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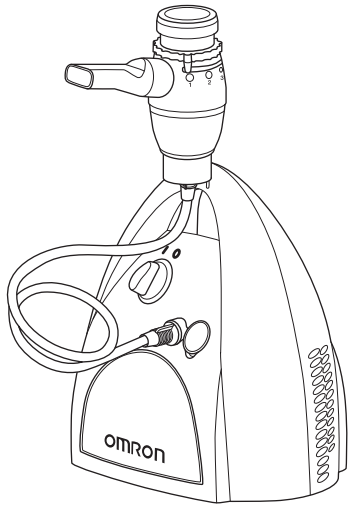


Compressor Nebulizer
A3 Complete
(NE-C300-E)

Instruction Manual

All for Healthcare

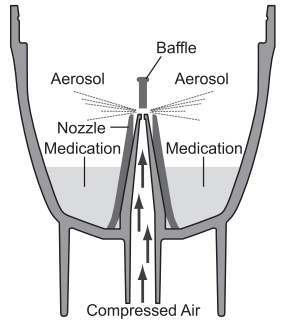
IM-NE-C300-E-05-11 /2018
3A3807 rev. 01

EN

Thank you for purchasing the OMRON A3 Complete.
This product was developed in conjunction with respiratory therapists for the successful treatment of asthma, chronic bronchitis, allergies and other respiratory disorders.
This is a medical device. Operate the device only as instructed by your doctor and/or respiratory therapist.

How the nebulizer kit works

The medication that is pumped up through the medication channel is mixed with compressed air which is generated by a compressor pump. The compressed air mixed with medication is turned into fine particles and sprayed when in contact with the baffle.



Manufacturer	**3A HEALTH CARE S.r.l.** Via Marziale Cerutti, 90F/G 25017 Lonato del Garda (BS) Italy
Distributor	**OMRON HEALTHCARE EUROPE B.V.** Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com
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	OMRON SANTÉ FRANCE SAS 14, rue de Lisbonne, 93561 Rosny-sous-Bois Cedex, FRANCE www.omron-healthcare.com

Made in Italy

Intended use

Medical Purpose
This product is intended to be used for inhaling medication for respiratory disorders.

Intended User
- Legally certified medical experts, such as doctor, nurse and therapist.
- Caregiver or patient under the guidance of qualified medical experts for home treatment.
- The user should also be capable of understanding general operation of A3 Complete and the content of instruction manual.

Intended Patients
Persons who suffer from respiratory disorders and require inhalation of medications.

Environment
This product is intended for use in a general household.

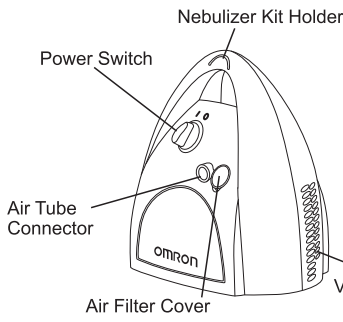
Durable period
Durable periods are as follows, provided the product is used to nebulize saline 3 times a day for 10 minutes each time at room temperature (23°C). Durable period may vary depending on usage environment.

Compressor (Main unit)	5 years
Nebulizer Kit	1 year
Mouthpiece	1 year
Nosepiece	1 year
Air Tube (PVC, 100cm)	1 year
Air Filter	70 applications
Mask (PVC)	1 year

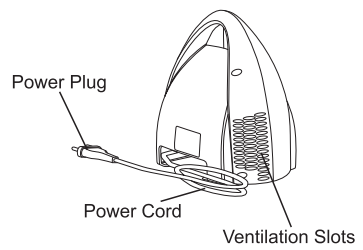
Precautions for use
Warnings and cautions described in the instruction manual should be observed.

