flyp™

Model fn2000m

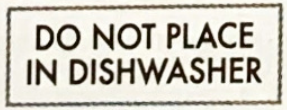
Pocket Portable Nebulizer User Guide

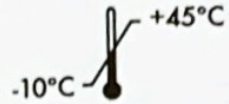
Fill™
Click™
Breathe™

**USER: READ THIS GUIDE BEFORE OPERATING THIS DEVICE.
SAVE THIS GUIDE FOR FUTURE REFERENCE.**

SYMBOLS

The symbols that appear on the box and the Flyp™ nebulizer are described below:

SYMBOL	MEANING
	Caution
	Consult instructions for use
	Keep dry
	Do not place in dishwasher

	Transient storage temperature limits -10˚C to 45˚C (14˚F to 113˚F)
℞ only	Federal law (USA) restricts this device to sale by or on the order of a physician or licensed practitioner.
	Type BF applied part
IP22	Protected against insertion of fingers and will not become damaged or unsafe during a test in which it is exposed to vertically dripping water when held at an angle.
	Bluetooth enabled technology

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Important information
to prevent damage to your
Flyp™ nebulizer

Important safety information
regarding hazards that may cause
personal injury

Before using your Flyp nebulizer for the first time, be aware of all warnings and safety information. Only use accessories approved by the manufacturer and referenced within this manual. If you do not fully understand all the warnings, safety precautions, and operating instructions, contact the Flyp customer service team at 844.FLYPNEB (359.7632) for technical support. ALWAYS KEEP THIS USER GUIDE HANDY.

TABLE OF CONTENTS

Section 1: INTRODUCTION

INTENDED USE

Indications for use:
The Flyp™ nebulizer, for use by adolescent and adult patients, is intended to aerosolize healthcare provider-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer. Flyp is intended for use at home or a medical facility, such as a hospital or doctor's office.

Intended user:
Flyp nebulizer, for use by adolescent and adult patients, should only be used by a patient under the supervision of a qualified medical expert, such as a doctor, nurse, or respiratory therapist. The user, or their actively assisting caregiver, should be capable of understanding all of the User Guide's contents. Flyp is intended for use by a single user. Flyp is not a life-saving device. Patients who are in severe respiratory distress, who are unconscious, or who are not breathing spontaneously should not use this device.

In an emergency, call 911 immediately for medical assistance.

Caution:
Federal law (USA) restricts this device to sale by or on the order of a physician or licensed practitioner.

Precautions:
All warnings and cautions described in the User Guide should be observed.

Service life:
The Flyp main unit has an expected service life of 36 months.

***Note:** The reservoir assembly (HypersonIQ™ Cartridge) should be replaced as needed, or every 3 months.

Section 2: SAFETY GUIDELINES

SAFETY GUIDELINES

Read this section to learn how to use Flyp™ safely and correctly and to prevent risks and injuries to you and others.

Keep this User Guide handy for future reference.

⚠ WARNING

Failure to follow these instructions could result in serious injury or damage to the device or other property. Read all the safety information below before using the device.

Medical device:
Flyp is a medical device, available only by prescription and for prescribed medications.

Be sure to follow a qualified medical expert's instructions.

Direct exhaled medication away from others.

If you are using Flyp to treat a serious condition, a back-up device is recommended.

However, in a life-threatening situation, ***NEVER*** rely on a nebulizer. Call 911 immediately for emergency medical assistance.

Use by others:
For single patient use only.
If others use it, infection may spread.

Medical use:
Flyp is intended solely to deliver prescribed medication to treat a respiratory condition. Using Flyp for any other purpose is dangerous, and neither the distributor, manufacturer, nor their affiliates can be held liable for any damage or injury caused by improper use or misuse.

Supervision required:
Adult supervision is required when the device is used by children and the infirm. If someone swallows small pieces, such as the Stopper, consult a doctor immediately. You should also be aware that the USB Wall Charger presents a potential choking hazard.

Cleaning:
Be sure to clean the Mouthpiece, Medication Reservoir and Stopper before using them for the first

time and after each subsequent use (refer to pages 29-32).

