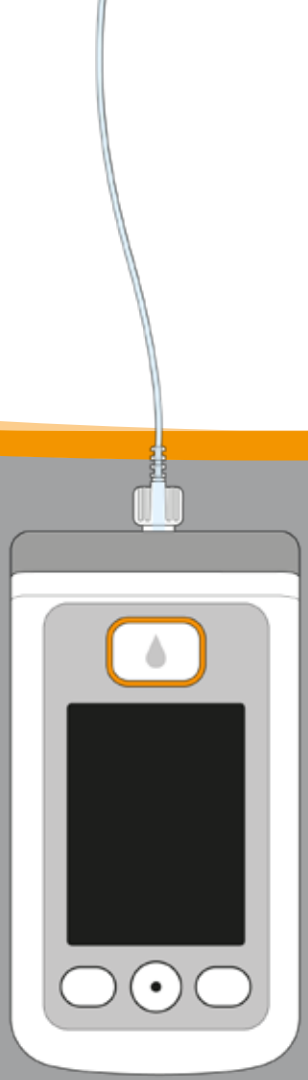
EVER Pharma D-*mine*® Pump

Instructions for Use



WELCOME

These Instructions for Use are intended for patients, their carers, and the medical professionals that use the EVER Pharma D-*mine*® Pump.

You have decided in consultation with your physician to administer your apomorphine therapy using an EVER Pharma D-*mine*® Pump. In order to ensure that you can safely handle your new device, it is important that you first become thoroughly familiar with it. Read these Instructions for Use carefully and discuss the handling of the pump and its accessories with your carer or your physician. In case of uncertainties, you can also telephone the Apomine® Nurse Support Service (ANSSER - phone: 1800 276 646) which is available to you during business hours, Monday to Friday (AEST).

Intended Use

The EVER Pharma D-*mine*® Pump is a medical device for safe and reliable subcutaneous delivery of the drug apomorphine at a concentration of 5 mg/mL for the treatment of Parkinson's disease.

USING THE EVER PHARMA D-*mine*® PUMP

Before starting drug administration, with the aid of the pump you will fill the reservoir with the drug contained in the vial. The pump is connected to your body via an infusion set and provides your body with a continuous supply of apomorphine. This form of therapy is referred to as **apomorphine pump therapy**.

This pump is only validated for use in Australia with Apomine® solution for infusion (apomorphine hydrochloride hemi-hydrate) from the Australian Sponsor.

The quantity of apomorphine that is automatically delivered over the course of a day is referred to as the **basal flow rate or basal rate**. Your physician adjusts it individually to suit your requirements. The basal rate settings for a day are referred to as the **basal profile**.

A **bolus** is an additional apomorphine administration by which apomorphine is delivered to your body at the push of a button if required. Your physician also presets the bolus amount to suit your requirements.

Your physician defines the dosing of the drug by means of the **delivery settings**. You must not change these unless instructed to do so by your physician.

INDICATIONS AND CONTRAINDICATIONS

The EVER Pharma D-*mine*® Pump is a portable infusion pump for subcutaneous infusion under outpatient conditions. It is not suitable for intravenous, intra-arterial, intraperitoneal, epidural or intrathecal infusion.

The EVER Pharma D-*mine*® Pump is intended for the infusion of 5 mg/mL apomorphine, which is available as a medicinal product in a 20-mL vial from InterPharma Pty Ltd.

The EVER Pharma D-*mine*® Pump is intended for use by adult patients, relatives and medical professionals. Patients with limited dexterity should seek assistance from their carers.

Please also refer to the patient information leaflet enclosed with the pharmaceutical product.

Please note the following usage instructions:

- Infusion pumps must only be used under professional, medical supervision (physicians, nurses).
- If used improperly, infusion pumps pose a serious health risk to the patient.
- The instructions for use of the infusion set used must be followed. Special attention should be paid to the sterile handling and the regular change of the injection site.
- Patients with cognitive impairment should not use the pump. The decision on a sufficient qualification is incumbent on the attending physician.

