

USER MANUAL

Device for the clearance of airway
secretions

FREE ASPIRE ADVANCED



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1. WARNINGS



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The manual is delivered together with the product, of which it constitutes an integral part, and it must be conserved by the purchaser

Customers are invited to notify us of any accidents and near-accidents encountered during the use of the products we manufactured and marketed, in order to take action against them, in compliance with current regulations regarding medical devices (Decree of the Ministry of Health November 15, 2005).

	<p>Reliable, resistant and lubrication-free, FREE ASPIRE ADVANCED is built in compliance with European product standards.</p> <p>FREE ASPIRE ADVANCED comes with the following components, which are an integral part of the product: patient equipment, filter, tool bag, and power cord.</p> <p>We recommend the replacement of patient equipment periodically (at least every 6 months of use). If properly used and maintained, the medical device has an average expected life in service of about five years.</p>
	<p>Air filter is to be periodically replaced when it is dirty, or it changes colour. Do not wash neither reuse the same filter. The filter must be checked regularly. The regular replacement of the filter is needed to ensure the correct performance of the pump. Please, contact your retailer or authorised assistant centre for the spare filter.</p>
	<p>Keep the cord away from hot surfaces.</p> <p>Never handle the plug with wet hands and do not use the product while bathing or showering. Never immerse the product in water. Should this happen unplug it immediately. Do not remove or touch the product immersed in water before having disconnected the plug. Do not use the product after its removal from water (immediately send it to your distributor).</p> <p>Repairs should be performed only by authorized personnel. Unauthorized repairs will void the warranty. Dispose of according to current regulations.</p>

2. STANDARDS COMPLIANCE

FREE ASPIRE ADVANCED is designed and built to conform to the Directive 93/42/EEC and subsequent amendments concerning medical devices.

FREE ASPIRE ADVANCED complies with the following standards:

- IEC 60601-1, edition 3.1 (Medical electrical equipment safety)
- IEC 60601-1-2, 4th edition (Electromagnetic compatibility)
- IEC 60601-1-6 (Usability)
- IEC 60601-1-11 (Medical electrical equipment prescriptions for home use)
- IEC 62304 Software for medical devices
- ISO 10993-1 (Biological evaluation of medical devices - Part 1: evaluation and testing)
- ISO 10993-5 (Biological evaluation of medical devices - tests for in vitro cytotoxicity)
- ISO 10993-10 (Biological evaluation of medical devices– tests for irritation and delayed-type hypersensitivity)



3. INTENDED USE AND CLASSIFICATION

FREE ASPIRE ADVANCED is a medical device thought and designed for the noninvasive clearance of airway secretions in both adult and pediatric patients, based on the expiratory flow acceleration. It can be used at home or in hospitals, without the usage of any probe.

FREE ASPIRE ADVANCED can be used by patients with neuromuscular disease that have ineffective cough or with healthy subjects to collect secretions for general lab analysis.

FREE ASPIRE ADVANCED reaches its performance under normal operating conditions. Known and predictable risks and any adverse events, are reduced to a minimum acceptable in relation to the benefits that it provides. The considerations of the performance and safety of the device are supported by appropriate clinical judgment.

The medical device can be used under medical staff supervision or under the supervision of non-medical personnel as long as properly instructed in compliance with the manual prescriptions, both in hospitals and at home.

Avoid its use outdoor under adverse weather conditions.

The operator is required to have the ability to activate the device and comprehend this manual, including drawings / assembly diagrams, as well as the symbolism of the control panel and display.

Traveling with FREE ASPIRE ADVANCED

When traveling it can be helpful to take along this manual so that the security personnel can more easily identify the system.

If you are traveling to a country with a line voltage different than the one you are currently using, a different power cord or an international plug adaptor may be required to make your power cord compatible with the power outlets of the country to which you are traveling.

FREE ASPIRE ADVANCED is supplied not sterile and it is reusable (the supplied accessories always meant for single-patient use).

The most frequently used functions are: packaging, transportation, placement, turning on the device, assembly of the circuitry, consulting the user's manual and reading the display, cleaning, turning off the device, repair and disposal of the device.

