OMRON

Wheeze Detector

WheezeScan

(HWZ-1000T-E)

EN
FR
DE
IT
ES
NL
RU
TR
AR

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

CE 0197 UK CA 0086

All for Healthcare

Table of Contents

Introduction EN2
- Safety Instructions EN2
- Intended Use EN2
- Receiving and Inspection EN2
- Important Safety Information EN3

1. Know Your Device EN7
- 1.1 Contents EN7
- 1.2 Part Names EN8

2. Installing Batteries EN9

3. Detecting Wheeze EN10
- 3.1 Taking a Measurement EN10
- 3.2 Checking Result EN14

4. Managing Results with Your Smart Device EN15

5. Maintenance EN16
- 5.1 Maintenance EN16
- 5.2 Storage EN16
- 5.3 Cleaning EN16

6. Troubleshooting EN17

7. Specifications EN19

8. Limited Warranty EN21

9. Guidance and Manufacturer's Declaration EN22

10. How the Device Works EN24

Introduction

Thank you for purchasing the OMRON WheezeScan. 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. The cause of these symptoms can be bronchitis, bronchiolitis or bronchial asthma.

Safety Instructions

This instruction manual provides you with important information about WheezeScan. To ensure safe and proper use of this device, READ and UNDERSTAND all of these instructions. **If you do not understand these instructions or have any questions, contact your OMRON retail outlet or distributor before attempting to use this device.**

Intended Use

The OMRON WheezeScan is intended to detect the presence of wheezing in infants, toddlers and children from 4 months to 7 years of age.
The WheezeScan shows “Wheeze” or “No Wheeze” as the result of measurement. The obtained results should be discussed with your physician.

Environment of use: home, clinic

Receiving and Inspection

Remove this device and other items from the packaging and inspect for damage. If this device or any other items are damaged, DO NOT USE and consult with your OMRON retail outlet or distributor.

Important Safety Information

Read the Important Safety Information in this instruction manual before using this device.

Follow this instruction manual thoroughly for your safety. Keep for future reference. For specific information about patient's symptoms, CONSULT WITH A PHYSICIAN.

⚠ WARNING **Indicates a potentially hazardous situation which, if not avoided, could result in death or 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.

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.

Battery Handling and Usage

- Keep batteries out of the reach of 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.

Unusable Environment

- 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

- 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

- 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.

- If battery fluid should get in patient's or your eyes, immediately rinse with plenty of clean water. Consult with a physician immediately.
- If battery fluid should get on patient's or your skin, wash the skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with a physician.
- DO NOT use batteries after their expiration date.
- Periodically check batteries to ensure they are in good working condition.
- ONLY use batteries specified for this device. Use of unsupported batteries may damage and/or may be hazardous to this device.

1. Know Your Device

1.1 Contents

Device

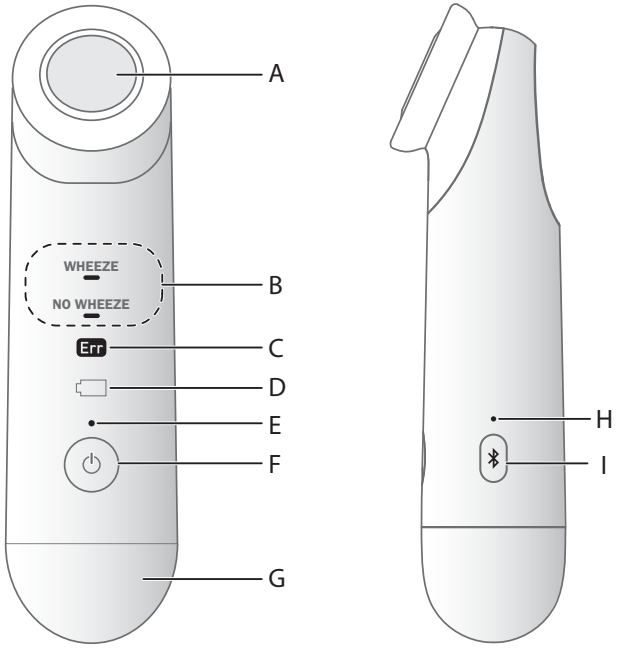
Storage case

2 “AAA” alkaline batteries

Instruction manual

Quick reference guide

1.2 Part Names



A	Sound sensor	**H**	Connection indicator
B	Display	**I**	[Connection] button
C	Error symbol		
D	Battery symbol Low: flashes / Depleted: lights		
E	Power indicator		
F	[Power] button		
G	Battery compartment		

2. Installing Batteries

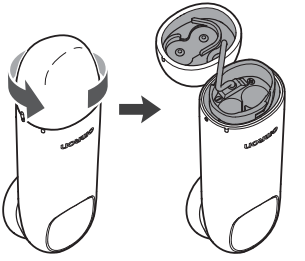
When the " ▭ " symbol flashes, it is recommended that you replace the batteries. To replace batteries, turn the device off and remove batteries. Then replace with 2 new alkaline batteries.

