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# **TYVASO™** **INHALATION SYSTEM**

## Instructions for Use

**TYVASO™**  
treprostinil INHALATION  
SOLUTION



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## General Instructions

The TYVASO™ Inhalation System should be handled with care.

Follow these important instructions to ensure proper use:

- Always unplug the device after each use.
- Do not immerse the device in water or other liquids.
- Do not place the device in a microwave or regular oven.
- Do not leave the device alone with a small child.
- Do not use the device near flammable liquids and materials or heated surfaces.
- Pay special attention to the instructions to help prevent damage to your TYVASO Inhalation System and help you get the best results.
- This device should only be used on the order of your doctor or licensed healthcare practitioner.

## Introduction

Your doctor has prescribed TYVASO™ (treprostinil) Inhalation Solution. Please see the accompanying Patient Package Insert for important safety information on TYVASO.

TYVASO is breathed in (inhaled) using the TYVASO Inhalation System, which consists of the OPTINEB®-ir Model ON-100/7 device and its accessories.

These Instructions for Use (IFU) for the TYVASO Inhalation System provide important safety information. It is important that you read these instructions and the TYVASO Patient Package Insert (PPI) before setting up and using the TYVASO Inhalation System. If you have any questions, talk to your doctor or specialty pharmacy provider.

Before beginning treatment with TYVASO, you will receive a Patient Starter Kit containing a 28 day supply of TYVASO and 2 complete inhalation devices (all accessories and supplies included). When you refill your prescription for TYVASO each month, you will receive a Refill Kit that contains a 28 day supply of TYVASO and new accessories. You will receive a replacement device every 2 years.

### IMPORTANT

- **Do not start treatment with TYVASO until you have been trained to use the TYVASO Inhalation System. Make sure you understand all of the directions. Always ask your doctor or specialty pharmacy provider if you are unsure of anything you are taught.**
- **TYVASO is for use only with the TYVASO Inhalation System.**

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## Preparing for Treatment With TYVASO

Gather the following supplies before starting treatment. Note: supplies are not shown to scale.

### 1. Inhalation device



### 2. Measuring cup with 45 mL of distilled water



Use only distilled water to fill your inhalation device once per day.

### 3. One TYVASO ampule



Use one ampule per day.

### 4. One of the provided power sources



AC wall plug



Rechargeable battery



12V DC car adapter

## 5. Accessories



Medicine cup\*



Dome assembly  
with baffle plate inside\*



Inhalation piece\*



Mouthpiece\*



2 Filter shells\*



Filters (use 2 per day)\*



Plugs\*



Storage box



Carrying case



Tracking sheet



Nose clip (optional)

Note: Supplies are not shown to scale.

\* These accessories are replaced every month. Replacement accessories are included in the Monthly Refill Kit.

## Using your TYVASO™ Inhalation System

### Filling the Inhalation Device Chamber and Medicine Cup

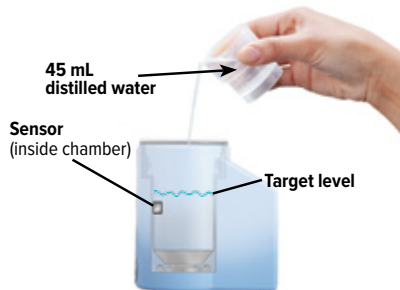
Before using the TYVASO Inhalation System, you should:

- Wash your hands



- Make sure the device is **NOT** connected to a power source
- Make sure the device is resting on a hard, flat surface during assembly

- 1** Fill the chamber of the device with 45 mL of distilled water (about 1.5 ounces or 3 tablespoons), using the measuring cup provided.

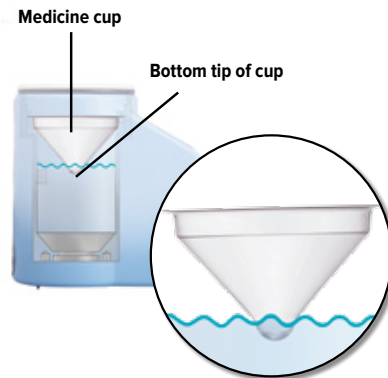


**ONLY USE DISTILLED WATER** in the device. Distilled water is highly purified water that can be purchased at most grocery stores and pharmacies. It is necessary for the device to function properly. If you use another type of water (such as bottled or tap water), the device may not function properly.

