# Airmatic

INSTALLATION AND USE MANUAL

LUZZANI DENTAL

Models:
- Airmatic
- Airmatic NA
- Airmatic S
- Airmatic SNA

LUZZANI DENTAL S.R.L.

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ED. 6 REV4
18/10/2023

MADE IN ITALY

CE
1370

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# 1 —— INDICAZIONI

## 1.1 — CONFORMITY ASSESSMENT

The product has been subjected to conformity assessment in compliance with MDR(EU) 2017/745 and it meets the regulation's essential requirements.

## 1.2 — GENERAL INFORMATION

- The Airmatic motor is a medical device for dental use.
- Electrical protection type: Class 1
- Degree of protection against direct contact: B
- Continuous service. The motor was designed in accordance with the very latest ergonomic and technical principles. The unit uses the side channel operating principle. The motor is made entirely of die cast aluminium, including the impeller. The induction motor is protected against overheating by a VDE approved thermostat; motor noise emissions are mitigated by an integral noise filter. The motor has been EMC emission tested.
- Each motor is checked individually through operating and electrical safety tests, and individual test reports can be retrieved via the batch number.
- All products are CE marked.
- The assembly and operating instructions are a substantial and integral part of the unit. The instructions must always be kept near the unit. Full compliance with these assembly and operating instructions is the basis for regulatory compliance and proper use of the equipment; all staff, including newly hired personnel, must be fully informed/instructed in this. The assembly and operating instructions must be passed on to the next user.
- Use original equipment parts to assure operator safety and trouble-free operation of the equipment. In addition, only accessories listed in the technical documentation or otherwise expressly approved by the manufacturer may be used. If accessories or consumables other than Luzzani Dental products are used, safe use and operation of the system can no longer be guaranteed. No claims will be recognised for damage caused by improper use.
- Luzzani Dental shall only be held liable for safety, reliability and operation of the equipment if assembly, adjustments, alterations, extensions and repairs are carried out by Luzzani Dental or by a company authorised by Luzzani Dental; moreover, it shall be held liable if the equipment is used in compliance with the instructions for assembly and use.
- The assembly and use instructions correspond to the specific design of the equipment when it is placed on the market and the basic technical safety regulations in force at that time. All the details concerning the commands, procedures, names, software and equipment mentioned are protected by copyright.
- The instructions may be reproduced for assembly and use, including partial reproduction thereof, only when authorised by Luzzani Dental in writing.
- Retain the original pack for use in the event of returns. Keep the pack out of reach of children. Only the original pack guarantees optimal protection of the equipment during transport. If the equipment needs to be returned while still under warranty, Luzzani Dental shall not be held liable for transport damage caused by inadequate or defective packing!
- Before replacing a part of the device, make sure the replacement part is original from the manufacturer and of the correct model.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should mbe used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The device contains no magnetically sensitive components or circuits within the enclosure or as part of an attached accessory.

## 1.3 — DISPOSAL OF THE UNIT

The equipment components must be discarded as electrical waste. The remaining metal parts must be discarded as metal waste. The product does not contain hazardous or toxic/ harmful substances and it does not come into contact with such substances during the work cycle. In any case, comply with local by-laws at all times.

## 1.4 — INFORMATION ABOUT THE MEDICAL DEVICE

The product is a medical device and it must be used exclusively by dentists, who assume responsibility for overseeing its proper use.

## 1.5 — COMPLIANT USE

Suction units must be used exclusively in conjunction with separators, to aspirate air and liquid during dental treatments, in dry suction systems, in dental practices and orthodontic clinics. Use is permitted only withinprofessional healtcare facility environment. The suction system must be cleaned and disinfected in compliance with the manufacturer's instructions. Code compliant use of the system also includes compliance with the instructions for assembly and use and observance of the installation, use and maintenance conditions. It is essential to install an upstream air-liquid separator.

## 1.6 — NON-COMPLIANT USE

Do not aspirate combustible or explosive mixtures. Do not

use the unit as a vacuum cleaner.