Note

- Replacing batteries does not delete previous results recorded in the device.
- The supplied batteries may have a shorter life span than new batteries.
- Disposal of used batteries should be carried out in accordance with local regulations.

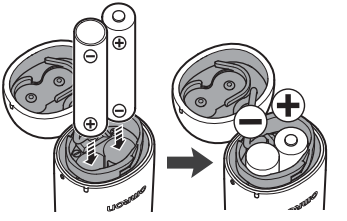
1 **Open the battery cover.**

Turn the battery cover anticlockwise to open.
DO NOT pull the battery cover strongly. The rubber may be torn off.



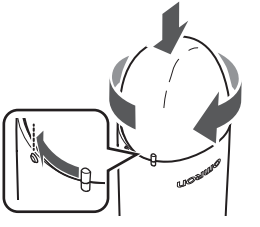
2 **Insert 2 "AAA" alkaline batteries as indicated in the battery compartment.**

Confirm the polarities are correctly aligned.



3 **Close the battery cover.**

Turn the battery cover clockwise to close.



3. Detecting Wheeze

3.1 Taking a Measurement

Do not use the device in locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.

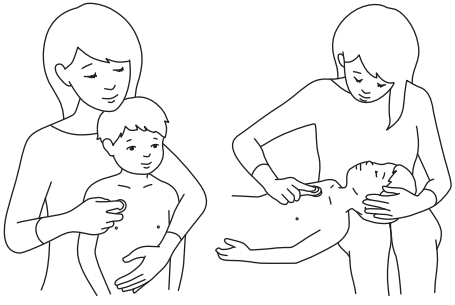
⚠ CAUTION

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.

1 **Remove phlegm and nasal mucus, if any, before taking a measurement.**

2 **Let the patient sit down or lay face up.**



3 Remove clothes to expose patient's chest. Being naked from the waist up is recommended.

⚠ WARNING

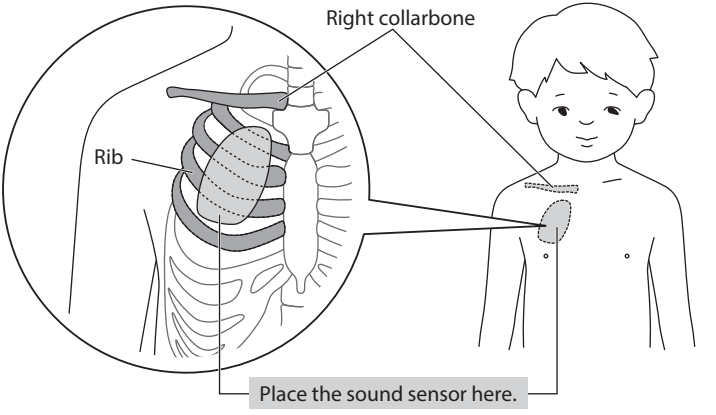
DO NOT place the sound sensor on clothes and DO NOT let clothes touch the device. This may cause an inaccurate result. ALWAYS place the sound sensor directly on the patient's skin.

4 Check where to place the sound sensor.

The sound sensor should be placed on the **right chest** under the right collarbone. For appropriate location on the body, see the illustration shown below.
To avoid damage to the sound sensor, wipe off baby oil or any chemical products from the patient's skin before taking a measurement.

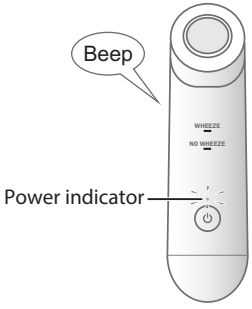
⚠ WARNING

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



5 Press the ⏻ button.

The device will beep and the power indicator will light green.



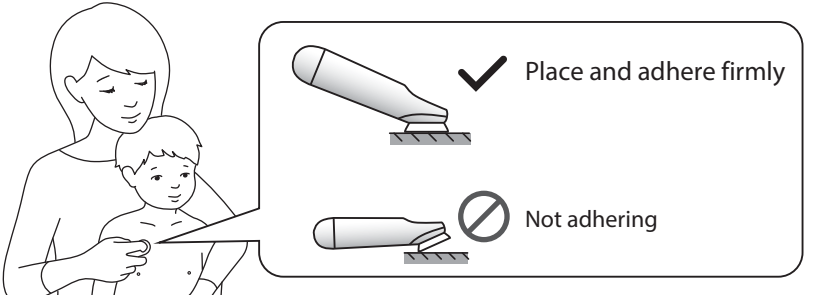
Note

- When the power is turned on, all indicators will light up for 2 seconds. Then, the previous measurement result (refer to section 3.2) will be displayed for 2 seconds.
- If you do not start a measurement within 30 seconds after turning the power on, " Err " symbol will appear. To restart the device, press and hold the ⏻ button to turn the power off and press it again to turn the power on.

