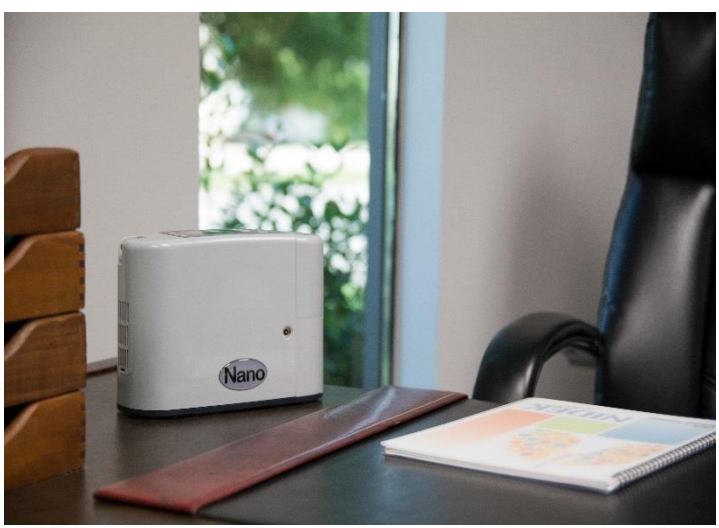
NIDEK Medical

Nano

PORTABLE OXYGEN CONCENTRATOR

INSTRUCTIONS FOR USE



For Nuvo Nano, model 855
(and variants thereof)
[Original language is English]

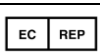
2010-8101CE-C May 2020

TABLE OF CONTENTS

1 SYMBOLS 4
2 GENERAL WARNINGS AND PRECAUTIONS 6
3 CONTRAINDICATIONS 7
4 YOUR DEVICE 8
4.1 INTENDED USE AND OPERATION 8
4.2 DEVICE FEATURES 9
4.3 POWER SUPPLY 10
4.4 HUMAN MACHINE INTERFACE (HMI) 11
4.5 SCREENS 12
4.6 SAFETY FEATURES AND ALARMS 15
4.7 PERFORMANCE AND SPECIFICATIONS 18
4.8 ACCESSORIES AND SPARE PARTS 20
5 UNPACKING AND INSPECTION 21
5.1 ENVIRONMENTAL STORAGE CONDITIONS 21
6 OPERATION 22
6.1 ENVIRONMENTAL OPERATING CONDITIONS 22
6.2 TRAVEL 23
6.2 START UP 24
6.3 SHUT DOWN 27
6.4 TROUBLESHOOTING 28
7 CLEANING AND MAINTENANCE 29
7.1 CLEANING 29
7.2 MAINTENANCE 30
8 DISPOSAL 32
9 EMC INFORMATION 33
10 CONFORMITY WITH EN 60601-1 35

1 SYMBOLS

These symbols are found in this Instructions for Use (IFU), on the device and shipping cartons, and on the device labels.

Symbol	Meaning
	WARNING – A hazard or unsafe practice that can result in serious injury or death if conditions are not avoided.
	CAUTION - A hazard or unsafe practice that can result in minor injury and / or property damage if conditions are not avoided.
NOTE	Note – Information important enough to emphasize or repeat
	Federal Law (US) restricts this device to sale by, or on the order of, a licensed physician. This oxygen concentrator should be used only under the supervision of a licensed physician.
	Complies with Applicable EU Directives; Including Medical Device Directive
	Authorized Representative in the European Community
	Do Not Smoke
	Do Not Expose to Open Flames
	Do Not Expose to Oil or Grease
	Manufacturer Name and Address
	Type BF Device
	Class II Protection
IP22	Protection from vertically falling water drops while in carrying bag

SYMBOLS (CONT.)

	Tools Required / Technician Only
	MR Unsafe - Keep Nuvo Nano outside the MRI scanner room. The device presents a projectile hazard.
	Do Not Dispose of as Unsorted Municipal Waste
	Keep in Dry conditions
	Direct Current (DC)
	Date of Manufacture
	Job Number (Lot / Batch number)
	Serial Number
	Catalog Number (Model number plus variant)
	Refer to Technical Information / Service Manual
	Refer to Instructions for Use / User's Guide
	Keep in Vertical Position
	FRAGILE – Handle with Care
	Temperature Limits for storage
	Humidity Limits for storage

Symbols used for the operation of the device can be found in §4.3.

2 GENERAL WARNINGS AND PRECAUTIONS

WARNING	This unit is not a life-support device. Any patient unable to communicate discomfort while using this device should receive additional monitoring.

WARNING	This device supplies highly concentrated oxygen enriched product gas that promotes rapid burning. **DO NOT** allow smoking or open flames within the same room of this device or the administration accessory (cannula). Failure to observe this warning can result in severe fire, property damage, and / or cause physical injury or death.

