

## New Product Information Sheet

Specifications subject to change  
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# Model (code): M300 Intelli IT (HEM-7143T1-D)



Versions	Remark	Date
1	1 <sup>st</sup> version, without key market visual	13/10/2021

## **M300 Intelli IT**

### **Accurate measurements in one touch**

#### **Product Name**

M300 Intelli IT (HEM-7143T1-D)

#### **Product Description**

Automatic Upper Arm Blood Pressure Monitor

#### **Product Category**

Electronic Sphygmomanometers

#### **Features**

- Intellisense
- Irregular heartbeat detection
- Hypertension indicator
- Body movement detection
- Cuff wrap guide
- 30 memories capacity
- Clinically Validated
- Omron Connect

#### **Packaging contents**

- Monitor
- Arm cuff (HEM-RML31)
- 4 "AA" batteries
- Storage case,
- Instruction Manual
- Guarantee card
- Blood pressure pass

## **General description**

M300 Intelli IT Automatic Upper Arm Blood Pressure Monitor uses the oscillometric method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

## **Intended use**

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. This monitor detects the appearance of irregular heartbeats during measurement and indicates this via a symbol with readings. It is mainly designed for general household use.

## **Application field /Environment**

It is mainly designed for general household use.

## **Intended User**

- This unit is intended to be operated by adults who can understand this instruction manual.
- Before using this device, please refer to ‘Important Safety Information’ section of the Instruction Manual. This device shouldn’t be used by people mentioned in these sections.

## **Indications for use**

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.

## **Operating principle**

The device operates on the oscillometric principle. It detects blood movement through the brachial artery and converts the movements into a digital reading.

## How to use the device?

Please refer to the instruction manual for full details on the application of this product.

### Main steps:

1. Prepare for a measurement. 30 mins before it you shouldn't drink alcohol, smoke, have a hot shower, consume hot beverages, eat or exercise. 5 minutes before the measurement relax and rest.
2. Install the batteries.
3. Download the "Omron connect" App on your smart device.
4. Switch on the "Bluetooth function" on your smart device. Pair your smart device with the Blood pressure monitor through the "Omron connect" app and follow the instructions from the App.
5. Apply the arm cuff on the left arm. (On using the right arm instead, follow the cuff wrap instructions under "To take a measurement on your right arm" at the end of sub-section 2.3).
6. Sit correctly and place your arm at your heart's level. Remain still and don't talk.
7. Take a measurement by pressing the START/STOP button.
8. Check readings. Consult sub-section 1.3 of the instruction manual on the symbols that may appear.

## Cleaning of the device

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your monitor and arm cuff, and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and arm cuff or other components in water.
- Do not use gasoline, thinners, or similar solvents to clean your monitor and arm cuff or other components.

## Maintenance

To protect your monitor from damage, follow the directions below:

- Changes or modifications not approved by the manufacturer will void the user warranty.

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

## **Transportation and storage conditions**

- Keep your monitor in the storage case when not in use.
- Do not store your monitor and other components:
  - If your monitor and other components are wet.
  - In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
  - In locations exposed to vibrations or shocks.
- Storage and transportation
  - Temperature range: -20°C to +60°C
  - Humidity range: 15% to 90%RH

## **Warnings**

*(Warning indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury.)*

It is important that you read all the warnings and precautions included in this instruction manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the unit!

- DO NOT use this monitor on infants, toddlers, children, or persons who cannot express themselves.
- DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.
- DO NOT use this monitor on an injured arm or an arm under medical treatment.
- DO NOT apply the arm cuff on your arm while on an intravenous drip or blood transfusion.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in

incorrect operation of the monitor and/or cause an inaccurate reading.

- DO NOT use this monitor in oxygen rich environments or near flammable gas.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- To help avoid strangulation, keep the air tube and AC adapter cable away from infants, toddlers, and children.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers, and children.

### AC Adapter (optional accessory) Handling and Usage

- DO NOT use the AC adapter if this monitor or the AC adapter cable is damaged. If this monitor or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

### Battery Handling and Usage

- Keep batteries out of the reach of infants, toddlers, and children.
- It is important that you read all the warnings and precautions included in this instruction manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the unit!
- DO NOT use this monitor on infants, toddlers, children, or persons who cannot express themselves.
- DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician.