There is a silver sensor on the inside wall of the chamber. This sensor must be completely covered with water. However, **DO NOT OVER-FILL** the chamber, or the medicine cup will not fit correctly.

- 2** Obtain one medicine cup and inspect it for any holes, cracks, or dents. Do not use the medicine cup if it is damaged.

Insert the empty medicine cup into the chamber of the device, making sure that the cup's bottom tip is in the distilled water.



#### **⚠ CAUTION**

**Make sure you insert only one medicine cup. Inserting multiple cups (possibly stuck together) will prevent the flow of medicine.**

**3**

Carefully tear or cut open the top of the foil pouch, making sure not to cut the ampules. Each pouch contains four (4) ampules.

Remove one (1) ampule of TYVASO.  
Keep unused ampules in the foil pouch because the TYVASO medicine is sensitive to light.

One ampule contains enough medicine for one day of treatment no matter how many breaths your doctor has prescribed.



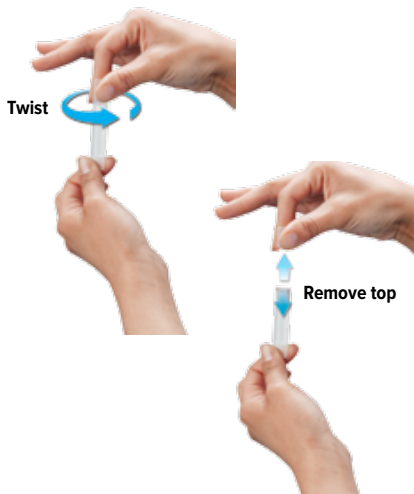
**⚠ CAUTION**

Ampules must be used within 7 days of opening foil pouch.

Discard any unused ampules after 7 days.

**4**

Gently hold the ampule and twist off its top.



**⚠ CAUTION**

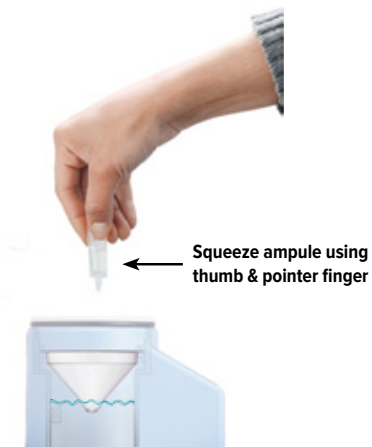
If any medicine from the ampule spills on your hands, wash your hands immediately.

Medicine contact with the skin can cause irritation.

**5**

Point the ampule straight down toward the medicine cup's center to avoid spills.

Gently squeeze the ampule's entire contents into the medicine cup. Squeeze repeatedly until ampule is empty.



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## Using your TYVASO™ Inhalation System

### Assembling the Accessories of the Inhalation Device

The TYVASO™ Inhalation System is made so the parts only fit together properly one way.

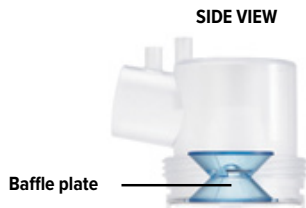
When the device is assembled correctly, the parts should fit together easily. Do not force the parts together.



1

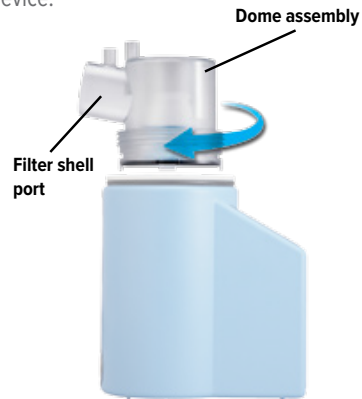
Make sure the blue plastic baffle plate and black ring are correctly placed in the center of the dome assembly. They should appear as they do in the image below.

If the baffle plate is loose or disconnected, secure it by gently pressing it into the bottom opening of the dome assembly before proceeding.



2

Screw the dome assembly onto the device clockwise (right) until you hear a click, indicating the dome assembly is fully connected to the medicine cup. Start with the filter shell port facing the back of the device.



### IMPORTANT

The dome assembly “clicks” only the first time it connects to the medicine cup. If you then realign the dome assembly you will not hear another click.