WARNING	Oxygen accelerates the combustion of flammable substances, therefore, DO NOT use oil, grease, petroleum based or other flammable products: • on the device • on the accessories (ex. cannula) • on the patient's face / neck • to lubricate fittings, connections, tubing, etc.

WARNING	A back up oxygen source is recommended for power outages or mechanical problems. The patient is responsible for making arrangements for alternate oxygen supply during travel.

WARNING	The settings of the Nano might not correspond with continuous flow oxygen. The settings of the Nano do not correspond with other brands or models of oxygen concentrators. Please see the specifications on pg 18 to determine your setting.

WARNING	For patient safety and benefit, DO NOT modify this system or equipment in any way.

GENERAL WARNINGS AND PRECAUTIONS (CONT.)

WARNING	Only persons who have read and understood this entire manual should be allowed to operate the device.
Rx Only	Federal Law (US) restricts this device to sale by, or on the order of, a licensed physician. This oxygen concentrator should be used only under the supervision of a licensed physician.

3 CONTRAINDICATIONS

WARNING	Those who continue to smoke (because of the increased fire risk and the probability that the poorer prognosis by smoking will offset the treatment benefit).
CAUTION	In certain circumstances, oxygen therapy can be hazardous. Please seek medical advice before using this device.

4 YOUR DEVICE

4.1 INTENDED USE AND OPERATION

The Nuvo Nano Portable Oxygen Concentrators are for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.

The device is not intended to be life-sustaining or life-supporting.

This device is not intended for newborn, infant or pediatric use.

This device is intended for single patient use.



WARNING	To ensure your safety, use only after one or more settings have been individually determined or prescribed for you at your specific activity levels – AND – only use the accessories that were used when your settings were determined.



WARNING	While undergoing oxygen therapy, if you feel discomfort or experience a medical emergency, seek medical assistance immediately.

The Nuvo Nano (Nano) begins its operation with air being pulled into the external air intake filter. This filtered air enters the compressor via a fine filter. Pressurized air then exits the compressor. Next, an electronic valve system directs the air into one of two tubes that contain molecular sieve (sieve beds). The molecular sieve adsorbs (physically attracts) the nitrogen from the air as it is pushed through the sieve beds, this process is called pressure swing adsorption (PSA). As one tube is generating the product gas, the other is being purged of the adsorbed nitrogen. After passing through the oxygen storage tank, the rate of product gas being delivered to the patient is set by a restricting orifice and pulse dose valve based upon detection of a breath. It then passes through a fine particle filter and thru a sensor that detects the oxygen concentration of the product gas before it exits the device through a flame-resistant outlet. Once the product gas leaves the device, it travels to the patient via oxygen tubing and a cannula inserted in the nose.

4.2 DEVICE FEATURES

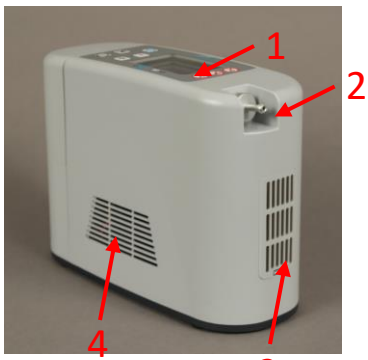


Figure 1

Front panel (Fig. 1)

1 – Human Machine Interface (HMI)
2 – Oxygen Product Outlet
3 – Cabinet Filter
4 – Air Exhaust

Intake Filter not pictured – accessed after removing Cabinet Filter (Fig. 1-3)
See pg. 29 for replacing.



Figure 2

Rear panel (Fig. 2)

5 – Battery
6 – Battery Release
7 – Power Supply Input

Technical Label not pictured – located on bottom of device.

4.3 POWER SUPPLY

BATTERY (PN 8100-1550)



One power supply option is our standard lithium ion battery. When fully charged, the battery can serve for up to 4 hours of operation.

To recharge the battery, install it in the Nano and connect the AC/DC Power Supply (below). Fully charging will take no more than 4 hours.

AC POWER SUPPLY

Another power supply option is our AC Power Supply (Power Supply) which combines the AC/DC Power Adapter (Adapter) and a country specific AC Cord (Cord) inserted in a functioning wall outlet. The Power Supply automatically adapts to input voltages from 100V to 240V (50-60 Hz) permitting use with most power sources throughout the world.

To attach the supply to the device: 1) insert C into D, 2) connect adapter B into Power Supply Input (Fig 2-7), 3) insert A into wall outlet.