The Main Unit should be cleaned every day, but it should ***NEVER*** be placed in water or washed in a dishwashing machine. ***ALWAYS*** disconnect and unplug the USB Wall Charger before cleaning the Main Unit.

Do not drop medication on the Main Unit or into its USB port. If you drop medication on either area, immediately wipe it off with gauze.

Battery:
The battery is not replaceable. Don't attempt to replace the battery yourself, as you may damage it. Overheating and injury could result. The lithium-ion battery should be replaced only by the manufacturer, and it must be recycled or disposed of separately from household waste. ***NEVER*** incinerate the battery. Incineration may cause the battery to rupture. If an ignition source exists, then fire and even an explosion could result. ***NEVER*** immerse the battery in water, as this may cause the battery to rupture.

Electronic device:
Flyp complies with all applicable electromagnetic compatibility (EMC) standards. You should, however, avoid operating it near other electronic devices.

If you are not going to use the unit for a long period of time, disconnect the USB Wall Charger.

Charging:
Flyp contains an internal, lithium-ion rechargeable battery that cannot be removed.

Charge Flyp only with the USB Wall Charger provided. ***NEVER*** use the device when it is charging.

Battery life should exceed 500 charge cycles. All batteries deteriorate over time if they are not used or charged. Do not store Flyp for long periods of time without charging it periodically. If Flyp is not used or charged for a long period of time, the battery may create a hazardous condition.

Proper handling:
Flyp contains sensitive components, including a stainless steel disk. Do not drop, crush, puncture, bend, heat, incinerate, or apply strong shock to the device or its parts.

Section 3: PRODUCT DESCRIPTION

FEATURES AND BENEFITS

Read this section to learn about Flyp's features and benefits.

Small and convenient:
Flyp™ fits in your pocket. There is no separate control unit, compressor, mask, hose or cup. And Flyp's convenient Draw-String Bag makes it easy to carry with you.

Flyp is rechargeable with a USB Wall Charger, like a cell phone. There are no disposable batteries.

Simple:
Flyp is designed for easy operation and delivers all medications approved for use with general-purpose nebulizers.

Silent:
Flyp operates almost silently.

Fast and efficient:
Flyp is designed to shut off automatically after 10 minutes to conserve battery life.

After proper cleaning Flyp should not take longer than 10 minutes to deliver 3 mL of normal saline (0.9%).

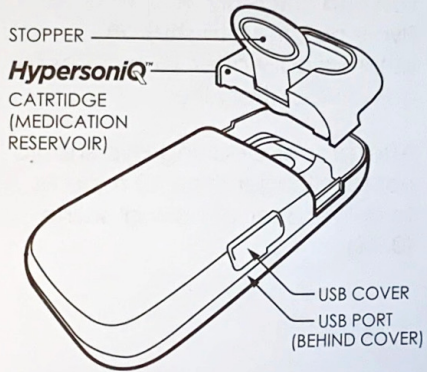
Self clearing function:
To active this mode, press and hold power button for 3 seconds to enter "clearing mode". Operate the unit for 2-3 minutes or until the reservoir is empty.