PRECAUTIONS

Change the insertion site each time you use the EVER Pharma D-*mine*® Pump. Do not inject into skin areas that are sore, reddened, inflamed or injured.
Only use an original and sterile EVER Pharma D-*mine*® Pump reservoir and follow the filling procedure strictly as described in these instructions.
For further information please read the patient information leaflet related to the pharmaceutical product available from your pharmacist.

Please read these instructions for use carefully and completely before you use the pump for the first time.

Keep the device away from small children and animals. The cable poses a risk of strangulation and the small parts pose a risk of choking.

CONTENTS

INTRODUCTION

The following symbols will help you to quickly find the information you need in these instructions for use:

This symbol indicates general notices and tips.

This symbol indicates warnings which you must always heed when using the pump in order to avoid possible risks to your health.

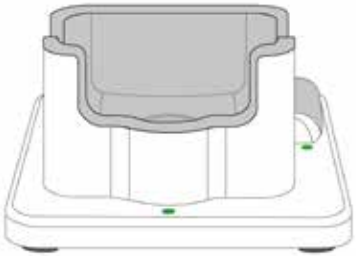
Section 4.2 This is how references to other sections will appear in these instructions for use.

1 2 3 The steps described in the instructions for use are numbered. Follow the sequence indicated when operating the pump.

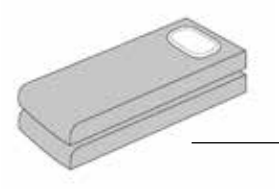
YOUR EVER PHARMA D-*mine*® Pump BOX CONTAINS:

EVER Pharma D-*mine*® Pump

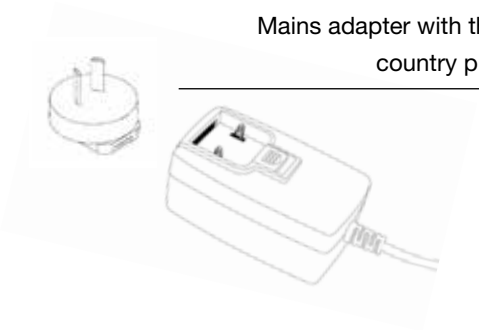
Carrying bag with
adjustable strap



Docking station



Two rechargeable batteries



Mains adapter with three country plugs

PUMP

The pump controls administration of the drug. It functions only in conjunction with a reservoir and a rechargeable battery.

RECHARGEABLE BATTERIES

The rechargeable batteries supply the necessary power to the pump. The second rechargeable battery can be charged at any time in the docking station.

DOCKING STATION

The docking station has three functions:
Charging the two rechargeable batteries and being a holder for the pump and vial during preparation.

MAINS ADAPTER WITH INPUT CONNECTOR

Use the power supply with one of the three included country plugs.

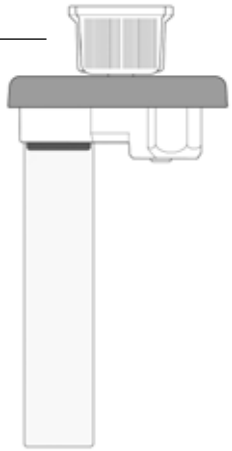
CARRYING BAG

The carrying bag provides a comfortable option to carry the pump on your belt, with the strap around your neck or diagonally across your body.

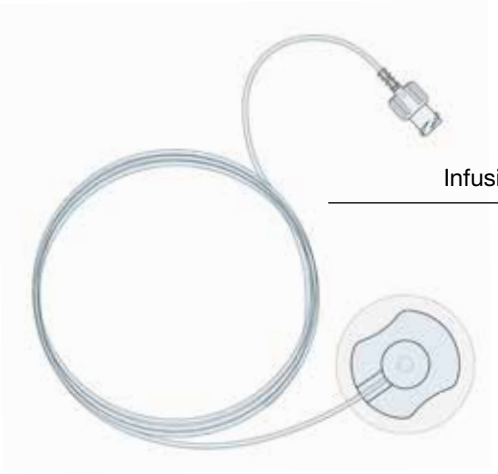
DISPOSABLE ACCESSORIES

Adapter

Reservoir



Infusion set



Vial

D-*mine*® Pump RESERVOIR

The reservoir serves as a receptacle for the drug. It must only be used once and is replaced each time a new vial is used.