FREE ASPIRE ADVANCED is classified as Class IIA, in compliance with Annex IX of the MDD 93/42 / EEC and subsequent amendments.

4. DESCRIPTION AND ASSEMBLY

The medical device MPR600 consists of the device (MPR601) and the patient equipment (KFAA), of which the mask / mouthpiece / catheter mount are the applied part. Restrictions of applied parts were applied to the entire chassis.

FREE ASPIRE ADVANCED can be reused on different patients (after cleaning the unit), while the use of patient equipment is strictly personal, to avoid the risk of cross-infection.

Patient equipment is supplied clean but not sterilized, inside a bag with the disassembled components.

The interfaces (small and large mask, mouthpiece and catheter mount), included into the patient accessories set, are to be intended as single-patient use and single-procedure.



Check the pictograms displayed on the package of each component included into the single-patient equipment.

Some examples:



Do not reuse



Expiry

CIRCUIT FOR FREE ASPIRE ADVANCED

Connect the previously pre-assembled circuit for Free Aspire to the air outlet nozzle of the medical device. The circuit consists of an adapter, corrugated tube of 10mm diameter and the connector for FA.

Connect the desired interface to the device (mask / mouthpiece/catheter mount).



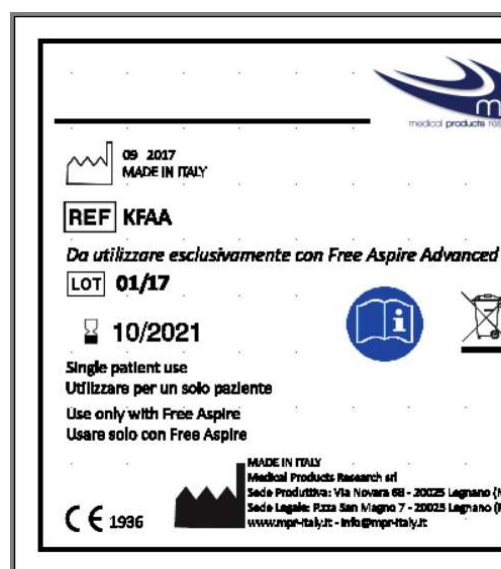
5. DEVICE IDENTIFICATION

- Control unit MPR601
Each unit is identified by a label placed on the bottom of the medical device
- Patient equipment KFAA
The patient equipment is identified by a label placed on each bag






Identification label of the control unit
















Identification label of the patient equipment





















	Manufacturer
	CE Marking, followed by the notified authority code
	It is mandatory to read the instructions for use
	Date of manufacture (year and month)
	Type BF applied part (the applied parts are the mask, the mouthpiece, the catheter mount, the display and the casing)
Ref	Commercial name
S.N	Serial number
	Do not dispose of as household waste

	Medical device of Class II
IP21	Protection degree against solid objects/dust and liquids: Protection against solid objects larger than 12 mm and against water drops
	AC Power / Operating specifications in alternating current (electricity grid powered)
	Non-sterile
	It doesn't contain latex
	It doesn't contain phthalates




6. PRECAUZIONI D'USO

	FREE ASPIRE ADVANCED is a medical device. The operation must comply with what is specified in this manual. Read carefully the manual for proper use and maintenance of the device. For any explanation, contact your distributor.
	Do not use FREE ASPIRE ADVANCED for a use other than that intended. The manufacturer assumes no responsibility for any misuse.
	Occasionally, the device has the secondary effect of reducing the pulmonary pressure in patients affected by pulmonary hypertension. Hence, check the patient conditions prior to use.
	Do not use the device in the presence of anesthetic mixture flammable with air, oxygen, nitrous oxide.
	Handle FREE ASPIRE ADVANCED and all components carefully, paying attention to potential dangers.
	Monitor the medical device and its operation on a regular basis in order to properly check whether specialized personnel intervention is necessary.
	Do not place the device in such a way that it could compromise its proper functioning.
	It is forbidden to open the device! Maintenance work must be performed only by qualified personnel authorized by the manufacturer.
	It is forbidden to modify the product. Unauthorized alterations may compromise its functioning and users' safety.
	Do not use the device in the presence of high electromagnetic fields. Electromagnetic interference may cause damages to the device or its malfunctioning.
	Use the device only for its intended purpose. Inappropriate use, besides causing damage to people and / or things, will void the warranty conditions listed below.
	The use of patient equipment is strictly personal.
	Do not dispose of as household waste! Follow the instructions contained in this manual in the section for disposal.
	<u>Use the device only with its original accessories, which are listed below.</u>
	Use the device and its accessories following your doctor's instructions. An erroneous use of the parts implies the risk of compromising the proper functioning of FREE ASPIRE ADVANCED .