Know your unit

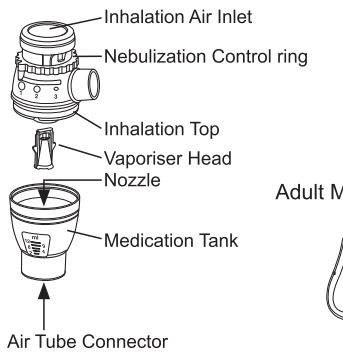
Compressor (Main Unit) x 1



Rear View



Nebulizer Kit x 1



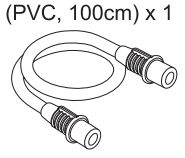
Mouthpiece x 1

Nosepiece x 1

Adult Mask (PVC) x 1

Child Mask (PVC) x 1

Air Tube
(PVC, 100cm) x 1



Instruction Manual

Important safety instructions

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.

(Usage)
- A single-patient use is recommended.
- Do not use the device for other use than nebulization for aerosol therapy. Manufacturer will not be held responsible for inappropriate use of the device.
- Use only original OMRON accessories as indicated in the instruction manual for this device.
- For type, dose, and regime of medication follow the instructions of your doctor or respiratory therapist. Before use check the position of the Nebulization Control ring.
- If you feel anything unusual during use, stop using the device immediately and consult your doctor.
- Do not use only water in the nebulizer for inhaling purposes.
- Keep the device out of the reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- In view of their length, the power cord and air tube could constitute a strangulation hazard.
- Do not store the air tube while there is moisture or medication remaining inside.
- Do not use or store the device where it may be exposed to noxious fumes or volatile substances.
- Do not use the device where it may be exposed to flammable gas.
- Do not cover the compressor with a blanket, towel, or any other type of cover during use.
- Always dispose of any remaining medication after use, and use fresh medication each time.
- Do not use in anaesthetic or ventilator breathing circuits.
- Do not block the ventilation slots. Never place the device where the ventilation slots may be obstructed during operation.
- Store the parts in a clean location for avoiding infection.

(Risk of electrical shock)
- Never plug or unplug the device with wet hands.
- The compressor and power cord are not waterproof. Do not spill water or other liquids on these parts. If liquid does spill on these parts, immediately unplug the power cord and wipe off the liquid with gauze or other absorbent material.
- Do not immerse the compressor in water or other liquid.
- Do not use or store the device in humid locations.
- Do not operate the device with a damaged power cord or plug.
- Keep the power cord away from heated surfaces.

(Cleaning and disinfecting)
Observe the rules below when cleaning or disinfecting parts. Failure to observe these rules may result in damage, inefficient nebulization or infection. For the instructions, refer to “Cleaning and disinfecting” section.
- Clean and disinfect the nebulizer kit, mask, mouthpiece or nosepiece before using them when as follows:
  - the first time after purchase
  - if the device has not been used for a long period of time
  - if more than one person uses the same device
- Be sure to wash or wipe the parts after use, and ensure that they are thoroughly disinfected and dried, and stored in a clean location.
- Do not leave the cleaning solution in the parts.

⚠ Caution: Indicates a potentially hazardous situation which if not avoided, may result in minor or moderate injury, or physical damage.

(Usage)
- Provide close supervision when this device is used by, on, or near children or invalids.
- Make sure that the parts are attached correctly.
- Make sure that the air filter is correctly attached.
- Make sure that the air filter is clean. If the air filter has been used for more than 70 applications, replace it with a new one.
- Do not tilt the nebulizer kit at an angle of greater than 45 degrees in all directions or shake it while in use.
- Do not use or store the device while the air tube is creased.
- Use only original nebulizing parts, air tube, air filter and air filter cover.
- Do not add more than 12 ml of medication to the medication tank.
- Do not carry or leave the nebulizer kit while the medication tank contains medication.
- Do not leave the device unattended with infants or persons who cannot express their consent.
- This product should not be used on patients, who are unconscious or are not breathing spontaneously.
- Do not subject the device or the parts to any strong shocks such as dropping the device on the floor.
- Do not distort the vaporiser head, or jab the nozzle of the medication tank with a pin or any sharp object.
- Do not insert fingers or objects inside the compressor.
- Do not disassemble or attempt to repair the compressor or power cord.
- Do not leave the device or its parts in extreme hot or cold temperature, or under direct sunlight.
- Do not block the air filter cover.
- Do not use the device while sleeping or if drowsy.
- Approved for human use only.
- The compressor may become hot during operation.
- Do not touch the compressor for other than necessary operation such as turning off the power while nebulizing.
- To avoid the medication residue on the face, be sure to clean the user’s face after removing the mask.
- To avoid injury to the nose mucosa, do not squeeze the nosepiece into the back of the nose.
- Make sure that the vaporiser head is correctly installed before use.
- Do not use a damaged nebulizer kit, mouthpiece or nosepiece.