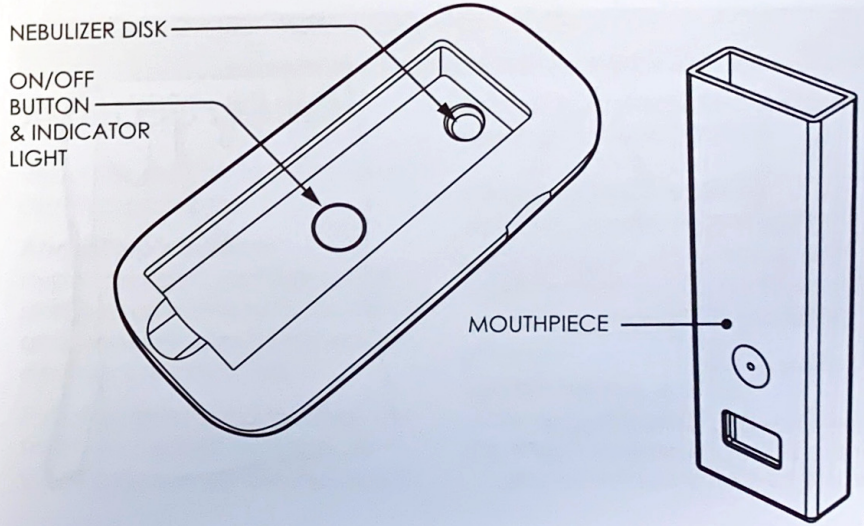
Section 4: FLYP™ AT A GLANCE

NAMES AND FUNCTIONS OF PARTS

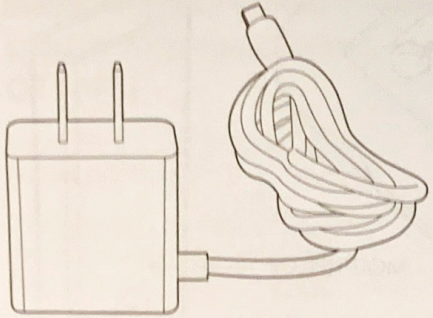
Read this section to learn the names and functions of the parts.

If any items are missing, contact the store where you purchased Flyp. You may also contact Flyp nebulizer customer service at 1-844-FLYPNEB

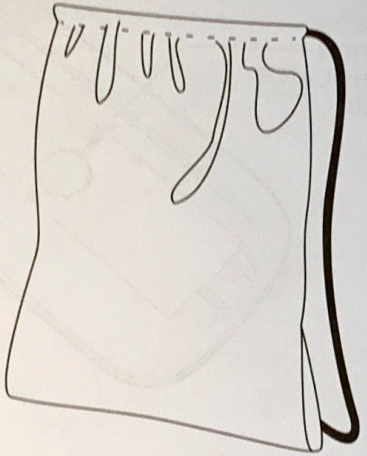




USB WALL CHARGER



DRAW-STRING BAG



Note: the Draw-String Bag is not intended to protect Flyp™. It is provided for convenience only.

Section 5: Using Flyp™

ABOUT Flyp's BATTERY

Read this section to learn how to use Flyp correctly.

About Flyp's battery:
Flyp is charged through a USB port, just as many cellular phones and portable electronic media devices are charged.

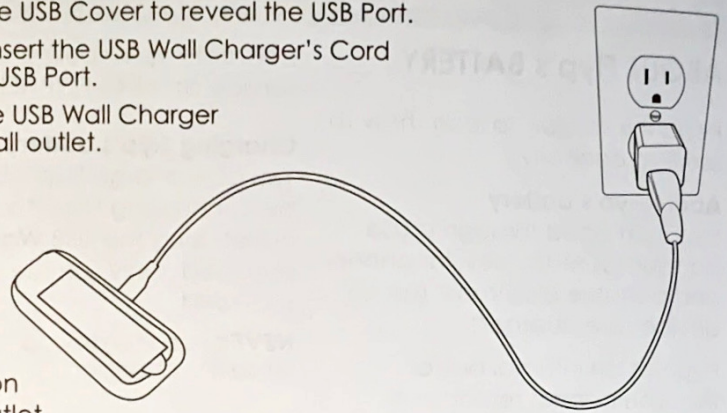
Flyp has an internal battery that you cannot replace. If your battery must be replaced, contact Flyp nebulizer customer service at 1-844-FLYPNEB

Charging Flyp's battery:
You can charge Flyp's battery by connecting Flyp™ to a wall outlet using the USB Wall Charger provided. Only use the charger provided.

NEVER use the device while it is charging.

To charge the battery with a wall outlet:

1. Open the USB Cover to reveal the USB Port.
2. Gently insert the USB Wall Charger's Cord into the USB Port.
3. Insert the USB Wall Charger into a wall outlet.