**3**

Insert the inhalation piece into the upper opening of the dome assembly.



**4**

Insert the mouthpiece into the inhalation piece.



**5**

Each day you will need to use a new filter in each filter shell.

To install a new filter:

- Open the filter shell by unscrewing the two halves.
- Place a new filter in one of the filter shell halves.
- Close the filter shell by screwing the two halves together until you can twist no further.

Note: New filter shells come with fresh filters already installed.

**Open**



**Close**



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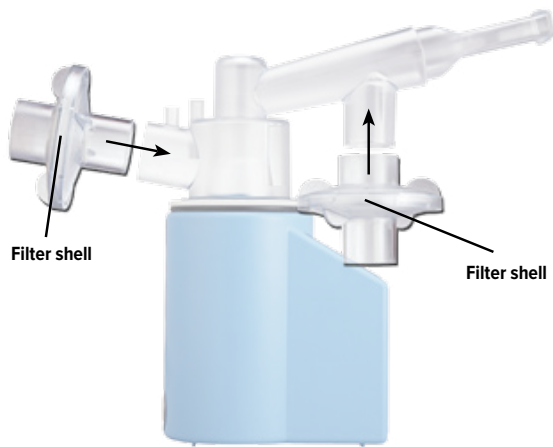
For current labeling information, please visit <https://www.fda.gov/drugsatfda>

## Assembling the Accessories of the Inhalation Device (continued)

6

Insert one of the filter shells into the filter shell port on the side of the dome assembly and insert the other filter shell into the port on the bottom of the inhalation piece. The two filter shells are identical and can be used in either opening.

Make sure to insert the filter shells straight into their ports, rather than at an angle. If necessary, rotate the inhalation piece so you can insert the filter shell without the device getting in the way.



7

When the device is fully assembled, it should appear as it does in the photo below.

Rotate the inhalation piece so you can best see the indicator lights and display screen, which provide important prompts during your treatment.



## Inhaling Your Medicine, TYVASO™ (treprostinil) Inhalation Solution

You will inhale TYVASO during 4 treatment sessions each day. During each treatment session, you will take a series of breaths, called a “cycle,” through the mouthpiece of the TYVASO™ Inhalation System. Each cycle equals 3 breaths of medicine.

1

Connect your device to one of the power source options by plugging one end of the power cord into the back of the inhalation device and the other end into the power source.



2

Turn on the device by pressing the ON/OFF button once (do not hold). When the power is on, the display screen will show “03,” and a yellow light will turn on next to the screen.



3

Hold the device as shown below, so that your hands do not cover the display screen or lights and that you can follow the visual prompts.



## Inhaling Your Medicine, TYVASO™ (treprostinil) Inhalation Solution (continued)

4

Perform steps A-G to complete one cycle of breaths (3 breaths).  
Follow the instructions exactly to make sure you receive the correct medication dose.

### IMPORTANT

1 cycle = 3 breaths.

A



Press the START/STOP button to begin treatment.

B



The power light turns green and the device emits two (2) short beeps.

C



While the device emits one (1) long beep, exhale completely.

D



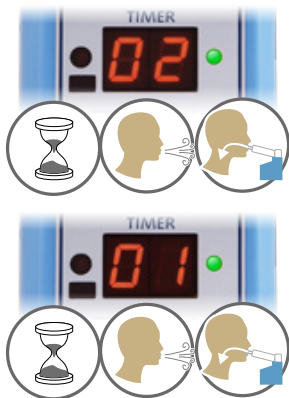
After the device emits a short beep and while the inhalation indicator light is flashing green and the device emits a beep, place your lips securely around the mouthpiece and inhale deeply.

**⚠ CAUTION**

If medicine is flowing you should feel or taste it in your mouth.

If you do not feel or taste any medicine, the TYVASO system might be set up incorrectly. See Troubleshooting section, pages 25-26, for details.

E



Repeat steps B through D two (2) more times.

The display screen will count down from "03" to "02" to "01".

F



After the third breath of the cycle, the display screen will show "00" then "En," indicating the 3 breath cycle is complete.

Record on the tracking sheet the number of breaths you inhaled.

G



Press the "ON/OFF" button to turn off the device.

See the next page for instructions on how to take multiple cycles of breaths.