- Ensure that both the parent and the patient DO NOT talk while the measurement is being taken.

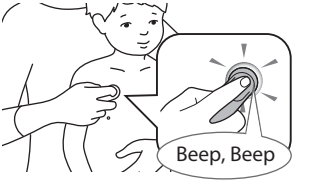
6 Apply the sound sensor to the patient's skin.

Place and adhere the sound sensor firmly.



7 The device will beep twice and begin measuring.

When the sound sensor is correctly placed on the body, the device gives twice the sound "beep" and the measurement starts automatically.
After the sound sensor is applied to the skin, the sensor will flash white while taking the measurement.



Note

- Ensure that the patient DOES NOT talk, cry or move while the measurement is being taken.
- Ensure that the patient continues to breathe normally.

8 Wait until the measurement is completed.

When the measurement is completed, the device beeps 3 times.
The maximum measurement time is 30 seconds.

Note

KEEP the sensor in close contact and DO NOT move the device until the device beeps 3 times. Otherwise the result may be inaccurate.

3.2 Checking Result

After the measurement, the result will be shown as pictured below.
If wheezing is not detected, “No Wheeze” will light white.
If wheezing is detected, “Wheeze” will light orange.

Wheezing is NOT detected

Wheezing is detected

EN

Note

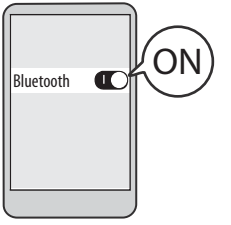
- The device automatically turns off within a maximum of 3 minutes after completing a measurement. You can turn the power off manually by pressing and holding the ⏻ button.
- If you want to check the last result, press the ⏻ button to turn the power on. You will see the last result displayed.
- If the device can not detect the sound correctly, it gives 2 longer beeps, “ Err “ symbol appears and the sound sensor flashes or lights orange. Refer to section 6 for more information.

4. Managing Results with Your Smart Device

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. Review the list of compatible smart devices at:
www.omron-healthcare.com/asthma-diary-compatibility
Follow the steps below to pair the device with your smart device.

Note
If you do not pair the device, measurements you take will not be stored in the WheezeScan's memory.

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.**

For more information about the app, refer to "Help" section of the app.

5. Maintenance

5.1 Maintenance

To protect the device from damage, please follow the directions below:

- Store the device in a clean, safe location.
- Changes or modifications not approved by the manufacturer will void the user warranty.

⚠ WARNING

- 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.

5.2 Storage

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 vapors such as bleach.
- In locations exposed to vibrations or shocks.

5.3 Cleaning

- 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.

⚠ CAUTION

- DO NOT wash or immerse the device in water.

6. Troubleshooting

If any of the below problems occur, check to make sure that no other electrical device is within 30 cm. If the problem persists, refer to the table below.

Problem	Possible cause	Solution
The sound sensor flashes orange and " Err " symbol appears.	The measurement did not start within 30 seconds after the power was turned on.	Place the sound sensor on the patient's body within 30 seconds after the power is turned on.
	The patient, parent or anyone near the patient was speaking.	• DO NOT speak while the measurement. • DO NOT use this device on a crying, speaking or moving patient.
	The device was used on clothes during the measurement.	DO NOT put this device on clothes. ALWAYS place this device on the patient's skin directly.
	The sound sensor was applied on an incorrect location on the body.	Apply the sensor on appropriate location (See sub-section 3.1 for measurement location).
	The sound sensor was not placed and adhered firmly on the skin.	KEEP the sensor in close contact with the patient and DO NOT move the device until you hear 3 beep sounds.

Problem	Possible cause	Solution
The sound sensor lights orange and " Err " symbol appears.	There is an external noise around the device.	• Take a measurement in a quiet place. • DO NOT talk while taking a measurement. • DO NOT apply this device on a crying patient.
The sound sensor does NOT flash or light orange but " Err " symbol appears.	An internal error occurred.	Contact your OMRON retail outlet or distributor.
flashes	Batteries are low.	Replacing all batteries with 2 new batteries is recommended. Refer to sub-section 2.1.
lights	Batteries are depleted or battery polarities are not properly aligned.	• Immediately replace all batteries with 2 new batteries. Refer to sub-section 2.1. • Confirm the batteries are properly inserted with polarities correctly aligned. Refer to sub-section 2.1.
No power. Nothing appears.		
Results change when taking measurements repeatedly.	The patient's condition is always changing.	NEVER diagnose or treat a patient based only on the result. Consult with a physician if you are concerned.

If you are not able to solve the problem, contact your OMRON retail outlet or distributor.