(Risk of electrical shock)
- Always unplug the device from the power outlet after use and before cleaning.
- Plug the device into the appropriate voltage outlet. Do not overload power outlets or use extension cords.
- Do not misuse the power cord.
- Do not wind the power cord around the compressor.
- Changes or modifications not approved by OMRON HEALTHCARE will void the user warranty.

(Cleaning and disinfecting)
Observe the rules below when cleaning or disinfecting parts. Failure to observe these rules may result in damage, inefficient nebulization or infection. For the instructions, refer to “Cleaning and disinfecting” section.
- Do not use a microwave oven, dish dryer or hair dryer to dry the device or the parts.
- Do not use an autoclave, EOG gas sterilizer or low temperature plasma sterilizer
- When disinfecting parts by boiling, make sure that the container does not boil dry. Otherwise it may also result in fire.

General Safety Precautions:
- Inspect the device and parts before using them each time, and check that there are no problems. In particular, be sure to check the following:
  - That the nozzle or air tube are not damaged.
  - That the nozzle is not blocked.
  - That the compressor operates normally.
- When using this device, there will be some noise and vibration caused by the pump in the compressor. There will also be some noise caused by the emission of compressed air from the nebulizer kit. This is normal and does not indicate a malfunction.
- Operate the device only as intended. Do not use the device for any other purpose.
- Do not use the device at temperatures greater than +40°C.
- Make sure that the air tube is securely attached to the compressor and nebulizer kit, and does not come loose. Twist the air tube plug slightly when inserting it into the air tube connectors to avoid the air tube disconnecting during use.
- To completely isolate the device from the power source unplug the plug from the power source.

Keep these instructions for future reference.

Important information regarding Electro Magnetic Compatibility (EMC)

NE-C300-E manufactured by 3A HEALTH CARE S.r.l. conforms to EN60601-1-2:2015 Electro Magnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual or at www.omron-healthcare.com. Refer to the EMC information for NE-C300-E on the website.

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

In conformity with Directive 2012/19/EU-WEEE, 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 wastes for disposal.

Optional Medical Accessories

(within the scope of EC Medical Device Directive 93/42/EEC)

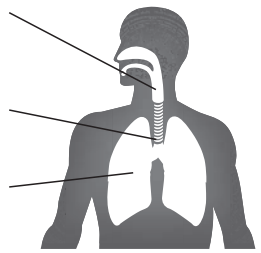
Model	Code
A3 Complete, Accessory Kit (contents: nebulizer kit, air tube, mouthpiece, nosepiece, adult mask, child mask)	NEB6001

Other Optional/Replacement Parts

Product Description	Model
A3 Complete, Air Filter Set (contents: 3 pieces)	3AC408

Technical Information about the Nebulizer Kit
The OMRON A3 Complete nebulizer is a medical device that generates an aerosol with variable characteristics to adapt to the patient's respiratory pathology. By regulating the "Nebulization Control Ring" on the nebulizer's inhalation top, it can produce an aerosol with the granulometric characteristics that will deposit the maximum amount of the drug in the respiratory tract being treated. The position of "Nebulization Control Ring" is chosen based on the indication of the following figure. Consult your doctor to recommend which position is best for your treatment.

Recommended use



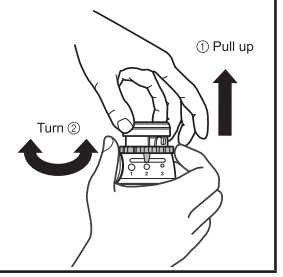
With the "Nebulization Control Ring" in position 1:
Particle size is +7.5 µm and is to treat diseases such as: rhinitis, sinusitis and pharyngitis, tonsillitis, laryngitis.

With the "Nebulization Control Ring" in position 2:
Particle size is between 4.5 and 7.5 µm and is to treat diseases such as: tracheitis and tracheobronchitis.

