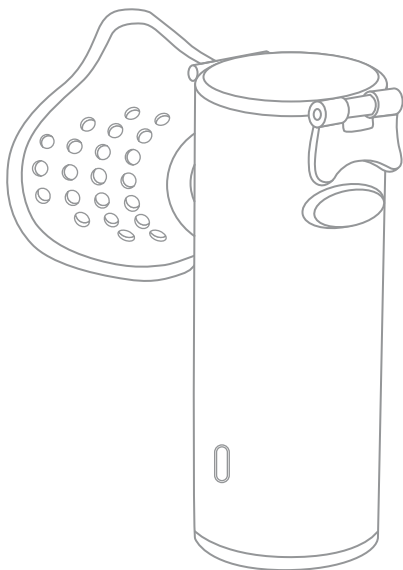


# frida baby<sup>®</sup>

## Ultra-Quiet Portable Nebulizer

INSTRUCTION MANUAL



# EASY AS 1, 2, BREATHE

Say buh-bye to bulky nebulizers. Our new Ultra-Quiet Portable Nebulizer keeps relief at hand for easy medicine delivery. It's compact and cordless without a ton of parts, so you can give your baby a breather, without giving yourself a headache.

## **BEFORE FIRST USE:**

This is an over-the-counter non-ventilatory nebulizer (atomizer) intended for use with various medications as directed by your doctor. Consult with your physician before using medication or solutions to determine if they can be used in a safe and effective manner. Please read all instructions, clean, and disinfect the device before use. Keep this manual for future reference.

## Indications for Use

The Frida Baby Ultra-Quiet Portable Nebulizer is designed to aerosolize liquid medications or isotonic saline for inhalation by pediatric (>1 month of age) patients at home or in childcare settings.

## Contents



1 Portable Mesh  
Nebulizer Unit



1 Pediatric  
Mask



1 Diffuser

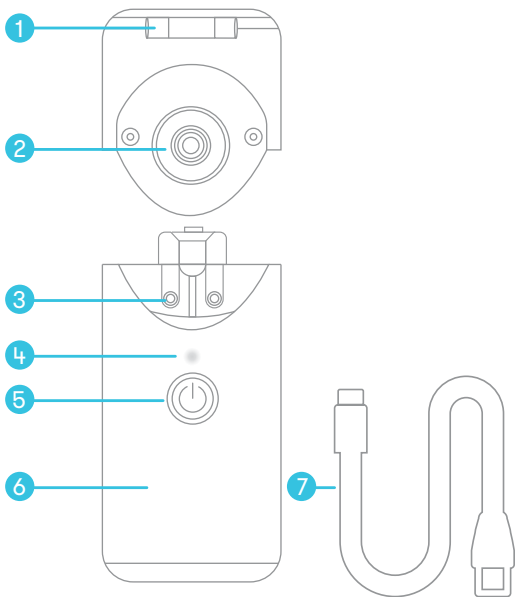


1 USB-C  
Charging Cable



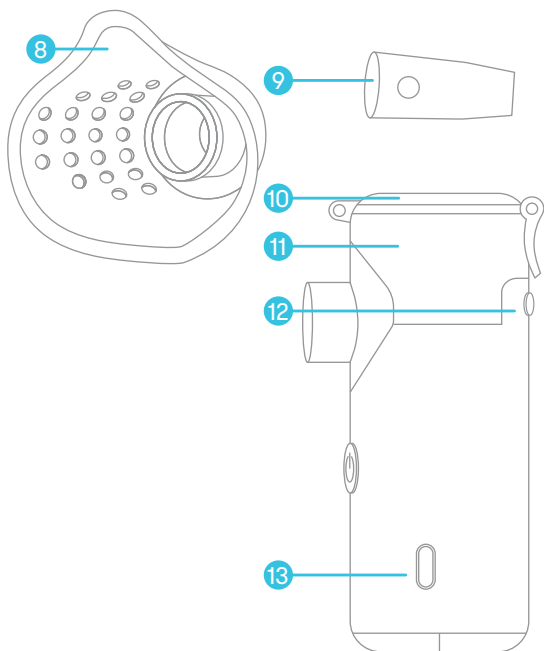
1 Instruction  
Manual

## Product Specifications



- 1 Cap and Lock
- 2 Mesh Plate
- 3 Electrodes
- 4 Indicator Light
- 5 Power Button
- 6 Main Unit
- 7 USB-C Cable

## Product Specifications



- 8 Pediatric Mask
- 9 Diffuser Attachment
- 10 Protective Cover
- 11 Medicine Container
- 12 Push Button (to release medicine container)
- 13 USB-C Charging Port

# SAVE THESE INSTRUCTIONS IMPORTANT SAFEGUARDS

## READ ALL INSTRUCTIONS BEFORE USING

### Contraindications:

- Not for use with anesthetic, respiratory or ventilator breathing systems.
- Children must use the device only under direct adult supervision.
- Do not use this device with Pentamidine.

