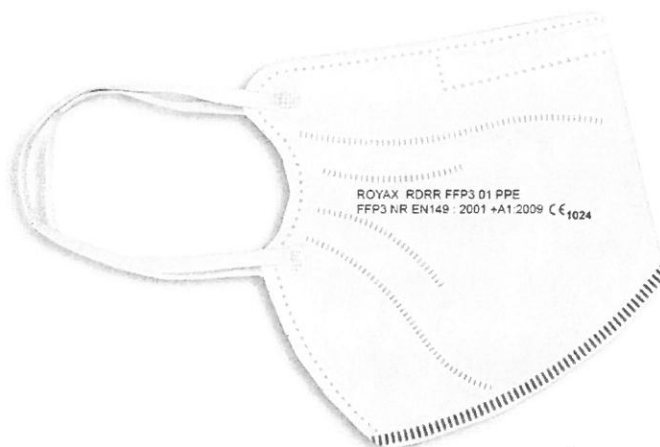


from
SAVE.
to **Vita...**

Royax Medical
Solution

User's Manual
FFP3 Respirator

Royax Medical
Solution



Filtering Face-Piece Respirator

Catalog codes: R-DP R-FFP3-01

ROYAX s.r.o.

© ROYAX-Obchodni 107, 251 01 Cestlice, Czech Republic Nov 2020

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Thank you for choosing a ROYAX product

This manual is intended to provide necessary information needed for using 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 users follow all these instructions for the proper use of this product prior to use and after-use. This manual does not provide any medical advice or instruction.

Proprietary rights: The information revealed 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 they may become themselves a source of an infection. Please follow the instructions set forth in this IFU.

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Legislation:

EN149:2001 + A1:2009

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1. DESCRIPTION

Royax high quality and performance FFP3 respirators which designed and manufactured in accordance with to the EN 149:2001+A1:2009 standard and provide **99.998% filter's efficiency** and protect you from a lot of viruses and airborne pollutants by filtering out the air you breathe.

Microorganisms (viruses, bacteria, fungi) can be transmitted by various routes. Respiratory protection is needed to prevent infection with organisms that are usually entered the body through inhalation (droplet/airborne). The respirator should be used together with other PPE for health care professional.

The respirator is recommended **for Health Care Provider (HCP) in close and direct contact** with a confirmed or suspected case of COVID-19. Also, respiratory protection is crucial to reduce risk of airborne infections spreading when the people cough, sneeze or speak.

Our FFP3 respirator are fitting to the face are meant to make a seal. Adjustable nose clip to prevent leakage and provide comfort.

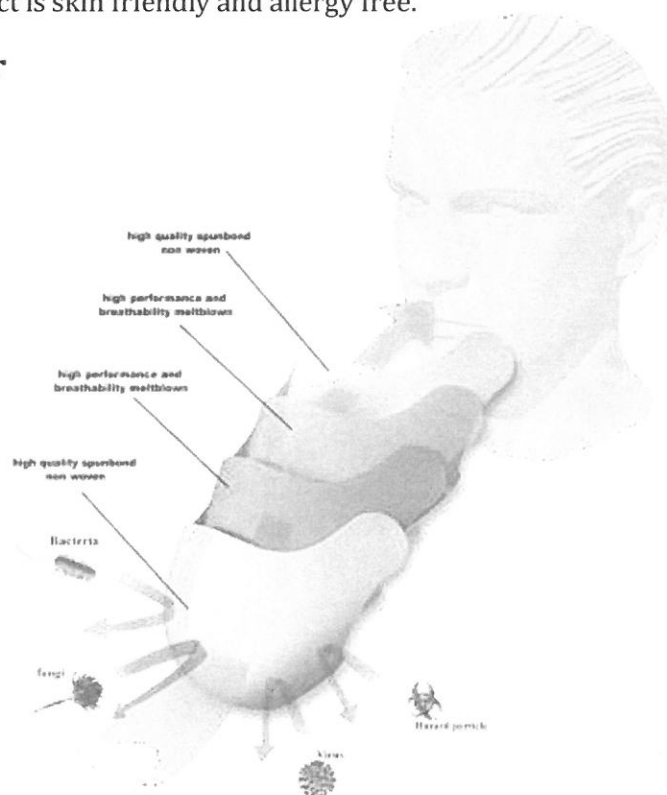
In order to achieve the correct sealing efficiency of the respirator of the FFP3 class of protection, it is necessary to use a coupling with a clamp behind the head. Without a head connection, the respirator doesn't provide FFP3 protection.

The respirator must be put on and removed in an order 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 consist of a 4-layers` construction (please refer to the 1.1. Article of this IFU), comprising two layers of high-quality spun bond material with smooth surface finish which covers two layers of outstanding performance 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.

Royax FFP3 respirator with high tech and high-quality material is able to meet higher filtration level and provide excellent protection. The product is skin friendly and allergy free.