Before starting drug administration, with the aid of the pump you will fill the reservoir with the drug contained in the vial.

ADAPTER

The adapter connects the reservoir to the vial during the filling process. It is already pre-attached to the reservoir when you remove the reservoir from the packaging.

INFUSION SET

The infusion set connects the pump to your body. The infusion set, like the reservoir, must only be used once and should be replaced at the latest when a new reservoir is used.

VIAL

Apomine® Solution for Infusion which has been prescribed to you by your physician is supplied in a 20-mL vial.

All disposable accessories must only be used once.

See Section 9 to find out where you can obtain disposable accessories.

NOTES FOR USE OF YOUR EVER PHARMA D-*mine*® Pump AND FOR YOUR SAFETY

To avoid health risks, observe the following warnings and safety notes when using the EVER Pharma D-*mine*® Pump. Please read these warnings and safety notes carefully before using the pump for the first time.

⚠ Before using the pump

- Only use the EVER Pharma D-*mine*® Pump if it has been prescribed to you by your physician.
- The infusion pump may only be used by persons who have been instructed in the operation of the pump.
- Never use a pump, reservoir, adapter, battery or docking station that is damaged
- The reservoir, the adapter, and the infusion set are sterile in their packaging. Do not use sterile products if their packaging is damaged or missing.

⚠ While using the pump

- Handle the device with clean hands. In particular, avoid all contact between the connection components of your pump and cosmetic products such as soaps, perfumes, body lotions, etc.
- Always follow the sequence of the steps indicated in the instructions for use.
- Avoid contact of the pump with water.
- Always carry the pump accessories with you. This enables you to charge or replace the battery if required.
- The reservoir, the adapter, and the infusion set are sterile in their packaging. Do not use sterile products if their packaging is damaged or missing.
- Use sterile products only once. Reuse of such materials can result in an infection.

