Instructions for Use (EN)

1. Product description FindAir ONE for pMDI

1.1. About FindAir ONE for pMDI

The FindAir ONE for pMDI is an electronic accessory device for pressurized metered dose inhalers (pMDIs). The device is mounted on the top of the inhaler canister. It is mechanically pressed whenever the patient uses the inhaler to deliver the medicine contained in the inhaler. Simple operation of the device allows the patient to use the product independently. The pressing of FindAir ONE for pMDI activates the electronic sensor inside the device enclosure. FindAir ONE for pMDI records the use of the inhaler. This data is stored in the FindAir ONE for pMDI. The FindAir ONE for pMDI is able to connect via Bluetooth to software on compatible mobile devices, tablets of choice to download data from the FindAir ONE for pMDI, and allow it, to be viewed and sent to appropriate databases. When there is no

connection to the device via Bluetooth data collection device, it is possible to make and store up to 127 usable records available in FindAir ONE for pMDI (maximum capacity). Data above 127 records is overwritten by the logic first in first out.

1.2 Contents of the FindAir ONE for pMDI package

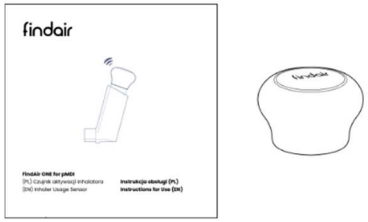


Figure 1. An overview of FindAir ONE for pMDI

The contents of the FindAir ONE for pMDI product package include:

- FindAir ONE for pMDI device
- User manual

1.3 Intended Use of FindAir ONE for pMDI.

The purpose of FindAir ONE for pMDI is to collect information on the use of the pMDI. The product is aimed at patients and professionals (doctors, researchers), who wish to collect data on the use of inhalers. The product is intended for adult patients and people under adult care, both children and adults requiring supervision. The product is intended for multiple use by one user. Up to 127 uses of the inhaler can be recorded and stored in FindAir ONE for pMDI.
FindAir ONE for pMDI can be used in indoor and outdoor settings such as at home, at work, and in the environment of specialist clinics.
The product is not intended for diagnosis or treatment and does not replace diagnosis by a doctor or treatment prescribed by a doctor.

1.4 Lifetime of the product

Shelf life	Product Shelf life is 36 months from the production date listed on the package label marked (11)
Service life	The product's operating time is 12 months from the date of first use. Service life is included in Shelf Life.

2. ⚠ Warning and Precautions.

I. To ensure the proper functioning of the device, it should not be used with inhalers other than compatible pMDI-type inhalers. Compatible pMDIs are those with metal cylindrical canister diameter dimensions between 19 - 23.5 mm.
II. Refer to the labeling provided with the Inhaler for instructions on use. Carry out all steps required to use your Inhaler according to the instructions.
III. FindAir ONE for pMDI is not intended for communicating emergency situations. In case of a medical emergency or need for assistance, the patient should call 911 in the USA or 112 UE, contact their physician, or go to the closest emergency service facility.
IV. Transmission of information in FindAir ONE for pMDI does not work in real-time; some information may be transmitted with a delay.

V. For patients, remove the FindAir ONE for pMDI if it hinders or prevents correct usage of the inhaler. Do not delay using the inhaler for the sake of attaching the FindAir ONE for pMDI to the inhaler.
VI. FindAir ONE for pMDI is not a dose counter. Do not use data collected by the FindAir ONE for pMDI sensor to determine the number of doses remaining in a medication tank. FindAir for pMDI does not record whether the inhaler was used correctly and how much of the medication was administered.
VII. It is recommended to rely on the dose indicator in the pMDI inhaler if it has one.
VIII. For patients, do not insert the device into your mouth. Choking hazard, swallowing risk - keep away from small children.
IX. Do not use if the skin of your hands is damaged or use with gloves.
X. This product contains a button cell or coin battery, keep it away from small children.
XI. Do not replace the battery in FindAir ONE for pMDI. Attempting to replace the battery may result in permanent damage to the device and it's malfunctioning.
XII. Do not place the device under running water, underwater, in a dishwasher, or washing machine. This action may result in permanent damage to the device and it's malfunctioning.
XIII. Do not place used devices or batteries in regular waste containers. Arrange for professional pick up which is commonly free of charge.
XIV. Any serious incident related to the product should be reported to the manufacturer via email: support@findair.eu and/ to the appropriate authority of the member state where the user or patient resides.