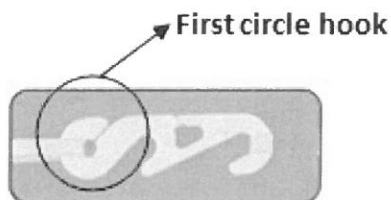
1.1 Component parts of the Respirator



Respirator fitting instructions:

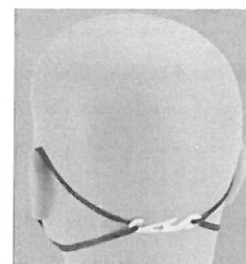
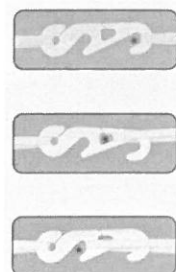
Wash your hands before putting on your respirator

- 1) Hold the ear loop of respirator and put it at first circle hook of head connection.



- 2) Pull the strap of the respirator back to the head and put it on one of other side 3 hook levels of head connection.

Double-sided head connection clip has 3 hook levels to account for different head sizes while ensuring your respirator properly hugs your face.



in order to achieve the correct sealing efficiency of the respirator of the FFP3 class protection, it is necessary to use a coupling with a clamp behind the head. Without a head connection, the respirator does not provide FFP3 protection.

- 3) Wear the respirator in the way that cover your nose and mouth thoroughly.
- 4) Press the nose clip and adjust respirator to your face.
- 5) Over the front of the respirator with both hands and check airleakage around your nose and mouth.
- 6) Make sure you can breathe easily



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 head connection, and then remove it.
- Hold the respirator by an ear loop.
- Immediately discard in proper container.
- Hand hygiene should be performed after removal and disposal of the respirator.

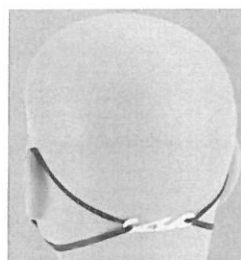
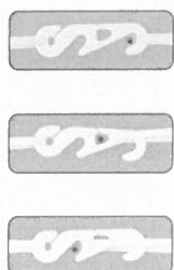


1.4.Warnings:

in order to achieve the correct sealing efficiency of the respirator of the FFP3 class protection, it is necessary to use a coupling with a clamp behind the head. Without a head connection, the respirator does not provide FFP3 protection.

head connection Providers to ensure a close fit without anything rubbing against your ear and it is one of the most popular ways to prevent behind-the-ear irritation.
Instruction to use respirator clips:

Simply wrap the elastic respirator's straps around the clip, rather than your ears, to make respirator fit & seal and you feel comfortable and immediately relieve pressure of your ear from long-term wearing of the respirator. This double-sided clip has 3 hook levels to account for different head sizes while ensuring your respirator properly hugs your face.



- Respirators should NOT be worn by children under age 2 or anyone who has trouble breathing, is unconscious, incapacitated, or otherwise unable to remove the respirator without assistance.
- Wear a respirator correctly for maximum protection.
- Don't put the respirator around your neck or up on your forehead
- Don't touch the respirator, and, if you do, wash your hands or use hand sanitizer to disinfect
- If respirator is damaged or if it becomes contaminated with respiratory secretions or other body fluids, it should be changed and dispose of as a health care waste.
- Leave contaminated area immediately and contact supervisor if you smell or taste contaminants or if dizziness, irritation, or other distress occurs.
- Do not use if the respirator is extremely crumpled.
- Do not use with beards or other facial hair or other conditions that prevent a well seal between your face and the face seal of the respirator.
- Do not use in oxygen deficient atmospheres less than 19.5% by volume at sea level.
- Do not use in poorly ventilated areas.
- Do not use for firefighting and sandblasting.
- Do not approach flames with the respirator and in general nearby free flames
- 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 explosive atmosphere.
- Store respirator away from contaminated areas when not in use.
- Be careful not to touch your eyes, nose, and mouth when removing and wash hands immediately after removing.
- Dispose of used product in accordance with applicable regulations of your country.

1.5. Notified body's information

Notified Body	Occupational Safety Research Institute (VUBP) Jeruzalemska 1283/9 110 00 Praha 1- Nove Mesto
Notified Body number	1024

2. CLEANING, DISINFECTION, MAINTENANCE and TRANSPORT

2.1. Cleaning and Disinfection:

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

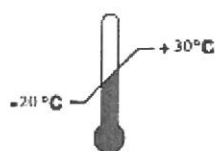
2.2. Maintenance:

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 case or pack when not in use. In every case, the product must be replaced after a period of one shift (8 hours).

2.3. Transport:

The protector must be transported in it's original packing (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

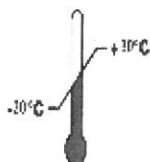
EN 149:2001+A1:2009

Personal protection equipment- Specific requirement of the Notified Bodies

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

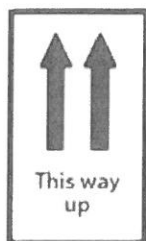


See information supplied by manufacturer

NR

NOT for REUSE

EN149:2001 + A1:2009



Right direction for storage sunlight



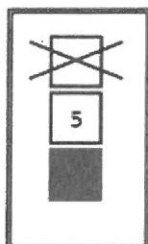
Keep away from



Carry by hand



Humidity : MAX 80%



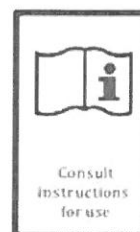
**Do not put more than
Limit 5 boxes on top of each other**



keep away from fire



Product is stackable



**Consult with the
Instruction for use
and information
supplied by the
producer**