To pause the treatment between breaths during a cycle, press the START/STOP button.

The display screen will show "PA."

To resume treatment, press START/STOP again.

If treatment is interrupted for any reason (for example, a power failure), first record the number of breaths you inhaled. Second, reset the device to begin a new cycle, then inhale only the number of breaths needed to complete the interrupted cycle.

## Inhaling Your Medicine, TYVASO™ (treprostinil) Inhalation Solution (continued)

If your treatment session requires more than 1 cycle of breaths (1 cycle equals 3 breaths), press the ON/OFF button at the end of a cycle of breaths to turn the device back on and take an additional cycle of breaths.

Repeat the inhalation steps (steps A through G) until you reach your prescribed number of breaths.

The recommended prescribed dose of TYVASO is up to 9 breaths (54 micrograms) per treatment session and up to 4 treatment sessions per day.

For example, if your doctor prescribed 9 breaths per treatment session, you would take 3 cycles of 3 breaths each to complete a treatment session.

### IMPORTANT

After each cycle, record the number of breaths you inhaled to ensure that you receive the proper dose of medicine.

### Example treatment session: 9 breaths (3 breaths = 1 cycle)

#### 1st cycle



Press ON/OFF twice, then START/STOP to begin next cycle

#### 2nd cycle



Press ON/OFF twice, then START/STOP to begin next cycle

#### 3rd cycle



Press ON/OFF once to turn off device

## Storing the TYVASO™ Inhalation System Between Treatment Sessions

If you have more treatment sessions left in the day, perform the following steps.

If you have completed your last treatment session of the day, skip to *Cleaning and Maintenance of the TYVASO Inhalation System*.

1

Disconnect the device from its power source.



## Storing the TYVASO™ Inhalation System Between Treatment Sessions (continued)

**2**

After finishing a treatment session, remove both filter shells.

Do NOT remove filters from filter shells until the last treatment session of the day.



### **IMPORTANT**

When removing accessories between treatment sessions, hold the device by its base to avoid spilling the medicine.

**3**

Remove the mouthpiece.



**4**

Remove the inhalation piece.



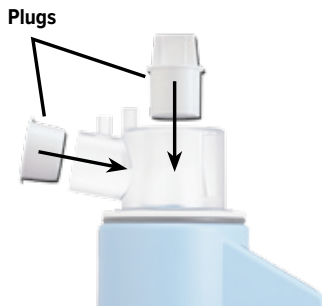
5

Leave the dome assembly and medicine cup (with the medicine still in it) connected to the device.



6

Insert a plug into each of the open holes on the dome assembly to prevent the medicine from spilling out.



### IMPORTANT

If the plugs are not in place, the medicine may spill. If you spill any medicine, start over with a new ampule. You should also replace the filters as medicine may have spilled on them.

7

Place the filter shells, inhalation piece and mouthpiece in the storage box provided to avoid losing or damaging them.



### IMPORTANT

Store the inhalation device in an upright position until the next treatment session.

You can place all components of the inhalation system in the carrying case until next use.

## Cleaning and Maintenance of the TYVASO™ Inhalation System

### End of Day Cleaning of the Accessories

**1**

Disconnect the device from the power source.



**2**

Remove both filter shells.



**3**

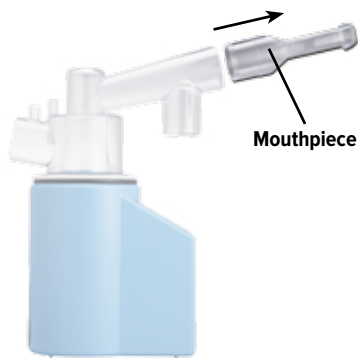
Open the filter shells by twisting in opposite directions.

Remove and discard the used filters.



4

Remove the mouthpiece.



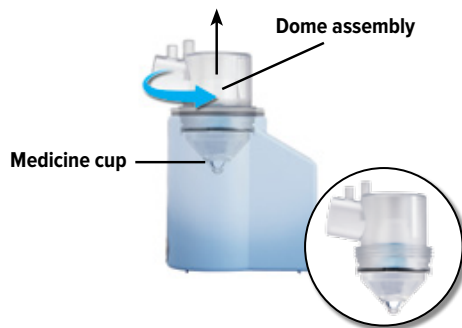
5

Remove the inhalation piece.