	<ul style="list-style-type: none"> • <u>Keep the device away from heat sources.</u> • <u>Place the device on a flat, stable surface.</u> • <u>Always unplug the appliance after use.</u> • <u>Do not use electric extension cables and/or adapters.</u> • <u>Unwind completely the power cord to prevent overheating.</u>
	Place FREE ASPIRE ADVANCED in such a way as to facilitate the access to the network disconnection system.
	Absolutely avoid contact with water or other liquids. In case of penetration of liquids within the casing, immediately unplug the device. Do not touch the appliance before having unplugged it from the power outlet. Do not use the device after water penetrated in it and contact your distributor.
	Never handle the plug with wet hands and do not use the product while bathing or showering. Never immerse the product in water. Should this happen unplug it immediately. Do not remove or touch the product immersed in water before having disconnected the plug. Do not use the product after its removal from water.
	FREE ASPIRE ADVANCED contains detachable small parts which could be swallowed. When the device is used by a minor the presence of an adult with full mental faculties is required. Do not leave the appliance unattended where it can easily be reached by children.
	The long tubes contained in FREE ASPIRE ADVANCED may pose a strangulation hazard.
	Before switching on FREE ASPIRE ADVANCED and beginning the therapy verify that there aren't any small objects or insects inside the tubes.
	Unplug FREE ASPIRE ADVANCED from the power outlet after each use and before any cleaning operation of the device.
	If FREE ASPIRE ADVANCED is moved from a location with temperature equal to the maximum storage temperature to another at room temperature do not use the unit for at least one day in order to allow the homogeneous cooling of the machine.
	If FREE ASPIRE ADVANCED is moved from a location with temperature equal to the minimum storage temperature to another at room temperature do not use the unit for at least one day in order to allow the homogeneous heating of the machine.
	Store in a clean, dry place, away from light, heat sources and weather conditions.
	Keep the appliance away from naked flames, heaters and humidity. Absolutely avoid contact with flammable gases and liquids.

	Do not expose the medical device to direct sunlight. Allow air to circulate freely around the unit. Do not cover it while it is running. Do not use it too close to the wall, the curtains or next to a radiator. Do not use in confined spaces such as a bookcase or a piece of furniture. Do not obstruct the tube.
	Keep the patient equipment under the environmental conditions specified in this manual.
	All the components are made of non-toxic, hypoallergenic materials, compliant with current regulations. It is recommended to use the original components and to comply with the conditions of storage and use listed below.
	In case of abnormal or potentially dangerous behavior by FREE ASPIRE ADVANCED , immediately contact service.
	Report immediately to qualified medical personnel any unusual symptom or discomfort that occurred during or after the use of the medical device.
	The device is not intended to record any patient or therapy data! Inserting an optional SD card (ref: AUT005) into the suitable slot, it is possible to record only the occurred technical errors.