The suction units cannot be used to aspirate secretions or other liquids. Any different use of the equipment is deemed to be non-compliant use.

The manufacturer shall not be held liable for damage caused by improper use of the equipment. The operator or the user alone shall be liable for that risk.

### 1.7 — USE OF PERIPHERAL EQUIPMENT

The units can be connected to one another, or to other devices, only on the condition that the safety of patient, user and surrounding environment is not jeopardised by this combination.

## 2 —— SAFETY

### 2.1 — GENERAL SAFETY INFORMATION

The unit is designed and built by Luzzani Dental in such a way as to eliminate all possible risks when it is used in compliance with the instructions. However, we provide the following safety instructions to minimise any residual risk.

- During operation of the appliance comply with local laws and directives! The equipment must not be modified or converted in any way, shape or form. Luzzani Dental does not warranty converted or modified equipment and shall not be held liable thereto. In the interest of proper operation and use of the unit, it the user is responsible for compliance with provisions and directives.
- Every time before the unit is used, the operator must check that it is in good condition and operating safely.
- The operator must have a detailed knowledge of the use of the unit.
- The product is not meant for use in explosion risk zones or atmospheres that facilitate combustion. Explosion risk zones can form following the use of flammable anaesthetics, detergents / disinfectants for the skin, and oxygen.

### 2.2 — SAFETY INFORMATION FOR ELECTRICAL PROTECTION

- During installation and before carrying out repairs on the equipment, follow the relevant electrical directives and safety standards, e.g. disconnect the unit from the electrical supply, checking the effective absence of power, and making sure the unit cannot be restarted. The mains voltage and frequency are shown on the unit.
- Before connecting the unit, check that the mains voltage and frequency shown on the unit correspond to the values of the power supply network.
- Before commissioning, check that the unit and lines are undamaged. Damaged lines and plug-in sockets must be replaced immediately.
- Never touch the patient and open plug and socket connections on the unit at the same time.

## 3 —— WARNINGS AND SYMBOLS

The following denominations or symbols for data of special significance appear in the instructions for assembly and use:


Instructions/orders and prohibitions for the prevention of injury to persons or significant damage to property.


Warning for dangerous voltage


Automatic starting


Hot surface


Manufacturer

## 4 —— TECHNICAL DATA

| Model | Airmatic | Airmatic NA | Airmatic S | Airmatic SNA |
|---|---|---|---|---|
| Power supply voltage (V) | 230 | 230 | 230 | 230 |
| Frequency (Hz) | 50 | 50 | 60 | 60 |
| Nominal current (A) | 1,86 | 1,86 | 1,96 | 1,96 |
| Absorbed current (A) | 1,86 | 1,86 | 1,96 | 1,96 |
| Starting current (A) | 9,5 | 9,5 | 9,5 | 9,5 |
| Cos ø | 0,96 | 0,96 | 0,96 | 0,96 |
| Electrical power (W) | 415 | 415 | 415 | 415 |
| Speed (rpm) | 2810 | 2810 | 3500 | 3500 |
| Operation | continuous | continuous | continuous | continuous |
| Weight (Kg) | 10,5 | 10,5 | 10,5 | 10,5 |
| Vacuum (mm water gauge) | 1300 | 1300 | 1400 | 1400 |
| Air flow rate (litres/ minute) | 1100 | 1100 | 1300 | 1300 |
| Noise level * (db(a), ±1,5) | Ca.64 | Ca.64 | Ca.64 | Ca.64 |
| Output (%ed) | 100 | 100 | 100 | 100 |

| | | | | |
|---|---|---|---|---|
| Temperature | | | | |
| Unit operation (°C) | +10 to +40 | +10 to +40 | +10 to+40 | +10 to +40 |
| Storage and transport (°C) | -10 to +60 | -10 to +60 | -10 to +60 | -10 to +60 |
| Air humidity | | | | |
| Unit operation | max 70% | max 70% | max 70% | max 70% |
| Storage and transport | max 95% | max 95% | max 95% | max 95% |
| Protection type | IP50 | IP50 | IP50 | IP50 |
| Protection class | I | I | I | I |
| Protection against water penetration | normal | normal | normal | normal |
| Vacuum connection | ø 30 mm (external) | ø 30 mm (external) | ø 30 mm (external) | ø 30 mm (external) |
| Exhaust connection | ø 30 mm (external) | ø 30 mm (external) | ø 30 mm (external) | ø 30 mm (external) |
| Device of | class 1 | class 1 | class 1 | class 1 |
| Device of | type B | type B | type B | type B |
| Insulation class | F | F | F | F |
| Manufacturer | Luzzani S.r.l., Via Torino 3<br>20030 - Senago (MI) - Italy | | | |

Equipment not suitable for use in the presence of anaesthetic mixtures that are inflammable with air or oxygen or nitrous oxide.

*According to the EN ISO 1680 standard on sound emission; values measured in a soundproofed room. Noise levels may be higher in highly reverberant rooms.

## 5 —— DESCRIPTION OF OPERATION

Airmatic Suction Units are employed in dry suction systems. These suction units can in fact be installed in all suitable rooms (on the floor above or below the treatment room), without constraints in terms of piping layouts. The air flow and vacuum required are produced using the side channel compression principle. The air exhausted from the suction unit must be routed to the exterior of the building, ideally above the roof. We recommend fitting a biofilter in the air exhaust line. The device is designed for continuous operation. The device has been tested for a service life of 10,000 hours.

## 6 —— INSTALLATION

Installation details are given also in the suction system's design information.

### 6.1 — PLACE OF INSTALLATION

- Ambient temperature must be no lower than +10 °C in winter and no higher than +40 °C in summer.
- Installation in rooms with specific functions, such as a boiler room, must be analysed beforehand in relation to building regulations.
- The unit must not be installed in a damp place.
- If the unit is installed in a cabinet or machine room, intake and exhaust air vents with a minimum section of 120 cm² must be provided. In the case of insufficient ventilation, fit a fan with minimum air flow of 2 m3/min. and create an air vent for cooling air recirculation.

### 6.2 — POSSIBLE INSTALLATIONS

A major advantage of dry suction systems is that they can be installed in any suitable room (also on upper and lower floors), without layout restrictions for the piping.

- Installation of the suction unit directly on the floor
- Installation on a console
- Wall mounting, suspended

For hygiene reasons and to prevent problems of odours/ motor overheating, we recommend venting the suction unit outside the building and equipping the related exhaust line with a biofilter.

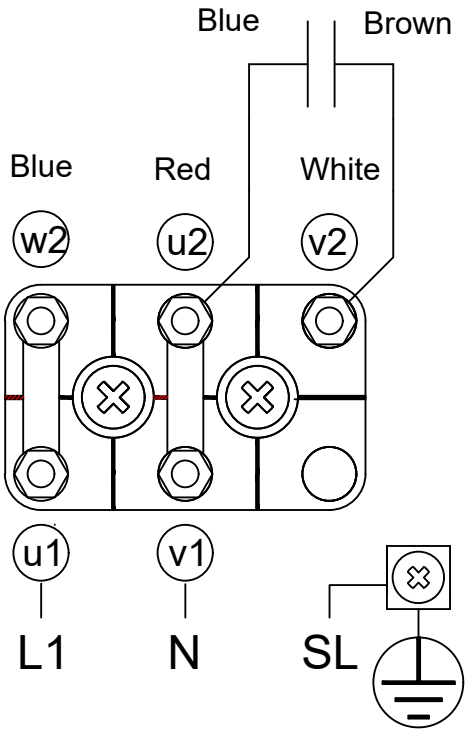
### 6.3 — FLEXIBLE HOSE MATERIAL

Use exclusively flexible spiral wire reinforced PVC hose for the suction line and water drain line, or equivalent hoses. Do not use: hoses that are unable to withstand the disinfectants and chemical products used in dentistry, rubber hoses, non-reinforced PVC hoses with insufficient flexibility.