XV. For data integrity reasons, do not use the FindAir ONE for pMDI with more than one patient.
XVI. In case of problems, contact support@findair.eu
XVII. The product does not sustain or support life, and no necessary intervention is required in case of its unsuitability.
XVIII. Setup and use the FindAir ONE for pMDI for children or disabled persons should be supervised by parents or caregivers who have familiarized themselves with the user manual.
XIX. Do not expose the product to extremely low or high temperatures. Extremely high or low temperatures may cause deformation of the device, shorten its lifespan, and also reduce the capacity and operating time of the battery. Refer to the operating and storage temperature limit in the package insert of the device.
XX. For data reception from the FindAir ONE for pMDI device, Bluetooth must be turned on, on the mobile device where the compatible application is installed.

3. Conditions for use and storage

FindAir ONE for pMDI can be used in indoor conditions such as home, office, airplane, and in outdoor conditions.

Recommended conditions for use and storage:

Optimal operating temperature:	0°C to +55°C (32-131°F)

Storage temperature:	-10°C to +60°C (14-140°F)
Relative humidity for use:	5-95%
Pressure:	700 - 1060 hPa

4. Hardware requirements

Parameters of inhalers compatible with FindAir ONE for pMDI: should have the following dimensions: Pressurized metered dose inhaler (1) with a metal cylindrical canister between 19 - 23.5 mm in diameter, extending above the case by at least 7 mm (2).

Example compatible pMDIs/medications: VENTOLIN®; ATRODIL; Aspulmo; Atimos; Foramed PLUS; Pulveril; Serevent; Budiair; Ribuspir; QVAR; Alvesco; Advair HFA; Seroflo; Seretide Evohaler; Flovent HFA Tilade; Intal; Vanceril; ProAir; Proventil HFA; Xoponoex HFA; Flixotide Evohaler; Riarify; Trydonis; Trimbow Atimos; FULLHALE; Budamate HFA; Budate HFA; Budecort HFA ;Esiflo HFA ; Salbair HFA ; Salbair-B HFA ; Tiate MDI; Tiomate MDI; Formoflo; Duomate MDI ; Foracort Inhaler; Aerocort HFA; Asthalin HFA; Beclate Inhaler; Duolin Inhaler; Duova Inhaler; Ipravent Inhaler; Levolin Inhaler; Maxiflo Inhaler; Serobid; Tiova Inhaler; Triohale Inhaler; Flutiform; Fostair/Fostex; Salamol; Sultanol N; Flovent HFA; Asmanex HFA

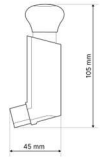


Figure 2. An example view of the inhaler compatible with FindAir ONE for pMDI

FindAir ONE for pMDI pairs by Bluetooth Low Energy on compatible mobile devices and wirelessly transmits data about inhaler usage to a compatible application where it can be accessed. The application requires a phone, tablet, or computer system support of Bluetooth Low Energy min. version 4.0

5. Preparation and creation of the software to connect with FindAir ONE for pMDI

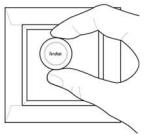
The devices can be operated by client software after implementation of the synchronization protocol made available by FindAir Sp. z o.o. to

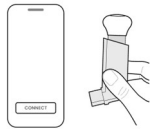
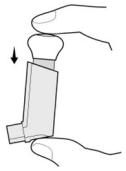
the client. The company can create a connection between software and FindAir ONE for pMDI. Software must be able to use Bluetooth Low Energy module- wirelessly min. version 4.0

6. Preparation and the first use of the FindAir One for pMDI by the patient/specialist

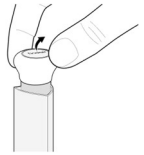
FindAir ONE for pMDI is delivered in Deep Sleep mode, i.e. the device is set to a low energy consumption state and is awaiting for activation. This mode is used for long-term storage to minimize power consumption and in this state Bluetooth communication is disabled. After activation, the device turns on Normal operating mode.

