Invacare[®] MoblVac[®]

Negative Pressure Wound Therapy (NPWT)



Patient Guide



Manufactured by:
Ohio Medical Corporation
IIII Lakeside Dr. Gurnee, IL 60031



Important Contact Information

our nurse's name:
our nurse's number:
our doctor's name:
our doctor's number:
Distributor information:
1oblVac® Technical/Clinical Hotline (toll free): 866-985-NPWT (6798
Product Number:
Product Serial Number

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3 General

3.1 Symbols

Warnings

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



DANGER

Danger indicates an 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 or minor injury or both.

! IMPORTANT

Indicates a hazardous situation that could result in damage to property if it is not avoided.

Gives useful tips, recommendations and information for efficient, trouble-free use.

4 Overview

4.1 Introduction

This guide is designed for patients and their caregivers while under Negative Pressure Wound Therapy (NPWT) with the Invacare MoblVac pump. Keep this guide in a safe place with other healthcare documents. This guide covers:

- Information on indications for use of the MoblVac® system
- · Contraindications to product use
- Warnings and precautions for safe and effective use of the MoblVac[®]
- General operation of the MoblVac® system

What is Negative Pressure Wound Therapy (NPWT)?

NPWT is a technique for wound closure that uses a vacuum source to create a lower pressure in the wound. The MoblVac® is a NPWT system that is used in hospitals, nursing homes, and at home to help promote wound healing. The MoblVac® is applied to your wound to draw out excess fluid, help protect against outside contaminants, and help improve blood flow, which ultimately helps in promoting healing.

How Long to Use Negative Pressure Wound Therapy (NPWT)?

Your healthcare professional will determine how long you need NPWT therapy and when to stop therapy, when they assess your wound at each dressing change.

Mobility

Your healthcare professional will discuss moving around while under Negative Pressure Wound Therapy, based on your wound and health situation. For patients who are told they can move around, the MoblVac can be operated on battery power and can be carried with an accessory carrying bag.

Electric or Battery Use

The MoblVac® is powered by electricity when it is plugged into an electric outlet.

Use the MoblVac® plugged into an electric outlet whenever possible.

The battery charges when the unit is plugged into an electric outlet.

Battery life is approximately 12 hours, if battery is fully charged and dressing has a good seal.

The battery powers the MoblVac® whenever the unit is turned on and the power cord is unplugged from electric outlet.

5 General Guidelines

5.1 General Guidelines



WARNING

DO NOT use this product or any available optional equipment without first completely reading and understanding these instructions and any additional instructional material such as owner's manuals, service manuals or instruction sheets supplied with this product or optional equipment. If you are unable to understand the warnings, cautions or instructions, contact a healthcare professional, Invacare Representative or technical personnel before attempting to use this equipment otherwise, injury or damage may occur.



ACCESSORIES WARNINGS

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.

! NOTICE

THE INFORMATION CONTAINED IN THIS DOCUMENT IS SUBJECT TO CHANGE WITHOUT NOTICE. Check all parts for shipping damage and test before using. In case of damage, DO NOT use. Contact Invacare/Carrier for further instruction.

This product is a medical device and sale is restricted to or by order of a physician.

This device must only be used for the person for whom it was ordered and only for the use for which it was intended.



WARNING

Monitor patient for excessive bleeding, which may result in serious injury or death. If sudden or increased bleeding is observed, immediately stop therapy and seek medical attention.

This device is to be used by or under the care of trained medical personnel only.

Do not use this or any electrical device in an explosive or flammable environment or in the presence of flammable anesthetics.

Infected wounds may require more frequent dressing changes. Constantly monitor wounds for signs of infection.

Negative pressure wound therapy (NPWT) is not approved for use on children.

6 Operation



WARNING

Pressure settings should not be changed by a patient, unless directed by a qualified healthcare professional. Operate unit only at physician prescribed pressure settings.

6.1 Operating the MoblVac

- I. Remove the collection canister from its packaging.
- 2. Firmly press the canister into place. Ensure the latch is firmly extended over the top of the canister.
- 3. Connect the extension tubing to the opening on the top of the collection canister.
- 4. Press down on the \bigcirc button on the front control panel of the unit. The green light should now be on.
- 5. Two types of therapy can be applied. Press the button on the control panel under the word "CONTINUOUS" if you have been told to apply continuous therapy. Press the button under the word "INTERMITTENT" if you have been told to apply intermittent therapy.
- 6. The digital gauge portion of the display will read 25 mmHg. This is the pressure level.
- 7. Increase the pressure to 75 mmHg (or the level you have been instructed by the physician) by pressing the button on the control panel beneath the word "**INCREASE**". The display will increase by 25 mmHg each time you press this button.
- 8. When therapy is complete, press the \circlearrowleft button to turn the unit off.
- 9. Disconnect the unit from patient.
 - 1

Refer to instructions on the back of the MoblVac unit. For more information, call 866-985-NPWT (6798) for the user manual.