## 7 —— ELECTRICAL CONNECTION

The electrical connection must be made in compliance with technical regulations governing installation of low voltage systems in medical facilities.

- Before commissioning the unit, check that the mains supply complies with the values shown on the data plate.
- The suction unit must be connected to the terminal strip as shown in the connection diagram. The connection circuit to the external mains supply network must incorporate a 230 V, 16 A circuit breaker with 3 mm contact gap in compliance with IEC 60601-1.




A 16 A, 250V fuse must also be provided between the circuit breaker and the unit on line L1. The unit is designed exclusively for aspiration of air. Any liquids or solids must be intercepted upstream by means of suitable filters and separators. The suction hose must be connected to the union marked IN. The exhaust hose must be connected to the union marked OUT.

- Suction units must be wired directly into the electrical system in a stable manner. Instructions for assembly and use of controllers.

### 7.1 — CONTROLLER (NOT SUPPLIED)

The suction units must be connected to a controller. The connection diagrams and electrical schematics are included in the controller instructions for assembly and use.

### 7.2 — MOTOR TERMINAL STRIP CONNECTIONS

Connect the controller power input wires to the respective terminals on the motor terminal strip.

## 8 —— COMMISSIONING

- Switch on the unit / power on the main power switch for the treatment room.
- Check that the suction unit is working.
- Make sure the connections are airtight.
- Carry out the electrical safety test of the controller and suction system in accordance with local regulations (e.g. directive governing installation, operation and use of medical products, legal requirements for users of medical products) and record the result.

In certain countries, medical products and electrical systems are subject to regular testing at predefined intervals. The operator must be aware of all such requirements.

## 9 —— CLEANING AND DISINFECTING THE SUCTION SYSTEM

After each treatment, aspirate a glass of cold water using the small suction cannula and the large cannula, even if the treatment has involved exclusively the use of the saliva ejector.

Do not use foam type cleaning products because they could damage the suction unit.

## 10 —— MAINTENANCE

To avoid infection risks, wear protective gloves when carrying out maintenance on the equipment.

## 11 —— IDENTIFICATION DATA AND WARRANTY

### 11.1 — CONSTRUCTION BATCH

Each motor has a serial number on the external casing to provide precise identification of the individual motor and hence the production batch. This number can be used to identify the time of construction and the batch control documents.

### 11.2 — WARRANTY

The product is warranted by the manufacturer for 12 months from the date shown on the delivery document. Any unauthorised tampering or alterations will immediately void the warranty and hold the manufacturer harmless from all liability for injury to persons or animals or damage to property caused by such unauthorised actions. The law court of Milan (Italy) has sole jurisdiction in the event of disputes.

## 12 —— TRANSPORT AND STORAGE

The AIRMATIC motor is supplied in a preformed polystyrene shell packed in a cardboard box. Transport and storage conditions:

- Ambient temperature: from -40 to +70°C
- Relative humidity: from 10 to 100%, also condensing
- Atmospheric pressure: from 500 to 1060 hPa

## 13 — FAULT REPORTING

To meet the requirements of MDR (EU) 2017/745, the manufacturer has set up an after-sales surveillance procedure to deal with any problems resulting from the use of its products.

Fault reporting requirements furthermore oblige user and manufacturer to inform the competent authorities of any incidents involving patients or users caused by malfunctions, degradation of characteristics and/or performance, or inadequacy of the instructions for use.

You are kindly requested to notify us of any faults by filling in the fault report form attached to the last page of the manual and sending it to our offices.

# FAULT REPORT FORM

PRODUCT _____

TYPE _____ BATCH _____

REPORTED BY _____

COMPANY _____

_____

_____

TYPE OF REPORT

☐ ANOMALY ☐ SUGGESTIONS ☐ _____

DESCRIPTION

_____

_____

_____

_____

_____

NOTES

_____

_____

_____

_____

_____

DATE _____ SIGNATURE _____

**SEND TO:**

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