6

Remove the dome assembly by turning it counter-clockwise (to the left). The medicine cup will stay attached to the dome assembly.



**⚠ CAUTION**

If any medicine from the medicine cup spills on your hands, wash your hands immediately.

Medicine contact with the skin can cause irritation.

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## End of Day Cleaning of the Accessories (continued)

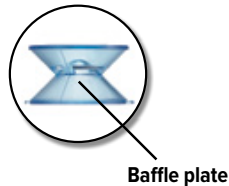
7

Remove the medicine cup by gently squeezing on the sides where it is attached to the dome assembly. Discard the medicine cup. Be careful not to spill the medicine when removing or discarding the medicine cup.



8

Remove the baffle plate by inserting a finger into the top of the dome assembly and gently pushing the baffle plate through the bottom of the dome assembly.

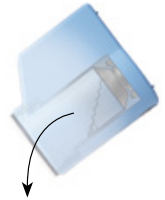


### IMPORTANT

Discard the remaining TYVASO™ (treprostinil) Inhalation Solution in an appropriate waste receptacle. Throw away the plastic medicine cup. Do not reuse the medicine cup.

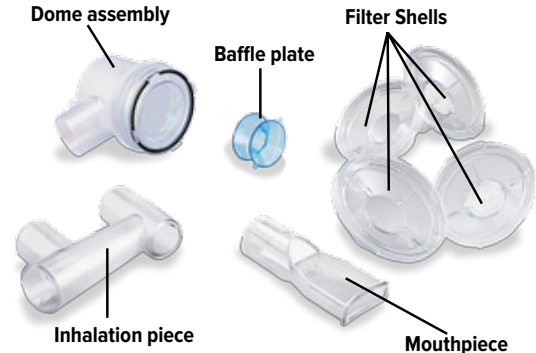
9

Empty the distilled water from the chamber and let the inhalation device air dry upside down.



10

Clean the accessories (pictured below) by hand in mild, soapy, warm water. Allow accessories to air dry.



### IMPORTANT

Do not place the inhalation device in water or in a dishwasher.

## 11

Once the accessories are dry, reinsert the baffle plate by gently pressing it into the bottom opening of the dome assembly. The baffle plate only fits in one direction, with its tabs closest to the dome assembly's bottom opening.



### IMPORTANT

**Make sure the baffle plate snaps completely into the dome assembly. It should sit level and centered in the dome assembly's bottom opening.**

## 12

Store filter shells, inhalation piece, and mouthpiece in the storage box. Store the dome assembly and device in the carrying case until the next day's treatment sessions.



### Weekly Cleaning

- Once a week, use a clean cloth to wipe the interior of the inhalation device chamber.

### Monthly Refill Kit

- Once a month, you will receive a refill kit that will come with a new set of accessories from your specialty pharmacy provider (appropriately discard the used dome assembly, inhalation piece, mouthpiece, and 2 filter shells.)

### Device Replacement

- The inhalation device should be replaced every two (2) years from your first day of use. Replacement inhalation devices will be supplied by your specialty pharmacy provider.

### IMPORTANT

**All repairs of the TYVASO™ Inhalation System must be performed by the manufacturer. Attempting to alter the device in any way voids the warranty and may cause a malfunction.**

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## Charging Your TYVASO™ Inhalation System Rechargeable Battery

- Your TYVASO Inhalation System is supplied with a portable, rechargeable battery. Do **NOT** use other batteries.



- Your battery can only be charged using the original AC wall plug that comes with your inhalation device.



- To charge the battery, connect the AC wall plug to the battery pack and plug the AC wall plug into an outlet.



- Your battery may take up to 10 hours to charge. It is not possible to use the TYVASO Inhalation System with the battery while it is recharging.

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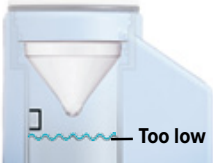
- You should connect the charged battery to the TYVASO Inhalation System only for your treatment .



- After your treatment session is complete, remove the power plug of the battery from the device.
- Always have your AC wall plug available for backup if the battery is not charged.



