

# easy**moov**6 Enteral feeding pump Instructions for use



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### 1 General information 1.1 Indications

### The Easymoov6 enteral feeding pump and giving sets are intended to deliver nutritional formula to the gastrointestinal system of patient from infant (>3kg) to adults fed by naso-gastric feeding tube, naso-jejunal feeding tube, gastrostomy or jejunostomy. The feeding pump and giving sets are intended to be used in clinical or home care settings by trained users ranging from laypersons to physicians. The Easymoov6 enteral feeding pump is for use with only the Vygon Easymoov6 giving sets.

# 1.2 Contraindications

 Do not use Easymoov6 pump for parenteral feeding. This device is not intended for intravenous use.

 Do not use Easymoov6 pump if enteral feeding is contraindicated. We recommend you contact your healthcare provider for further instructions.

• Easymoov6 have not to be used in the case of non-functional or inaccessible digestive tract, ischemia, intestinal obstruction, serious diarrhea, active gastrointestinal bleeding or patient refusal. This pump is not for use with premature patients.

## 1.3 Complications

Pump enteral feeding may lead to digestive complications such as diarrhea, vomiting, reflux, regurgitation with possible inhalation, bloating, refeeding syndrome, constipation, intestinal obstruction. Feeding flow rate and feeding solution must be adapted to suit the patient and the patient's condition should be assessed regularly.

## 1.4 Safety and warning

1. Read these instructions thoroughly before using the pump.

## Environment

2. Do not use pump near flammable gases.

3. Do not install the pump in dusty places or places likely to be exposed to vibrations, shocks, heat ignition sources, etc.

4. Do not store pump in damp places.

5. Do not store pump in the refrigerator.

6. This pump is not intended to be used in MRI environments or in the presence of strong magnetic fields.

## Nutrition

7. Use only dedicated Easymoov6 enteral giving sets with Easymoov6 pump. Easymoov6 is not compatible with other pump giving sets.

8. Proper operation of pump requires door is closed and latched. Make sure door is closed and latched when pump is running.

9. Patients with diabetic disorders must be subject to enhanced surveillance.

10. Use commercially available pre-packed or commercially prepared feeding solutions formulated for use with a feeding pump that are prescribed by a licensed healthcare provider, dietician, or nutritionist. In case of powder based preparation, make sure the powder is fully dissolved to avoid the formation and accumulation of lumps which could alter the pump's performances. Do not use homemade blenderized food not sufficiently liquidized or containing pieces of food. In the case preparation is too thick or heterogeneous, it is preferable to choose another way of administration.



- 11. In case of paediatric use, it is necessary to precisely follow the indications of chapter 3.2 in order to ensure a right flow accuracy. The feeding bag shall be placed at 6.0 inches above the pump. When administering formulas or milk containing thickeners, it is recommended to program the volume to administer whether than using the "Use entire bag" (see page 15)
- 12. "Use entire bag" mode must not be used with seriously ill patients, children, or patients extremely sensitive to air introduction in the stomach when enterally fed. It is recommended to use continuous mode with a specific volume set up for these users.
- 13. The formula bag shall ALWAYS be placed above the pump. If it is not the case, it will have an adverse effect on the accuracy.
- 14. Use only tubing having a state of cleanliness compatible with medical use. The tubing and the feeding tube should be flushed after each feeding. Tubing should not be used for more than 24 hours.
- 15. The pump is intended to be programmed while stationary. Do not program pump during ambulation.

### Electric risks

- 16. Only use the supplied AC adapter to charge your Easymoov6 pump (see section 12.3).
- 17. Always disconnect the AC adapter and turn off the pump before cleaning or servicing.
- After cleaning, make sure the AC adapter is completely dry before plugging into an electrical outlet.
- 19. Do not use the power adapter if damaged or if it encounters any liquid.
- 20. Implanted patient (such as ICDs, pacemakers, and neurostimulators) need to refer to the implanted device Instruction For Use to know if there is any restriction to use an electrical equipment with DC motor and other items that cause electromagnetic interference, such as Easymoov6 pump.

### Other risks

- 21. Do not disassemble pump. Opening may affect function of device and voids the warranty.
- 22. Never use a damaged pump without first having it inspected by the manufacturer.
- 23. Strangulation hazard: Avoid leaving power adapter cord, feeding set tubing or other choking hazards where infants or young children can come in contact. If these objects get wrapped around a child's neck, strangulation and death can occur.
- 24. Choking hazard: The pump and disposable giving sets contain small parts which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler, or infant, which could result in suffocation and death. Keep all small components out of reach of small children.
- 25. Risk of fall: The power adapter cord, giving set tubing, and pump accessories may cause a tripping hazard. Avoid leaving wires, cords, or tubing in a pathway where a person could trip and sustain an injury.
- 26. Avoid using accessories, detachable parts and materials with the pump that are not recommended in this manual. Use only approved Easymoov6 accessories with the pump. Failure to use Easymoov6 accessories could result in damage to the pump or physical injury.

### 1.5 Device recycling

At the end of the product's life cycle, the pump should be discarded at an electrical/electronic waste recycling center.

# Important: Easymoov6 pump contains a battery that should be recycled according to appropriate regulations.

### 2 Pump overview 2.1 General description



### 2.2 Front panel

- 4 indicator lights
- Large, color LCD display
- Keys used to program or launch the feeding



The LCD screen includes both text and images indicating instructions or information for each stage or status of the pump.