1

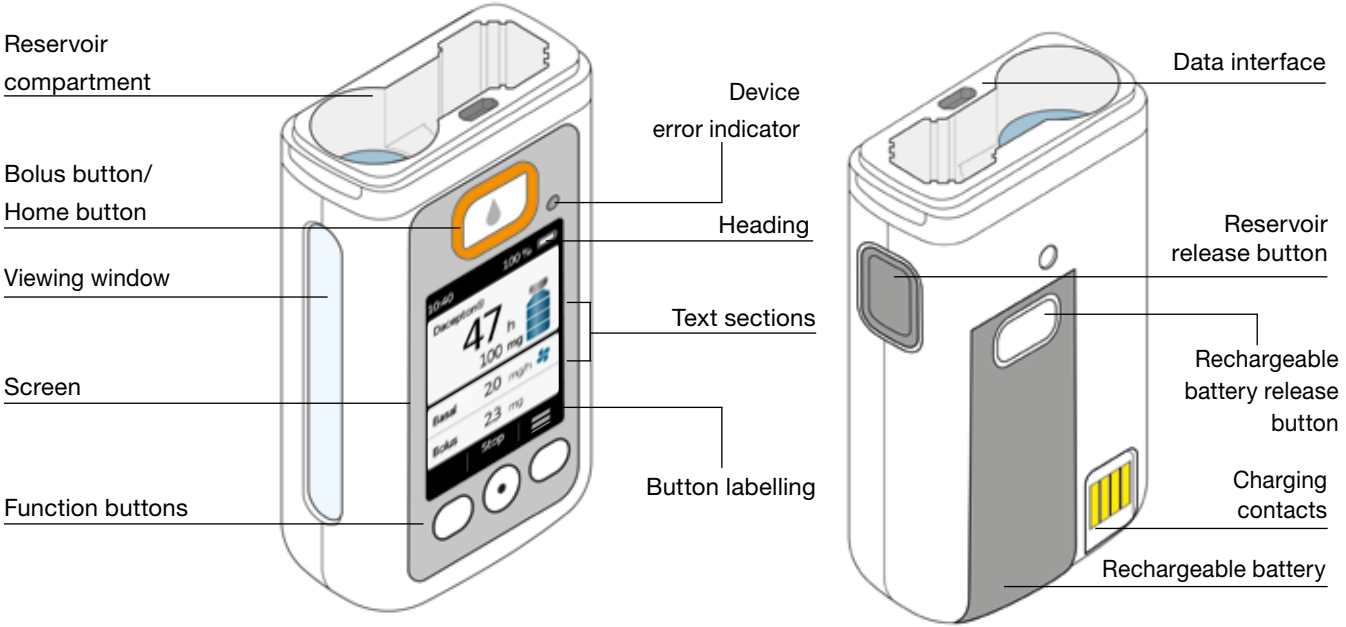
GENERAL INFORMATION ON OPERATING THE SYSTEM

1.1 Operating the EVER Pharma D-*mine*® Pump

1.2 Operating the docking station

1

1.1 THE EVER PHARMA D-*mine*® Pump



BOLUS BUTTON

The bolus button enables fast delivery of a bolus.

Section 4.2

When pressed and released quickly, the bolus button serves as “Home button” and the main screen will be shown.

DEVICE ERROR INDICATOR

A signal light is integrated on the front side of your pump. It will flash red if the internal check of the pump has detected an error. In such cases, drug delivery is discontinued and an audible signal is emitted.

Section 7.2

RELEASING THE RESERVOIR

When the reservoir is inserted into the pump it will snap into place audibly. You can release the reservoir and remove it by pressing the release button at the right side of the pump.

SCREEN

The pump is equipped with an illuminated colour screen which provides you with important information concerning pump status, drug delivery, alarms, etc. The screen will switch off automatically if you do not operate the device for more than one minute. You can switch the screen on again anytime by pressing any function button.

The screen of your pump is divided into four sections:

The **heading** displays general information, such as time and state of charge of the rechargeable battery. While you are operating the pump, the device shows you the progress of that particular function.

The two **text sections** display the most important information concerning the operation and control of the pump.

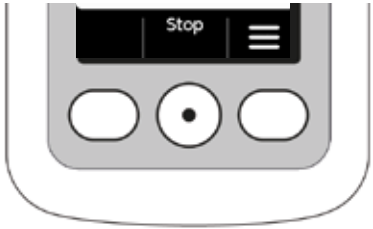
The **function button section** at the bottom provides a description of each of the function buttons.

FUNCTION BUTTONS

Three function buttons are provided to operate the pump. These are located below the screen.

The function of these 3 buttons changes, depending on the selected mode. The current function of the buttons is always indicated in the function button section of the screen. They are presented in these instructions for use as follows:

Example



It is possible that all three function buttons are disabled. If this is the case, the corresponding field in the function button section will remain empty. By holding the funtion buttons “up” or “down”, the counter inceases or decreases automatically.

DATA INTERFACE

The data interface is exclusively intended for data communication and is not a charging port for the rechargeable batteries.

BUTTON LOCK

When the screen is switched off, the function buttons are locked. To disable the button lock, proceed as follows:

1. Press any function button. The screen will switch on.

2. Press  . The device will unlock all buttons.

VIEWING WINDOW

The fill level of the reservoir can be checked through the viewing window in the pump housing.

AUDIBLE SIGNALS

Your pump brings important events during operation to your attention with the aid of audible signals.

You can adjust the volume of these signals.

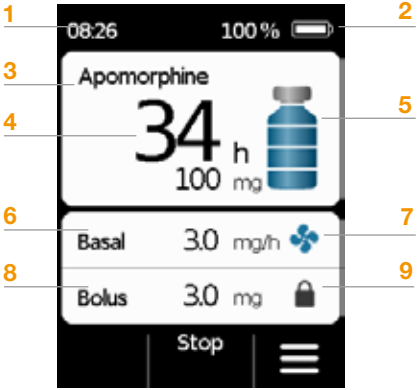
Alarm signals

ERROR	Signal sequence: two consecutive, equally short audible signals that repeat every 16 seconds
WARNING	Signal sequence: four short audible signals, two each in alternation

Notice signals

OK	a short, high audible signal
Not OK	a long, deep audible signal
Ready	three long audible signals, ascending tone sequence
Finished	three short audible signals, descending tone sequence

THE MAIN SCREEN OF THE PUMP



1 Current time

2 State of charge of the rechargeable battery

3 Drug name

4 Time and mg left until the reservoir is empty

> The value indicates the remaining time until the reservoir is empty, if the drug is delivered at the currently set basal rate.
> The actual time will be shorter if you deliver additional boluses. If the basal rate is set to 0 mg/h, no time indication will be shown!

5 Filling level of the reservoir: one bar is equivalent to 25%

6 Currently set basal rate in milligrams per hour

7 Symbol appears when delivery of the basal rate is enabled

8 Currently set bolus amount in milligrams

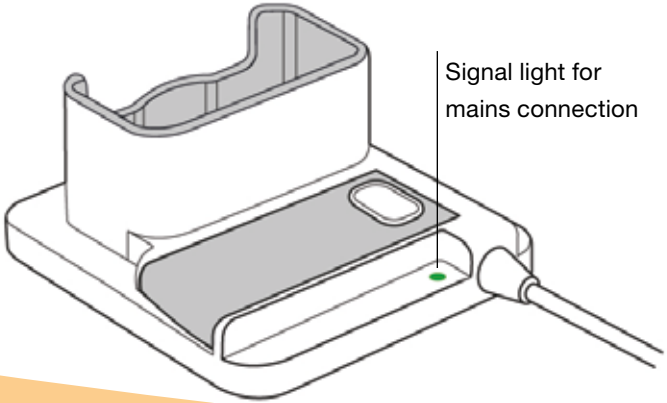
9 Symbol appears when delivery of the bolus is locked

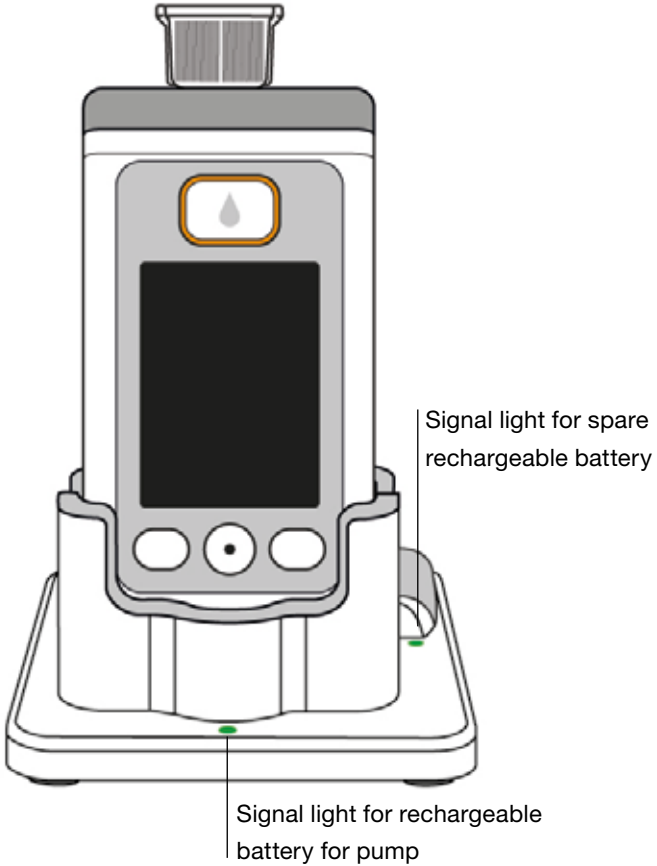
1.2 OPERATING THE DOCKING STATION

The docking station has three functions:

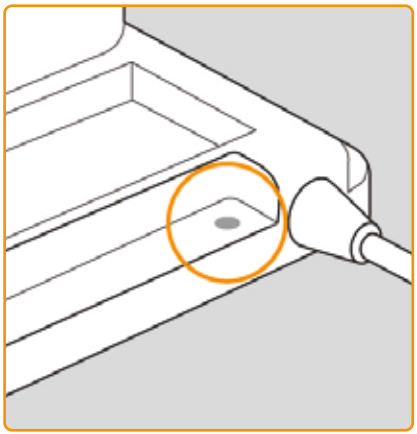
- Charging the two rechargeable batteries
- Holder for the vial
- Holder for the pump during preparation

⚠
- If the docking station malfunctions, the rechargeable batteries cannot be charged.
- Do not forget to take the docking station with you.



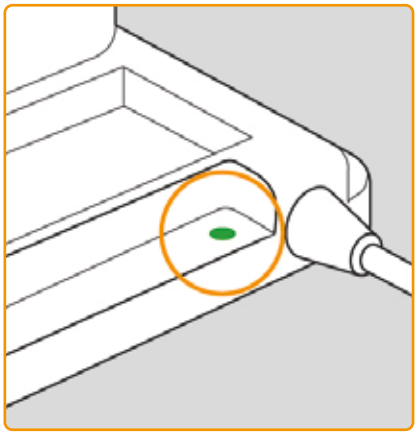


SIGNAL LIGHTS MAINS CONNECTION



OFF

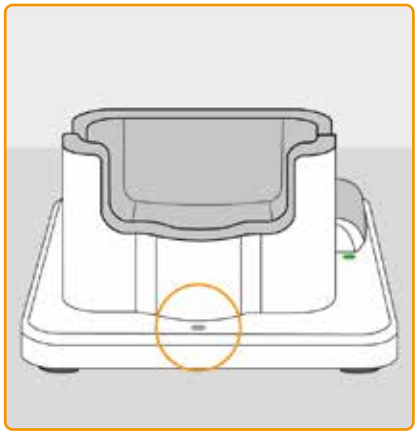
The docking station is not connected to the power supply.



GREEN

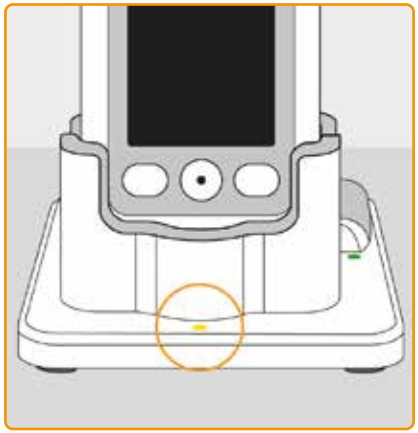
The docking station is connected properly to the power supply.