7. Specifications

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	**Bluetooth®** 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

- These specifications are subject to change without notice.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects of 12.5 mm diameter and greater such as a finger, and against oblique falling water drops which may cause issues during a normal operation.
- Operation mode is classification in accordance with IEC 60601-1.

About a wireless communication interference

This product operates in an unlicensed ISM band at 2.4 GHz. In the event this product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this product, there is a possibility that interference may occur.
If interference occurs, stop the operation of the other devices or relocate this product away from other wireless devices before attempting to use it.

8. Limited Warranty

Thank you for buying an OMRON product. This product has been constructed using high quality materials and great care has been taken in its manufacturing. It is designed to give you a high level of comfort, provided that it is properly operated and maintained as described in the instruction manual.

This product is warranted by OMRON for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product are warranted by OMRON. During this period of warranty OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts.

The warranty does not cover any of the following:

A. Transport costs and risks of transport.
B. Costs for repairs and / or defects resulting from repairs done by unauthorised persons.
C. Periodic check-ups and maintenance.
D. Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted above.
E. Costs arising due to non-acceptance of a claim (those will be charged for).
F. Damages of any kind including personal caused accidentally or from misuse.
G. Calibration service is not included within the warranty.

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) for contact information.

Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.

The warranty will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer.

9. Guidance and Manufacturer's Declaration

- Hereby, OMRON HEALTHCARE Co., Ltd., declares that the radio equipment type HWZ-1000T-E is in compliance with Directive 2014/53/EU.
- The full text of the EU declaration of conformity is available at the following internet address: www.omron-healthcare.com
- This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co., Ltd., Japan.
- Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device.

Symbols Description

	Applied part - Type BF Degree of protection against electric shock (leakage current)	IP XX	Ingress protection degree provided by IEC 60529
	CE Marking		UKCA marking
SN	Serial number	UDI	Unique device identifier
MD	Medical device		Temperature limitation
	Humidity limitation		Atmospheric pressure limitation
	Necessity for the user to consult this instruction manual		Power on / off
	Date of manufacture		The direction of correct polarity of the battery
	Need for the user to follow this instruction manual thoroughly for your safety.		To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

Important information regarding Electromagnetic Compatibility (EMC)

HWZ-1000T-E conforms to EN60601-1-2:2015 Electromagnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at www.omron-healthcare.com. Refer to the EMC information for HWZ-1000T-E on the website.

Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life.

To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

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.

10. How the Device Works

What is asthma?

Asthma is a condition in which the airways narrow and swell and produce extra mucus. This can make breathing difficult and trigger coughing, wheezing and shortness of breath.

Asthma can't be cured, but its symptoms can be controlled. Because asthma often changes over time, it's important that you work with your doctor to track the signs and symptoms and adjust the treatment as needed.

Asthma symptoms

Asthma symptoms vary from person to person. A person may have infrequent asthma attacks, have symptoms only at certain times — when exercising, or have symptoms all the time.

Asthma signs and symptoms include:

- Coughing
- Wheezing
- Runny nose or other cold symptoms
- Awakening due to coughing or difficulty breathing
- Being less active than usual

What is wheeze?

Wheezing is a high-pitched whistling sound made while breathing. It's often associated with difficulty breathing. Wheezing may occur during breathing out (expiration) or breathing in (inhalation).

How does WheezeScan work?

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 analyze the breathing sounds for the presence of wheezing.

https://www.omron-healthcare.com/

<table>
<tr><td colspan="2">Manufacturer
 </td><td>OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN</td></tr>
<tr><td colspan="2">EU-representative
EC REP</td><td rowspan="2">OMRON HEALTHCARE EUROPE B.V.
Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS
www.omron-healthcare.com</td></tr>
<tr><td colspan="2">Importer in EU</td></tr>
<tr><td colspan="2">Production facility</td><td>OMRON DALIAN Co., Ltd.
No. 3, Song Jiang Road, Economic and Technical Development Zone, Dalian 116600, China</td></tr>
<tr><td rowspan="3">Subsidiaries</td><td>Importer in the United Kingdom and UK responsible person</td><td>OMRON HEALTHCARE UK LTD.
Opal Drive, Fox Milne, Milton Keynes, MK15 0DG, UK
www.omron-healthcare.com/distributors</td></tr>
<tr><td colspan="2"></td><td>OMRON MEDIZINTECHNIK HANDELSGESELLSCHAFT mbH
www.omron-healthcare.com/distributors</td></tr>
<tr><td colspan="2"></td><td>OMRON SANTÉ FRANCE SAS
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Made in China

Issue date
Date de publication
Ausgabedatum
Data di pubblicazione
Fecha de publicación : 2022-11-01
Datum van publicatie
Дата выпуска
Teslim tarihi
تاريخ الإصدار

IM-HWZ-1000T-E-02-09/2022
3289265-0B