7. DISPLAY SYMBOLS

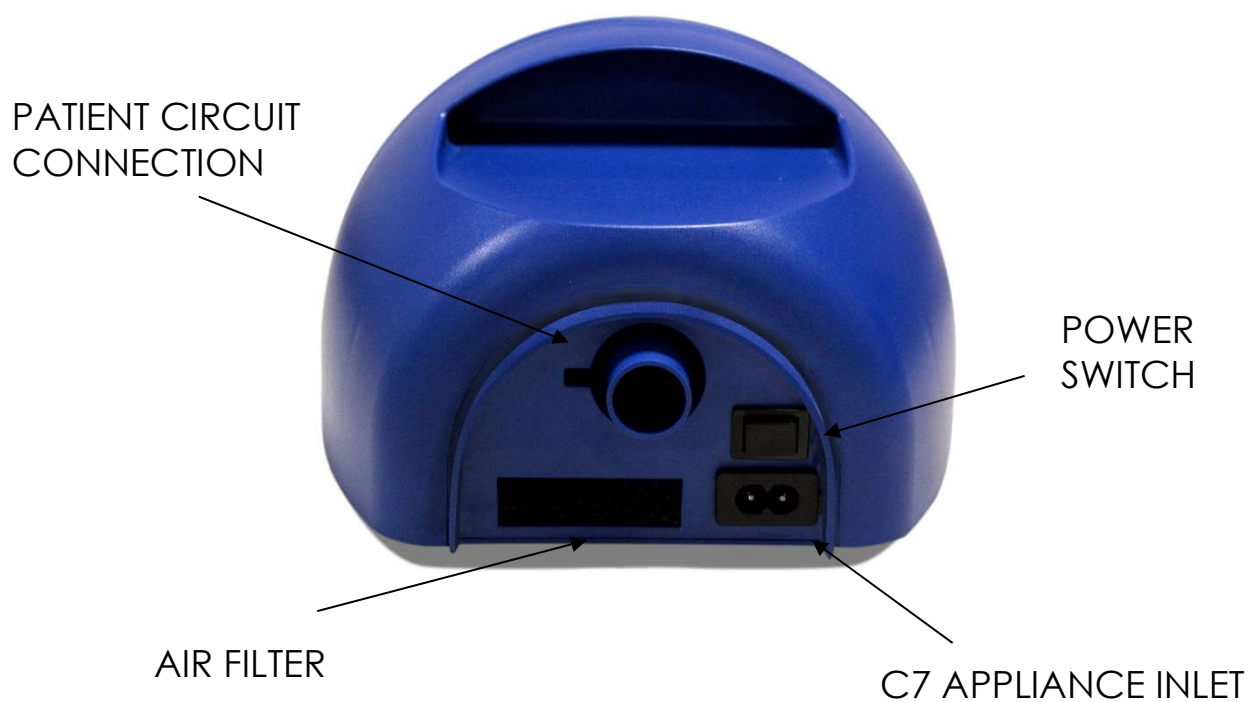
Symbol	Description
	Warning signal
	Cancel selection
	Confirm selection

8. CONTROLS

Picture of frontal part



Picture of posterior part



9. USE

1. Device placement

Place **FREE ASPIRE ADVANCED** on a horizontal and stable surface allowing air to circulate beneath it. (do not place it on bed sheets or other soft surfaces). Make sure the device is away from heating or cooling equipment. The device must be placed no farther than 100 cm from the patient to avoid the disconnection of the tube from the device.

2. Assembly of accessories for machine-patient connection

Assembly the circuit for the chosen therapy (detailed instructions below) and connect it to the machine by attaching it to the nozzle on the rear flange.

3. Air filter installation

Insert the air filter in the proper location on the rear flange of the device.

4. Power supply

Plug the socket end of the power cord into the C7 appliance inlet on the back of the device.

Turn on **FREE ASPIRE ADVANCED** by pressing the power switch on the back of the device.

5. Use

When you turn on the device the following menu will show on the display. The selectable modes of use have been previously set and saved by the specialist.



Free Aspire

SW v1.0.0

Press the control knob to access to the FREE ASPIRE mode.
Position the cursor on PROG P1.



07.03.18

Press the control knob to can move to PROG P2.

Prog P2	
Level 3	Time 04:30
Date 07.03.18	Therapy 01 of 03
EXIT	START THERAPY

Assembly the Free Aspire Advanced circuit as explained in paragraph 4 and connect it to the nozzle on the device.

Select START THERAPY and press the control knob to start the therapy.