How do I know if the MoblVac is working?

- The green light above the button shows that the MoblVac is working.
- The control panel of the MoblVac therapy unit will go into sleep mode to conserve energy.
- Sleep mode will cause the screen to fade gradually.
- · If you touch any button on the control panel, the unit goes out of sleep mode and the control panel illuminates.

6.2 Alarms

Canister Full Alarm



This alarm will sound when the canister is full.

- I Press the "PAUSF" button
- 2. Remove the collection canister and dispose of as instructed by your healthcare professional.
- 3. Replace with a new canister and restart.



If the unit continues to alarm, please refer to the "troubleshooting" section of this manual.

Excessive canister changes (or canister full alarms) may indicate that there is excessive bleeding.

Leak Alarm

If the pump runs constantly and the unit goes into a leak alarm mode, perform the following

- A. Press the "SILENCE" button on the control panel.
- B. Check the patient dressing, canister, and tube connection for leaks.
- C. Seal leaks.
- D. Once the leaks have been sealed, the pump will become silent.



If the unit continues to alarm, please refer to the "troubleshooting" section of this manual.

The leak alarm indicates that there is a leak in the dressing. This may be due to improper application, patient movement, or excessive bleeding.

Battery Alarm



The alarm will sound when the battery needs recharging.

I. Plug the electric cord into an electric outlet to charge the battery.

6 OPERATION

6.3 Disabling Sleep Mode

You can disable the sleep mode and keep the control panel constantly illuminated.

- To disable the sleep mode follow these steps:
 - i. Press the "OPTIONS" button
 - Press the "SLEEP OFF?" button.
- ①

The text above the button will change to "SLEEP ON?" indicating sleep mode is turned off. The screen will remain illuminated.

- iii. Press the "RETURN" button to return to the vacuum level screen.
- The sleep mode can be turned on again, perform the following:
- Press the "OPTIONS" button.
- Press the "SLEEP ON?" button.
- 3. The text above the button will change to "SLEEP OFF?" indicating sleep mode is turned on.
- 4. Press the "**RETURN**" button to return to the vacuum level screen.
 - **①**

It is recommended to only disable the sleep mode when the unit is plugged into wall power. The battery will drain very quickly with sleep mode disabled.



WARNING

Complications

Call your healthcare provider immediately if there is:

- A change in the color or amount of fluid in the canister.*
- The canister fills quickly with blood.*
- The dressing leaks fluid or fails to seal.*
- If the wound smells bad**
- If the wound gets worse**
- If you experience increased pain or discomfort**

*This may indicate excessive bleeding, which may cause serious injury or death. If there is excessive bleeding, stop therapy immediately. Call 911 (or local emergency number) and take emergency measures to control bleeding.

**This may indicate an infection.

6.4 Monitoring - Periodically Check:

- Ensure that vacuum is being applied to the wound
- Check that the battery is charged
- The canister should be changed at least once a week or when 2/3 full
- Excessively frequent canister replacement may be a sign of excessive bleeding
- · Dispose of used canisters in accordance with local ordinances, regarding disposal of potentially infected or biohazard materials
- Do not open canister
- Ensure that all previous dressing materials are removed prior to new dressing application
- Do not block the vents on the battery cover

7 Patient User Guidelines

7.1 Indications for Negative Pressure Wound Therapy

The MoblVac® NPWT pump is an AC/DC powered portable aspirator that provides negative pressure for the application of wound drainage. Negative Pressure Wound Therapy has been used with many types of wounds including: ¹⁻⁷

- pressure ulcers
- · chronic wounds
- acute wounds
- · surgical wounds
- · neuropathic and diabetic wounds

- explored enterocutaneous fistulas
- · leg ulcers
- traumatic wounds
- fasciotomy wounds from compartment syndrome

7.2 Contraindications



WARNING

ALWAYS consult the patient's physician before using the MobIVac system.