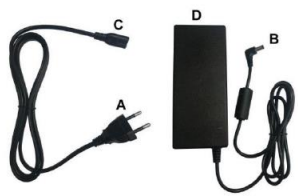


Figure 3

Description	Part Number
Adapter	8100-1540
US Cord	4500-1311
EU Cord	4500-1330
UK Cord	4500-1341

** Additional country specific cords available upon request.

WARNING	DO NOT use power supplies or power cables other than the ones listed above. The use of non-specified supplies and cables may create a safety hazard and / or impair device performance.

CAUTION	It is the responsibility of the patient to periodically check the battery and replace as necessary. Nidek Medical assumes no liability for persons choosing not to adhere to manufacturer recommendations.

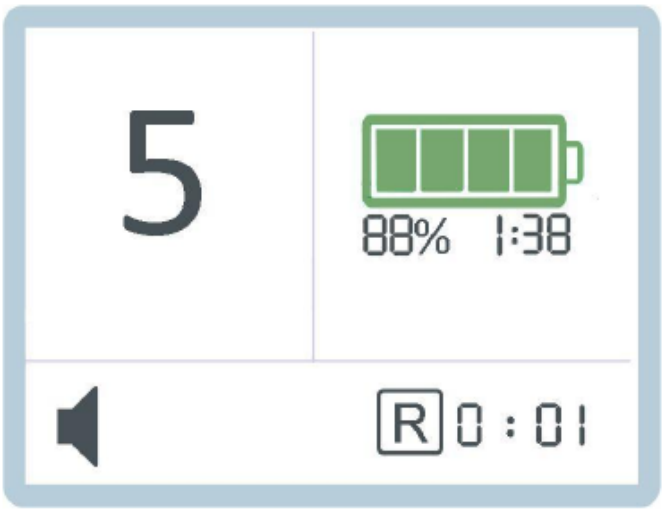
4.4 HUMAN MACHINE INTERFACE (HMI)



Symbol	Meaning	Operation
	On / Off	- Press once to turn “ON” - Press and hold for one second to turn “OFF”
	Mute Audible Alarms	Press this button to toggle between the audible alarm being on or off.
	Info / Specifications	Press this button to display the information of the device.
+ -	Adjust Flow Settings	Press these buttons to adjust the flow setting up or down
	Breath Detection Indicator	This blue indicator will light when a breath is detected and a pulse dose is administered.
	Alarm Indicator	This yellow indicator will light when there is an active alarm that may require response.

4.5 SCREENS

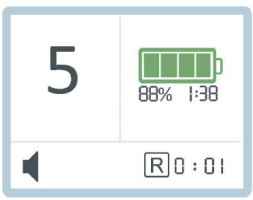
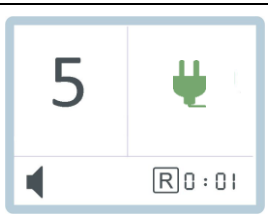
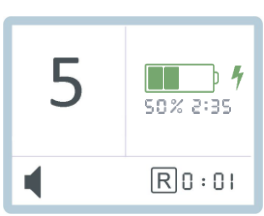
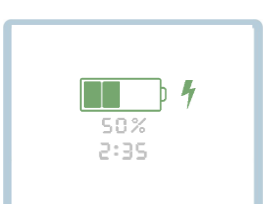
HOME SCREEN



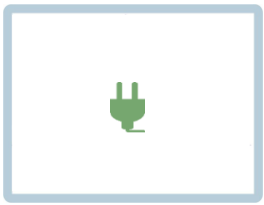
Icon	Description
5	Flow Setting (from 1 to 5)
	Battery Charge Level
	Device Run Time (H:MM*) (single use)
	Alerts are Muted
	Alerts are Audible

* display upper limit is HHHH:MM

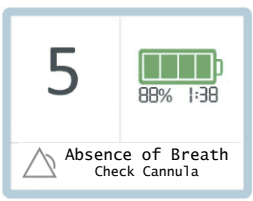
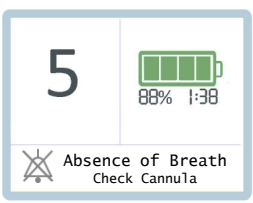
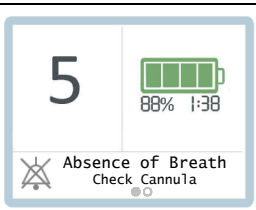
POWER SUPPLY SCREENS

	• Device is ON • Only battery attached (Power Supply not attached) • Battery level shows ▪ percentage remaining ▪ time remaining (H:MM)
	• Device is ON • Only battery attached (Power Supply not attached) • Battery level ≥ 25%
	• Device is ON • Only Power Supply attached (No battery attached)
	• Device is ON • Battery attached; charging ▪ Power Supply attached • Battery level shows ▪ percentage charged ▪ time remaining to fully charge battery (H:MM)
	• Device is OFF • Battery attached; charging ▪ Power Supply attached • Battery level shows ▪ percentage charged ▪ time remaining to fully charge battery (H:MM)

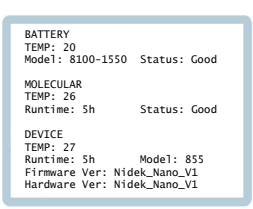
POWER SUPPLY SCREENS (CONT.)