## Troubleshooting the TYVASO™ Inhalation System

Problem	Possible causes	Corrective actions
<b>Low battery (LB)</b> 	<ul style="list-style-type: none"><li>• Low battery.</li></ul>	<ul style="list-style-type: none"><li>• Unplug the battery from the device. Charge the battery by attaching it to the AC wall plug and outlet.</li></ul>
<b>Low hydrogen (LH)</b> 	<ul style="list-style-type: none"><li>• Defective adapter (AC wall plug or 12V DC adapter)</li></ul>	<ul style="list-style-type: none"><li>• Ensure that the plug is properly connected to an outlet.</li><li>• If the device is properly plugged in and still does not function, contact your specialty pharmacy provider for a replacement.</li></ul>
<b>Low hydrogen (LH)</b> 	<ul style="list-style-type: none"><li>• Distilled water level in the device chamber is too low or the device chamber is empty.</li></ul> 	<ul style="list-style-type: none"><li>• Unplug the device from its power source. Empty the device chamber then refill it with 45 mL of distilled water.</li></ul>
	<ul style="list-style-type: none"><li>• The distilled water you are using is too purified.</li></ul>	<ul style="list-style-type: none"><li>• Empty device chamber. Add 1 teaspoon of tap water to the measuring cup. Fill measuring cup to 45 mL line with distilled water. Pour measuring cup's contents into device chamber.</li></ul>

**Problem**

**No medicine comes out of the device during a treatment session**

**Possible causes**

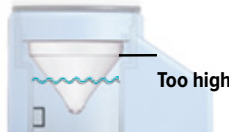
- Damaged medicine cup.



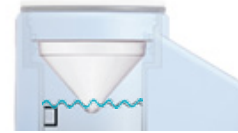
**Corrective actions**

- Unplug the device from its power source. Replace the medicine cup.

- Distilled water level in the device chamber is too high.



- Unplug the device from its power source. Empty the device chamber then refill it with 45 mL of distilled water.




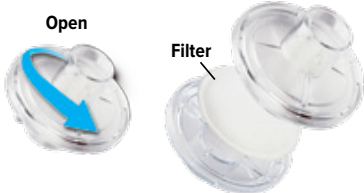


- Multiple medicine cups attached to the dome assembly.



- Unplug the device from its power source. Remove and dispose of all medicine cups. Insert new medicine cup into device chamber and fill with 1 ampule of TYVASO.

## Troubleshooting the TYVASO™ Inhalation System (continued)

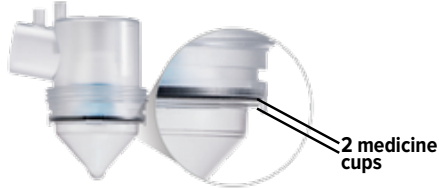
Problem	Possible causes	Corrective actions
<b>No medicine comes out of the device during a treatment session (continued)</b>	<ul style="list-style-type: none"><li>No TYVASO™ (treprostinil) Inhalation Solution in the medicine cup.</li></ul> 	<ul style="list-style-type: none"><li>Unplug the device from its power source. Fill medicine cup with 1 ampule of TYVASO.</li></ul>
	<ul style="list-style-type: none"><li>Device not connected to a power source.</li></ul> 	<ul style="list-style-type: none"><li>Connect device to a power source.</li></ul> 
<b>Difficult to breathe in medicine through the mouthpiece</b>	<ul style="list-style-type: none"><li>Filter is clogged.</li></ul>	<ul style="list-style-type: none"><li>Unplug the device from its power source. Replace filter (see page 9).</li></ul> 

**Problem**

**No “click” was heard when attaching the dome assembly**

**Possible causes**

- Multiple medicine cups attached to the dome assembly.



**Corrective actions**

- Unplug the device from its power source. Remove and dispose of all medicine cups. Insert new medicine cup into device chamber and fill with 1 ampule of TYVASO.

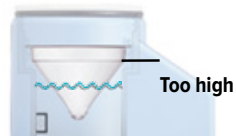
- Dome assembly is not securely in place.



- Unplug the device from its power source. Screw on dome assembly until you hear a “click”.



- Distilled water level in the device chamber is too high.



- Unplug the device from its power source. Empty device chamber then refill device chamber with 45 mL of distilled water.