The MoblVac® NPWT pump should not be used under the following conditions:

- necrotic tissue with eschar present
- · untreated osteomyelitis
- · non-enteric or unexplored fistulas
- · malignancy in wound
- exposed vasculature
- exposed nerves
- · exposed anastomotic site
- · exposed organs



WARNING

Precautions: Patient Risk Factors/Characteristics to consider before NPWT use

The following is a list of health factors that your health care provider has been advised to consider before prescribing use of the MoblVac® as part of your medical treatment. If you have any questions or concerns about these risk factors, consult with your health care professional.

- · Patients at high risk for bleeding and hemorrhage
- Patients on anticoagulants or platelet aggregation inhibitors (common types of blood thinners/anti platelets include, but are not limited to: COUMADIN®, warfarin, heparin, LOVENOX®, aspirin, Plavix®, etc.), as excessive bleeding may occur. If you are unsure, please check with your physician. Always advise your physician of all medications you are taking. This includes both prescription medicines and those you buy over the counter.
- · Patients with:
 - Friable vessels and infected blood vessels
 - Vascular anastomosis
 - Infected wounds
 - · Osteomyelitis
 - Exposed organs, vessels, nerves, tendon, and ligaments
 - Sharp edges in the wound (i.e. bone fragments)
 - Spinal cord injury (stimulation of sympathetic nervous system)
 - Enteric fistulas

7 PATIENT USER GUIDELINES



WARNING

- · Patients requiring:
 - MRI
 - · Hyperbaric chamber
 - Defibrillation
- · Patient size and weight
- · Use near vagus nerve (bradycardia), such as neck (or anorectal) wounds where the vagus nerve may be exposed
- · Circumferential dressing application in an extremity
- Mode of therapy intermittent versus continuous negative pressure
- Position the device and tubing to avoid a tripping hazard and to avoid the patient lying on the tubing, or otherwise pulling it from the wound site, which could cause additional wounds
- DO NOT apply skin prep wipes directly onto open wounds
- Take extra precaution to ensure a sterile environment when NPWT is used on patients who are immuno-suppressed (such as patients with HIV, undergoing chemotherapy, with transplants or on certain medications) or patients who are colonized with exotic organisms

7.3 Wound Dressing Kit Instructions for Use



WARNING

Dressing changes should be done by qualified healthcare professionals.

Prior to application of this dressing kit, it is the responsibility of the medical professional to properly assess the wound and to ensure that the proper course of treatment is being followed.

1. Irrigate the wound bed thoroughly with normal saline and pat surface dry.

Prep:

- 1. Apply skin prep to any exposed skin that will be covered by the transparent film.
- 2. Allow to dry.
- 3. For heavy draining wounds or macerated wounds, apply a window frame of transparent film about the wound edge to assist in sealing.

Dress:

- 1. Cut one non-adherent layer to the approximate size of the wound.
- 2. Put this layer across the bottom of the wound bed.
- 3. Cut the drain to the appropriate size for the wound area and place into wound.
- 4. Ensure that the drain does not extend beyond the wound bed.



CAUTION

Do not place drain into an unexplored wound.

- 5. Open the gauze dressing pack and moisten with normal saline.
- 6. Lightly fill the gauze into the wound to completely cover the drain.
- 7. Fill the recessed area to skin level.



CAUTION

Ensure that the gauze is properly moistened with normal saline before sealing the wound.

Ensure that the moistened gauze does not extend to the healthy tissue around the wound (called the periwound area).

Seal

- 1. Where the drain tube exits the wound, place a strip of paste beneath the tube.
- 2. Cut transparent film or select appropriate size to allow at least one inch of intact skin beyond wound edges.
- 3. Place transparent film over gauze-filled wound.
- 4. Squeeze dressing into place over tube and paste to create an airtight seal.

7 PATIENT USER GUIDELINES



If patient is sensitive to adhesives, discuss with your healthcare provider. A substitute for the paste such as thin hydrocolloid may be suitable. Window frame the hydrocolloid on the periwound area. Allow the transparent film to lie on the hydrocolloid border.

Begin Wound Drainage

- 1. Connect the drain tubing directly to the suction canister using the extension tubing included.
- 2. Before continuing, make sure that the tubing is not crimped or pinched, and that there are no obvious obstructions.
- 3. Apply continuous suction and observe the wound site.
- 4. The wound dressing shall shrink noticeably, and the clear dressing will look wrinkled.
- 5. If sealing does not occur, check the dressing for proper sealing against the skin and at the tubing exit site. Readjust the seal as necessary and reapply suction.
- 6. Check the wound dressing at regular intervals for leaks.