With the "Nebulization Control Ring" in position 3:
Particle size is between 2 and 4.5 µm and is to treat diseases such as: asthma, bronchitis, bronchiolitis, bronchiectasis, bronchopneumonia.

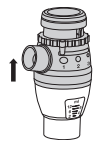
How to identify the position on the nebulizer
On the inhalation top, there are 3 dots; the small dot corresponds to position 3, the medium dot to the position 2 while the big dot to the position 1. On the ring, there is a bulging tooth which is correspondent to the chosen position.

How to modify the position of the nebulizer
To modify the position of the Nebulization Control Ring, pull up the inhalation air inlet up to its maximum extension with one hand, while with the other hand turn the ring to the desired position.
Then release the inhalation air inlet to fix the position.
Important: It is not possible to turn the ring if the inhalation air inlet is not pulled up. A locking mechanism prevents accidental rotation.

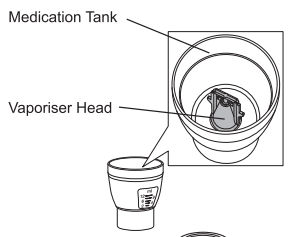


How to use

1. Make sure that the power switch is in the off (O) position.
2. Plug the power plug into a power outlet.
3. Remove the inhalation top from the medication tank by gently pulling it up.

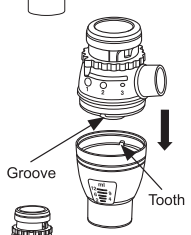


4. Add the correct amount of prescribed medication into the medication tank.



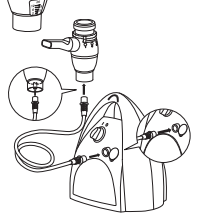
5. Verify the presence of the vaporiser head inside the medication tank.
6. Put the inhalation top back inside the medication tank.

   Attention: To close the nebulizer, align the tooth of the medication tank with the groove of the inhalation top, as shown in figure.

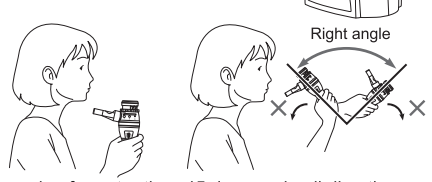


7. Attach the mask, mouthpiece or nosepiece to the nebulizer kit tightly.

8. Attach the air tube. While twisting the air tube plug slightly, push it firmly into the air tube connector.



9. Hold the nebulizer kit as indicated on the right. Follow the instructions of your doctor or respiratory therapist.



⚠ **Caution:**
Do not tilt the nebulizer kit at an angle of greater than 45 degrees in all directions. Medication may flow into the mouth or it may result in ineffective nebulization.

10. Turn the power switch to the on (I) position. As the compressor starts, nebulization begins and aerosol is generated. Inhale the medication. Exhale through the nebulizer kit.
11. When treatment is completed, turn the power off and unplug the compressor from the power outlet.

Cleaning and daily disinfecting

Cleaning

Clean the parts after each use to remove residual medication. This will prevent inefficient nebulization and reduce risk of infection.

■ Washable parts

• **Nebulizer Kit, Mask (PVC)/Mouthpiece, Nosepiece**
Wash them in warm water and mild detergent (neutral detergent). Rinse them thoroughly with clean hot tap water, gently tap to remove excess water and allow to air dry in a clean place.
It is advisable to replace the A3 Complete Nebulizer Kit after some 100 to 120 treatments on single patient or after about 20 boiling cycles.

■ Non-washable parts

• **Compressor, Air Tube (PVC)**
Firstly, make sure that the power plug is unplugged from the power outlet. Wipe clean with a soft cloth moistened with water or mild detergent (neutral detergent).

• **Air Filter**
Do not wash or clean the air filter. If the air filter becomes wet, replace it. Damp air filters can cause blockages.

Disinfecting

Always disinfect the parts after the last treatment of the day. If the parts are heavily stained, replace them with new ones.

To select a method for disinfection, refer to the table below.