# 2.3 Initial pump set up

• Switch on pump to initialize software.



• The initial screen indicates the pump serial number and software version. Name can be customized on the screen.

</>>> III:09ем FU Languages FN English Next language (+)

Confirm change

• If used for the first time, the pump will prompt the language to select.



() → () 11:09 <sub>PM</sub>		(1)
Runi	ning 🜔	(2)
🚫 Rate	Total	   
125 mL/h	1000 mL	(3)
Time left	Total Fed	
4 h 24 min	450 mL	(4)
Hold to	pause	(5)

(1) Notification header the lock rate & volume mode is activated Im the intermittent mode is activated (not shown) - the keypad is locked (see section 4.3) indicates sound level indicates battery level 3:09<sub>AM</sub> clock

(2) Activity bar The flashing play symbol is displayed and the steady green «PLAY» LED indicates feeding is running.

# (3) Upper part of the screen

Indicates the parameters programmed for the feeding (flow rate and volume to be administered).

(4) Lower part of the screen Indicates time left and volume administered

# (5) Action bar

Indicates action to be done. To pause the feeding, press and hold 
— until the green bar fills entirely (see section 4.2 image).



• The pump will indicate if no tubing is installed. Note: if the tubing is correctly installed and this message persist, replace tubing.



• To prime tubing, press 🕣 then press . The following screen will be displayed:

Note: before priming the tubing, the screen will indicate to disconnect tubing from patient.

» 11:09рм

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• The screen will indicate that the tubing is being primed. The remaining priming time is displayed at the bottom of the screen. The prime may be stopped at any time by pressing .

Priming duration is approximately 1 minute 45 seconds. If tubing is not completely primed repeat priming.

•When pump is running, the following symbols will be displayed:

SYMBOL	EXPLANATION
🚫 Rate	The flow rate: in mL/h, from 1 to 400 mL/h.
Total	The volume programmed: programmed in mL, from 1 to 9,999 mL.
Total Fed	The volume administered: in mL, since the launch of the feeding.
Time left	Time left: time remaining before the end of feeding.
Ø	Flashing symbol: indicates the pump is operating.
<b>I</b> )	Battery symbol: indicates the pump's charge level and/or charging status.

If a volume was set, the screen will display:



Display with programmed volume (example 1000 mL). If no volume was set («use entire bag» selected) this display will appear:



Note: the screen backlighting can be changed at anytime during the feeding by pressing any key.

Кеу	Function	Observation
Ċ	PUMP SWITCH ON: by pressing the key OFF: by pressing and holding for 3 seconds	Home screen Shutdown screen
	MULTIFUNCTIONAL KEYS Makes it possible to select or launch a sequence: -Stop the prime -Validate flow rate and volume to be delivered -Start the feeding -Activate pause mode -Mute the alarm for 2 minutes -Resume feeding from pause state -Select settings in the menu	Key requires either a single press of the button or a press and hold to select a function.
-+	PROGRAMMING - Flow rate from 1 to 400 mL/h - Volume range from 1 to 9,999 mL - Navigate in the menu by scrolling through settings DURING FEEDING: To use the lock keypad option, press and hold (+) and (-) for 3 seconds to lock or unlock the keypad.	Keys locked from the launch of the feeding. For more information about lock keypad option, see section 4.3.
5	Go back to the previous stage	Key locked during feeding and pause.
Menu	ACCESS MENU -Adjust pump settings -Adjust nutrition mode (access protected by a code) -Visualize pump data	Menu access available outside of the nutrition mode. Available in limited access (without nutrition mode) when pump is paused.

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## 3 Starting up 3.1 Installation of t

# 3.1 Installation of the pump

Easymoov6 pump is delivered with an uncharged battery. Before use, charge using the AC adapter provided with the pump (see section 9.1).

Easymoov6 pump can be fixed onto a vertical pole using the pole clamp provided with the pump. It is also available as an accessory (see section 12.3).

# Important: in order for Easymoov6 pump and its alarms to operate properly, only use Easymoov6 enteral giving sets manufactured by Vygon.

# 3.2 Loading tubing

Connecting tubing to the feeding bag:

- Check the integrity of the packaging.
- Open the bag and remove the tubing.
- Connect the tubing to the feeding bag.
- Hang the feeding bag on the vertical pole.
- Install tubing on the pump and prime tubing (see section 3.3).



To ensure pump accuracy, the feeding bag liquid level shall be placed at 6.0 inches (15.2 cm) higher than the pump rotor.

# 3.3 Tubing installation

### Tubing diagram:



#### (1) Open Easymoov6 pump cover.

(2) Place the silicone loop around the rotor and make sure the cassette is in the right direction.

(3) Push the cassette in the middle of the pins with your thumb and make sure the cassette is well postioned between the two black pins. Guide both tubes down, in line with their respective slots.

(4) Close the pump cover, then place the adapter into the designated slot.

Remove the protective cap from the tubing.

Launch automatic priming (see section 3.5). Connect the tubing to the patient enteral feeding tube and program the pump.



### 3.4 Switching On the Pump

KEYS TO BE PRESSED	EFFECTS	MESSAGES DISPLAYED ON THE SCREEN	
OPress key until a beep is heard.	Switching on the pump initiates a self-test: - of the 4 lights - of the beeping sound - of the screen	Helio John Doe CaSymoovó Creco Vana Live SM: 1407000105 V1.50	

Important: when switching the pump on, make sure the LCD screen and the four lights operate properly and the beeping sound is audible. After the self-test phase, messages are displayed to help you program the feeding.