CAUTION

Infected wounds may require more frequent dressing changes. Constant monitoring of the wound must be done to check for signs of infection.

Patient must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately stop therapy and take appropriate actions.

The TruSeal[™] Kink has not been studied on pediatric patients. Patient size and weight must be considered when prescribing.

Dressing Changes



CAUTION

Dressing changes should be done by qualified healthcare professionals.

Your healthcare professional will determine how often to change dressings.

- Initial Application The TruSeal™ Link dressing kits are typically changed 48 hours after the initial application of therapy.
- Subsequent Dressing Changes If the patient is comfortable and if no dressing leak is present, dressing changes should occur 2-3 times per week. Some wounds may require more frequent dressing changes.



CAUTION

Dressings should be checked at regular intervals.

In the event of heavy drainage or drainage with sediment, more frequent dressing changes may be needed. Infected wounds may require more frequent dressing changes. Consult with your healthcare professional in determining dressing changes.

Ensure that all previous dressing materials are removed prior to new dressing application.

Washing and Showering



CAUTION

DO NOT use the MoblVac while washing or near water, DO NOT submerge.

Disconnect the tubing from the MoblVac therapy unit before showering or washing to avoid damage to the unit.

The clear dressing which covers the wound is water resistant, but you should avoid submerging the dressing in water.

Reconnect the tubing to the MoblVac unit as soon as you have finished washing, and turn on the unit. Refer to Operating the MoblVac on page 8.

Dressing in Place without MoblVac® Therapy

If $MoblVac^{\otimes}$ Negative Pressure Wound Therapy is interrupted, the dressing may be left in place up to 72 hours from the initial application of that dressing, according to clinical documentation from the gauze dressing manufacturer. (Kerlix[™] AMD[™] antimicrobial gauze by Covidien[™]).

8 Troubleshooting

8.1 Troubleshooting



For additional information, please contact MobIVac Technical/Clinical Hotline at 866-985-NPWT (6798).

PROBLEM	CAUSE	SOLUTION
Pump does not turn on when the power switch is depressed.	Battery is not charged. Defective unit.	Charge battery Call MoblVac Technical/Clinical Hotline at 866-985-NPWT (6798) for assistance.
Leak alarm continues to sound.	I. Improper tubing connection or leak in the patient dressing.	I. Check all patient vacuum connections to ensure they are air tight, and that the tubing is connected properly to the collection canister. Apply additional ostomy paste around edge of dressing to reseal.
	2. Canister is not sealed properly to housing.	2. Firmly press on the canister in a downward motion while the pump is running to ensure a proper seal.
	3. Dirt or contaminate on the collection canister seal.	3. Press the "PAUSE" button and remove the collection canister. Visually inspect the sealing area on the canister and the housing, and remove any debris or contaminate that is compromising the seal. Replace canister and restart.
	4. Canister is cracked or defective.	4. Replace collection canister.
	5. Defective unit.	5. Call MoblVac Technical/Clinical Hotline at 866-985-NPWT (6798) for assistance.

PROBLEM	CAUSE	SOLUTION
Canister alarm continues to sound.	I. Unit is not completely upright, causing fluid to prematurely sound alarm.	I. Unit must be used in completely upright position.
	2. Contaminate on canister alarm contact area.	2. Press the "PAUSE" button and remove the collection canister. Visually inspect the electrical contact area on the canister and the housing, and remove any debris or contaminate that is compromising the electrical connection. Replace canister and restart.
	3. Defective unit.	3. Call MoblVac Technical/Clinical Hotline at 866-985-NPWT (6798) for assistance.
No vacuum to patient.	I. Unit is in the "PAUSE" mode.	I. Press "RUN" button.
	2. Unit is in the " OFF " cycle during intermittent mode.	2. Wait for the " OFF " cycle to finish timing, and the unit will cycle to the " ON ".
	3. Collection canister is full and alarm has been silenced.	3. Replace collection canister, and restart unit.
	4. Pressure regulator is set at zero.	4. Press "INCREASE" button to raise vacuum pressure.
	5. Exhaust vents in back of machine are blocked.	5. Ensure adequate ventilation by removing any obstructions.
	6. Defective unit.	6. Call MoblVac Technical/Clinical Hotline at 866-985-NPWT (6798) for assistance.

9 REFERENCES

9 References

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Yes, you can: