



New Product Information Sheet

Specifications subject to change
© OMRON HEALTHCARE EUROPE B.V.

Model (code):
VIVA (HBF-222T-EBK)

Product description: *Body Composition Monitor*

Product category: *Body Composition Analyzers*

Model (code): *VIVA (HBF-222T-EBK)*



LEGAL MANUFACTURER

OMRON HEALTHCARE Co., Ltd
53, Kunotsubo, Terado-cho, Muko, KYOTO,
617-0002 Japan

PRODUCTION FACILITY

Krell Precision (Yangzhou) Co., Ltd
No.28 Xingyang Road,
Economic Development Zone,
Yangzhou, Jiangsu 225009,
China

EU REPRESENTATIVE

OMRON HEALTHCARE EUROPE B.V.
Scorpius 33, 2132 LR Hoofddorp,
THE NETHERLANDS

Included accessories / optional accessories

N/A

General description

VIVA OMRON's Connected Body Composition Monitor is a medical device meant for measuring and displaying the following body composition parameters on both device and OMRON connect app:

- Body Weight
- Body Fat (in %)
- Visceral Fat (up to 30 levels)
- Skeletal Muscle (in %)
- Resting Metabolism (in kcal)
- BMI (Body Mass Index)

Packaging content

The manufacturer produces VIVA with the applicable accessories included, necessary for the application of its intended purpose.

Box includes: Body Composition Monitor, 4 AAA alkaline batteries (LR03), setup instructions, instruction manual.

Purpose

This product is intended to be used for measuring and displaying the following body composition parameters:

- Body Weight
- Body Fat (in %)
- Visceral Fat (up to 30 levels)
- Skeletal Muscle (in %)
- Resting Metabolism (in kcal)
- BMI (Body Mass Index)

Application field

This unit is intended to be operated by adults who can understand this instruction manual. It is not for professional use in hospitals or other medical facilities, it is intended for home use only.

Intended user

The OMRON Body Composition Monitor VIVA is suitable for persons from 10 to 80 years old. The age range for the Skeletal Muscle percentage, Skeletal Muscle percentage classification, Visceral Fat level, Visceral Fat level classification and Resting Metabolism is 18 to 80 years old.

With a body weight between 2 and 150 kg and height between 100.0 and 199.5 cm.

* When the height of a person is less than 100.0 cm or more than 199.5 cm:

BMI and body composition measurement results are for reference.

Indications for use

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

This product is intended to be used for measuring and displaying the following body composition parameters:

- Body Weight
- Body Fat (in %)
- Visceral Fat (up to 30 levels)
- Skeletal Muscle (in %)
- Resting Metabolism (in kcal)
- BMI (Body Mass Index)

Features (Particularities)

Key features

- 6 body metrics:
 - Body Weight
 - Body Fat (in %)
 - Visceral Fat (up to 30 levels)
 - Skeletal Muscle (in %)
 - Resting Metabolism (in kcal)
 - BMI (Body Mass Index)

- Classification of Body Fat, Visceral Fat, Skeletal Muscle and BMI are shown on the display and within the OMRON connect application
- Clinically Validated Accuracy
- OMRON connect app with history of measurements and trends
- **Bluetooth®** low energy technology
- 'STEP ON' Technology
- User Auto Recognition
- 4 Users + Guest
- 4 sec Fast Reading
- Stand Alone
- Compact, slim design 28.5 cm x 28.0 cm (28 mm slim and 1.6 kg light)
- Large and easy to read LCD display (5.8 cm x 7.8 cm)
- Maximum weight 150 kg with 100g increments
- Measurement units: kg & cm / lb & inch / st-lb & inch

Description of operating principle

The VIVA measures the body fat percentage by the Bioelectrical Impedance (BI) method. Muscles, blood vessels and bones are body tissues with a high water content that conducts electricity easily. Body fat is tissue that has little electric conductivity. The VIVA sends an extremely weak electrical current of 50 kHz and less than 500 μ A through your body to determine the amount of fat tissue. This weak electrical current is not felt while operating the VIVA. In order for the scale to determine your body composition, it uses the electrical impedance, along with your height, weight, age and gender information to generate results based on OMRON's data of body composition.

How to use the device

Everyday use:

1. Step onto the unit
2. Device is recognizing the user and measurements are shown on a display
3. Data is transferred to OMRON connect app once device goes OFF
4. Check and monitor your results in OMRON connect app.

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

Technical data

Product Category	Body Composition Analyzers
Product Description	Body Composition Monitor
Model (code)	VIVA (HBF-222T-EBK)
Display*	<p>Body Weight: 2.0 to 150.0 kg with an increment of 0.1 kg (4.4 to 330.0 lb with an increment of 0.2 lb) (0 st 4.4 lb to 23 st 8.0 lb with an increment of 0.2 lb)</p> <p>Body Fat percentage: 5.0 to 60.0% with an increment of 0.1%</p> <p>Skeletal Muscle percentage: 5.0 to 50.0% with an increment of 0.1%</p> <p>BMI: 7.0 to 90.0 with an increment of 0.1</p> <p>Resting Metabolism: 385 to 3999 kcal with an increment of 1 kcal</p> <p>Visceral Fat Level: 30 levels with an increment of 1 level</p> <p>Body fat percentage, Skeletal muscle percentage and BMI classification: – (Low) / 0 (Normal) / + (High) / ++ (Very High) 4 levels</p> <p>Visceral fat level classification: 0 (Normal) / + (High) / ++ (Very High) 3 levels</p> <p>* The age range for the Body Fat percentage and Body fat percentage classification is 10 to 80 years old.</p> <p>* The age range for the Skeletal Muscle percentage, Skeletal Muscle percentage classification, Visceral Fat level, Visceral Fat level classification and Resting Metabolism is 18 to 80 years old.</p>
Transmission Protocol	Bluetooth® low energy technology
Wireless Communication	<p>Frequency range: 2.4 GHz (2400 - 2483.5 MHz)</p> <p>Modulation: GFSK</p> <p>Effective radiated power: <20 dBm</p>
Setting Items*	<p>The following information can be stored for up to 4 persons.</p> <p>Measurement unit kg&cm / lb&inch / st-lb&inch</p> <p>Birth date 1st January, 1900 to 31st December, 2045</p> <p>Gender Male / Female</p> <p>Height 100.0 to 199.5 cm with an increment of 0.5 cm (3' 4" to 6' 6 1/2" with an increment of 1/4")</p> <p>* When the height of a person is less than 100.0 cm or more than 199.5 cm: BMI and body composition measurement results are for reference.</p>
Weight Accuracy	<p>2.0 kg to 40.0 kg: ± 0.4 kg (4.4 lb to 88.2 lb: ± 0.88 lb)</p> <p>(4.4 lb to 6 st 4.2 lb: ± 0.88 lb)</p> <p>40.0 kg to 150.0 kg: ± 1% (88.2 lb to 330.0 lb: ± 1%)</p> <p>(6 st 4.2 lb to 23 st 8.0 lb: ± 1%)</p>
Accuracy (S.E.E.)	<p>Body Fat percentage: 3%</p> <p>Skeletal Muscle percentage: 3.5%</p> <p>Visceral Fat Level: 2 levels</p>
Durable Period	5 years
IP Classification	<p>IP21*</p> <p>*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. This device is protected against vertically falling water drops which may cause issues during a normal operation.</p>
Power Supply	4 AAA alkaline batteries (LR03)
Battery Life	Approximately 6 months (When AAA alkaline batteries are used in four measurements, four data transfers and four persons a day at a room

	temperature of 23°C)
Operating Temperature/ Humidity/Air Pressure	+5°C to +40°C, 30% to 85% RH (no-condensing), 860 hPa - 1060 hPa
Storage and Transport Temperature/ Humidity/Air Pressure	-20°C to +60°C, 10% to 95% RH (no-condensing), 860 hPa - 1060 hPa
Weight	Approximately 1.6 kg (including batteries)
External Dimensions	Approx. 285(W)×28(H)×280(D) mm (Approx. 11 1/5"(W)×1 1/10"(H)×11"(D))
Contents	Body composition monitor, 4 AAA alkaline batteries (LR03), setup instructions, instruction manual

This device fulfils the provisions of EC directive 93/42/EEC (Medical Device Directive).

Hereby, OMRON HEALTHCARE Co., Ltd., declares that the radio equipment type VIVA (HBF-222T-EBK) is in compliance with Directive 2014/53/EU.

Materials used in main device

Description	Material
Top Plate	Toughened Glass
Top Cover	High Density Polyethylene Plastics
Bottom Cover	High Density Polyethylene Plastics
Foot Rubber	Polyurethane
Caution Seal	Polyethylene terephthalate
Battery Cover	High Density Polyethylene Plastics
Sensor Cover	Acrylonitrile Butadiene Styrene
Foot Electrode	Stainless Steel
Package	Cardboard
Instruction Manual	Paper

Title page of Instruction Manual
(9 languages – English / French / German / Italian / Spanish /
Dutch / Russian / Turkish / Arabic)

OMRON



Body Composition Monitor VIVA (HBF-222T-EBK)

- Instruction Manual
- Gebrauchsanweisung
- Mode d'emploi
- Manual de instrucciones
- Manuale di istruzioni
- Gebruiksaanwijzing
- РУКОВОДСТВО ПО ЭКСПЛУАТАЦИИ
- Kullanım Kılavuzu

• كتيب الإرشادات

EN
DE
FR
ES
IT
NL
RU
TR
AR

Thank you for purchasing the OMRON Body Composition Monitor.
Before using this unit, please be sure to read this Instruction Manual carefully to understand the safe and proper use.
Please store this Instruction Manual carefully for future reference.

All for Healthcare

IM-HBF-222T-EBK-03-09/2017
3135909-5C

Unfolded package design of main device

Main device:





Accessories:
N/A

Packaging specifications from Explanation Diagram

Package	Amount	Approx. weight	Approx. dimensions W x D x H, mm
Main Unit	1	1.6 kg	285 x 280 x 28 mm
Package	1	2.2 kg	332 x 43.5 x 320 mm
Master Carton	6	14.1 kg	352 x 294 x 357 mm
EAN code	401567211090 8		

List of Harmonized EN Standards

The device is classified as a medical device: Class I with Measuring Function (MDD Annex IX Rule 12)

Product Category for RoHS: Category 8 (Medical devices)

General applicable directives: Applicable Medical Device Directive 93/42/EEC

Standards:

EN ISO 15223-1: 2016

EN 1041: 2008+A1:2013

EN 60601-1: 2006+A1:2013

EN 60601-1-2: 2015

EN 60601-1-6: 2010+A1:2015

EN 60601-1-11: 2015

EN 62304: 2006+A1: 2015

EN 62366: 2008+A1: 2015

EN ISO 10993-1: 2009/AC: 2010

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN ISO 14971: 2012

General applicable directives: Radio Equipment Directive 2014/53/EU

Standards:

EN 300 328 V2.1.1 EN 301 489-1V2.1.1

EN 301489-17V3.1.1 EN 62479:2010

EN 60950-1: 2006+Amd.11: 2009+Amd.1: 2010+Amd.12: 2011

General applicable directives: RoHS Directive 2011/65/EU

Standards:

EN 50581:2012

Operation and care

Cleaning of the device

- Always keep the unit clean before use.
- Wipe the unit with a soft dry cloth. If necessary, use a cloth moistened with water or detergent and squeeze it well before wiping the unit, then wipe off with a dry cloth.
- Do not use benzene or thinner, or other volatile solvents to clean the unit.
- Do not wash the unit with water.

Warnings

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

Definitions are as follows:

Danger: Improper use may cause danger resulting in death or serious injury.

Warning: Improper use may result in possible death or serious injury.

Caution: Improper use may result in injury or property damage.

Danger:

Never use this unit in combination with medical electronic devices such as:

- (1) Medical electronic implants such as pacemakers.
- (2) Electronic life support systems such as an artificial heart/lung.
- (3) Portable electronic medical devices such as an electrocardiograph.

This unit could cause these devices to malfunction, posing a considerable health risk to users of these devices.

Warning:

- Keep the unit out of the reach of young children. Contains small parts that may cause a choking hazard if swallowed by infants.
- Do not use the unit on slippery surfaces, such as a wet floor.
- Do not jump onto the unit, or bounce on the unit.
- Do not use this unit when your body and/or feet are wet, such as after taking a bath.
- Stand on the unit bare-footed. Standing on the unit with socks on may cause you to slip and injure yourself.
- Do not step on the edge or display area of the unit.
- People with disabilities, or who are physically frail, should always be assisted by another person when using this unit.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult a physician immediately.
- Do not use this product in hospitals, aircrafts or other environments where the use of radio waves is restricted.
- This product emits radio frequencies (RF) in the 2.4 GHz band. Do not use this product in locations where RF is restricted, such as on an aircraft or in hospitals.

Caution:

- Do not disassemble, repair, or remodel the unit.
- Do not begin a weight reduction or exercise program without consulting a physician or healthcare specialist first. Self-diagnosis could injure your health.
- During measurement, make sure that no mobile phone or any other electrical devices that emit electromagnetic fields is within 30cm of this device. This may result in incorrect operation of the device and/or cause an inaccurate reading.
- Use batteries specified for this unit. Do not insert the batteries with the polarities in the wrong direction.
- Replace worn batteries with new ones immediately.
- Do not dispose of batteries in fire.

- If battery fluid should get on your skin or clothing, immediately rinse with plenty of clean water.
- Remove the batteries from this unit when you are not going to use it for a long period of time (approximately three months or more).
- Do not use different types of batteries together.
- Do not use new and worn batteries together.
- Always wash your feet before using the unit. If you are suffering from a foot infection or other skin disease, you may cause infection to other people.
- When the unit will be used by several people, wipe the unit with a damp cloth moistened with mild detergent after using it. Then wipe it dry.
- Do not use this unit for purposes other than described in this manual.
- As this unit is a precision instrument, do not drop, vibrate, or apply strong shock.

Data Transmission:

- Do not replace the battery while your measurement result is being transferred to your smart device. This may result in the incorrect operation of your monitor and failure to transfer your measurement result.
- Do not place integrated circuit cards, magnets, metal objects, or other devices that emit electromagnetic fields near this monitor while your measurement result is being transferred to your smart device. This may result in the incorrect operation of your unit and failure to transfer your measurement result.

Incorrect Measurement

Incorrect measurement might occur to the following users:

Elderly people (over 81 years old) / People with a fever / Body builders or highly trained athletes / Patients undergoing dialysis / Patients with osteoporosis who have very low bone density / Pregnant women / People with swelling.

- Because the body composition such as body water might greatly deviate from the average value.

Disposal

As there is a risk of environmental pollution, follow your applicable national and local legal regulations regarding disposal or recycling of this equipment and batteries. The main constituents of each part are listed in the table "Materials List".

Transportation and storage conditions

Do not store the unit in the following conditions:

- Humidity, where moisture or water may get into the unit
- High temperatures, direct sunlight or dusty places
- Places with the risk of sudden shocks or vibrations
- In places where chemicals are stored or where corrosive gas is present.

Storage and transportation:

Temperature range: -20 to +60°C (-4 to 140°F)

Humidity range: 10 to 95% RH (no-condensing)

Atmospheric pressure: 860 to 1060 hPa

Warranty and lifetime

Warranty of the body composition monitor: 3 years.

Lifetime of the body composition monitor: 5 years.

Repair

Do not carry out repairs of any kind by yourself. This product is calibrated at the time of manufacture. If at any time you question the accuracy of measurements, please contact your authorized OMRON distributor. In general it is recommended to have the device inspected every 2 years to ensure correct functioning and accuracy.

Servicing

The device is not user serviceable. Return it to an authorized OMRON retail outlet or distributor in case of any problem listed in Troubleshooting chapter of the Instruction Manual.