Normal operating mode (Service Life) – a standard operating mode in which all subsystems operate. The device remains idle until it detects its first use. Event records are created and saved when a button press is detected. If necessary, the device can be connected to a companion app via Bluetooth Low Energy, and through it download usage data. If the device is not connected and has already been activated, it remains in a state of continuous signal sending.

1.	Remove the FindAir ONE for pMDI device from its packaging by picking it up with two fingers from the sides, without pressing the activator mechanism.	
2.	Before starting, click on the element of the device activator mechanism (pressing the top of FindAir ONE outer case) once, to activate it.	
3.	After activation, attach the device to the top of your pMDI inhaler bottle. Make sure to avoid triggering the activator mechanism. Ensure that the device is fully applied and will not slide off.	

4.	If you wish (optional) to use the device with an app, place the add-on near the mobile device screen and follow the instructions in the app. Ensure that Bluetooth is enabled on your mobile device.	
5.	When the device is correctly attached, the add-on registers each time the inhaler bottle is pressed using the activator mechanism. At this point, the device is ready to use.	

Removing and Replacing the Device

6.	To remove the add-on in order to transfer it to another inhaler, grasp it from the sides and pull it in a direction opposite to the inhaler until it slides off. The cap should be kept on the inhaler and not removed unless it is necessary.	
Reviewing Inhaler Usage Data		
7.	The records from the FindAir ONE for pMDI can be automatically uploaded via Bluetooth. The upload of new records will occur automatically as long as the FindAir ONE for pMDI is within range of the mobile device with enabled Bluetooth (approx. 20 meters or 64 feet) and properly set mobile app	

WARNING! Usages within the first minute of the device's operation may not be recorded. After activating, wait 60 seconds before starting to use it with the inhaler.

WARNING! It is important to carefully apply and remove FindAir ONE for pMDI to avoid triggering the activator mechanism. Lack of caution may result in registering usage at the moment of applying and removing the add-on.

7. FindAir ONE for pMDI with mobile apps

The FindAir ONE for pMDI device is able to send data to dedicated mobile applications.

WARNING! If the user received or acquired the device along with a partner application, then the user should go through the pairing process according to the instructions for the partner application.

8. Operational Guidelines

8.1 Degree of Protection

The device is protected to the degree of IP22 - protection against solid foreign objects (12.5mm and larger in diameter) and water droplets when tilted at any angle up to 15° from the vertical in any direction.

WARNING: Do not expose the product to very low or very high temperatures. Extremely high or low temperatures as well as humidity may cause distortion of the outer case of the device, reduce its lifespan, and affect battery capacity and operating time.

WARNING: Using the product in the presence of high-intensity electromagnetic radiation sources may lead to damage or improper functioning of the product.

8.2 Battery Replacement

The FindAir for pMDI battery is not replaceable.
The battery is not rechargeable. Once depleted a new FindAir ONE for pMDI device will be required.

WARNING: Do not replace the battery - Attempting to replace the battery may result in permanent damage to the device or malfunctioning.

8.3 Cleaning of the FindAir ONE for pMDI

When cleaning the FindAir ONE for pMDI as a single user, please remove the device from your inhaler before cleaning. Clean the device from the external side only. Check if the sensor is clean and repeat if necessary. Leave it to dry in a warm place.

When cleaning the device:

- Do not immerse the device in running water.
- Do not clean the device beneath the water's surface.
- Do not place the device in a dishwasher, washing machine, etc.
- Do not use chemicals or detergents.

9. Impact on the Environment - Disposal

- Energy management of the product is done through software, which minimizes energy consumption.
- Disposal of components that are not repairable, such as the battery, is carried out in accordance with the regulations in force in the respective country.
- Dispose of or recycle in accordance with regulations for your country, as applicable for electronic devices containing a lithium coin cell battery. Ensure that the inhaler is removed from the FindAir ONE for pMDI prior to disposal.
- EU only: Do not dispose of the FindAir ONE for pMDI sensor as unsorted municipal waste. The FindAir ONE for pMDI must

be recycled in accordance with Directives 2012/19/ EU and 2006/66/EC. To arrange for the return or disposal of the FindAir ONE for pMDI contact the supplier.

