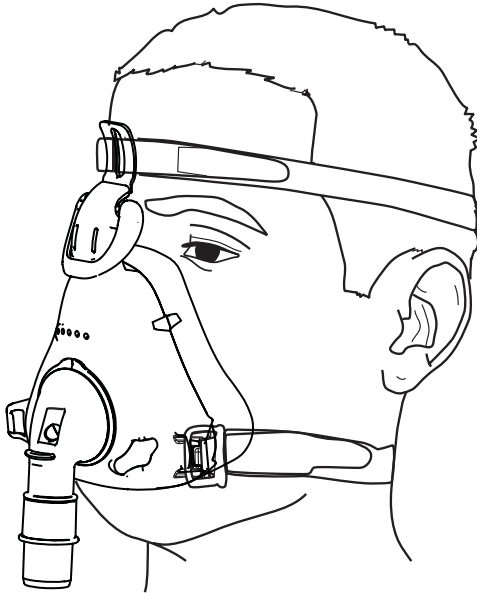


# Owner's Manual

## **Invacare<sup>®</sup> Twilight<sup>™</sup> Full Face Mask**



**LATEX  
FREE**

This owner's manual is to be used in conjunction with the supplemental sheet provided, part no. 1150693.

USER: Before using this product, read the owner's manual and supplemental sheet and save for future reference.

DEALER: The owner's manual and supplemental sheet **MUST** be given to the end user.

**For more information regarding  
Invacare products, parts, and services,  
please visit [www.invacare.com](http://www.invacare.com)**



**Yes, you can.®**

## SPECIAL NOTES

Signal words are used in this manual and apply to hazards or unsafe practices which could result in personal injury or property damage. Refer to the table below for definitions of the signal words.

SIGNAL WORD	MEANING
DANGER	Danger indicates a imminently hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Warning indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Caution indicates a potentially hazardous situation which, if not avoided, may result in property damage.

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## NOTICE

**THE INFORMATION CONTAINED IN THIS DOCUMENT IS SUBJECT TO CHANGE WITHOUT NOTICE.**

Check **ALL** parts for shipping damage. **DO NOT** use if shipping damage is noted. Contact dealer/carrier for further instruction.

The Invacare Twilight Full Face Mask is intended to be used with positive airway pressure (PAP) devices such as CPAP and Bi-Level, which provide 4-20 cmH<sub>2</sub>O for the treatment of adult obstructive sleep apnea. There is a port on the mask to allow for pressure measurement. The mask is to be used on adult patients (> 30 kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single or multiple patient re-use.

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## WARNING

**DO NOT** install, maintain or operate this equipment without first reading and understanding this manual. If you are unable to understand the **DANGERS/ WARNINGS/CAUTIONS** and **INSTRUCTIONS**, contact your home healthcare provider before attempting to use this equipment - otherwise injury or damage may result.

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## ACCESSORIES WARNING

Invacare products are specifically designed and manufactured for use in conjunction with Invacare accessories. Accessories designed by other manufacturers have not been tested by Invacare and are not recommended for use with Invacare products.

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## REGISTER YOUR PRODUCT

The benefits of registering include:

1. Safeguarding your investment.
2. Ensuring long-term maintenance and servicing of your product.
3. Receiving updates with product information, maintenance tips and industry news.

**Register ONLINE at [warranty.invacare.com](http://warranty.invacare.com)**

Please have your model number and purchase date available to complete your registration.

Any registration information you submit will only be used by Invacare Corporation and protected as required by applicable laws and regulations.

## SECTION I—GENERAL GUIDELINES

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### **WARNING**

**SECTION I - GENERAL GUIDELINES** contains important information for the safe operation and use of this product.

If oxygen is used in conjunction with a PAP machine and the full face mask, the oxygen flow **MUST** be turned **Off** when the PAP machine is not operating. If the oxygen flow is left **On**, oxygen may accumulate within the tubing, machine enclosure, or the mask surroundings. Accumulated oxygen in the tubing, machine enclosure, or the mask surroundings may increase the risk of fire.

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### **CAUTION**

“Caution: Federal law restricts this device to sale or rental by or on order of a physician, or any other practitioner licensed by the law of the state in which he/she practices to use or order the use of this device.”

At low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

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This Twilight Full Face Mask should be used only with PAP systems recommended by your physician or respiratory therapist. A mask should not be used unless the PAP system is turned On and operating properly.

This mask is a full face mask, which covers both the nose and the mouth.

NEVER block the vent hole or holes associated with the mask.

DO NOT use an electrically conductive breathing tube.