Prog P2	
Level 3	Time 04:30
Date 07.03.18	Therapy 01 of 03
EXIT	START THERAPY

To end the treatment, select the entry STOP THERAPY and pressed the control knob.

The screenshot shows a digital display with a dark blue background and white text. At the top, it says 'Prog P2'. Below that, there are two sections: 'Level 3' and 'Time 02:24'. Underneath these is a horizontal progress bar that is mostly white with a small blue segment on the left. Below the bar, it shows 'Date 17.04.18' and 'Therapy 01 of 03'. At the bottom, there are two buttons: 'EXIT' on the left and 'STOP THERAPY' on the right.

On the screen the following parameters are shown:

- Prog P2: it corresponds to the program that the patient is performing;
- Level: it indicates the intensity level of the Free Aspire therapy set by the physician;
- Time: it refers to the remaining time duration of the therapy;
- Time bar: the bar gets colored with the time passing. At the beginning of the therapy the bar is completely white, at the end it's totally blue.
- Date: it corresponds to the date of the current day.
- Therapy: the first value indicates the therapy number being executed in the day; the second value refers to the number of therapies that the patient has to perform per day.

The number of therapies that have to be performed daily by the patient is not stringent: since this therapy has no contraindications for the patient, more therapies can be carried out in respect to the number prescribed by the physician.

If the therapy is interrupted before the end of the time set, the remaining therapy duration is kept valid in the next 30 minutes, during which the therapy can be continued. At the end of the 30 minutes, the therapy that has not been completed will be counted in the performed therapies number only if at least the two-third of the therapy duration was executed.

To safely end the treatment, position the cursor on STOP THERAPY and press the control knob. Afterwards, the power switch on the rear of the device can be pressed to shut it down.

10. MODES OF OPERATION

The secretion clearance mode with Free Aspire technology works by simple acceleration of the expiratory flow. This acceleration is only active during the exhalation phase and it is proportional to the expiratory flow of the patient. It follows the patient's natural respiratory rhythm and does not require any collaboration.

11. ERRORS





Errors list with explanation

ALLARM	TYPE	CONTROL KNOB COLOR	NOTES
FAULT	1	Steady yellow	Blower Error
TECH	1	Steady red	EEPROM Writing Error
TECH	2	Steady red	EEPROM Reading Error
TECH	4	Steady red	MCU Internal Error
TECH	5	Steady red	Timeout EEPROM communication

If you encounter one of these errors is recommended to restart the machine. If the error occurs again after restarting, contact technical support.

Inserting an optional SD card (ref: AUT005) into the suitable slot, it is possible to record the technical errors occurred during use.

12. CLEANING AND DISINFECTION

	WARNING: before carrying out any cleaning or maintenance of FREE ASPIRE ADVANCED , disconnect the power plug.
	Always wear DISPOSABLE GLOVES during disassembly and cleaning operations, in order to avoid contact with infected material or pathogenic germs.
	If the patient is affected by pathologies at risk of contamination, eliminate and replace all accessories after each use.
	If the environment of use and/or drying is at risk of contamination, delete and replace all accessories after each use.

FREE ASPIRE ADVANCED cleaning intervals

INTERVAL	ACTION
Before first use	Clean the reusable accessories (FA circuit in KFAA MPR331)
Before and after each use	Clean device (paragraph 12.1)
Daily	Clean and disinfect FA circuit in KFAA MPR331 (paragraph 12.2)
Monthly	Clean air inlet filter (paragraph 12.3)
At least every 6 months	Replace air inlet filter (paragraph 12.3)
	Replace FA circuit in KFAA MPR331 (paragraph 12.2)

On change of patient	Hygiene treatment, replace the reusable accessories and the filter.
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12.1 Cleaning of FREE ASPIRE ADVANCED

Clean the external surface of the device before and after each use by the patient or more frequently, if necessary. Never wash the appliance under water or by immersion; use only a cloth moistened with non-abrasive and non-aggressive detergent. Do not use abrasive powders, alcohol or solvents. Do not autoclave **FREE ASPIRE ADVANCED**. Protect the device and its internal components from liquids, humidity or high pressure that could damage it.

12.2 Cleaning and disinfection of FA circuit in KFAA MPR331:

Clean and subsequently disinfect the reusable single patient FA circuit before the first use and daily.

Cleaning:

1. Disconnect the FA circuit from the medical device and disassemble the components.
2. Rinse the FA circuit and all its components with warm drinking water, taking care to remove any biological residues adhering to the surfaces.
3. Proceed with the mechanical washing of the components of the FA circuit in non-boiling hot water (maximum 60 ° C), using a neutral detergent (for example, neutral detergent for dishes)
4. Rinse thoroughly with warm drinking water, taking care to remove all detergent residues.
5. Leave to air dry. Make sure all accessories are dry before proceeding with the disinfection procedure.

Disinfection:

1. Prepare a disinfectant solution based on sodium hypochlorite.
Use an electrolytic chlorine oxidant, i.e. a disinfectant containing 1.15% sodium hypochlorite (e.g. Amuchina® MD).
Proceed with the 5% dilution:
Pour 50 ml of disinfectant into 950 ml of non-boiling hot drinking water (maximum 60 ° C). (Keep the proportion of the parts if you want to dilute in a larger volume).
2. Immerse the components in the solution for 15 minutes.
3. Rinse all components thoroughly with warm drinking water
4. Leave to air dry. Make sure that all accessories are dry before reassembling the FA circuit.

The FA circuit must be replaced at least twice a year.

After cleaning and disinfection, carefully examine the components for damage. Replace damaged components.

12.3 Air inlet filter:

Regularly check the integrity of the air filter (gray spongy filter MPR289) before and after each use of the device.

If the filter is broken, excessively dirty or changes color, proceed with the replacement:

1. Make sure the device is turned off, then remove the air inlet filter from the grill.
2. Insert the new filter in its seat, making sure it is correctly positioned.

It is recommended to replace the filter at least 2 times a year.

Thorough filter cleaning is recommended at least monthly:

1. Rinse the air inlet filter with warm drinking water.
2. Wash the filter in warm non-boiling water (maximum 60 ° C), using a neutral detergent (for example, neutral detergent for dishes)
3. Rinse the filter thoroughly in warm drinking water, taking care to remove all detergent residues.
4. Leave to air dry. Make sure the filter is dry before mounting it on the device.

12.4 Patient change:

For each patient change it is necessary:

- clean the device as provided in section 12.1 and proceed with the subsequent sanitization with a disinfectant suitable for plastic materials (for example Meliseptol®);
- replace ALL accessories with new kits;
- replace the air inlet filter;
- clean the power cable and the device bag by simply wiping with a soft cloth with disinfectant.

13. MAINTENANCE

FREE ASPIRE ADVANCED is maintenance-free.

If the unit requires maintenance, this should only be performed by experienced personnel as reported in the service manual.

14. PROBLEMS AND POSSIBLE SOLUTIONS

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device doesn't turn on	Power cord damaged or disconnected	Check that the power cable is intact and properly inserted in the device and in the electric socket. Check the voltage of the electrical grid.
The device is turned on but there is no airflow	The tube connected to the mask is bent or entangled	Lay the tube carefully. Restart the machine.

The device doesn't work	The thermal protection is on because the unit has been operating too close to a heat source or in temperatures above 40 °C	Turn off the device and leave it at room temperature for at least 30 minutes
The air flow is warmer than usual	The temperature of the air may slightly vary based on the room temperature	Make sure that the medical device is properly ventilated

15. USE CONTIDIONS AND STORAGE

Use conditions and storage once the device is unpacked

Temperature: min. 5°C; max 38°C

Humidity: min. 15%; max 90% (non-condensing)

Atmospheric pressure: from 700 hPa to 1060 hPa

16. TRANSPORTATION AND STORAGE

Transportation and storage conditions:

-25°C ÷ 5°C

5°C ÷ 35°C from a non-condensing situation up to a relative humidity of 90%

35°C ÷ 70°C from water vapor pressure up to 50 hPa

For proper transport and storage of the device, keep the original packaging intact. The product is delivered within a cardboard box closed with packaging tape and in perfect hygienic conditions. At the delivery, check that the delivered material is the ordered one and that it was not damaged during transport.



For any abnormalities, keep the packaging and contact the carrier and Medical Products Research srl within 48 hours of the delivery. In absence of specific agreements, the items travel at the purchaser's risk.

17. TECHNICAL SPECIFICATIONS

Model: **FREE ASPIRE ADVANCED**

AC Voltage Source: 100-240V AC – 50-60Hz

Electrical absorption: 25W

Type of protection against electric shock: Class II

Degree of Protection Against Electric Shock: Type BF Applied Part

Degree of Protection Against Ingress of Water and Dust: IP21

Dimensions and weight: 20.5 x 22 x 15 cm – 1,08 Kg

Modes:

1. Free Aspire

Level	Adjustable 1-5
Therapy duration	Adjustable up to 30 min
Daily therapies number	OFF-1/12
Use of the medical device	Continuous

2. Flow levels

Levels	Flow (L/min)
1	19.6
2	27.2
3	38.2
4	48.2
5	58.2

Sound: the sound of the device is less than 60 dBA at a distance of 1 meter and in frontal position

Compliance: Medical Device Directive 93/42 / EEC

Warranty: 24 months

18. WASTE DISPOSAL

Disposal instructions pursuant to Art. 26 of Italian Legislative Decree no. 49 of 14 March 2014 "Implementation of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)" "Implementation of Directive 2012/19 / EU on Waste Electrical and Electronic Equipment (WEEE)": the crossed bin symbol on the appliance indicates that the product must be disposed of separately from other waste at the end of its useful life.



Separate collection of this product at the end of its operating life is organized and managed by the manufacturer. When the user will need to dispose of the device he will have to contact the manufacturer and follow his instruction in order to allow the separate collection of the machine.



Appropriate separate collection for the subsequent dispatch of the appliance for recycling, treatment and environmentally compatible disposal helps prevent negative impact on the environment and human health and promotes recycling of the materials making up the product.



Illegal dumping of the product by the holder implicates the penalties established by laws governing waste disposal.

The disposal of patient accessories must comply with national legislation and hospital regulations for the disposal of biohazardous waste.

19. WARRANTY CONDITIONS

WARRANTY CERTIFICATE

Valid 24 months from the date of purchase

WARRANTY CONDITIONS

1. The appliance is guaranteed for 24 months from the date of purchase against any flaw caused by the materials or the construction, provided that it has not been tampered with by the customer or by unauthorized personnel.
2. The warranty covers the replacement or repair of components that relate to the production
3. For sanitary-hygienic reasons the medical device replacement is forbidden since the device is strictly personal.
4. Parts subjected to natural wear and damage resulting from misuse, falls, transport, lack of maintenance or any other cause not attributable to the manufacturer are excluded from this warranty.
5. The manufacturer is not responsible for any damage, direct or indirect, arising from improper or reckless use of the product.
6. In case of malfunctioning, the appliance must be sent to your distributor properly cleaned and packed attaching this warranty certificate completely filled out together with the sale receipt or your purchase invoice, otherwise the warranty will be invalidated, and the amount of the service consequently charged.
7. The shipping costs and the delivery of the device are charged to the customer.
8. The manufacturer is not liable for extensions of the warranty period assured by a third party.

WARNING: THIS WARRANTY IS ONLY VALID IF THE WARRANT CERTIFICATE IS COMPLETELY FILLED OUT IN COMBINATION WITH RECEIPT/INVOICE

MOD.: FREE ASPIRE ADVANCED

LOT: _____ SERIAL NUMBER: _____

DETECTED FLAW: _____

Attach the sales receipt or purchase invoice	Distributor (stamp and signature)

20.ACCESSORIES LIST


Code	Accessory
MPR601	FREE ASPIRE ADVANCED device
MPR329	Small double compartment bag for FREE ASPIRE ADVANCED
ROP001	Europe-C7 connector power cord 2mt
MPR330	FREE ASPIRE ADVANCED manual
MPR192	Neutral box with MPR logo
MPR332	Filter replacement kit
Code	KFAA Components
MPR77	Mouthpiece
MPR331	Circuit for FA in KFAA
MPR75	Small mask
MPR76	Large mask
MPR156	Catheter mount



Use only original product. Replacing broken or worn parts with low-quality or self-made products can compromise the device efficiency, as well as voiding the warranty.