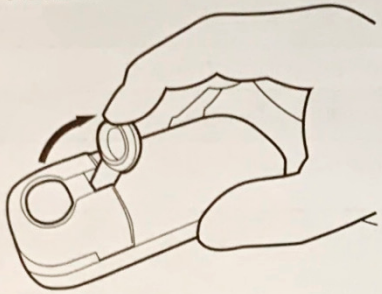


Connection via wall outlet

Indicator Light	= Status
No light	Power off
Solid blue light	Power on
Blue light blinking	Low battery
Solid yellow light (plugged-in)	Battery is fully charged
Yellow light blinking (plugged-in)	Battery is charging
Yellow light and blue light blinking together	Flyp is in cleaning mode
Solid yellow and Blue light	HypersonIQ cartridge is not properly attached or there is no medication in the reservoir. Flyp™ will turn off in 10 seconds

FILLING MEDICATION RESERVOIR WITH MEDICATION

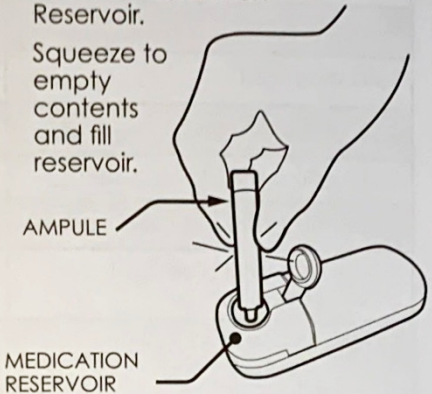
There is no need to remove the Medication Reservoir to fill it with medication.



STEP 1

2. Insert the medication ampule into the Medication Reservoir.

Squeeze to empty contents and fill reservoir.



STEP 2

3. Close the Reservoir. Be careful not to touch any part of the Stopper that may come in contact with your medication. Then close the Reservoir Cover.

Note: the Medication Reservoir's maximum capacity is 6mL.

STEP 3

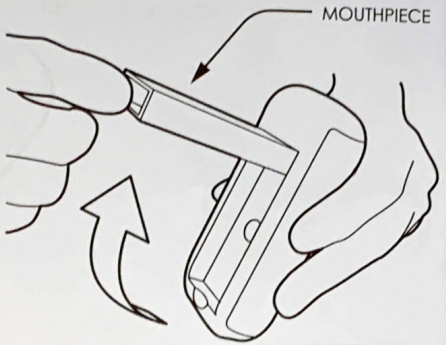
TURNING FLYP ON & OFF

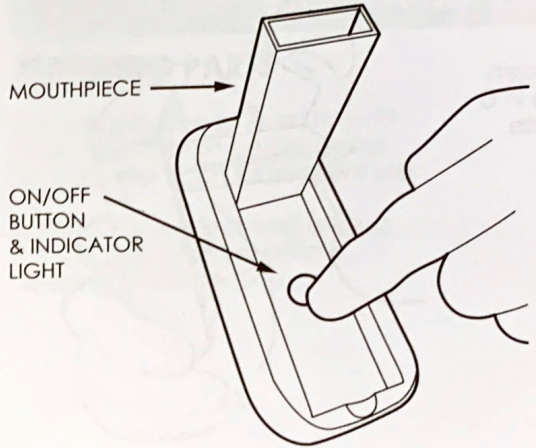
Gently raise the Mouthpiece using your index finger, revealing the On-Off Button and On-Off Indicator Light.

To turn Flyp™ on, press the On-Off Button. The blue On-Off Indicator Light will light. Visually confirm that an aerosol mist is flowing from the Mouthpiece's end.

To turn Flyp off, press the On-Off Button again. The blue On-Off Indicator Light will no longer be lit.

Flyp will automatically turn off after 10 minutes.





INHALING PRESCRIBED MEDICATION

Place the Mouthpiece between your lips. Inhale and breathe in a calm manner at a normal rate.

Section 6: CLEANING & DISINFECTING

CLEANING PARTS

Read this section to learn how to clean Flyp™, both before its first use and after each subsequent use.

ALWAYS disconnect and unplug the USB Wall Charger before cleaning or disinfecting

CLEANING *HypersoniQ*™ DISK

1. Open the stopper on the HypersonIQ cartridge (medication reservoir).

2. Fill the reservoir half-way with ~3ml distilled water Close the stopper.

3. Gently raise the Mouthpiece with your index finger.

4. **Press and hold the power button for 5 seconds.** Blue AND yellow indicator lights will start to blink and Flyp will produce a pulsing aersosol.