ONLY a physician is qualified to diagnose and treat high blood pressure.

- DO NOT use this monitor on an injured arm or an arm under medical treatment.
- DO NOT apply the arm cuff on your arm while on an intravenous drip or blood transfusion.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT use this monitor in oxygen rich environments or near flammable gas.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- To help avoid strangulation, keep the air tube and AC adapter cable away from infants, toddlers and children.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers and children.

## **Cautions**

*(Cautions indicate a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.)*

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this monitor on an arm where intravascular access or therapy, or an arteriovenous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury.

- Consult with your physician before using this monitor if you have had a mastectomy.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the arm cuff when it is applied on your upper arm.
- Remove the arm cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emit electromagnetic fields is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
- DO NOT use this monitor in a moving vehicle such as in a car or on an aircraft.
- DO NOT drop or subject this monitor to strong shocks or vibrations.
- DO NOT use this monitor in places with high or low humidity or high or low temperatures. Refer to specification chapter in the instruction manual.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- DO NOT use this monitor in high-use environments such as medical clinics or physician offices.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising, and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.



- Remove tight-fitting or thick clothing from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use the arm cuff on persons whose arm circumference is within the specified range of the cuff.
- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. OMRON recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor 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 temperature, refer to section 6.
- DO NOT use this monitor after the durable period has ended. Refer to specification chapter in the instruction manual.
- DO NOT crease the arm cuff or the air tube excessively.
- DO NOT fold or kink the air tube while taking a measurement. This may cause an injury by interrupting blood flow.
- To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.
- ONLY use the AC adapter, arm cuff, batteries and accessories specified for this monitor. Use of unsupported AC adapters, arm cuffs and batteries may damage and/or may be hazardous to this monitor.
- ONLY use the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect readings.
- Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied. NOTE: refer to "If your systolic pressure is more than 210 mmHg" in sub-section 3.1 of the instruction manual for additional information.
- Read and follow the "Correct Disposal of This Product" in section 11 when disposing of the device and any used accessories or optional parts.

## AC Adapter (optional accessory) Handling and Usage

- Fully insert the AC adapter into the outlet.
- When unplugging the AC adapter from the outlet, be sure to safely pull from the AC adapter. DO NOT pull from the AC adapter cable.
- When handling the AC adapter cable:
  - Do not damage it. / Do not break it. / Do not tamper with it.
  - DO NOT pinch it. / Do not forcibly bend or pull it. / Do not twist it.
  - DO NOT use it if it is gathered in a bundle.
  - DO NOT place it under heavy objects.
- Wipe any dust off of the AC adapter.
- Unplug the AC adapter when not in use.
- Unplug the AC adapter before cleaning this monitor.

## Battery Handling and Usage

- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 4 "AA" alkaline or manganese batteries with this monitor. DO NOT use other types of batteries. DO NOT use new and used batteries together. DO NOT use different brands of batteries together.
- Remove batteries if this monitor will not be used for a long period of time.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately.
- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury, or pain persists, consult with your physician.
- DO NOT use batteries after their expiration date.
- Periodically check batteries to ensure they are in good working condition.

### **Disposal procedure**

- 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.
- Disposal of used batteries should be carried out in accordance with

local regulations.

### **Warranty and lifetime**

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.

	Warranty	Lifetime (Service Life)
Monitor:	3 years	5 years
Cuff:	1 year	5 years

### **Repair**

During the period of warranty OMRON will, without charge for labor or parts, repair or replace the defect product or any defective parts. Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.

### **Servicing**

The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life. It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult your authorized OMRON dealer or the OMRON Customer Service at the address given on the packaging or attached literature.

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

### Technical data

<b>Product description</b>	Automatic Upper Arm Blood Pressure Monitor
<b>Product Category</b>	Electronic Sphygmomanometers
<b>Model (code)</b>	M300 Intelli IT (HEM-7143T1-D)
<b>Display</b>	LCD digital display
<b>Cuff Pressure range</b>	0 to 299 mmHg
<b>Blood pressure measurement range</b>	SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg
<b>Pulse measurement range</b>	40 to 180 beats / min.
<b>Accuracy</b>	Pressure $\pm$ 3mmHg, Pulse $\pm$ 5% of display reading
<b>Inflation</b>	Automatic by electric pump
<b>Deflation</b>	Automatic pressure release valve
<b>Measurement method</b>	Oscillometric method
<b>Transmission method</b>	Bluetooth® Low Energy
<b>Wireless communication</b>	Frequency range: 2.4 GHz (2400 - 2483.5 MHz); Modulation: GFSK Effective radiated power: < 20 dBm
<b>Operating mode</b>	Continuous operation
<b>IP classification</b>	Monitor: IP20 / Optional AC adapter: IP21
<b>Rating</b>	DC6 V 4W
<b>Applied part</b>	Type BF (arm cuff)
<b>Power Source</b>	4 "AA" batteries 1.5 V or optional AC adapter (input AC 100-240 V 50-60 Hz 0.12 -0.065 A)

<b>Battery life</b>	Approximately 500 measurements (using new alkaline batteries and included arm cuff. Depending on the type of battery and arm cuff.)
<b>Durable period (Service life)</b>	Monitor: 5 years / Cuff: 5 years / Optional AC adapter: 5 years
<b>Operating conditions</b>	+10 to +40 °C / 15 to 90% RH (non-condensing)/ 800 to 1060 hPA
<b>Storage / Transport conditions</b>	-20 to +60 °C / 10 to 90% RH (non-condensing)
<b>Cuff circumference applicable to the monitor</b>	17 to 42 cm (included arm cuff: (22 to 42 cm)
<b>Memory</b>	Store up to 30 readings
<b>Weight</b>	Monitor: approximately 250 g (not including batteries) / Arm cuff: approximately 170 g
<b>Dimensions (approximate value)</b>	Monitor: 103 mm (W)× 82 mm (H)× 140 mm (L) Arm cuff: 145 mm × 594 mm (air tube: 750 mm)
<b>Contents</b>	Monitor, Arm cuff (HEM-RML31), 4 "AA" batteries, Storage case, Instruction Manual, Guarantee card, Blood Pressure pass
<b>Protection against electric shock</b>	Internally powered ME equipment (when using only batteries) Class II ME equipment (optional AC adapter)

## Overview of Accessories

### Included Accessory

Product Description	Model
Easy Cuff	HEM-RML31

### Other Optional Accessories

Product Description	Model
AC Adapter	HHP-CM01
CS2 Small Cuff	HEM-CS24


### Materials used in main device

Parts name	Material
Housing	HIPS WT (High Impact Polystyrene White)
Battery Cover	HIPS WT (High Impact Polystyrene White)
Front Panel	T0.188 PET
Cuff	Cotton, Polyester
Package	Coated board E/F
Instruction Manual	Wood free paper

### Materials for (optional) accessories

Parts name	Material	
Cuff	Cloth, fabric	Cotton or Nylon, PVC (Polyvinyl Chloride)
	Air Tube	PVC (Polyvinyl Chloride)
	Air plug to device	ABS (acrylonitrile butadiene styrene)
	Air plug to cuff	PC (Polycarbonate)
AC Adapter	DC Cord	PVC (Polyvinyl Chloride)
	Print case	PPE (Polyphenylene Ether)

## Package specifications/ Logistic information

Package	Amount	Approximate weight	Approximate dimensions (w*d*h)
Main Unit	1	250 g	103 mm x 140 mm x 82 mm
Sales Package	1	640 g	125 mm x 118 mm x 165 mm
Master Carton	10	7.25 kg	623 mm x 276 mm x 208 mm
UDI-DI/EAN code	4015672113077  4 015672 113077		
Minimum order quantity	10		
HS/CN custom commodity code	9018901000		

## Title pages of Instruction Manual

# OMRON

### Automatisches Oberarm- Blutdruckmessgerät

### M300 Intelli IT (HEM-7143T1-D) Gebrauchsanweisung



IM-HEM-7143T1-D-01-10/2020  
5674697-2A  
Ausgabedatum: 2021-05-17

All for Healthcare

## Unfolded package design of main device and accessories

Main device:





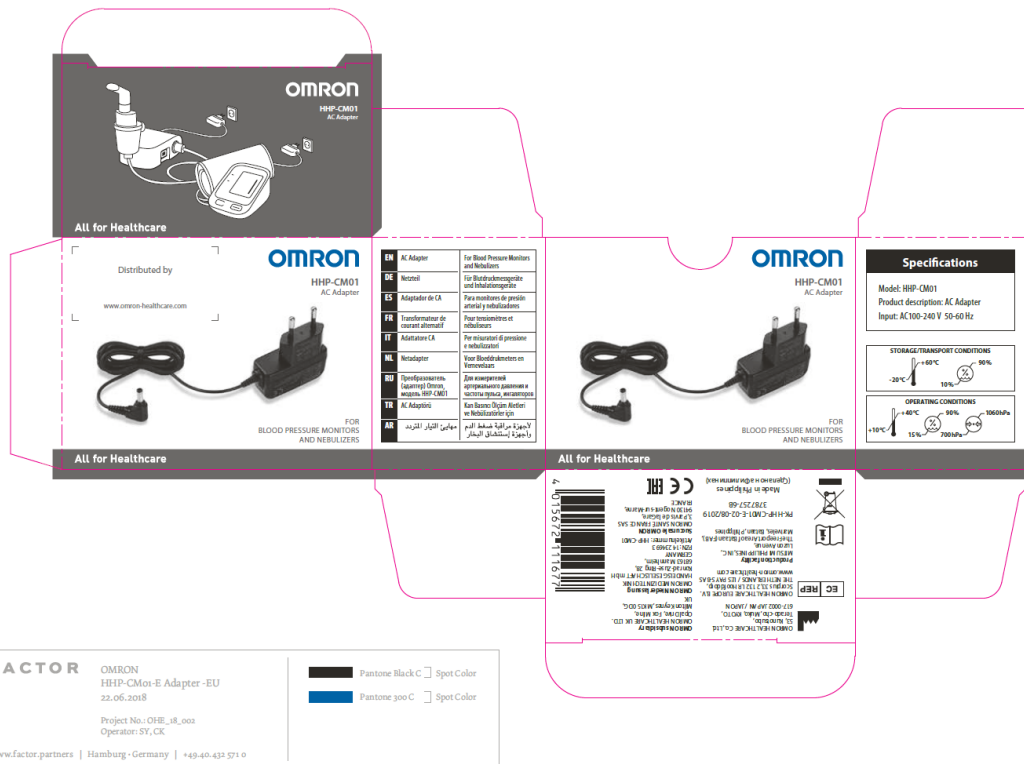
## Included Accessory



## Optional Accessories



Project No.: OHE\_19\_003  
Operator: CK  
www.factor.partners | Hamburg - Germany | +49-40-432 1



## List of Classification, Applicable Directives/Regulations and Harmonized EN Standards

The device is classified according to Medical Device Regulation (EU)2017/745 ANNEX VIII, Rule 10 as Class IIa medical device.

### Regulation (EU)2017/745 (Medical Device Regulation)

- EN 1041:2008+A1:2013
- EN 1060•1:1995+A2:2009
- EN 1060•3:1997+A2:2009
- EN 60601-1:2006+A1:2013
- EN 60601-1•2:2015
- EN 60601-1-6:2010+A1:2015
- EN 60601-1•11:2015
- EN 62366-1:2015
- EN 62304:2006+A1:2015
- EN 62366-1:2015

EN IEC 80601-2-30:2019  
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 81060-2:2019+A1:2020

Directive 2011/65/EU(RoHS)  
EN ISO 63000:2018

Directive 2014/53/EU  
EN 300 328 V2.2.2  
EN 301 489-1 V2.2.3  
EN 301 489-17 V3.2.4  
EN 62479:2010  
EN IEC 62368-1:2020+A11:2020

## **LEGAL MANUFACTURER**

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## **PRODUCTION FACILITY**

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## **EU-REPRESENTATIVE**

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