PAP systems are intended to be used with special masks which have vent holes to allow continuous flow of air out of the mask. When the PAP machine is turned On and functioning properly, new air from the PAP machine flushes the exhaled air out through the mask exhalation vent holes. However, when the PAP machine is not operating, not enough fresh air is provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of PAP systems.

The mask may not be suitable for those with risk of gastric regurgitation or similar conditions.

For patients who are unable to remove the mask, it **MUST** be used under qualified supervision.

At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP systems.

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## SECTION 2—USING THE MASK ASSEMBLY

### Assembling the Cushion

*NOTE: For this procedure, refer to SECTION A in supplemental sheet provided.*

1. Remove the cushion from the plastic bag and install onto the mask frame.
2. Align the keying features at the bottom and sides of the cushion to the mating keying features on the mask frame.
3. Gently push the cushion ribbing down into the mounting channel on the mask frame.

*NOTE: The cushion is completely seated in the mounting channel when the cushion and the mask frame meet forming a gapless seam around the outside edge.*

### Inspecting the Mask

*NOTE: For this procedure, refer to SECTION B in supplemental sheet provided.*

*NOTE: Wash the headgear before using it for the first time, as dye may run. Refer to Cleaning the Mask and Headgear on page 9.*

*NOTE: Invacare recommends washing your face before fitting the mask. This will remove excess facial oil and extend the life of the mask.*

Check the following:

- Check that the valve flap is clean and dry.
- Inspect the valve flap for any damage or wear.
- Ensure that the valve flap is mounted to the mask swivel.
- Ensure that the mask and tubing swivels rotate properly.
- Ensure the port is plugged.
- Ensure the exhalation vent holes are clear.

### Check Valve Function

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#### **WARNING**

**DO NOT use the mask if the valve flap is damaged or missing.**

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*NOTE: If the valve flap is damaged, distorted, or torn, it should be replaced with a new part.*

*NOTE: For this procedure, refer to SECTION C in supplemental sheet provided.*

1. Connect a standard 22mm bore, 6-foot tube from your flow generator to the hose swivel by pressing the tube end over the swivel.
2. Turn On the flow generator.

3. Check that the valve functions properly by sealing off the cushion facial opening. The valve flap should cover and seal the large opening in the mask swivel.
4. Turn the flow generator Off. The flap should return to a straight position and not be blocking the large opening in the mask swivel.

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 **WARNING**

**DO NOT place the mask on your face unless the PAP machine is turned On. Otherwise, injury may occur.**

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### Fitting the Mask

*NOTE: For this procedure, refer to SECTION D in the supplemental sheet.*

1. Before fitting the mask, unfasten one or both of the headgear clips from the mask frame (D-1).
2. Place the mask on the face with the headgear straps behind the head (D-2).
3. Fit the mask loosely over the nose and mouth with minimal pressure.
4. Reattach both headgear clips to the mask frame (D-2).
5. Adjust the mask as follows:
  - A. Lift the forehead lever to the unlocked position (D-3).
  - B. Slide the forehead support up or down until it contacts the forehead and the upper portion of the cushion lightly touches the bridge of the nose (D-3).
  - C. Lower the forehead lever to lock the forehead support in the desired position (D-4).

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 **WARNING**

**DO NOT pull the straps too tight. This can cause skin irritation and may deform the cushion causing a leak. If the mask and headgear are adjusted correctly and a problem persists, contact your health care professional.**

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6. Adjust the strap length as needed using the hook and loop fasteners (D-5 and D-6).

*NOTE: If a leak occurs, adjust the forehead support. If this does not work, tighten or loosen the headgear straps by readjusting the hook-and-loop fasteners.*

*NOTE: Proper mask fit should allow full contact of the cushion without excessive pressure on the face.*

## **Removing the Mask and Headgear**

*NOTE: For this procedure, refer to SECTION D in the supplemental sheet provided.*

1. Place your thumb and forefinger around one of the headgear clips (D-1).
2. Gently pull the headgear clip away from your face.

*NOTE: It is not necessary to remove the headgear straps from the clips or the forehead support when removing the mask.*

3. Pull the mask forward and lift it upwards and over the head.

## SECTION 3—CLEANING THE MASK

### Disassembling the Mask for Cleaning

*NOTE: For this procedure, refer to SECTION B, SECTION C, SECTION E, and SECTION F on supplemental sheet.*

1. Detach the headgear from the forehead support by unfastening the hook-and-loop fastener tabs from the headgear and sliding the straps out of the slot in the forehead support (SECTION C).