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## Specifications

### Inhalation Device

Model	ON-100/7
Size	98 x 66 x 105 mm
Weight, control unit	280 g
Types of power supply	120/240V AC wall plug 12V DC car adapter 12V rechargeable battery
Power supply	12V DC, 1.5A maximum
Operating power consumption	18 Watt maximum
Ultrasonic frequency	2.4 MHz (nominal)
Nebulization rate	<0.6 mL/min
MMAD (Mass Median Aerodynamic Diameter)	2.0 $\mu\text{m}$ (respirable fraction = 85%)
1 cycle (3 breaths)	18 micrograms treprostinil
Medicine cup capacity	6.0 mL
Contact fluid chamber capacity	approximately 45 mL
Electric protection class	II Type B
Storage temperature/humidity	-5 to 40°C/20-80% RH
Operating temperature/humidity	15 to 25°C/40-75% RH

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### Accessories

ON-100HPA	Rechargeable battery
ON-100Z	12V DC car adapter
ON-100N-US	AC wall plug
ON-102/1	Medicine cup
ON-109	Filters
ON-115	Storage box
ON-120	Plugs
ON-118	Measuring cup
ON-101	Filter shell
ON-103/1	Dome assembly with black ring and baffle plate
ON-104	Inhalation piece
ON-105	Mouthpiece
ON-110	Black ring
ON-117B	Baffle plate (blue)
	Carrying case

### Packaging Dimensions (Approximate Length x Width x Height)

Patient Starter Kit (PSK)	12.2" x 9.5" x 16"
Monthly Refill Kit (MRK)	9.5" x 6.6" x 12.1"

Specifications

## Glossary

**Accessories:** Parts of the TYVASO™ Inhalation System. See page 5.

**Ampule:** A sealed, lightweight clear plastic vial containing a 1 day supply of TYVASO™ (treprostinil) Inhalation Solution.

**Baffle plate:** A blue plastic piece that fits inside the dome assembly. The baffle plate helps create the pressure necessary to turn a liquid solution such as TYVASO into particles that are small enough to inhale.

**Black ring:** A round seal that fits on the bottom of the dome assembly. The seal ensures that TYVASO does not mix with the distilled water in the device chamber.

**Cycle:** A group of 3 breaths. Each treatment session with TYVASO contains between 1 and 4 cycles depending on the number of breaths your doctor prescribes.

**Device chamber:** The hollow portion in the center of the inhalation device into which distilled water and the medicine cup are placed.

**Display screen:** A small screen on the inhalation device that displays number and letter prompts to guide you through your treatment sessions.

**Distilled water:** Water that is highly purified so that it contains only essential elements.

**Dome assembly:** The plastic accessory that contains the baffle plate and connects the mouthpiece, inhalation piece, and filter shells to the base of the inhalation device.

**Filter:** The white pad that goes into the filter shells.

**Filter shells:** Plastic accessories that hold the filters.

**Inhalation piece:** The plastic accessory that connects the mouthpiece with the dome assembly.

**Inhalation device:** The base of the TYVASO Inhalation System to which the accessories connect. The inhalation device contains the display screen and lights.

**Inhale:** How you will breathe in TYVASO with the TYVASO Inhalation System.

**Medicine cup:** The disposable plastic cone-shaped cup into which TYVASO is poured. The medicine cup fits inside the inhalation device chamber.

**Mouthpiece:** The plastic part that you will breathe through (using your mouth) to inhale TYVASO.

**Plugs:** Plastic accessories that are inserted into the openings of the dome assembly between treatment sessions. Plugs help keep TYVASO from spilling if the inhalation device tips over.

**Prompts:** The audio and visual signals that help guide you through the treatment sessions.

**Sensor:** The silver object on the inside wall of the device chamber. The sensor must be covered with distilled water for the TYVASO Inhalation System to function properly.

**Specialty pharmacy provider:** A pharmacy that carries only specialized medicines and medical devices. Your specialty pharmacy provider is a good source of information about TYVASO and the TYVASO Inhalation System.

**Treatment session:** One of 4 daily sessions during which you will take TYVASO.

**TYVASO:** The prescription medicine that you will use with the TYVASO Inhalation System.

**TYVASO Inhalation System:** A system used to inhale the medicine, TYVASO. You may only use the TYVASO Inhalation System to take TYVASO.

To review TYVASO Inhalation System components, see *The TYVASO Inhalation System* on page 4.