	• Device is OFF • Only Power Supply attached (No battery attached)

ALARM SCREENS (See §4.5 for all active alarm messages and actions)

	Active Alarm in Audible Mode
	Active Alarm in Mute Mode
	Multiple Active Alarms (screen will display scrolling alarm messages)

INFORMATION SCREEN

	Information includes: Battery temperature, battery status, molecular (sieve) temperature, molecular (sieve) runtime, device model, device temperature, device runtime, firmware version, hardware version

4.6 SAFETY FEATURES AND ALARMS

SAFETY FEATURES

Fire Break: This device is fitted with a metal fire break at the Oxygen Product Outlet (Fig 1-2). This break will keep fire from entering the device.

Auto Pulse Mode: This mode is enabled when no breath has been detected for 15 seconds. The device will begin to pulse automatically about once every 3 seconds until it detects a breath. Once it detects a breath, it will exit auto pulse mode and begin delivering pulses based on your breathing.

ALARMS

In the event of an alarm, the "Alarm Indicator" (§4.3) will light yellow and activate the intermittent audible alarm (2 short beeps in 15 second intervals).



WARNING	The device has an audible alarm to alert the user of problems. In order that the alarm may be heard, the maximum distance that the user can move away from it must be determined to suit the surrounding noise level. While wearing device in carrying bag, ensure alarm can be heard.

ACTIVE ALARM MESSAGES

Message Display	Explanation and Action
Absence of Breath Check Cannula	No breath detected for more than 15 seconds. Auto pulse mode enabled. Check if cannula is connected firmly, not kinked, worn correctly and breathing through nose.
Low Oxygen: < 87% Contact Provider	Oxygen concentration is below 87% for more than 5 minutes (continuous). Contact equipment provider for maintenance.
Low Oxygen: < 50% Contact Provider	Oxygen concentration is below 50% for more than 5 minutes (continuous). Device will shut down after 30 seconds. Contact equipment provider for maintenance.
Low Battery Charge Now	Battery level is between 5% and 20%. Connect AC/DC power supply to charge.
Battery Depleted Connect to Adapter	Battery level is less than 5%. Device will shut down after 10 seconds. Replace battery or connect Power Supply to charge.
Battery too Cold Warning: Consult IFU	Battery temperature is too low (< 0°C / 32°F). Device will shut down after 10 seconds. Move to a warmer environment and restart.
Battery too Hot Only Use Adapter	Battery temperature is too high (> 65°C / 149°F). Device will shut down after 10 seconds. Disconnect battery and use Power Supply until battery has cooled, then reattach and restart.
System too Cold Warning: Consult IFU	System temperature is too low (< 0°C / 32°F). Device will shut down after 10 seconds. Move to a warmer environment and restart.
System Too Hot Warning: Consult IFU	System temperature is too high (> 65°C / 149°F). Device will shut down after 10 seconds. Move to a cooler environment and restart.
Battery Exhausted Contact Provider	Battery health is less than 50% (charge / discharge has exceeded 500 cycles) Replace battery soon (contact equipment provider).
Low Input Voltage Check Adapter	Supplied input voltage is less than 17V. Device will be powered by battery only. Replace AC/DC Power Adapter (contact equipment provider).

SAFETY FEATURES AND ALARMS (CONT.)

Message Display	Explanation and Action
Sieve Bed Fail Contact Provider	Sieve bed does not work or has become invalid. Device will shut down after 10 seconds. Replace Sieve bed (Contact equipment provider).
Power Supply Fail Contact Provider	System voltage is less than 10.5V. Device will shut down after 10 seconds. Attach fully charged battery. Replace AC Power Supply (contact equipment provider).
Replace Sieve Bed Contact Provider	Sieve bed is expired / Sieve bed chip error. Replace Sieve bed (Contact equipment provider).
Compressor Fail Contact Provider	Compressor does not work. Device will shut down after 10 seconds. Contact equipment provider for maintenance.
Valve Check Fail Contact Provider	Valve does not work (not switching). Device will shut down after 10 seconds. Contact equipment provider for maintenance.
Cooling Fan Fail Contact Provider	Fan does not work. Device will shut down after 10 seconds. Contact equipment provider for maintenance.
Gas Supply Fail Contact Provider	Product gas supply is abnormal. Device will shut down after 10 seconds. Contact equipment provider for maintenance.
Sys Startup Fail Contact Provider	Concentration does not reach 87% within startup period. Device will shut down after 10 seconds. Contact equipment provider for maintenance.
Gas Obstruction Contact Provider	Output gas tube is blocked / cannula is kinked. Device will shut down after 30 seconds. Contact equipment provider for maintenance.
Breath Sensor Fail Contact Provider	Breath sensor does not work. Device will shut down after 30 seconds. Contact equipment provider for maintenance.
Oxygen Sensor Fail Contact Provider	Oxygen sensor does not work. Device will shut down after 30 seconds. Contact equipment provider for maintenance.
Gas Delivery Fail Contact Provider	Oxygen delivery has not been detected. Device will shut down after 30 seconds. Contact equipment provider for maintenance.
Tank Pressure Fail Contact Provider	Tank pressure is abnormal. Device will shut down after 30 seconds. Contact equipment provider for maintenance.