- The product may generate electromagnetic interference at minimal levels.

10. Symbols

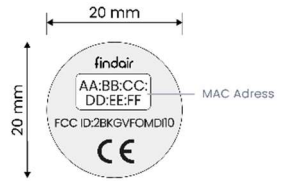


Figure 3 Device Label

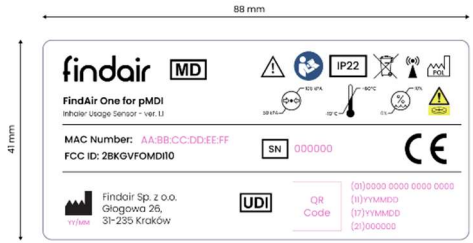


Figure 4 Packaging Label

Symbol	Meaning
CE	EU only: European conformity mark

IP22	The degree of protection provided by the enclosure of the electrical device
SN	Serial number
	Manufacturer's Symbol (Contact Information)/ Date of manufacture
	Country of manufactured
	Symbol - always read the instructions before use
	Temperature limit

	Humidity limitation
	Atmospheric pressure limitation
	Warning symbol WEEE; waste - electrical components; disposal in accordance with national regulations.
	Note - Important information on the packaging/instruction manual.
	Symbol - Device contains a low-power radio frequency (RF) transmitter.
MD	EU only: Medical Device
UDI	A Unique Device Identifier (UDI) is a unique numerical or alphanumeric code associated with a medical device.

INGESTION HAZARD: This product contains a button cell or coin battery.
DEATH or serious injury can occur if ingested.
A swallowed button cell or coin battery can cause Internal Chemical Burns in as little as 2 hours.
KEEP new and uses batteries **OUT OF REACH of CHILDREN.**
Seek immediate medical attention if battery is suspected to be swallowed or inserted inside any part of the body.

11. Disposal

The disposal of the FindAir ONE for pMDI add-on should be done following the regulations in place in your country.

WARNING: Do not dispose of used devices or batteries in regular waste bins. You can return the device to the manufacturer, distributor, or a specialized waste disposal company for proper disposal.

12. Troubleshooting

In case of noticing any malfunction, abnormalities, defects, deterioration in the performance of the product, incorrect labeling, incorrect instructions for use, or a medical incident, the user should

discontinue the use of the product and contact the manufacturer. Any serious incident related to the product should be reported to the manufacturer via email: **support@findair.eu** and to the relevant authority in the user's or patient's country of residence.

Address of the website:	https://findair.eu/contact.html
E-mail:	support@findair.eu
Phone number:	(+48) 789 397 142

Declaration of Conformity (EU) FindAir Sp z o.o. declares that FindAir ONE for pMDI is in compliance with the General Safety & Performance Requirements and other relevant provisions of Regulation EU 2017/745.

FindAir Sp z o.o declares that the radio equipment FindAir ONE for pMDI complies with Directive 2014/53/EU.

Electromagnetic Compatibility

The FindAir ONE sensor does not perform as intended where loss or degradation would result in unacceptable risk.

Emissions /Immunity Test and Standard	**Compliance Level**
Radiated EMI CISPR 11	Group 1 Class B
Electrostatic Discharge IEC 61000-4-2	± 8 kV contact, ± 2/4/8/15 kV air
Radiated RF EM Fields IEC 61000-4-3	10 V/m: 80 MHz – 2,7 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 V/m: 704-787, 5100 to 5800 27 V/m: 380 to 390 28 V/m: 430 to 570, 800 to 960, 1700 to 1990, 2400 to 2570

FCC Statement (US)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

"Harmful interference" is defined by FCC as any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with FCC rules.

The Grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Contact Information
Producent/Manufacturer:
FINDAIR SP Z O.O.
ul. Głogowa 26, 31-235 Kraków
email: support@findair.eu

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