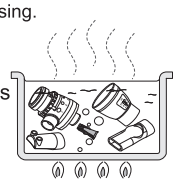
○: applicable X: not applicable

Disinfecting method	Parts	Mouthpiece	Nosepiece	Nebulizer Kit	Adult Mask** (PVC) Child Mask** (PVC)	Air Tube (PVC, 100cm)	Air Filter
	Materials	PP	PP	PP	Mask: PVC (Phthalate free)	PVC (Phthalate free)	PP
A	Disinfecting ethanol	○	○	○	○	X	X
	Sodium hypochlorite / Milton*	○	○	○	○	X	X
	Quaternary ammonium / Osvan*	○	○	○	○	X	X
	Chlorhexidine / Hibitane*	○	○	○	○	X	X
	Amphoteric Surfactant / Tego*	○	○	○	○	X	X
B	Boiling	○	○	○	X	X	X

* An example of commercially available disinfectant.
** Elastic band (non-latex). Do not disinfect.

A. Use a commercially available disinfectant. Follow the instructions provided by the disinfectant manufacturer.
Note: Never clean with benzene, thinner or a flammable chemical.
Note: After having washed the Nebulizer Kit with the available disinfectant, please rinse with clean warm water and dry thoroughly before using.

B. Applicable parts may be boiled between 15 to 20 minutes.
After boiling, carefully remove the parts, shake off excess water and allow to air dry in a clean environment.



⚠ **Caution: Handling the Vaporiser Head**
- Always wash the vaporiser head after each use.
- Do not use a brush or pin to clean the vaporiser head.
- When disinfecting the parts by boiling, be sure to boil them in plenty of water.
- Do not boil vaporiser head together with objects other than applicable nebulizer accessories.

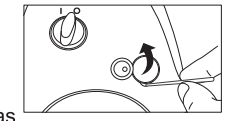
Removing condensation from the air tube

If there is moisture or liquid remaining in the air tube, be sure to follow the procedure below to remove any moisture from within the air tube.

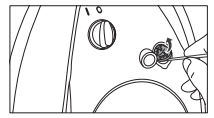
1) Make sure that the air tube is connected to the air connector on the compressor.
2) Remove the air tube from the nebulizer kit.
3) Turn on the compressor and pump air through the air tube to expel the moisture.

Changing the air filter

If the air filter has changed colour, or has been used for more than 70 applications, replace it with a new one.



1. Raise the air filter cover as shown in figure.
2. Remove the old air filter with a sharp object, such as a toothpick, and insert the new air filter.



3. Fit the air filter cover into its housing making sure it is flush to the surface.

Notes:
- Use only OMRON air filters designed for this device. Do not operate without a filter.
- Do not attempt to wash or clean the filter. If the air filter becomes wet, replace it. Damp air filters can cause blockages and may increase risk of infection.
- There is no front or back orientation for the air filters.
- Check that air filters are clean and free of dust before inserting them.

Troubleshooting

Check the following if the device should fail during operation.

Problem	Cause	Remedy
Nothing happens when the power switch is turned.	Is the power plug plugged into a power outlet?	Check that the plug is inserted in a power outlet. Unplug then reinsert the plug if necessary.
No nebulization or low nebulization rate, when the power is on.	Is there medication in the medication tank?	Add the correct amount of medication to the medication tank.
	Is there too much/little medication in the medication tank?	
	Is the vaporiser head missing or not assembled correctly?	Attach the vaporiser head correctly.
	Is the nebulizer kit assembled correctly?	Assemble the nebulizer kit correctly.
	Is the nozzle blocked?	Make sure that the nozzle is free of blockages.
	Is the nebulizer kit tilted at a sharp angle?	Make sure that the nebulizer kit is not tilted at an angle of more than 45 degrees.
	Is the air tube connected correctly?	Make sure that the air tube is correctly connected to the compressor and nebulizer kit.
	Is the air tube folded or damaged?	Make sure that the air tube does not contain kinks.
	Is the air tube blocked?	Make sure that the air tube is free of blockages.
	Is the air filter dirty?	Replace the air filter with a new one.
The compressor is abnormally loud.	Is the air filter cover attached correctly?	Attach the air filter cover correctly.
The compressor is very hot.	Is the compressor covered?	Do not cover the compressor with any type of cover during use.
	Are the ventilation slots blocked?	Do not block the ventilation slots.