*NOTE: It is not necessary to detach the clips from the headgear for daily washing unless desired.*

*NOTE: It is not necessary to completely disassemble the mask for daily cleaning in the home. The mask can be cleaned and rinsed while still assembled. It is recommended to disassemble the mask for cleaning at least once per week.*

2. Lift the forehead lever to the unlocked position (E-2).
3. Rotate the forehead support and remove from mask frame (E-3).
4. Rotate the forehead lever outward and remove from the mask frame (E-4).

*NOTE: It is not necessary to remove the forehead support after every use. It can be cleaned and rinsed while it is mounted to the mask frame.*

5. Remove the cushion from the mask frame by slowly pulling the cushion off (SECTION B).
6. Remove the retaining ring on the outside of the mask swivel (F-1).
7. Remove the mask swivel by rotating it back through the opening in the mask frame (F-2).
8. Remove the hose swivel by pulling it off the mask swivel (F-3).
9. Gently remove the valve flap by pulling it out of the mask swivel (F-3).
10. Uncover the port by grabbing the tab on the port plug and gently pulling up (F-4).
11. Remove the port plug from the mask frame by holding it near the attachment point and gently pulling it straight out (F-4).

*NOTE: Placing the components in the wash solution first can ease in the removal of the port plug from the mask frame.*

*NOTE: It is not necessary to remove the valve flap and the port plug completely after every use. They can be cleaned and rinsed while attached to the mask frame.*



## Cleaning the Mask and Headgear

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### CAUTION

**ALWAYS** be sure to remove any foreign material (dirt, lint, etc.) from the exhalation vents.

**DO NOT** use bleach, chlorine, aromatic-based cleaning solutions, scented oils, or moisturizing or antibacterial soaps to clean the mask components. These solutions may cause hardening and reduce the life of the product.

**Alcohol** may be used to clean the silicone cushion **ONLY**. **DO NOT** use alcohol to clean the mask frame, headgear or air tubing.

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### **WARNING**

**DO NOT** expose any part of the mask system or tubing to direct sunlight as it may cause mask deterioration.

**ALWAYS** rinse mask thoroughly after cleaning. Insufficient rinsing of cleaning agents can result in severe skin rash, irritation and skin breakdown. Discontinue using the mask if there is an allergic reaction to any part of the mask, and contact your healthcare professional.

**Washing the mask in an automatic dishwasher is not recommended. Doing so may damage or affect the life of the valve flap or the product. Also, the automatic dishwasher cleaning and rinsing agents may leave a residue on the mask, which may cause skin irritation.**

**For multi-patient use/reuse, clinicians should refer to the Mask Disinfection and Sterilization Guide (p/n 1130216).**

**The headgear cannot be disinfected or sterilized. Refer to instructions below for washing the headgear.**

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*NOTE: Wash the entire mask system (except the headgear) after each use.*

*NOTE: Wash the headgear at least once per week.*

*NOTE: ALWAYS hand wash the headgear to increase the life of the product.*

1. Disassemble the mask. Refer to Cleaning the mask on page 8.
2. Hand wash the headgear in warm or cool water using a mild detergent.
3. Rinse the headgear thoroughly and allow to air dry.
4. Hand wash the mask components using a mild detergent, such as hand dishwashing detergent, in warm water.
5. Rinse the mask components thoroughly and allow them to air dry.

## Assembling the Mask

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### CAUTION

Replace the mask or mask component if damaged or deteriorated. Dispose of any damaged or broken parts in an environmentally friendly manner or as normal household waste.

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### WARNING

**DO NOT** use the mask if the valve flap is damaged or missing.

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*NOTE: For this procedure, refer to SECTION A, SECTION C, SECTION E, and SECTION F on supplemental sheet provided.*

1. Inspect all components for damage or wear.
2. Replace the port plug onto the mask frame by pushing the barb on the port plug into the hole in the mask frame while gently pulling the barb through from the other side until the barb snaps into place (F-4).
3. Push the port plug down over the port on the mask frame to seal the port (F-4).
4. Check that the valve flap is clean and dry (F-3).
5. Slide the valve flap into the slot in the mask swivel. Gently pull it through from the inside while pushing it in from the outside until it snaps into place (F-3).
6. Snap the hose swivel onto the mask swivel (F-3).
7. Insert the mask swivel through the opening in the mask frame from the inside (F-2).
8. Lock the mask swivel into place on the outside of the mask frame by slipping the retaining ring over the mask swivel (F-2).
9. Push the retaining ring into the groove on the swivel until it snaps in place (F-1).