4.7 PERFORMANCE AND SPECIFICATIONS

The performance of the device (especially the oxygen concentration) is quoted at 21°C (70°F) and one atmosphere. The specifications may change with temperature and altitude.

Model	**855**
Description	Nuvo Nano Oxygen Concentrator
Power Supply AC Input	100 to 240 VAC / 50 to 60 Hz
Rechargeable Battery	14.54VDC Voltage / 6.8Ah Rated Capacity
User Interface	2.8 inch large LCD color display
Average Oxygen Content	87% to 96% at all settings
Breathing Frequency	10 to 40 breaths per minute
Inspiratory Trigger Sensitivity	≤ 0.12 cm H2O
Maximum Outlet Pressure	25 PSI
Dimensions (L x W x H)	22.6cm x 8.9cm x 16.5cm (8.9 in x 3.5 in x 6.5 in)
Weight	2.1 kg (4.7lbs)
Noise Level	49 dBA (on setting 2)
Battery Duration	Up to 4 hours
Battery Charging Time	Not more than 4 hours
Protection Class	Class II Components: Type BF
Ingress Protection*	IP22

* Complies with EN 60529:2001 + A2:2014 rating of **IP22**; enclosure protects internal electrical components against vertically falling water drops at a 15° tilt and for particulates larger than 12.5mm while in carrying bag.

* Complies with EN 60601-1:2006 [11.6.3]; enclosure protects internal electrical components against spilling of a glass of water

FLOW CONTROL SETTINGS AND PULSE VOLUMES

Settings	1	2	3	4	5
Breath Rate	Pulse Volumes (ml)				
10	21	42	63	84	100
15	14	28	42	58	66.7
20	10.5	21	31.5	42	50
25	8.4	16.8	25.2	33.6	40
30	7	14	21	28	33.3
35	6	12	18	24	28.6
40	5.3	10.5	15.8	21	25

±15% at Standard Temperature and Pressure, dry (STDP)*
± 25% over the rated environmental range
* STDP is 101.3kPa at an operating temperature of 20°C, dry

Materials in direct or indirect contact with the patient

Item	Material
Concentrator enclosure	**PC+ ABS**
Printed labels	**Polycarbonate**
HMI	**PET**
Oxygen product outlet	**Aluminum**
AC Power Supply	**PVC**
Cabinet air filter	**Stainless Steel Screen**
Intake Filter	**100% Wool Felt**
Product Filter	**PP + Glass Fiber**
Pipe/Tubing	**Aluminum, PVC, polyurethane and/or silicone**

4.8 ACCESSORIES AND SPARE PARTS

The accessories used with the device must be oxygen compatible, designed for oxygen therapy use, biocompatible and comply with the general requirements of the FDA QSR or the 93/42/EEC European Directive, or any other applicable regulatory requirements.

The accessories below, available from **Nidek Medical Products, Inc.** and our distributors, comply with these requirements.

Contact your equipment supplier to obtain these accessories.

Item	Part Number
Adult Cannula With 2m (7ft) of tubing, rated at 6 LPM	9012-8780
Carrying Bag	8100-1650
Silicone Sleeve	8100-1675
AC / DC Power Adapter	8100-1540
Battery	8100-1550
Intake Filter (set of 5)	8100-1181
Cabinet Filter	8100-1031

WARNING	Improper patient connection to and use of the cannula may result in injury, including strangulation. To reduce the risk of this occurring, avoid situations that might cause the cannula or hose to become entangled about the patient's neck and do not attach more than 7.6m (25 ft) in length of tubing.

CAUTION	Ears, nose and neck may become irritated after prolonged exposure to the cannula. For relief, only a water-based lubricant is recommended.

CAUTION	The use of certain administration accessories and/or spare parts which are not recommended by the manufacturer may reduce its performance and void the manufacturer's responsibility.