Note: the menu is accessible without installing tubing by pressing (Men). If tubing is not installed, the message «load tubing» appears (see section 3.3). You will only be able to program the feeding once the tubing has been installed and primed.

## 3.5 Tubing priming



During priming, the pump checks whether the tubing is filled properly. If priming does not run smoothly, the following message is displayed:

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Prime stopped	Air in tubing was detected. Check tubing to find the source of the
Air detected	<ul> <li>- Verify that the tubing connection is secured with the bag</li> <li>- Verify that the bag is not empty</li> </ul>
	After solving the problem, press 🔵 button to prime tubing again. If the priming message error persists and no air is in line, please contact customer service.
Restart prime	

Important: always prime tubing before starting feeding using automatic priming mode (presented above). Disconnect patient during priming.

# 4 Using the pump4.1 Simplified mode programming

The instructions below indicate how to program the pump in simplified mode once the priming phase is completed.

Note: the following screen may be displayed after the priming phase. For more information, refer to section 6.





# Important: before launching the feeding, it is important to make sure the feeding parameters registered are verified.

\*Use entire bag: if the user selects this option, the pump will be programmed to operate without setting a specific volume. The pump will operate until the feeding bag is empty. Please refer to Safety and Warning 11. and 12. when using this mode.

Activity notice: no action during the last 2 minutes.



During the pump configuration phase, any programming interruption of more than 2 minutes will trigger an alarm. The pump will beep and display a message indicating the operation to be carried out. A beep confirms that the action has been taken after pressing the green key and returns to the previous screen.

## 4.2 Pause mode in simplified mode

It is possible to pause the feeding at any time for a maximum period of 15 minutes:

KEYS TO BE PRESSED	EFFECTS	MESSAGES DISPLAYED ON THE SCREEN				
Press and hold for 3 seconds and the progress bar fills up (green bar at the bottom of the screen)	Pump paused Feeding stopped: Remains PAUSED as long as no other keys are pressed on the keypad (duration of the pause: 15 min)	( 12 Ti 4F	Runn Rate 25 mL/h ime left h 24 min Hold to	() ILLING INDIG () ILLING INDI	Pau A Rate 125 mL/h Time left 4 h 24 min Change rate or Resume	Contractions of the section of the s

Important: when the pump is **PAUSED**, both the Infrared and Ultrasound sensors remain active. If the tubing is pulled out, the pump will detect this anomaly by signaling a «Downstream set error» or an «Upstream set error» alarm (see section 8).

Note: to pause the pump, make sure the keypad is not locked (key icon — in the header). In this case, refer to section 4.3 to unlock the keyboard and pause the pump after.

The following parameters may be modified when the pause mode is activated in simplified mode:

Press the 📀 key to access the flow rate screen.

The action always reflects the data displayed at the time of the operation.

# Important: **BEFORE** resuming the feeding, make sure the feeding parameters programmed are verified.

# 4.3 Locking the keypad

During the feeding, it is possible to lock the keypad. To do so, press and keys together for 3 seconds. Do the same action to unlock it.

The - logo appears when the keypad is locked.

Special case: when the alarm starts sounding, the keypad automatically unlocks.





# 5 Navigating in the Menu

# 5.1 Accessing the Menu

The menu is not accessible during feeding. Navigation is accessible through the Menu key.

- The menu has three options:
- Pump settings
- Nutrition mode
- Pump data

### Special case: «Nutrition mode»:

This mode is protected by a passcode. The access is limited and not available during a feeding or pause mode.

Scroll through the menu by pressing  $\odot$  or  $\Theta$ .

Pressing the 🕤 or the Menu key to exit the menu will bring the user to the prior screen.

### Menu options during programming:



### Menu options during a feeding or pause mode:





Access to nutrition mode is not possible when the pump is running or in pause mode. If the user tries to access this mode while the pump is running or in pause mode, this screen will be displayed.

To access this mode, switch pump off and back on. Refer to section 5.3 to program a Nutrition mode.

## 5.2 Pump settings



Note: to lower the buzzer level, press and to turn it up, press  $\bigcirc$ . Once setting is chosen, press to validate.

# 5.3 Nutrition mode5.3.1 Code access for nutrition mode







Navigation through the nutrition mode is authorized by entering a 4 digit passcode.

The default code is «1234». This code may be changed by using the software.

Press O or O to scroll through the numbers, then press O to move on to the next digit. Repeat this operation until code is selected.





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## 5.3.2 Lock rate & volume mode

This mode allows the user to lock the flow rate and volume to be administered. Thus, if the patient is not able to program the pump on their own, the rate and volume to be administered could be previously programmed in the «Lock Rate & Volume».

This means that if the patient is not able to program the pump on their own, the flow rate and volume to be delivered can be pre-programmed in the «Lock rate & volume» mode by another user, and the patient will simply turn on the pump and start feeding.

# Important: «lock rate & volume» mode cannot be modified when the pause mode is activated during a feeding (see section 5.3.4).

«lock rate & volume» mode is deactivated if the pump is not used within 24 hours.

To set the «lock rate & volume» mode, follow the instructions below:

- Press oto select the mode (1).

- Press  $\odot$  or  $\Theta$  to use the «lock rate & volume» mode by selecting yes or no (2).

- Set the flow rate (3), choose the volume option (4) and adjust volume (5) by pressing  $\odot$  or  $\odot$ .

- Press on in order to move on to the next step.

- Check that the flow rate and the volume to be administred (6) correspond to the parameters chosen then press to save the settings. The display «settings saved» will appear after 2 seconds (7). Then the pump automatically goes back to priming or the review step, depending on where the user was before getting into the «lock rate & volume» mode.



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Once all the parameters have been selected, the «lock rate & volume» mode will be active and the logo  $\bigcirc$  will appear at the top of the screen. Once the parameters are locked and tubing has been primed (see section 3.5), a "review nutrition" screen will be displayed before launching the feeding.

Start nutrition

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Feeding running in «lock rate & volume» mode: Pause mode in «lock rate & volume» mode:



Note: to lock the keypad, refer to section 4.3.

### 5.3.3 Intermittent mode

This mode allows the user to program up to 8 bolus feedings\*. This will allow the user to switch on the pump and start the bolus feeding without programming. If patient cannot program the pump by himself, he will just have to switch on the pump and start the feeding because feeds would have been previously programmed in the intermittent mode by another user.

\*Nutrition mode where flow rate and volume are programmed.



Important: intermittent mode parameters cannot be modified when the pause mode is activated during a feeding (see section 5.3.4).

Intermittent mode deactivates if the pump is not used within 24 hours.

To set the intermittent mode, follow the instructions below:

- Press o to select the intermittent mode (1).
- Press  $\odot$  or  $\odot$  to use the intermittent mode by selecting yes or no (2).
- Choose the number of bolus feedings (3) (feeding + pause time) from 1 to 8.

- In the programing screen (4), adjust the flow rate  $\bigotimes$  (5), the volume [] (6) and the pause time between each feeding (7) by pressing O or O. Please note that to set the volume, it is not possible to « Use entire bag» option in intermittent mode.

- Choose to keep the same settings for all boluses or define new ones by pressing  $\odot$  or  $\Theta$  (8/9).

- End of programming: Final review screen appears (10). Check that total volume, total time and number of bolus feedings are correct then press  $\bigcirc$  to confirm the values.

The display «setting saved» appears for 2 seconds (11) and then the pump automatically go back to priming stage.



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### Note: it is possible to program a delayed feeding with the intermittent mode.

Different screens in intermittent mode:



Note: to lock the keypad, refer to section 4.3.

# 5.3.4 Nutrition mode deactivation

Programmed «Lock rate & volume» and «intermittent» modes are stored in the pump for 24 hours after the pump has been switched off.

To deactivate the «lock rate & volume» or «intermittent» mode, follow the steps below:

- After switching on the pump, press Menu to access the menu.

- Press igodot and igodot to select the nutrition mode (1) and press  $\bigcirc$  to confirm.

- Choose the mode to be deactivated (2) («lock rate & volume» or «intermittent» mode) by pressing  $\textcircled{\begin{tmatrix} \bullet \end{tmatrix}}$  and  $\boxdot$  and confirm by pressing  $\textcircled{\begin{tmatrix} \bullet \end{tmatrix}}$ .

- Select «no» (3) with O and  $\bigodot$  keys and confirm by pressing  $\bigcirc$ .





Note: during feeding, it is impossible to enter the Nutrition mode. To enter this mode, switch the pump off and on as the screens display below:





# 5.4 Pump data





## 6 Resuming an unfinished nutrition

It is possible to resume an unfinished feeding after the pump has been switched off. The pump stores the information linked to the previous feeding for 4 hours, as long as the volume programmed has not been reached (Total Fed < Volume  $\bigcirc$ ).

To resume feeding, prime the tubing and the pump will prompt to resume the previous unfinished feeding.



Press O or  $\bigodot$  to choose whether to resume feeding by selecting yes or no.

If you press and confirm «yes», a «Review nutrition» screen will indicate the status of the feeding to be resumed.

This function works in all modes.



If you press o to confirm the feeding will resume from the time it was stopped.

When feeding is interrupted, pump records the administered volume. Thus, when the pump is switched back on, it proposed to resume the unfinished nutrition with the same settings. Administration will keep going until reaching total volume previously programmed. In the example above, the patient received 650 mL and stopped the feeding. When the feeding is resumed, 350 mL will be administered to complete a targeted total volume of 1000 mL.





# 7 Stopping the pump

Easymoov6 pump may be stopped under the following conditions:

- Programming phase or menu
- Pause during feeding
- Alarm



Press and hold 🕑 for 3 seconds to stop the pump. The progress bar will fill up.

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The exit screen indicates the pump shutdown.

Important: rinse and clean the feeding tube and the pump set according to the rules of the facility. Do not use the pump set for more than 24 consecutive hours.

# 8 Alarms and trouble shooting guide

When an anomaly is detected, the pump will signal alerts and/or alarms visually and audibly:

- Beeping sounds
- Alarm light switched on
- Message on the screen

Alerts will not stop the feeding; alarms will stop the feeding.

In case of an alarm, press **o** to silence alarm. Then, correct the cause of the anomaly and press **o** to resume the feeding.

Note: alarm will start sounding again after 2 minutes of silencing. To silence it again for 2 minutes, press . The alarm will sound every 2 minutes until the problem is solved. Press again to resume feeding.

4 levels of alerts/alarms:

- Information: no sound & no LED
- Low priority alerts & alarms: specific sound & solid yellow LED (65.7dBA at 1 meter in maximum volume orientation)
- Medium priority alarms: specific sound & yellow LED flashing
- (65.7dBA at 1 meter in maximum volume orientation)
- High priority alarms: specific sound & red LED flashing
- (65.8dBA at 1 meter in maximum volume orientation)

When the alarm is muted, the user will have to solve the problem and restart the feeding again by pressing **•**.



When this icon is displayed on the screen, this means that the audible alarm is silenced for a period of 2 minutes.







# Alerts/Alarms messages and corrective actions:

DISPLAY	ALARMS	PRIORITY SOLUTIONS	
Cow battery  Low battery  Less than 30 min remaining  Dismiss notice  Running  Low battery  Low battery  Less than 30 min remaining  Dismiss notice	<b>Battery alert</b> - 30 minutes remaining - Indicates pump status (running, pause, intermittent mode) - Does not stop the feeding	Low	Charge the battery by connecting the AC adapter to the pump and power source
Connect to power Silence alarm	<b>Empty battery alarm</b> (5 minutes of battery life remaining) - Stops the feeding	High	Charge the battery by connecting the AC adapter to the pump and power source
Control II.09 <sub>MU</sub> End of nutrition less than 5 min Control II.09 <sub>MU</sub> Control II.09 <sub>MU</sub> Control II.09 <sub>MU</sub> Control II.09 <sub>MU</sub> Time left Control II.09 <sub>MU</sub> Time left Control II.09 <sub>MU</sub> Control II.09	<b>End of feeding alert</b> (5 minutes remaining in programmed feeding) - Does not stop the feeding	Low	- Wait until the end of the feeding, or - Pause the pump to modify the feeding settings, or - Switch the pump off

DISPLAY	ALARMS	PRIORITY	SOLUTIONS
Characteristics of the second	Programmed volume reached alarm	Medium	End of the feeding, switch the pump off or press to program a new feeding
Paused Nutrition paused longer than 15 min Silence alarm	Long pause alarm	Medium	Relaunch pause or resume feeding
Air or bag empty	Empty bag or air in the tubing alarm: - Stops the feeding Time to trigger an alarm at 1mL/hr: 16 min Time to trigger an alarm at 120mL/hr: 2 min	Medium	End of feeding or empty bag. In case of an unexpected «air» alarm, check that the tubing is properly positioned in its slot, disconnect from patient, then launch another automatic prime
Classical de la construcción de	Upstream set error: - Occlusion upstream of the tubing. - No tubing, or the tubing is not fitted properly into the slot of the ultrasound sensor. - Stops the feeding. Time to trigger an alarm at 1mL/hr: 11 min Time to trigger an alarm at 120mL/hr: 1 min	High	- Release upstream occlusion. - Make sure the tubing is correctly positioned

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DISPLAY	ALARMS	PRIORITY	SOLUTIONS
Cownstream set error	Downstream set error alarm: - Stops the feeding Occlusion between the pump and the patient Or; the Cassette is not positioned correctly between the two black pins Or; presence of feeding in the cassette branch between the two black pins (see picture below) Time to trigger an alarm at 1ml/hr: 95 min Time to trigger an alarm at 120ml/hr: 1 min	High	Release occlusion between pump and patient. Ensure that the branch of the cassette is empty Or Check the cassette and position correctly between the two black pins Note : if the alarm is still not resolved, replace tubing
Rotor error Rotor error Check set Contact tech support Phone: +33 139 926 415 questions@vygon.com Silence alarm	<b>Rotor failure alarm:</b> - Stops the feeding	High	Contact customer service
Battery error Battery error Contact tech support Phone: +33 139 926 415 questions@vgon.com Silence alarm	<b>Battery failure alarm:</b> - Stops the feeding	Medium	Contact customer service
System error System error Contact tech support Phone: +33 139 926 415 questions@vygon.com Silence alarm	<b>System error alarm:</b> - Internal failure or soiled black pins. - Stops the feeding	High	Contact customer service
Power indicator light remains off	Faulty power adaptor		Request a new AC adap- tor (see section 12.3).

# 9 Batteries

# 9.1 Charge

Easymoov6 pump runs on an internal NiMH battery that is not accessible to users. The pump is supplied with an uncharged battery.

Charging time: 2 hours 30 minutes.

To charge the battery, connect the pump using the power adapter supplied by Vygon. Important: battery must be fully charged before first time use.

This symbol indicates the pump is connected to a power source.

If the pump is stored for long periods, the battery must be recharged at least once every three months.

Room temperature during charging must be between 10°C (50°F) and 40°C (113°F).

# 9.2 Battery Replacement

It must be replaced by VYGON authorized personnel, who will dispose of the faulty battery according to appropriate regulations.

# 10 Maintenance

### 10.1 Cleaning

### **General Cleaning Directions**

Caution:

· Only personnel trained in the cleaning of medical devices should perform cleaning.

• Failure to follow the cleaning procedures described herein could result in hazards to users.

•WARNING: to avoid electrical shock never clean Easymoov6 pump or AC adapter with power plugged into an outlet or pump switched on.

• WARNING: prevent liquid from entering the pump to avoid electrical shock hazard, fire hazard or damage to electrical components. Do not submerge Easymoov6 pump or its accessories in water or cleaning solutions.

• WARNING: make sure the AC adapter is completely dry before plugging into an electrical outlet.