*NOTE: Align the keying features at the bottom and sides of the cushion to the mating keying features on the mask frame (SECTION A).*

10. Gently push the cushion ribbing down into the mounting channel on the mask frame.

*NOTE: The cushion is completely seated in the mounting channel when the cushion and the mask frame meet forming a gapless seam around the outside edge.*

11. If necessary, reattach the forehead support as follows:
  - A. Slide the forehead lever onto the mask frame (E-4).
  - B. Position the forehead lever into the unlocked position (E-3).

- C. Slide the forehead support into the mask frame and place at desired position (E-2).
  - D. Lower the forehead lever to lock the forehead support in the desired position (E-1).
12. Attach the headgear to the mask by sliding the upper headgear straps through the loophole of the forehead support. The tan side of the headgear goes against the head and the Invacare label will be on the outside of the upper strap (SECTION C).
  13. Loosely secure each side of the upper headgear strap by folding them back and using the hook-and-loop fastening strips to secure the ends of the straps to the upper headgear strap (SECTION C).
  14. Slide the lower headgear strap through the loopholes of the headgear clips (SECTION C).
  15. Loosely secure each side of the lower headgear strap by folding them back and using the hook-and-loop fastening strips to secure the ends of the straps to the lower headgear strap (SECTION C).

*NOTE: Prior to use, inspect the mask and check the valve function. Refer to Inspecting the Mask and Check Valve Function on page 5.*

## **WARRANTY**

**PLEASE NOTE: THE WARRANTY BELOW HAS BEEN DRAFTED TO COMPLY WITH FEDERAL LAW APPLICABLE TO PRODUCTS MANUFACTURED AFTER JULY 4, 1975.**

**This warranty is extended only to the original purchaser/user of our products.**

**This warranty gives you specific legal rights and you may also have other legal rights which vary from state to state.**

**Invacare warrants the Twilight Full Face Mask to be free from defects in materials and workmanship for a period of 90 days from date of purchase. If within such warranty period any such product shall be proven to be defective, such product shall be repaired or replaced, at Invacare's option. This warranty does not include any labor or shipping charges incurred in replacement part installation or repair of any such product.**

**Invacare's sole obligation and your exclusive remedy under this warranty shall be limited to such repair and/or replacement.**

**For warranty service, please contact the dealer from whom you purchased your Invacare product. In the event you do not receive satisfactory warranty service, please write directly to Invacare at the address on the back cover, provide dealer's name, address, date of purchase, indicate nature of the defect and, if the product is serialized, indicate the serial number. Do not return products to our factory without our prior consent.**

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**LIMITATIONS AND EXCLUSIONS: THE FOREGOING WARRANTY SHALL NOT APPLY TO SERIAL NUMBERED PRODUCTS IF THE SERIAL NUMBER HAS BEEN REMOVED OR DEFACED, PRODUCTS SUBJECTED TO NEGLIGENCE, ACCIDENT, IMPROPER OPERATION, MAINTENANCE OR STORAGE, COMMERCIAL OR INSTITUTIONAL USE, PRODUCTS MODIFIED WITHOUT INVACARE'S EXPRESS WRITTEN CONSENT (INCLUDING, BUT NOT LIMITED TO, MODIFICATION THROUGH THE USE OF UNAUTHORIZED PARTS OR ATTACHMENTS; PRODUCTS DAMAGED BY REASON OF REPAIRS MADE TO ANY COMPONENT WITHOUT THE SPECIFIC CONSENT OF INVACARE, OR TO A PRODUCT DAMAGED BY CIRCUMSTANCES BEYOND INVACARE'S CONTROL, AND SUCH EVALUATION WILL BE SOLELY DETERMINED BY INVACARE. THE WARRANTY SHALL NOT APPLY TO PROBLEMS ARISING FROM NORMAL WEAR OR FAILURE TO ADHERE TO THE FOLLOWING INSTRUCTIONS. THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND THE SOLE REMEDY FOR VIOLATIONS OF ANY WARRANTY WHATSOEVER, SHALL BE LIMITED TO REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT PURSUANT TO THE TERMS CONTAINED HEREIN. THE APPLICATION OF ANY IMPLIED WARRANTY WHATSOEVER SHALL NOT EXTEND BEYOND THE DURATION OF THE EXPRESS WARRANTY PROVIDED HEREIN. THE MANUFACTURER SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES WHATSOEVER. THIS WARRANTY SHALL BE EXTENDED TO COMPLY WITH STATE/PROVINCIAL LAWS AND REQUIREMENTS.**

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Rev A - 9/07