21.ELECTROMAGNETIC COMPATIBILITY INFORMATION


ELECTROMAGNETIC EMISSIONS		
This device is intended for use in the electromagnetic environment specified below. The user or the customer of this device should make sure it is used in such an environment.		
EMISSIONS TEST	IEC 60601-1-2 TEST LEVEL	INFORMATION ABOUT THE ELECTROMAGNETIC ENVIRONMENT
RF emissions CISPR 11	Group 1	The device makes use of RF energy only for its internal functioning. It emissions are extremely low, and they likely do not cause any interference for the surrounding electronic devices.
RF emissions CISPR 11	Class B	All the domestic locations are suitable for the use of the device, even those directly connected to the low-tension, public power supply that is provided for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	



Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	
	<p>The device complies with IEC 60601-1-2 Electromagnetic Compatibility of Medical Electrical Equipment. However, it is good precaution not to use the device in proximity of high-power devices or devices emitting, by their nature, strong electromagnetic fields.</p> <p>Mobile phones, or other radio equipment used in proximity of the equipment, may affect its functioning</p> <p>If it is necessary to use the appliance close to other devices it should be observed to check its proper functioning in the configuration in which it is used.</p> <p>Avoid using extension cords or adapters to the power cord. Do not cut or remove the ground prong from the power plug.</p> <p>The device must be connected to the power grid only with the supplied power cable of 1.80m length. With this cable, the appliance complies with the Electromagnetic Compatibility standards. Using cables of different lengths may result in increased emissions or decreased immunity against radio interference.</p>	

ELECTROMAGNETIC IMMUNITY

This device is intended for use in the electromagnetic environment specified below. The user or the customer of this device should make sure it is used in such an environment.

IMMUNITY TEST	IEC 60601-1-2 TEST LEVEL	COMPLIANCE LEVEL	INFORMATION ABOUT THE ELECTROMAGNETIC ENVIRONMENT
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The floor can be in wood, concrete or ceramic. If the floor is covered by synthetic material, the relative humidity should be at least at 30 %
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for power supply lines ±1 kV for input-output lines	The power supply quality should be the one of a standard domestic environment.

Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The power supply quality should be the one of a standard domestic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% dip in U _T) for 0,5 cycles 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 cycles	<5% U _T (>95% dip in U _T) for 0,5 cycles 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 cycles	The power supply quality should be the one of a standard domestic environment. If the user requires the continuous functioning of the device, even during a temporal interruption of the power supply, it's advised to provide the device with a continuity group (UPS), or to connect it to an electrical network equipped with an emergency system (battery). It's advisable, in this case, to be provided with one or more spare batteries.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields must have the same frequency of the standard domestic environment.
	NOTE: U _T is the a.c. mains voltage prior to application of the test level		
Conducted RF IEC 61000-4-6	10 Vrms da 150 kHz a 80 MHz	10 V eff	The portable RF communication devices cannot be used at a distance from the device (power cord included)

Radiated RF IEC 61000-4-3	10 V/m da 80 MHz a 2,7 GHz	10 V/m	<p>inferior to the one recommended and computed in respect to the transmitter frequency.</p> <p>Recommended distance:</p> $d = 1,2\sqrt{P}$ <p>from 150 kHz to 80 MHz</p> $d = 1,2\sqrt{P}$ <p>from 80 MHz to 800 MHz</p> $d = 2,3\sqrt{P}$ <p>from 800 MHz to 2,5 GHz</p> <p>where P is the maximum power in Watt in output from the transmitter according to the transmitter manufacturer and d is the recommended distance for its use, expressed in m (m).</p> <p>Interferences in proximity of devices marked by the symbol below can be verified.</p> 
	<p>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, over the frequency range 150 kHz to 80 MHz should be less than 3 V.</p>		



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