# **Cleaning Chemicals**

• A mild dish washing detergent in water solution should be used for general cleaning.

• To remove all visible soil, wipe down the pump with a non abrasive, a sponge or a soft cloth moistened with the cleaning solution.

• To remove soil from hard to reach crevices, use a soft brush.

• Caution: Use of cleaners and disinfectants other than the cleaning solution described in the instructions for use may cause significant damage to the pump and may void warranty.

# **Cleaning Frequency**

• It is recommended that the pump be cleaned to eliminate stains and soils after each tubing use or at least every day.

• A cleaning is also necessary when the pump is allocated to a new patient.

# Pump Housing Cleaning

Refer to General Cleaning Directions before starting.

• Clean outside surface with warm soapy water (mild detergent) and a non-abrasive sponge, paper towel or soft cloth.



### Pump AC adapter cleaning

- Refer to General Cleaning Directions before starting.
- AC adapter normally does not require cleaning. If soiling of AC adapter is observed, unplug from outlet and wipe the exterior surfaces of AC adapter with non-abrasive dry or slightly damp cloth.
  Allow excess moisture to evaporate from AC adapter prior to use.
- Caution: avoid exposing AC adapter to excess moisture, as this can lead to an electrical shock or fire hazard. The power adapter is rated IP40 which is not water resistant.

### **Rotor cleaning**

- Refer to General Cleaning Directions before starting.
- Open the cover.
- Use a cotton swab to clean the rollers thoroughly with mild detergent.

## Sensors cleaning

- Open the cover.
- Use a damp cotton swab to clean the sensors and the pathway where the cassette is seated.

### 10.2 Disinfection

### **Disinfection chemicals**

- Pump can be disinfected with the following solutions:
- An alcoholic disinfection spray suitable for medical device with less than 40% of alcohol.
- A 0.5% chlorine bleach mixture for a minimum duration contact of 10 minutes.

# Important: repeated disinfections with these solutions can damage the plastic housing.

### Important: device can not be sterilized.

### **Disinfection frequency**

• For better patient and personnel protection against the risks of contamination, clean according to the General Cleaning Directions and disinfect per facility guidelines is recommended daily for the housing surfaces of the device.

• It is necessary to clean and disinfect the pump after each use when these devices are used for multiple patients. This is to prevent spreading bacteria, viruses, and other germs between patients that interact with the same pump.

# 10.3 Storage

Clean Easymoov6 pump before storing it. When using Easymoov6 pump after extended storage, the battery must be fully recharged (see section 9.1).

- Easymoov6 pump must be stored in a cool, dry place:
- Storage temperature: 0 to 40°C (32°F to 104°F)
- Maximum ambient humidity is 93% without condensation.

## 10.4 Technical Maintenance

For safety reasons, and in order to retain the warranty, only persons authorized by VYGON can carry out maintenance on Easymoov6 pump.

Regular technical maintenance is recommended. In the event of faulty operation, technical maintenance must be carried out systematically.

For technical maintenance, contact:

VYGON Customer Service 8 rue de Paris 95440 Ecouen – France EXPORT:Tel.: +33 1 39 92 64 15 export@vygon.com

Pumps sent to the customer service must be returned in their original packaging, along with a description of the product defect and only after a Return Goods Authorization has been issued.

## 11 Warranty

Easymoov6 pump warranty covers technical faults occurring during normal use within 24 months of its delivery date, not including the battery for which the warranty is 6 months.

The warranty covers repair and replacement of faulty parts due to material and workmanship defects. Warranty is valid for the original purchaser only.

The warranty shall not apply if:

- Pump is damaged following inappropriate use, after being dropped or incorrectly stored
- Serial number has been changed

• Pump has been opened, repaired, altered or adjusted by personnel other than those authorized by Vygon.

• Pump has not been used with Easymoov6 tubing, battery or manufacturer power adapter. Pumps under warranty should be returned in accordance with the instructions.

For repairs, including during the warranty period, shipping, postage, insurance and call out costs to or from Vygon are at the customer's expense.

Vygon shall not be liable for loss of or damage to the device during transport to our customer service centre. With the exception of the obligations set out in this limited warranty, Vygon shall not be liable for direct or indirect damage or damage by natural forces, regardless of the damage, whether based on an agreement or the law or any other legal theory, even if Vygon has been informed of the potential damage.

If, upon receipt, pump packaging is damaged, you must ensure it is noted on the courier's paperwork.

## 12 Technical Specifications and Symbols

### 12.1 Specifications

Dimensions:  $5.4 \times 5.0 \times 2.5$  inches (H x L x D) Weight: 1.4 lbs (with battery) Casing: PC ABS V0 Protection: IP 44 Battery: 7.2V 2Ah NiMH (Nickel Metal Hybride) Display: LCD Front panel: 6 sealed keys Indicators: 4 lights Main power adapter: External AC/DC - IP 40 Input: 100 V ~240 V ~ 50 Hz - 60 Hz



Output: 12V direct current / 1.5A Charging temperature: 10°C (50°F) and 40°C (104F) Operating temperature: 5°C (41°F) to 40°C (104°F) Storage temperature: 0°C (32°F) to 40°C (104°F) Operating humidity: 15% - 93% RH non-condensing Storage humidity: < 93% RH non-condensing Operating and storage pressure: 700 hPa - 1060 hPa Operating and storage illuminance 50 lux - 3000 lux Keep away from sunlight in operating and storage

### 12.2 Performances

Pump with continuous volumetric rotary peristalsis for enteral feeding. Flow rate range: From 1 to 400 mL/h - Setting increments: 1 mL/h Accuracy:

Easymoov6 pump delivers the dose at the specified rate within +/-5% or 0.5ml/h, whichever is larger, for all delivery rates no matters the type of Easymoov6 giving set. The following conditions must however be respected:

- Using new Easymoov6 set for no longer than the recommended hours of usage
- Fluid head height at +6.0 inches  $\pm$  0.3 inches (+15.2 cm +/- 0.8 cm) with respect to center of rotor
- Fluid: water, commercially prepacked or prepared feeding solutions formulated for use with a feeding pump
- Room temperature 22+/- 2 °C (72 +/- 3 °F)
- Room pressure : 1000 +/- 60 hPa
- Back pressure: 0.05 bar

Confirmation of accuracy is conducted per the IEC 60601-2-24 standard for Infusion. Devices, as applicable for enteral feeding. For more information on pump accuracy, in particular for intermediate rate (120 mL/h) during 2 hours, see appendix A. Out of these bounds, the pump delivers the dose within +/-10% volumetric flow rate accuracy as essential performance.

### Single fault conditions:

Easymoov6 triggers an alarm when the following single fault conditions occur:

- Downstream occlusion
- Upstream occlusion
- Wrong set position
- Torque of rotor out of specifications
- System failure

Defaults in normal conditions:

Easymoov6 triggers an alarm when the following fault in normal conditions:

- Air presence
- Low battery charge
- Priming: automatic filling of the tubing at 600 mL/h for 1 minute 45 seconds
- Occlusion pressure: 0.9 bar +/- 0.2 bar (13 +/- 3 psi)
- Volume range: from 1 to 9,999 mL Setting increments: 1 mL
- Memorization of feeding parameters: 24 hrs

- Pause: 2 minutes, renewable - unlimited if deliberate

- Autonomy: 20 hours at 125 mL/h (fully charged battery)

(If the pump is out of battery and automatically switch off, the running feeding and/or the modes programmed will still appear when switching on the pump after the complete charge.) Charging time: 2 hours 30 minutes (depending on the state of the battery and the ambient temperature)

- Expected service life of Easymoov6 battery is 2 to 3 years of life, depending on usage.

- Pump and accessories are designed to provide a minimum of 5 years shelf life.

- Vygon may modify these specifiations without notice or obligation.

## 12.3 Accessories

REFERENCE	DESIGNATION	COMMENTS
1MVVPM6CHAx	AC adapter	Supplied with pump
1MWPM6ACP	Pole clamp	Supplied with pump
0VEPM6BAG	Compact backpack	Optional
0VESUPPOMP	Pump table holder	Optional

Use of Easymoov6 backpack:

- Install the set on the pump according to section 3.2.
- Feeding bag shall be hooked to the specific clip.
- Pump shall be placed in the bottom pouch.
- Program the feeding according to section 3.

Use of pole clamp:

- Install the pole clamp on the IV pole and make sure it is well fixed.
- Attach Easymoov6 pump to the pole clamp.
- Check everything is well fixed.
- Program the feeding according to section 3.

# 12.4 Compliance

Easymoov6 is an enteral feeding pump that complies with the following recognized standards:

- $\mbox{ }$  Electrical shock, fire, and mechanical hazards were mitigated according to IEC 60601-1 (3rd edition).
- Confirmation of accuracy was conducted per the CEI 60601-2-24 standard for Infusion devices, as applicable for enteral feeding.



# 12.5 Symbols

	Follow instructions for use in the Operator's Manual before operating Easymoov6 pump
RX	Federal (USA) law restricts this device to sale by or on the order of a physician
Ŕ	EN 60601-1 Type BF degree of protection against electrical shock: No electrical connection to patient drop from any angle from height of 3 feet (1 meter) shall not damage pump operation
	Class II equipment (degree of protection against electrical shock), double insulated
IP44	EN 60529 degree of protection : • Protected against tools, wires or solid foreign bodies with Ø > 1 mm • Splashed water from any direction shall have no effect
IPOX	EN 60529 degree of protection (adapter ): Not water resistant
MR	This pump is not intended for use in an MRI environment or in the presence of strong magnetic fields.
	Manufacturer
$\sim$	Date of manufacture
SN	Serial number
REF	Order reference
×	Keep away from sunlight (label located on box)
Ť	Keep dry (label located on box)
<u>(%)</u>	Humidity limitations (label located on box)
$\mathbf{X}$	Limit temperature (label located on box)
X	The pump is an electrical and electronic device and must be disposed according to WEEE Directives
<b>C E</b> 1639	CE mark: device complies with the requirements of European regulations.

### 13 Contact

Contact Vygon's customer service if you have additional questions:

### VYGON Customer Service 8 rue de Paris 95440 Ecouen - France EXPORT:Tel.: +33 1 39 92 64 15 export@vygon.com

### 14 Electromagnetic conformity declaration

Easymoov6 pump has been built and tested according to ES 60601-1 (3rd edition), IEC 60601-1-2:2007 and 60601-1-2:2014.

The pump is intended for use in the electromagnetic environment specified in the table. The user of the pump should ensure that it is used in such an environment.

Electromagnetic disturbances could cause disruption or malfunction of the pump with essential performance alteration.

