

from
SAVE.
to Vita...

Royax Medical
Solution

User Manual FFP1 -Respirator



Filtering Face-Piece Respirator

Catalogue code: R-DP-R-FFP1-01

ROYAX S.R.O.

Thank you for choosing a ROYAX product
Filtration efficiency for allergens is 99%, working particles P1 99%
and for dust particles PM2, 5 and 10 it is 100%.

This manual is designed to provide the information needed for using the Face-Piece Respirator (hereinafter referred to as “Product” or “Respirator”)

Disclaimer: All applicable instructions on the usage of the product and safety precautions are integrated in this document. ROYAX takes no responsibility for damages caused by the improper use of the product. It is highly recommended that wearers follow all these instructions for the proper use of this product prior to and after-use. **This manual does not provide any medical advice or instruction.**

Proprietary rights: The information contained in this manual is the property of ROYAX (hereinafter referred such “Manufacturer”), Czech Republic. ROYAX reserves design and manufacturing rights of this product.

Conservation of the manual: This manual must be kept together with the product for the life of the product.

Disposal of the product: Removal and disposal have to be performed very carefully, because the product itself may become a source of infection through use. Please follow the instructions set out in this document.

Legislation:

EN149:2001 + A1:2009 partly applied RfU02.075 revision 1 of the notified Bodies VG2 against COVID-19
PPE (EU) 2016/425

ROYAX: Obchodni 107, 251 01, Cestlice, Czech Republic

T/F: +420 321 123 111/2

www.royax.eu

info@royax.eu

Contents

1. DESCRIPTION	3
1.1 Component parts of the respirator	3
1.2 Respirator fitting instructions	4
1.3 Respirator removal	4
1.4 Warnings	5
2. CLEANING, DISINFECTION, MAINTENANCE and TRANSPORT	5
2.1 Cleaning and disinfection.....	5
2.2 Maintenance	5
2.3 Transport.....	5
2.4 Storage condition.....	5
3. SYMBOLS AND OTHER NECESSARY INFORMATION.....	6
3.1 Validity	6
3.2 Symbols	6
4. EU DECLARATION OF CONFORMITY	8



1. DESCRIPTION

Royax high quality and performance respirators work using electrostatic properties to attract and then to trap the tiniest of existing particles.

Our respirator is designed to protect against living organisms such as Virus, bacteria, fungi and also fine dust, fibers, aqueous mists, oil-based mists.

Microorganisms (Virus, bacteria, fungi) can be transmitted by various routes. Respiratory protection is needed to prevent infection with organisms which usually enter the body through inhalation (droplet/airborne).