### **WARNING**

- Check with your doctor before use with medicine. This is a non-ventilatory respirator. Only use medication or solutions as directed by your doctor.
- Do not use with ester, fat or suspended particles, including herbal medicines.
- This device is intended for single-patient use to prevent cross-contamination. Ensure the device is cleaned and disinfected before use.
- Do not use the device if the child has sensitive skin or an active skin condition in the treatment area or any other conditions which in your doctor's opinion would make it unsafe for them to be treated.
- Always check the inside of the mask and diffuser for debris before use.

- Do not use the device while lying down, or while bathing.
- Do not connect the device to other equipment not described in the instructions.
- Use this product only for its intended use and as instructed as described in this manual.
- Do not operate the device near the heating device or open fire. Keep the power cord away from heated surfaces.
- Never use the device around flammable substances or in the presence of a flammable anesthetic mixture.
- Do not disassemble, repair, or alter the device.
- Inspect before use. Never use a damaged device, power cord, or plug.
- Do not dry the device or its accessories with an appliance such as a microwave oven, hair dryer, etc.
- Do not allow the device or its accessories to contact corrosive liquids or gasses.
- To reduce the risk of electric shock: Do not use or store the device in humid locations, such as a bathroom. Do not immerse the respirator in water or other liquids or operate with wet hands.
- The device must be operated using the provided power source.
- Do not charge the device on an aircraft.

- Keep the device away from small children, people with learning difficulties, or those who are physically challenged. Small parts can be a choking hazard. The charging cable may result in strangulation or asphyxiation due to its length.

In case of any performance issues, refer to the troubleshooting section of the manual.

## Operating Instructions

### BEFORE FIRST USE:

Consult your physician for medication or solutions to use with the device. Clean and disinfect the nebulizer before using.

1. Before Use: Ensure the nebulizer is disconnected from the USB cord.
2. Add solution to the medication container. Close the cap and lock.  
**Note:** Max volume is 8 ml.
3. Remove the protective cover and attach the face mask or diffuser, keeping the nebulizer upright to prevent leaking.  
**a. Go Maskless:** Use Diffuser Attachment - Hold 1 inch away from child's nostrils.
4. Press and hold the Power Button for 3 seconds to turn on/off. The device has two working modes which can be changed by pressing the Power Button.



- a. High + Fast:** Default mode, indicated by Solid Blue Indicator Light
  - b. Low + Slow:** Secondary mode, indicated by Blue-Green Flashing Indicator Light
- 5.** Hold the device to the child's face and direct them to breathe normally.
- 6.** The device will run a ten-minute session before automatically turning off. We recommend taking a short break before continuing treatment.
- 7.** After using, follow the cleaning instructions under Care and Cleaning to ensure proper function of the device with future uses.

## Indicator Lights

<b>Flashing Blue Light</b>	If plugged into USB-charging cable, light indicates charging. If not plugged in, indicates low battery.
<b>Solid Green Light</b>	Fully charged
<b>Solid Blue Light</b>	Nebulization Mode: High + Fast (Default)
<b>Flashing Blue-Green Light</b>	Nebulization Mode: Low + Slow (Second Press)

## TIPS + TRICKS

- The device will auto turn off after ten minutes for a break.
- The device & its user must be in an upright position to operate effectively.
- Do not exceed the maximum fill line of 8ml.

## Care + Cleaning

Clean the parts of this device before using for the first time, after every use, when the device has not been used for an extended period, or when parts become contaminated.

## MEDICINE CONTAINER

1. If just used, empty the nebulizer of any leftover medicine. Remove the mask or diffuser from the nebulizer and separate the medicine container by pushing the Push Button. Discard any remaining solution from the medicine container.
2. Reattach the medicine container. Fill the container with 5-10 ml of hot water (85°C / 185°F recommended) and close the cap to lock.
3. Run the nebulizer for 2-3 minutes to clear residual medicine from the mesh plate.

4. Rinse the medicine container with water and wipe any excess water from the container using a microfiber cloth or gauze.
5. Allow components to air dry completely.

## **NEBULIZER UNIT**

1. CAUTION: Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the device in water or other cleaning liquids.
2. Gently wipe the nebulizer body and the electrodes which connect the unit to the medicine container with 70% Isopropyl Alcohol.
3. Wipe mesh plate using only medical gauze or cotton swabs.
4. Place the Protective Cover over the Mesh Plate for maximum safeguarding.

## **MASK/DIFFUSER ATTACHMENT**

1. Rinse with soap and water. Allow to air dry fully before storing.

## **DISINFECTING**

1. Repeat cleaning instructions with 70% Isopropyl Alcohol.
2. Do not boil or steam sterilize mask or diffuser.

## Troubleshooting Guide

Check the following if your Portable Nebulizer isn't working correctly.

Problem	Potential Cause
<b>Unit does not turn on.</b>	<ol style="list-style-type: none"><li>1. Low battery</li><li>2. The device is damaged or malfunctioning.</li></ol>
<b>The device does not nebulize</b>	<ol style="list-style-type: none"><li>1. The device is positioned incorrectly for dispensing medicine.</li><li>2. The medicine container is not filled with enough medication.</li><li>3. The device is damaged or malfunctioning.</li></ol>
<b>Nebulization rate is extremely low.</b>	<ol style="list-style-type: none"><li>1. The battery is low.</li><li>2. The mesh plate is stained or clogged.</li><li>3. The medication container is not filled with medication or solution, or the medicine is not suitable for nebulization.</li><li>4. The device is damaged or malfunctioning.</li><li>5. The electrodes on the main unit are dirty.</li></ol>

## Troubleshooting Guide

Check the following if your Portable Nebulizer isn't working correctly.

### Solution

1. Charge the device
2. Please contact customer service

1. Hold the device in an upright position.
2. Fill with medication or isotonic saline solution.
3. Contact customer service.

1. Charge the device using the USB-C cord provided.
2. Clean the mesh plate.
3. Fill with suitable medication or solution as recommended by your child's doctor.
4. Contact customer service.
5. Carefully clean electrodes.

## Troubleshooting Guide

Check the following if your Portable Nebulizer isn't working correctly.

Problem	Potential Cause
<b>The blue power indicator light is flashing.</b>	<ol style="list-style-type: none"><li>1. The battery level is low.</li></ol>
<b>The blue power indicator light turns on, but the device nebulizes weakly or is taking too long to complete treatment.</b>	<ol style="list-style-type: none"><li>1. Nebulization rates vary based on the medication or solutions used.</li></ol>
<b>The medication container is leaking.</b>	<ol style="list-style-type: none"><li>1. The top of the medication container is not properly closed.</li><li>2. The device is inverted or held at an angle.</li><li>3. The medication container is broken.</li></ol>

## Troubleshooting Guide

Check the following if your Portable Nebulizer isn't working correctly.

Solution
<ol style="list-style-type: none"><li>1. Charge the device using the USB-C cord provided.</li></ol>
<ol style="list-style-type: none"><li>1. Treatment times may vary among medications or solutions.</li></ol>
<ol style="list-style-type: none"><li>1. Secure the lock on the medication container.</li><li>2. Hold the device in an upright position.</li><li>3. Ensure the child is seated in an upright position.</li><li>4. Contact customer service.</li></ol>

## Technical Data


<b>Product Name:</b>	Frida Baby Ultra-Quiet Portable Nebulizer
<b>Model:</b>	12800100
<b>Battery Type:</b>	Re-chargeable lithium-ion
<b>Battery Voltage:</b>	3.7V
<b>Power Consumption:</b>	Approx. 1.5W
<b>Power Source:</b>	Input 5V
<b>Battery Life:</b>	The battery can be used for approximately 5 days after charging if operating the device for 30 minutes a day. The battery cycle life is 300 cycles.
<b>Dimensions:</b>	Approx. 1.65 (W) x 4.68 (H) x 2.16 (D) in. 42 x 55 x 109mm
<b>Weight:</b>	3.52oz (105g)



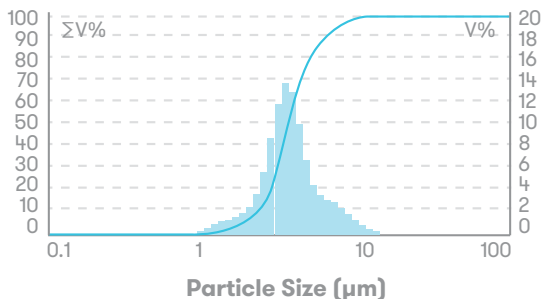
## Technical Data

<b>Safety Grade:</b>	BF, internally powered equipment
<b>Vibration Frequency:</b>	Approx. 110KHz $\pm$ 10KHz
<b>Nebulization Rate:</b>	$\geq 0.2\text{ml/min}$
<b>Medicine Temperature:</b>	$<40^{\circ}\text{C}$
<b>Noise Level:</b>	$\leq 50\text{dB(A)}$
<b>Particle Size:</b>	MMAD $<5\mu\text{m}$
<b>Medicine Capacity:</b>	8ml maximum, 0.5ml minimum
<b>Operating Temperature:</b>	$5^{\circ}\text{C}\sim 40^{\circ}\text{C}$

## Technical Data

Storage & Transport Conditions	
Temperature:	-25-70°C
Relative Humidity:	≤93% RH
Air Pressure:	70.0-106.0 kPa
Additional Information:	Store out of direct sunlight and open ventilation.
 <b>CAUTION</b>	<ol style="list-style-type: none"><li>1. Do not store near corrosive gasses, heat, or open flames.</li><li>2. Keep out of the reach of children.</li></ol>

## Fog Particle Volume Testing



- This test uses 0.9% saline solution under the condition atmosphere of temperature  $25 \pm 1$  degree Celsius, with humidity of  $60\% \pm 5\%$  R.H.
- Horizontal line represents particle diameter, left vertical line represents cumulative percentage of volume (corresponding to curved line upward trend). Right vertical line represents range of volume percentage (corresponding to graph histogram variable).

## Certification + Reference to Standards

<b>Electrical Safety:</b>	ANSI/AAMI ES60601-1 2005/(R)2012 and A1 2012, C1 2009/(R)2012 and A2 2010/(R)2012 Medical electrical equipment - Part 1 General requirements for basic safety and essential performance (IEC 60601-1 2005, MOD)
<b>EMC:</b>	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
<b>Household:</b>	IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11 General requirements for basic safety and essential performance - Collateral Standard Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

<b>Cytotoxicity (GLP)</b>	<p>ISO 10993-5 Third edition 2009-06-01</p> <p>Biological evaluation of medical devices - Part 5 Tests for in vitro cytotoxicity</p>
<b>Sensitization (GLP)</b>	<p>ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10 Tests for Irritation and Skin Sensitization.</p>
<b>Irritation or intracutaneous reactivity (GLP)</b>	<p>ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10 Tests for Irritation and Skin Sensitization.</p>
<b>Acute Systemic Toxicity (GLP)</b>	<p>ISO 10993-11 Third edition 2017-09</p> <p>Biological evaluation of medical devices - Part 11 Tests for systemic toxicity</p>
<b>Genotoxicity (GLP)</b>	<p>ISO 10993-3 Third edition 2014-10-1</p> <p>Biological evaluation of medical devices - Part 3 Tests for genotoxicity, carcinogenicity, and reproductive toxicity</p>

<b>Implantation (GLP)</b>	ISO 10993-6 Third edition 2016-12-01  Biological evaluation of medical devices -- Part 6 Tests for local effects after implantation
<b>Exposure Assessment (GLP)</b>	ISO 18652-1 First edition 2017-03; Exposure Assessment for Dry Gas Pathway
<b>Particulate Matter (GLP)</b>	ISO 18562-2 First edition 2017-03  Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2 Tests for emissions of particulate matter
<b>Gas Emission VOC</b>	ISO 18562-3 First edition 2017-03  Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3 Tests for emissions of volatile organic compounds

## FCC Statement

The 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.

**WARNING:** Changes or modifications not expressly approved by Fridababy could void the user's authority to operate the equipment.

**NOTE:** 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 a qualified technician for help.

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