See section 12.2 for essential performance details.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions					
Easymoov6 pump is intended for use in the electromagnetic environment specified below. Easymoov6 user should assure that it is used in such an environment.					
Emissions test	compliance	Electromagnetic environment - guidance			
RF emissions (CISPR 11)	Group 1	Pump uses RF energy for its internal function. Easymoov6 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.			
RF emissions (CISPR 11)	Class B	Pump is suitable for use in all establishments, including domestic establishments and those directly connected			
Harmonic emissions (IEC 61000-3-2)	Class A	to the public low- voltage power supply network that supplies buildings used for domestic purposes.			
Voltage fluctuations/ flicker emissions (IEC 61000-3-3)	Complies				
Radiated Disturbance Immunity (IEC60601-1-2/IEC 61000-4- 3:2006)	Complies				
Conducted Disturbance Immunity (IEC 60601-1-2/IEC 61000-4- 6:2013)	Complies				
Power Frequency Magnetic Field Immunity (IEC 60601-1-2/IEC 61000-4- 8:2009)	Complies				
Voltage dips and sags Immunity (IEC 60601-1-2/IEC 61000-4- 11:2004)	Complies				
Electrical Fast Transient / Bursts Immunity (IEC 60601-1-2/IEC 61000-4- 4:2012)	Complies				
Electrostatic Discharge Immu- nity (IEC 60601-1-2/IEC61000-4- 2:2008)	Complies				
Surge Immunity (IEC 60601-1-2/ IEC 61000-4- 5:2005)	Complies				

Guidance and Manufacturer's Declaration – Electromagnetic Immunity								
Easymoov6 pump is intended for use in the electromagnetic environment specified below. Easymoov6 user should assure that it is used in such an environment.								
Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment -Guidance					
Electrostatic discharge(ESD) (IEC 61000-4-2 per IEC 60601- 1-2:2014)	± 6kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.					
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment					
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differen- tial mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.					
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95% dip in UT )for 0,5 cycle 40 % UT (60 % dip in UT )for 5 cycles 70 % UT (30 % dip in UT )for 25 cycles < 5 % UT (>95 % dip in UT ) for 5 sec	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	Main power quality should be that of a typical commercial or hospital environment. Esaymoov6 pump allow continued operation during power mains interruptions via the internal battery.					
Power frequen- cy (50/60 Hz) magnetic field (EN IEC 61000- 4-8 per EN IEC 60601-1-2: 2014)	30 A/m	Class 2 (30 A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.					

**NOTE:** UT is the A.C. main voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity						
Easymoov6 pump is intended for use in the electromagnetic environment specified below. Easymoov6 user should assure that it is used in such an environment.						
Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment -Guidance			
Conducted RF IEC 61000- 4-6 Radiated RF IEC 61000-4-3	3 V from 150 kHz to 80 MHz 6 V in ama- teur radio bands 10 V/m from 80 MHz to 2,7 GHz	3 V 6V 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Easymoov6 pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance : $d=1,2\sqrt{P}$ $d=1,2\sqrt{P}$ 80 MHz to 800 MHz $d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with the following symbol:			

NOTE 1: at 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2:** these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radiobroadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Easymoov6 enteral feeding pump is used exceeds the applicable RF compliance level above, Easymoov6 pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Easymoov6 enteral feeding pump.

 $^{\rm b}$  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# Recommended separation distances between portable and mobile RF communications equipment and Easymoov6 pump

Easymoov6 pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Easymoov6 pump can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and Easymoov6 pump recommended below, according to the maximum output power of the communication equipment.

Rated maximum						
output power of	Separation distance according to frequency of transmitter					
transmitter						
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,7 GHz			
	d= 1,2√P	d=1,2√P	d = 2,3√P			
0,01	0,12	0,12	0,23			
0,1	0,38	0,38	0,73			
1	1,2	1,2	2,3			
10	3,8	3,8	7,3			
100	12	12	23			

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1:** at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**NOTE 3:** An additional factor of 10/3 has been introduced into the formulae used in the calculation of the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz; this is intended to reduce the likelihood of interference that mobile/portable communications equipment could cause, if inadvertently introduced into the patient's areas.

**NOTE 4:** these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and by reflexions from structures, objects and people.

**WARNING:** use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**WARNING:** use of an AC adapter other than those specified or provided by manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**WARNING:** portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Easymoov6 pump including AC adapter specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.





## Appendix A - Accuracy Graphs

The following graphs illustrate the accuracy of the pump per the IEC 60601-2-24 standard. The graphs are shown for the intermediate rate 120 mL/hr for 2 hours and 24 hours.





### Accuracy Trumpet Curve 2nd Hour at 120 mL/hr Rate



### 8th Hour Curve on Accuracy

8th Hour Accuracy Curve at 120 mL/hr Rate



Accuracy Trumpet Curve 8th Hour at 120 mL/hr Rate



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# NOTES

# 23rd Hour Curve on Accuracy 23rd Hour at 1 mL/h



# Accuracy Trumpet curve 23rd Hour at 1 mL/h







# NOTES



Medwin 9 Allée de la Vigne Grande 34600 Les Aires - FRANCE

> Vygon 5 rue Adeline 95440 ECOUEN - FRANCE Tel :+ 33 (0)1 39 92 64 15 Fax :+ 33 (0)1 34 29 19 34 www.vygon.com - questions@vygon.com