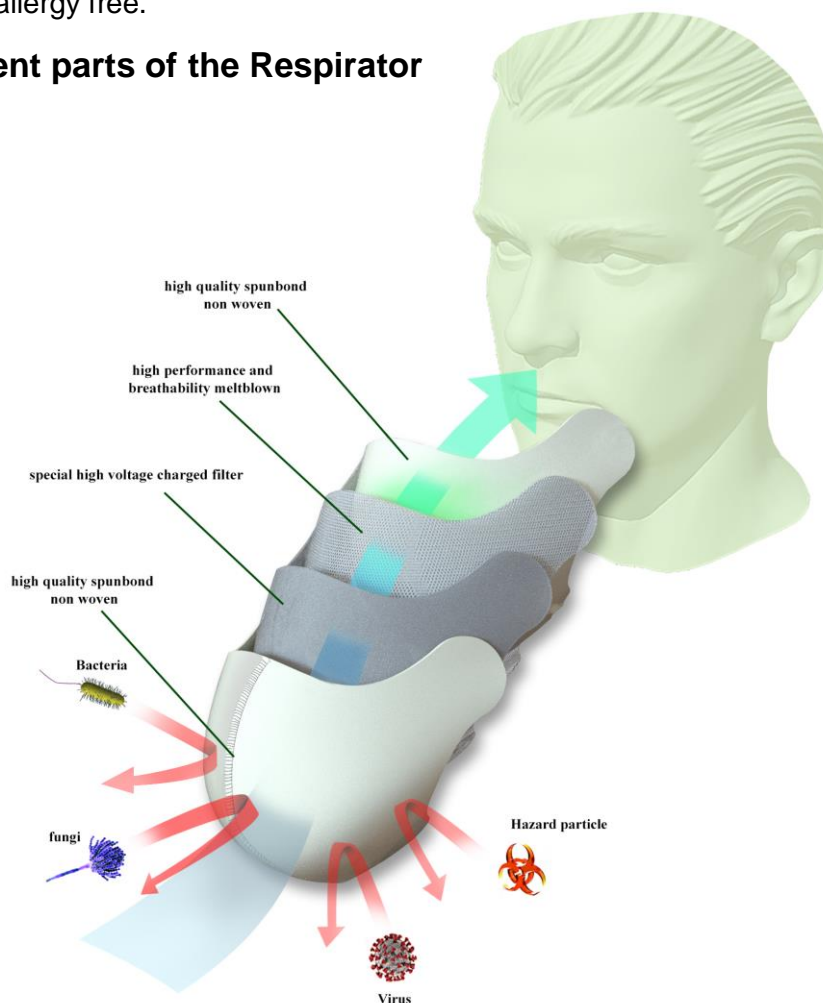
Also, respiratory protection is crucial to reduce risk of airborne infections spreading when the people cough, sneeze or speak.

Our respirator product is closely face-fitting in order to make a seal. Additionally an adjustable nose clip is incorporated to prevent leakage and provide comfort.

The respirator must be put on and removed in a routine that minimizes the potential for cross contamination. Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and may result in sickness or death

The respirators are of a 4-layer construction (see diagram 1.1 below), comprising two layers of high-quality spun bond material with a smooth surface finish which covers two layers of outstanding performance non woven special filter and melt blown filter material that is electrostatically charged. The electrostatic element attracts and then traps the tiniest of particulate whilst remaining easy to breathe through. The non-valve construction ensures that the wearer does not exhale potentially harmful organisms to others nearby. The product is skin friendly and allergy free.

1.1 Component parts of the Respirator



1.2. Respirator fitting instructions:

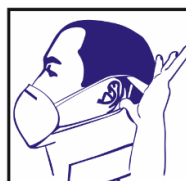
- 1) Hold the ear loop of mask with both hands.



- 2) Pull the strap of the mask back to the ear and fit comfortably.



- 3) Wear the mask in the way that cover your nose and mouth thoroughly.



- 4) Press the nose clip and adjust mask to your face.



- 5) Over the front of the respirator with both hands and check air leakage around your nose and mouth.



1.3. Respirator removal:

During use, respirators may become contaminated and should not be touched. However, if touched the hands must be washed immediately and thoroughly.

Removal and disposal has to be performed very carefully, because in use the respirator may itself become a source of infection.

Instructions for removal:

- Pull the ear loop from behind one ear, and then the other.
- Hold the respirator by an ear loop.
- Immediately discard in proper container.
- Hand hygiene should be performed after removal and disposal of the respirator.



1.4. Warnings:

- If the respirator is damaged or if it becomes contaminated with respiratory secretions or other body fluids, it should be changed and disposed of as a health care waste item.
- Do not use if the respirator is extremely crumpled.
- Do not use with beards or other facial hair or if other facial conditions prevent a good seal between the face and edges of the respirator.
- Do not use in oxygen deficient atmospheres of less than 19.5% by volume at sea level.
- Do not use in poorly ventilated areas.
- Do not use for firefighting and sandblasting.
- Washing with alcohol, water and detergent will damage the respirator irreversibly.
- Autoclaving and other forms of heating also damage the respirator.
- Reuse is forbidden.
- The respirator shall not be used for more than one shift.
- Do not touch the front of the respirator when you remove it.
- Replace respirator with a new one as soon as it becomes damp or humid.
- Do not use in an explosive atmosphere.
- Store respirator away from contaminated areas when not in use.
- Dispose of used product in accordance with applicable regulations of your country.