5. Allow the aerosol mist to flow from the raised Mouthpiece for 1~2 minutes.

6. Power Flyp off by pressing the power button.

7. Remove HypsersonIQ cartridge and shake out excess water.

8. Let the main unit, cartridge, and mouthpiece dry on a clean, dry towel.

9. Allow the interior to dry fully prior to using again.

It is important to clean the HypersonIQ disk after each use in order to prevent the buildup of residual medication. If these steps are not followed, the disk may become blocked – impacting performance. Please see troubleshooting on page 36 in case of a suspected blockage.

DEEP CLEANING

Residual medication can accumulate over time and cause buildup on the disk which may slow aerosol production. To prevent this, a deep cleaning with distilled white vinegar (5%) or Flyp cleaning solution on a weekly (or more frequently as-needed) basis is recommended.

1. Check the HypersonIQ cartridge to make sure it is empty.

2. Open the stopper on the HypsersonIQ cartridge (medication reservoir).

3. Fill the reservoir approximately half-way with ~3ml distilled white vinegar (or Flyp cleaning solution). Close the stopper.

4. Gently raise the Mouthpiece with your index finger.

5. **Press and hold the power button for 3 seconds.** Flyp will enter a cleaning mode indicated by Blue AND yellow blinking lights. Flyp will produce a pulsing aerosol.

6. Allow the aerosol mist to flow from the raised Mouthpiece for 1~2 minutes

7. Power Flyp off by pressing the power button.

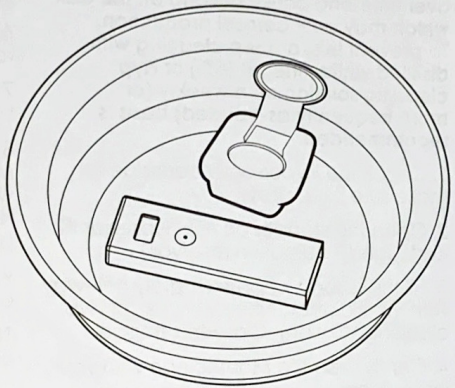
8. Remove HypersonIQ cartridge and Mouthpiece. Rinse both under running water, ensuring the stopper of the HypersonIQ cartridge is in the open position.

9. Let the cartridge and mouthpiece dry on a clean, dry towel.

10. Allow the interior to dry fully prior to using again.

OPTIONAL DISINFECTION

Read this section to learn how to disinfect Flyp. Although disinfection is optional, it is recommended that you do it at the end of every day.



RESERVOIR CARTRIDGE AND MOUTHPIECE:

Step 1.Remove the reservoir and mouthpiece from Flyp.

Step 2. Soak the mouthpiece and cartridge in 70% ethyl alcohol for 10 minutes. Make sure both are completely submerged in the alcohol.

Step 3. Remove mouthpiece and cartridge from the alcohol bath and rinse under running water.

Step 4. Let dry on a clean, dry towel.

DISINFECTING THE MAIN UNIT'S EXTERIOR:

Step 1. Wipe exterior with clean, dry towel moistened with ethyl alcohol.

Step 2. Allow Flyp to sit for 5 minutes.

Step 3. Moisten with a clean dry towel with water and wipe exterior to remove the ethyl alcohol.

Step 4. Let dry on a clean, dry towel.

Section 7: TROUBLESHOOTING

TROUBLESHOOTING

Most problems with the device can be solved by following this advice.

The following table describes possible troubles, their causes, and what corrective action to take.

If these corrective actions do not return Flyp™ to full working order, read the next section, "Support."

TROUBLE	POSSIBLE CAUSE	CORRECTIVE ACTION
The nebulization rate is extremely low.	The battery is low.	Charge Flyp using a USB port. Refer to pages 22-23.
	An air bubble has formed in the medication's pathway.	Tap the back of the Main Unit with your index finger until normal flow resumes.
	The Nebulizer Disk has become clogged with medication.	See deep cleaning instructions. Refer to page 33.
The On-Off Indicator Light is on, but there is no mist.	The Medication Reservoir is not correctly inserted.	Remove the Medication Reservoir and install it correctly.
	The Medication Reservoir is not filled.	Fill with medication. Refer to pages 24-25.
	Check that Flyp has been properly cleaned.	See deep cleaning instructions. Refer to page 33.

Section 8: SUPPORT

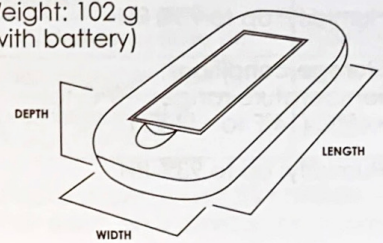
You can find more information about using Flyp™ on our website. To learn about service and support, and to view tutorials, go to: www.flypnebulier.com

NOTES:

Section 9: INFORMATION

TECHNICAL DATA

Technical Specifications:
Length: 119 mm
Width: 54 mm
Depth: 27 mm
Weight: 102 g
(with battery)



SPECIFICATIONS

Indications for use:
The Flyp™ nebulizer, for use by adolescent and adult patients, is intended to aerosolize healthcare provider-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer. Flyp is intended for use at home or a medical facility, such as a hospital or doctor's office.

Power supply:
Shenzhen Simsukian Electronics Technology,
model SK12G-0050100U
Rated 100-240V, 50/60Hz, 0.2A

Patient population:
Adolescent to adult

Method of operation:
Piezoelectric/Ultrasonic

Power source:
Lithium-ion battery (rechargeable)

Weight:
Flyp: 102 g (with battery)

Dimensions:
27 x 119 x 54 mm (Main Unit)

Sound level:
<35 dBA at 1 meter

Operating conditions:
Temperature range: 5°C to +40°C (+41°F to +104°F)

Humidity: up to 95% RH

Storage conditions:
Temperature range: -10°C to +45°C (14°F to +113°F)

Humidity: up to 93% RH

Aerosol Performance			
	Albuterol sulfate	Ipratropium bromide	Cromolyn sodium
MMAD (μ)	2.31 +/- 0.10	2.17 +/- 0.05	2.26 +/- 0.11
GSD (geometric standard deviation)	1.60 +/- 0.07	1.48 +/- 0.03	1.54 +/- 0.06
Total delivered dose (μ)	1038.8 +/- 127.3	230.8 +/- 19.3	958.4 +/- 129.0
Total respirable dose (μ)	921.6 +/- 70.3	209.4 +/- 14.9	857.7 +/- 84.4
Respirable fraction (% mass 0.4-4.7μ)	87.8%	90.3%	88.1%

All data shown at a 95% confidence level. Medications were tested 3 times each on 3 devices for a total of 27 sample data points.

Aerosol Performance			
	Albuterol sulfate	Ipratropium bromide	Cromolyn sodium
Coarse particle dose (µ)	69.2 +/- 36.1	7.4 +/- 3.8	85.7 +/- 37.2
Fine particle dose (µ)	969.7 +/- 74.2	223.4 +/- 16.3	872.7 +/- 80.9
Extra fine particle dose (µ)	374.9 +/- 42.0	89.8 +/- 6.7	356.7 +/- 47.4
Coarse fraction (>4.7µ)	6.7%	3.1%	8.9%
Fine fraction (<4.7µ)	92.4%	96.3%	89.7%
Extra fine fraction (<1.0µ)	35.7%	38.7%	36.6%

All data shown at a 95% confidence level. Medications were tested 3 times each on 3 devices for a total of 27 sample data points.

ELECTROMAGNETIC COMPATIBILITY

With the increased number of electronic devices, such as computers and cellular phones, medical devices in use may be susceptible to electromagnetic interference. This interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Do not use cellular phones and other electronic devices that generate electromagnetic fields near the medical device.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this User Guide.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement

parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

EMC Tables. The following tables are provided in accordance with IEC 60601-1-2: 2014, ed. 4.0.

Guidance and Manufacturer's Declaration - Emissions
The Flyp™ fn2000m is intended for use in the electromagnetic environment specified below. The customer or user of the Flyp fn2000m should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
Radiated Emissions: CISPR 11	Class B	
Conducted Emissions: CISPR 11	Class B	

EMC Tables. The following tables are provided in accordance with IEC 60601-1-2: 2014, ed. 4.0.

Guidance and Manufacturer's Declaration - Emissions
The Flyp™ fn2000m is intended for use in the electromagnetic environment specified below. The customer or user of the Flyp fn2000m should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
Harmonics: IEC61000-3-2	Not Applicable	
Flicker: IEC61000-3-3	Not Applicable	The Flyp fn2000m is suitable for use in all establishments, including domestic, and those directly connected the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Immunity
The Flyp fn2000m is intended for use in the electromagnetic environment specified below. The customer or user of the Flyp fn2000m should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD: IEC61000-4-2	±8kV Contact ±2KV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±2KV, ±4kV, ±8kV, ±15kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be 30%.
EFT: IEC61000-4-4	+/- 0.5 KV L1 and L2 +/- 1 KV L1 and L2	+/- 0.5 KV L1 and L2 +/- 1 KV L1 and L2	Mains power quality should be that of a typical commercial or hospital environment.
Surges: IEC61000-4-5	+/- 0.5 KV L1 and L2 +/- 1 KV L1 and L2	+/- 0.5 KV L1 and L2 +/- 1 KV L1 and L2	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity
The Flyp™ fn2000m is intended for use in the electromagnetic environment specified below. The customer or user of the Flyp fn2000m should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips and interruptions: IEC61000-4-11	0 % UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT: 1 cycle 70% UT: 25 cycles for 50 Hz Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz	0 % UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT: 1 cycle 70% UT: 25 cycles for 50 Hz Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Flyp fn2000m requires continued charging during mains power interruptions, it is recommended that the Flyp fn2000m be powered from an uninterruptible power supply or battery.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power Frequency 50/60Hz Magnetic Field: IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity
The Flyp™ fn2000m is intended for use in the electromagnetic environment specified below. The customer or user of the Flyp fn2000m should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF: IEC61000-4-4	3 Vrms 0.15-80 MHz 6 Vrms in ISM and Amateur radio bands	3 Vrms 0.15-80 MHz 6 Vrms in ISM and Amateur radio bands
Radiated RF: IEC61000-4-3	10 V/m 80 MHz - 2.7 GHz 1 kHz @ 80% AM	10 V/m 80 MHz - 2.7 GHz 1 kHz @ 80% AM

Electromagnetic Environment – Guidance	
Portable and mobile communications equipment should be separated from the Flyp fn2000m by no less than the distances calculated/listed below:	
D=(3.5/V1)(Sqrt P) 150kHz to 80 MHz	where P is the max. power in watts and D is the recommended separation distance in meters.
D=(3.5/E1)(Sqrt P) 80 to 800 MHz	Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).
D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz	Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separation Distances for the Flyp fn2000m
The Flyp™ fn2000m is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Flyp fn2000m can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Flyp fn2000m as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)
0.01	0.116667	0.116667	0.233333
0.1	0.368932	0.368932	0.737865
1	1.166667	1.166667	2.333333
10	3.689324	3.689324	7.378648
100	11.66667	11.66667	23.33333

DISPOSAL & RECYCLING

⚠ CAUTION

Your Flyp must be disposed of properly, according to local laws and regulations. Because this product contains a battery, the product must be disposed of separately from household waste. When your Flyp reaches its end of life, contact your local authorities to learn about recycling options.

WARRANTY

The Flyp main unit is warrantied for a period of thirty-six (36) months from the date of purchase against defects in manufacturing. All warranties are based on typical usage and following care instructions.

We will, at our option, repair or replace without charge your device. Repair or replacement is our only responsibility, and your only remedy, under the warranty.

HypersonIQ Cartridge is warrantied for a period of six (6) months from the date of purchase.

Section 10: REPLACEMENT PARTS AND ACCESSORIES

PART	REORDER NUMBER
Mouthpiece	MP-1000
HypersonIQ Replacement Head	hs2000m
USB Wall Charger	DC-1000
Mask Adapter	MA-2000
Draw-String Bag	AIR-4000
User Guide	AIR-5000
Cleaning Kit	CS-2000

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