s intended use as determined by the manufacturer:

This product is intended to be used on a patient whose illness was diagnosed as bronchitis, bronchiolitis or bronchial asthma.

## Features (Particularities)

OMRON developed the WheezeScan as a device with innovative listening technology to identify “wheeze” or “no wheeze” quickly and accurately. It is a convenient tool to help parents to manage their children’s asthmatic symptoms at home.

This device can pair with your smart device and you can manage the measurement results with your smart device using the “OMRON Asthma Diary” app.

## **Key features**

- Unique wheeze sensor: Detects the presence of wheeze
- Quick measurement: result in 30 seconds
- OMRON Asthma Diary app: Manage and track results with your smart device
- Especially developed for children from 4 months to 7 years old

## **Description of operating principle**

### **How it works**

WheezeScan acts much like the stethoscope the doctor uses when listening to the lungs. By placing the sensor on the patient’s chest for 30 seconds of normal breathing, the device can catch and then analyse the breathing sounds for the presence of wheezing.

## **How to use the device**

Main steps:

1. Install the batteries
2. Remove phlegm and nasal mucus, if any, before taking a measurement.
3. Let the patient sit down or lay face up.
4. Remove clothes to expose patient’s chest. Being naked from the waist up is recommended.
5. Check where to place the sound sensor.
6. Press the power button.
7. Apply the sound sensor to the patient’s skin.
8. The device will beep twice and begin measuring.
9. Wait until the measurement is completed.
10. The device will indicate ‘WHEEZE’ or ‘NO WHEEZE’

Review the Instruction Manual for the full details on the application of this product.

## How to use the “OMRON Asthma Diary” app

This device can pair with your smart device and you can manage the measurement results with your smart device using the “OMRON Asthma Diary” app. Follow the steps below to pair the device with your smart device:

1. Enable Bluetooth on your smart device.
2. Download and install the “OMRON Asthma Diary” app onto your smart device.
3. Open the app on your smart device and follow the instructions.

To review the list of compatible, please visit the website: [www.omron-healthcare.com/asthma-diary-compatibility](http://www.omron-healthcare.com/asthma-diary-compatibility)

### Technical data

Product category	Wheeze Detectors
Product description	Wheeze Detector
Model (code)	WheezeScan (HWZ-1000T-E)
Patient age range	From 4 months to 7 years old
Power source	2 “AAA” alkaline batteries 3 V (2 x 1.5 V)
Battery life	Approx. 450 measurements (using new alkaline batteries)
Durable period (service life)	5 years
Transmission method	<b>Bluetooth®</b> Low Energy
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation: GFSK Effective radiated power: < 20 dBm
IP classification	IP 22
Operating conditions	+5 to +40 °C / 15 to 90 % RH (non-condensing) / 700 to 1060 hPa
Storage / transportation conditions	-20 to +60 °C / 10 to 90 % RH (non-condensing)
Weight	Approx. 55 g (not including batteries)
Dimension	Approx. 33 (w) x 27 (d) x 121 (l) mm
Applied part Protection against electric shock	Type BF (sound sensor) Internally powered ME equipment
Operation Mode	Continuous operation
Memory	Stores up to 150 readings
Maximum temperature of the applied part	Lower than +48 °C

## Materials used in main device and all accessories

### Materials used in main device (HWZ-1000T-E)

Parts Name	Material	Grade
MAIN HOUSING	Polycarbonate	L-1225L
POWER BUTTON	Acrylonitrile Butadiene Styrene	700-314
CONNECTION BUTTON	Acrylonitrile Butadiene Styrene	700-314
SENSOR COVER	Silicone Rubber	CHN-9500-U
HEAD HOUSING	Polycarbonate	ML-3206ZT
BATTERY COVER	Polycarbonate	L-1225L
TOUCH COVER	Acrylonitrile Butadiene Styrene	700-314

### Materials used in storage case (HWZ-1000T-E)

Parts Name	Material	Grade
MAIN CASE	Acrylonitrile Butadiene Styrene	700-314
COVER CASE	Acrylonitrile Butadiene Styrene	700-314

## OMRON

Wheeze Detector

# WheezeScan

(HWZ-1000T-E)

Instruction Manual  
Mode d'emploi  
Gebrauchsanweisung  
Manuale di istruzioni  
Manual de instrucciones  
Gebruiksaanwijzing  
Руководство по эксплуатации  
Kullanım Kılavuzu