Note: If the suggested remedy does not solve the problem, do not try to repair the device - no parts of the device are user serviceable. Return the device to an authorized OMRON retail outlet or distributor.

Technical data

Product Description:	Compressor Nebulizer
Model (code):	A3 Complete (NE-C300-E)
Rating:	230V~ 50 Hz
Power Consumption:	140VA
Operating Temperature/ Humidity/Air Pressure:	+10°C to +40°C / 10% to 95% RH 690 - 1060hPa
Storage and Transport Temperature/Humidity/ Air Pressure:	-20°C to +70°C / 5% to 95% RH 690 - 1060hPa
Weight:	Approx. 1.3 Kg (compressor only)
Dimensions:	Approx. 130 (W) x 215 (H) x 190 (D) mm
Contents:	Compressor, Nebulizer Kit, Air tube (PVC, 100 cm), Mouthpiece, Nosepiece, Adult Mask (PVC), Child Mask (PVC), Instruction Manual.

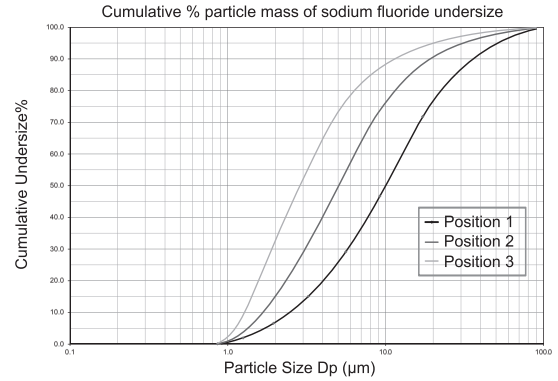
= Class II equipment
= Type BF applied part
O = Power off
Consult the instructions for use
IP21 = Ingress Protection
I = Power on
~ Alternating current
CE 0051

Technical data for the OMRON A3 Complete Compressor with the A3 Complete nebulizer kit:

Appropriate Medication Quantities:	2 ml minimum - 12 ml maximum		
Sound:	Noise level (at 1 m distance) 65 dB		
	Nebulizer control ring in position 1	Nebulizer control ring in position 2	Nebulizer control ring in position 3
Particle Size (MMAD):	Approx. 10 µm	Approx. 5 µm	Approx. 3 µm
Nebulization Rate (by weight loss):	Approx. 0.7 ml/min	Approx. 0.5 ml/min	Approx. 0.3 ml/min
Aerosol Output (3 ml, 1% NaF):	Approx. 0.45 ml	Approx. 0.53 ml	Approx. 0.36 ml
Aerosol Output Rate (1% NaF):	Approx. 0.15 ml/min	Approx. 0.12 ml/min	Approx. 0.1 ml/min

MMAD = Mass Median Aerodynamic Diameter

Result of cascade impactor measurements for particle size



Notes:
- Subject to technical modification without prior notice.
- The device may not work if the temperature and voltage conditions are different to those defined in the specifications.
- The device fulfils the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN13544-1:2007+A1:2009, Respiratory therapy equipment - Part1: Nebulizing systems and their components.
- Performance may vary with drugs such as suspensions or high viscosity. See drug supplier's data sheet for further details.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. The compressor is protected against solid foreign objects of 12.5 mm diameter and greater such as a finger, and against vertically falling water drops which may cause issues during a normal operation.
- See website of OMRON HEALTHCARE EUROPE for complete up to date information. URL: www.omron-healthcare.com

Warranty

Thank you for buying an OMRON product. This product is constructed of high quality materials and great care has been taken in its manufacturing. It is designed to give you every satisfaction, provided that it is properly operated and maintained as described in the instruction manual.
This product is guaranteed by OMRON for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product is guaranteed by OMRON. During this period of guarantee OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts.
The guarantee 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 guaranteed 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.
Should guarantee 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, contact us for information.

Repair or replacement under the guarantee does not give rise to any extension or renewal of the guarantee period.
The guarantee will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer. OMRON reserves the right to refuse the guarantee service if any unclear information has been given.