2. CLEANING, DISINFECTION, MAINTENANCE and TRANSPORT

2.1. Cleaning and Disinfection:

Washing with alcohol, water and detergent will damage the respirator irreversibly.

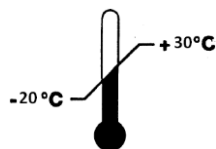
2.2. Maintenance:

The life of the respirator depends on the time of use, care and maintenance. Before use, do a thorough inspection of the product. If any part of the product is damaged, replace the entire product immediately. We recommend that respirator is kept in a suitable clean case or package when not in use. In every situation, the product must be replaced after a period of one shift (max 8 hours).

2.3. Transport:

The product must be transported in its original packaging (cellophane).

2.4. Storage conditions:



Temperature : -20°C to +30°C



Humidity :Max 80%

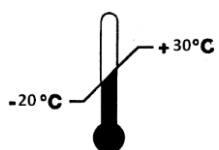
3. SYMBOLS AND OTHER NECESSARY INFORMATION

3.1. Validity:

The product is with a validity of 5 years after the manufacturing date shown on the package.

Explanation of markings on the product and packing

3.2. Symbols



Temperature : -20°C to +30°C (Storage condition)



Humidity : MAX 80% (Storage condition)



Reference number for identifying product (catalogue No)



Product lot number for product traceability (batch code)



Manufacturer name and address/ Production date :yyyy-mm



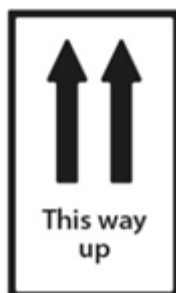
End of shelf life /yyyy-mm



See information supplied by manufacturer



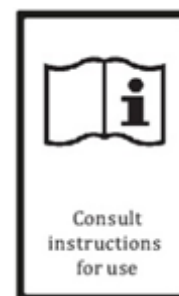
Keep dry



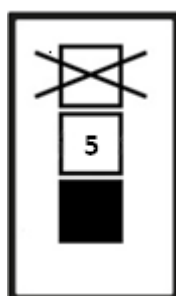
Right direction for storage



Keep away from sunlight



Consult with the instruction for use and information supplied by the producer



Do not put more than
Limit 5 boxes on top of each other



keep away from fire



Product is stackable



Carry by hand

EU DECLARATION OF CONFORMITY**No. 20200501/1****According to Directive PPE (EU) 2016/425**

Manufacturer:	ROYAX, s.r.o.
Address:	Obchodní 107, Cestlice, 251 01, Czech Republic
Name of Device:	Respirator face mask
Device Types` Codes:	R-DP-R-FFP1-01
Category of Device: III	According to Annex I RISK CATEGORIES OF PPE (Classification) of the EU Community Council Directive (EU) 2016/425.

ROYAX, s.r.o. hereby under its sole responsibility declares that the above specified personal protective equipment has been determined as the Category III device according to the requirements of Annex I of the European Community Council Regulation 2016/425.

ROYAX, s.r.o. further declares that the product complies with the relevant provisions of Regulation 2016/425 concerning personal protection equipment and in particular the conformity of the product with the Essential Requirements in Annex II of the Regulation and is the subject of the EU Type Examination Certificate.

The product has been designed, developed, manufactured and tested in accordance with all applicable standards and by using a quality management system according to EN ISO 13485:2016.

Standards Applied:

EN149:2001 + A1:2009 Partly applied with RfU02.075 Version 1 COVID-19 Specific Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking and quality control procedures for the final product according to Module C2 of the PPE Regulation 2016/425

Prague**ROYAX s.r.o.****NAME: Rambod Afrashteh****Position :CEO****SIGNATURE:****Royax** Medical SolutionROYAX, s.r.o.
Obchodní 107
251 01 Cestlice
IČ: 247 55 346E: info@royax.eu
T: +420 321 123 111
www.royax.eu