دليل الإرشادات

**All for Healthcare**



EN

FR

DE

IT

ES

NL

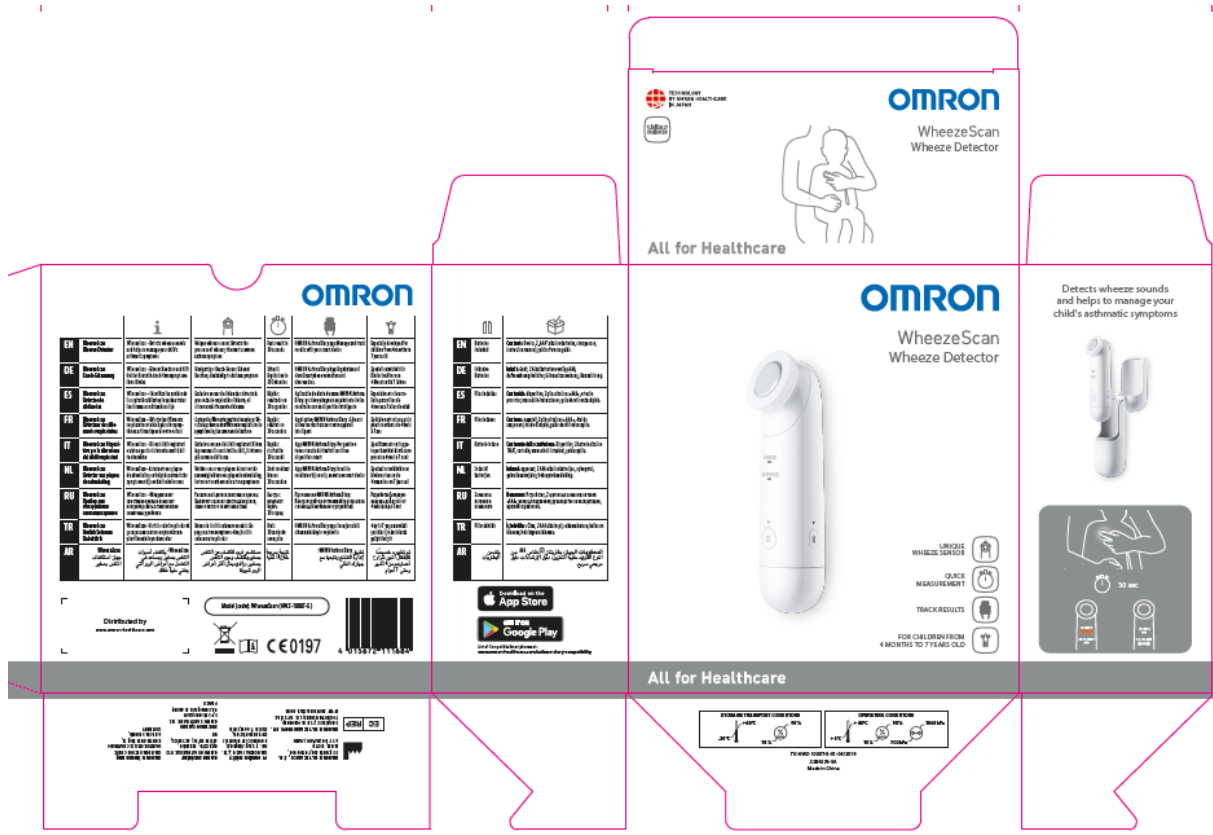
RU

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## Unfolded package design of main device and accessories

### Main device:



### Packaging specifications from Explanation Diagram

Package	Amount	Approx. weight	Approx. dimensions W x D x H, mm
Main Unit	1	58g	33 x 27 x 121 mm
Package	1	490g	154 x 77 x 169 mm
Master Carton	10	5.6kg	334 x 313 x 209 mm
EAN code	4015672111684		



## List of Harmonized EN Standards

The device is classified as a medical device, class IIa.

Applicable Medical Device Directive (93/42/EEC) standards:

EN 1041:2008+A1:2013  
EN 60601 · 1:2006+A1:2013+A12:2014  
EN 60601·1·2:2015  
EN 60601·1·6:2010+A1:2015  
EN 60601·1·11:2015  
EN 62304:2006+A1:2015  
EN 62366·1:2015  
EN ISO 10993·1:2009/AC:2010  
EN ISO 10993·5:2009  
EN ISO 10993·10:2013  
EN ISO 13485:2016  
EN ISO 14971:2012  
EN ISO 15223·1:2016  
EN ISO 17664:2017

Radio Equipment Directive 2014/53/EU

EN 300 328 V2.1.1  
EN 301 489-17 V3.1.1  
EN 62368·1:2014  
EN 301 489-1 V2.1.1  
EN 62479:2010

RoHS Directive 2011/65/EU

EN50581:2012

## Operation and care

### Cleaning of the device

- Use a soft cloth moistened with sanitizing alcohol to clean the sound sensor.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean the device other than the sound sensor, and then wipe with a dry cloth.
- DO NOT use any abrasive or volatile cleaners.
- DO NOT use gasoline, thinners or similar solvents to clean the device.

## Warnings

Read all the information in the instruction manual and any other literature included in the box before using the device.

**Warning:** Indicates a potentially hazardous situation which, if not avoided, could result in serious injury.

- NEVER diagnose or treat a patient based only on the result from this device. ONLY a physician is qualified to diagnose and treat patient's respiratory disease.
- This device is intended for use on a patient whose illness was diagnosed as bronchitis, bronchiolitis or bronchial asthma.
- Consult with a physician to discuss the results of the measurement with this device.
- If a patient is having signs and symptoms of chest tightness, shortness of breath, coughing or wheezing, a wheeze may not be detected because:
  - the breathing sound is too loud or too soft;
  - the wheeze is at extremely small amplitude, extremely short duration, extremely high frequency or extremely low frequency;
  - an asthma attack occurs without wheezing.