NOTE	Cannula should be rated for at least 6 LPM

5 UNPACKING AND INSPECTION

The Nano is packaged to protect the device from damage while being transported and stored. After the device is removed from the package, inspect for damage. If damage is detected, please contact your equipment provider.

Your package will contain the following items:

Nano Oxygen Concentrator, two batteries (neither connected to the device), AC/DC Power Adapter, country specific AC Cord, silicone sleeve, carrying bag, five (5) intake filters, one (1) cannula with 2m (7ft) of tubing, and this instructions for use manual.

If you do not plan to use your device immediately, please consult the Environmental Storage Conditions below.

5.1 ENVIRONMENTAL STORAGE CONDITIONS

The device should be stored in a dry area, with an ambient temperature between -20°C to 70°C (-4°F to 158°F) at 5-90% relative humidity.

Oxygen concentration can be affected after prolonged periods of storage – check device before use.

6 OPERATION

WARNING	DO NOT use in explosive atmosphere. To avoid risk of fire and explosion the concentrator should be kept away from heat sources, incandescent sources, solvents, Aerosols, etc.
WARNING	Unit should be placed and operated in a well-ventilated space that is free of pollutants or fumes and protected from the elements with adequate lighting.
WARNING	For patient safety and benefit, no modification to the equipment is allowed. It is also not recommended to interconnect the device with any equipment or accessories not specified in this guide.
WARNING	Device must have power to operate. In the event of power loss and for continued operation a backup source is recommended.
CAUTION	The Nano is designed for continuous use. For optimal life of the sieve beds, it is recommended to operate the device frequently.
CAUTION	DO NOT use in a Magnetic Resonance (MR) environment (MRI, X-ray, etc.). May cause device malfunction.

6.1 ENVIRONMENTAL OPERATING CONDITIONS

The device should be operated in a dry area, with an ambient temperature between 5°C to 40°C (41°F to 104°F) at 10-90% relative humidity.

The device can be operated at an altitude of up to 3000m (10,000 ft) at a temperature of 21°C (70°F) without causing product degradation.

6.2 TRAVEL

When traveling, bring enough charged batteries with you to power your device for no less than 150% of the expected duration of travel (ex. 4-hour flight / ride, have at least 6 hours of battery available).

NOTE	Some modes of transportation (ex. aircraft, train, bus, boat) may be equipped with onboard electrical power. You may have an opportunity to request a seat with a power port that can be used to power your device. Check with your carrier for availability and power port compatibility to your device. It's a good idea to purchase an adapter found at electronic and travel stores.

TRAVEL BY AIR ADDITIONAL INFORMATION

The FAA allows the Nano onboard all U.S. aircraft, here are a few points to make traveling by air easy.

1) Ensure your device is clean, in good condition and free from damage or other signs of excessive wear or abuse.

2) Bring enough charged batteries with you to power your device for no less than 150% of the expected duration of your flight, ground time before and after the flight, security screenings, connections and a conservative estimate for unanticipated delays.

3) FAA regulations require that all extra batteries to be individually wrapped and protected to prevent short circuits and carried in carry-on baggage onboard aircraft only.

CAUTION	Traveling to a different altitude (for example, from sea level to mountains) may affect your blood oxygen level. Consult your physician or a medical professional, if you feel discomfort or experience nausea or dizziness.

NOTE	Some airlines may equip their aircraft with their aircraft with onboard AC electrical power. However, availability varies by airline, type of aircraft and class of service. You must check with your airline(s) for availability and any specific requirements for battery life duration 48 hours before traveling.

NOTE	To transition from battery power to aircraft electrical power, it's recommended to remove the battery and connect the AC Power Supply into available power.

6.2 START UP

1. Ensure that the device power is turned OFF.

2. Ensure that the cabinet filter (Fig 1-3) is in place and that the air intake and air exhaust are not blocked.



CAUTION	Blocked air circulation can cause internal heat build-up causing the device to shut down. See §4.5 for Alarm Messages and responding actions.

CAUTION	DO NOT operate the Nano without the cabinet filter and intake filter. Intake of particles into the system can damage the device.

3. Install the battery. Once in place, the latch will return to the upper position and make an audible sound (click).



See §7.2 for battery maintenance and care.

4. Connect the AC Power Supply to the device. The green LED on the power supply block will be illuminated and the device will beep.



WARNING	DO NOT place anything in the power supply port (Fig. 3-D) other than the supplied cord. Do not place anything in the power supply input (Fig. 2-7) other than the supplied AC/DC Power Adapter.

WARNING	DO NOT use power supplies or power cables other than the ones listed above. The use of non-specified supplies and cables may create a safety hazard and / or impair device performance.

WARNING	DO NOT wrap cords around power supply for storage. DO NOT drive, drag or place objects over cord. Doing so may lead to damaged cords and a failure to provide power to the device.

CAUTION	Power supply is not waterproof. Do not disassemble the power supply.

5. Attach the cannula to the oxygen outlet fitting (Fig 1-2). Ensure cannula and tubing is not kinked.



6. Turn on the Nano by quickly pressing the ON/OFF button (§4.3). The indicator light will flash and the display will show the Nidek Medical Products, Inc. logo upon startup.

CAUTION	There is a two minute warm up time where the Nano is building up oxygen concentration. Under special conditions, a longer warm up time may be necessary (ex. Cold storage or operation temperatures).

CAUTION	The Nano will enter a mandatory auto pulse mode 30 seconds after powering on device and last for a duration of 30 seconds, during which no breaths will be detected.

7. Adjust your setting to the flow rate prescribed by your physician or clinician by pressing the + and – buttons (§4.3) until the desired setting is shown on the display (1 to 5). Please see §4.6 for the corresponding flow settings and their corresponding volume values.

8. Wear the cannula on your face and breathe through your nose.



If no breath is detected for 15 seconds, it will enter auto pulse mode. The device will begin to pulse automatically about once every 3 seconds until it detects a breath. Once it detects a breath, it will exit auto pulse mode and begin delivering pulses based on your breathing.

Be mindful of the visual and audible alarm signals that will alert you to an issue with your device. See §4.5 for all alert messages and actions.

WARNING	While undergoing oxygen therapy, if you feel discomfort or experience a medical emergency, seek medical assistance immediately.

NOTE	The display may become darker if there is no operation of the device after 30 seconds. Press any button to light up the display.

6.3 SHUT DOWN

At the end of treatment, press the ON/OFF button for two seconds to stop the device.

WARNING	Make sure during operation and after shut down that the cannula is facing away from soft surfaces and clothing. Excess oxygen can accumulate and cause ignition if exposed to a spark or open flame.

CAUTION	When the AC cord is disconnected from the wall outlet, disconnect the AC Power Supply from the device to avoid unnecessary battery discharge.

CAUTION	During operation the AC/DC Power Adapter may get hot. Make sure the power supply has cooled before handling.

6.4 TROUBLESHOOTING

The table below lists some common problems and actions you can take. If you can't resolve the problem, please contact your service provider.

Problem	Possible Cause	Recommended Solution
Device won't Turn On	Battery is not installed correctly.	Remove the battery and reinstall.
	Battery is depleted.	Use the AC Power Supply to operate the device (with the battery inserted) to recharge the battery.
	The AC Power Supply has poor contact.	Check power supply connection. Verify green light on adapter is solid.
No Oxygen	The device is not turned on.	Turn on the device.
	Cannula is kinked or obstructed.	Check cannula and the connection to oxygen outlet
	Equipment failure.	Check alarm message and follow recommended action accordingly.
Oxygen not at Full Concentration	The device is warming up.	Wait 2 minutes for the device to warm up.
	The sieve beds require servicing.	Contact your equipment provider for replacement beds.
Alarm Occurs	List of Alarm Messages in §4.5	List of Recommended Actions in §4.5

7 CLEANING AND MAINTENANCE

7.1 CLEANING

CLEANING YOUR DEVICE

Only the outside of the device is to be cleaned. After making sure the device is OFF, use a soft, dry cloth or, if necessary, a damp sponge, to wipe the cabinet enclosure. Then thoroughly dry with wipes and an alcohol-based solution. This should be done as required.

This device is intended for single patient use, it should not be used on multiple patients.

NOTE	Acetone, solvents or any other flammable products must not be used. Do not use abrasive powders.

CLEANING AND REPLACING FILTERS

The cabinet filter screen must be cleaned on a weekly basis to ensure adequate air flow through the device. Clean the screen with a mild liquid detergent and water. Ensure the screen is dry before reinstalling.

The intake filter must be replaced every 12 weeks to ensure clean air is being pulled into the compressor. To replace the intake filter, remove the cabinet filter screen, remove the intake filter from the intake chamber, install new intake filter, install cabinet filter screen.



CLEANING AND REPLACING ACCESSORIES

The tubing and cannula should be used according to the manufacturer's instructions. To prevent the spreading of bacteria and viruses, the same tubing and cannula should not be used on multiple patients. Follow your local governing ordinances for disposal and recycling of the tubing and cannula.

To clean your carrying bag, use a damp cloth and mild detergent and then wipe dry.

7.2 MAINTENANCE

PREVENTIVE MAINTENANCE

The manufacturer's instructions for the preventive maintenance of the devices are defined in the service manual, (Ref. 2010-8105). Check with your service provider for any updates to recommended schedules. The work must be carried out by suitably trained technicians certified by the manufacturer.

Use original spare parts only (see §4.8) from Nidek Medical Products, Inc. or our distributors. Upon request, the supplier can provide circuit diagrams, spare parts lists, technical details or any other information of use to qualified technical personnel for parts of the device which are designated as being the manufacturer's responsibility or by the manufacturer as repairable.

WARNING	DO NOT disassemble due to danger of electrical shock. Refer servicing to qualified service personnel.

BATTERY CARE AND MAINTENANCE

A few simple steps can ensure proper performance and long battery life. Please only use approved batteries and power supplies.

1. To extend the life of your battery, the device should be used and stored in temperatures between 5°C and 35°C (41°F and 95°F) for extended periods of time.

The number of cycles the battery will last is highly dependent upon the temperature at which the battery is charged. The recommended room temperature should not exceed 24°C (75°F) when charging the battery.

2. If the device will not be used for a long period of time, remove the battery completely from the device.

3. Store the battery in a cool, dry place and with a charge of 40-50%.

The Nano continuously displays battery percentage and time remaining. These displayed values are only an estimate and the actual value may vary.

4. Batteries should not be left dormant for more than 90 days at a time.

EXPECTED SERVICE LIFE

Service Item	Expected Life
Nuvo Nano System	5 years
Molecular Sieve Beds	1 year
Battery	500 full charge / discharge cycles

The accuracy of the expected service life is dependent on the environment of usage and the preventive and required maintenance performed.

8 DISPOSAL

All waste from the device (Patient Circuit, Filters, Etc.) must be disposed of using methods appropriate to the civil authority of the location where disposed.

This device has been supplied by an environmentally aware manufacturer. A majority of the parts in the device are recyclable.

Follow local governing ordinances and recycling plans regarding disposal of the device or components normally used in operation. Any accessories not original to the device must be disposed of in accordance with the individual product markings for disposal. Furthermore, as part of the marking directive 93/42/EEC, the serial number of the device disposed of must be sent to Nidek Medical if the unit has the CE marking.

9 EMC INFORMATION

The device has been designed to meet EMC standards throughout its service life and to provide oxygen enriched product gas. If there is a condition where the device is not meeting the specifications outlined in §4.7 “Performance and Specifications”, the device will alarm.

If there are alarms affecting the concentration or delivery of the product gas, attempt to move the device to a different area to determine if the issue is due to electromagnetic interference with other equipment in the vicinity.

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions:

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 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	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground	Mains power quality should be that of a typical home or hospital 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 Cycle at 45 degree increments 70% U_T (30% Dip in U_T) for 0.5 seconds <5% U_T (>95% Dip in U_T) for 5 Seconds	<5% U_T (>95% Dip in U_T) for 0.5 Cycle at 45 degree increments 70% U_T (30% Dip in U_T) for 0.5 seconds <5% U_T (>95% Dip in U_T) for 5 Seconds	Mains power quality should be that of a typical home or hospital environment. If the user of the Device required continued operation during power mains interruptions, it is recommended that the Device be powered from an uninterruptible power supply or battery.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level			

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended 30 cm separation distance. Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and Manufacturer's Declaration – Electromagnetic Emissions:

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Device uses RF energy only for its internal. Function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

10 CONFORMITY WITH EN 60601-1

The manufacturer, assembler, installer or distributor are not considered to be responsible themselves for the consequences on the safety, reliability and characteristics of a device unless the:

- Assembly, fitting, extensions, adjustments, modifications or repairs have been performed by persons authorized by the party in question.
- Electrical installation of the corresponding premises complies with local electrical codes. (e.g. IEC/NEC)
- Device is used in accordance with the instructions for use.

If the replacement parts used for the periodic servicing by an approved technician do not comply with the manufacturer's specifications, the manufacturer is not responsible in the event of an accident or non-performance.

This device complies with the requirements of the FDA Quality System Regulation and 93/42/EEC European directive but its operation may be affected by other devices being used nearby, such as diathermy and high frequency electrosurgical equipment, mobile telephones, CB and other portable devices, microwave ovens, induction plates or even remote control toys or any other electromagnetic interferences which exceed the levels specified by the EN 60601-1-2 standard.



Nidek Medical Products, Inc.
3949 Valley East Industrial Drive
Birmingham, Alabama 35217 U.S.A.
Tel: 205-856-7200 Fax: 205-856-0533
info@nidekmedical.com
www.nidekmedical.com

EC REP

EU Representative
mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen, Germany
Tel: +49-511-39-08 95 30
Fax: +49-511-39-08 95 39
info@mdi-europa.com
www.mdi-europa.com

CE 0413

2010-8101CE-C May 2020