Always take action as prescribed by a physician, no matter what the result from this device is.

This device also may incorrectly detect any noise as a wheeze because various sounds

are occurring in patient's body such as:

- voice or cry of a patient;
- nasal obstruction sound;
- sputum sound etc.

• DO NOT use in case of severe asthma attack or respiratory failure. Consult with a physician immediately.

• Take a measurement again if you are concerned about the result. This device can detect.

wheeze only while taking a measurement. Wheeze can occur after taking a measurement.

If you are still concerned after taking a measurement again, consult with a physician.

• DO NOT use this device on a chest that is injured or that is under medical treatment.

• DO NOT disassemble or attempt to repair this device. This may cause an inaccurate

result. This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

**Caution:** Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.

- ONLY apply this device on a patient who is between 4 months old and 7 years old.
- ONLY parents who are advised by a physician, caregivers, school nurses and physicians are allowed to use this device. DO NOT let patient use this device on his/her own.

- An inaccurate result may happen when:
  - clothes touch the device (ALWAYS place the sound sensor on the patient's skin directly);
  - the device is used on crying, speaking or moving patients;
  - the sound sensor is placed on an incorrect place on the body;
  - the sound sensor is placed on the body too strongly or too lightly;
  - the sound sensor is not adhered to the body;
  - the patient's chest has too much muscle or fat.
- Stop using this device and consult with a physician if you or the patient experience skin irritation or discomfort.
- DO NOT use this device for any purpose other than detecting wheeze.
- DO NOT use in a location where there is moisture or a risk of water splashing on this device. This may damage this device.
- DO NOT wash or immerse the device in water.
- DO NOT use chemicals other than alcohol to clean the sound sensor.
- DO NOT drop or subject this device to strong shocks or vibrations.
- DO NOT use this device in places with high or low humidity or high or low temperatures. Refer to "Operating conditions" in section 7.
- This device may not work when the sound sensor is damaged. If it happens, contact your OMRON retail outlet or distributor.

### **Important Safety Information:**

- This device does not have a waterproof structure. Contact customer support immediately if the device is exposed to or submerged in water.
- Contact customer support if the device receives a strong shock such as being dropped.
- During operation, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 30 cm of this device. This may result in incorrect operation of the device and/or cause an inaccurate indication.
- DO NOT use this device with other medical electrical (ME) equipment simultaneously.  
This may result in incorrect operation of the device and/or cause an inaccurate indication.
- Ensure that this device has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate indication. OMRON recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the device is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information on operating and storage/transport temperatures, refer to section 7.
- Read and follow the "Correct Disposal of This Product (Waste Electrical & Electronic Equipment)" in section 9 when disposing of the device and any used accessories.
- DO NOT keep touching the sound sensor for more than 1 minute.
- This device cannot be used in an environment with noise at 60 dB or above, such as:
  - near working vacuum cleaners, hair dryers or washing machines

- in moving vehicles
- in noisy public or private areas

In any of these places, an error may occur while taking a measurement.

### **Data Transmission**

- This product emits radio frequencies (RF) in the 2.4 GHz band. Turn off the Bluetooth® feature in this device and remove batteries when in RF restricted areas.
- DO NOT replace batteries while readings are being transferred to your smart device. This may result in incorrect operation of this device and failure to transfer readings.

### **Battery Handling and Usage**

- Keep batteries out of the reach of infants, toddlers or children.
- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 2 “AAA” alkaline batteries with this device. DO NOT use other types of batteries. DO NOT use new and used batteries together.
- Remove batteries if this device will not be used for a long period of time.

## **Disposal**

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

## **Transportation and storage conditions**

- Ensure that this device has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate indication. OMRON recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the device is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information on operating and storage/transport temperatures, refer to section 7.
- Store the device in a clean, safe location.
- Changes or modifications not approved by the manufacturer will void the user warranty.
- Put the device in the storage case, and store in a clean, safe location.
- Do not store the device:
  - If the device is wet.
  - In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapours such as bleach.
  - In locations exposed to vibrations or shocks.

**Storage and transportation conditions:**

Temperature range: -20 to +60°C

Humidity range: 10 to 90%RH (non-condensing)

**Warranty and lifetime**

Warranty of the product: 3 years.

Durable period (service life): 5 years

Battery life: Approx. 450 measurements (using new alkaline batteries)

**Repair**

DO NOT disassemble or attempt to repair this device. This may cause an inaccurate result. This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

**Servicing**

Should warranty service be required please apply to the dealer whom the product was purchased from or an authorised OMRON distributor. For the address refer to the product packaging / literature or to your specialised retailer. If you have difficulties in finding OMRON customer services, visit our website ([www.omron-healthcare.com](http://www.omron-healthcare.com)) for contact information.