RECHARGEABLE BATTERY FOR PUMP



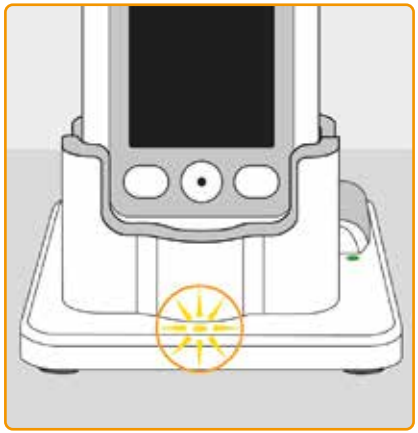
OFF

No device in the docking station or rechargeable battery for pump not connected properly



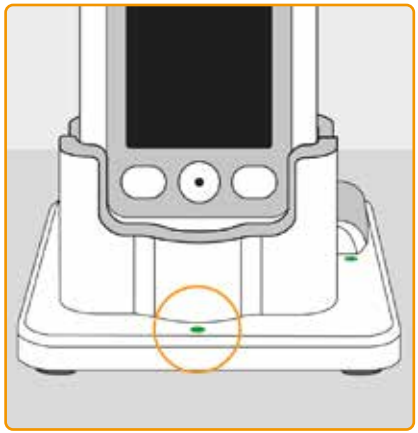
YELLOW

Rechargeable battery for pump connected to docking station, charging is in progress



YELLOW, FLASHING

Error during charging of rechargeable battery for pump, see Section 7.5.2

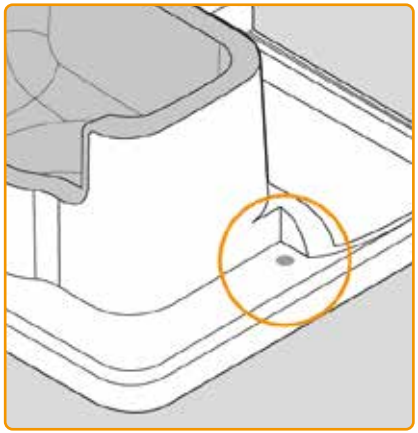


GREEN

Rechargeable battery in the pump fully charged

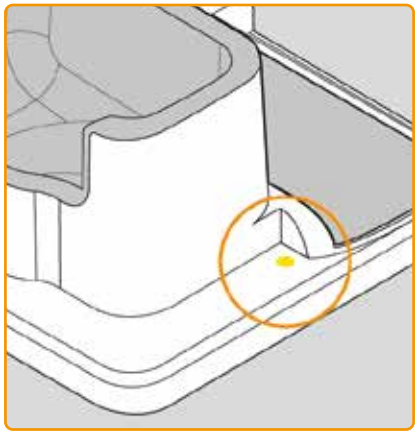
The pump and rechargeable battery can be removed from the docking station at any time without damaging them. It is not necessary to completely recharge the rechargeable battery.

SPARE RECHARGEABLE BATTERY



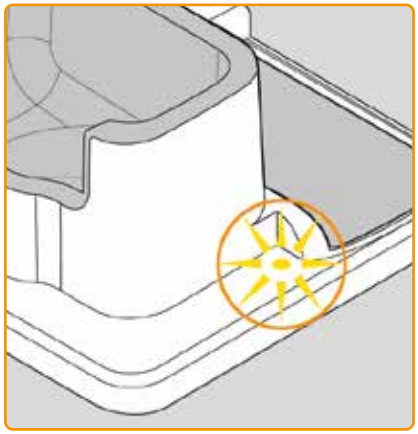
OFF

The spare rechargeable battery is not inserted.



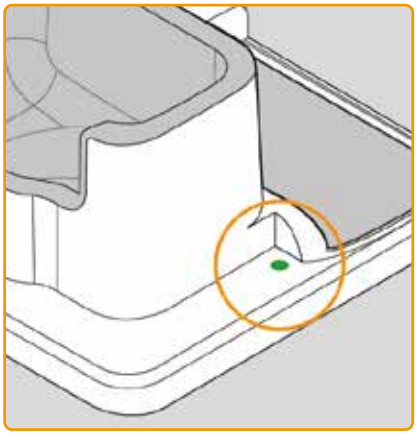
YELLOW

The spare rechargeable battery is inserted, charging is in progress



YELLOW, FLASHING

Error while charging, see Section 7.5.2



GREEN

Spare rechargeable battery fully charged

2

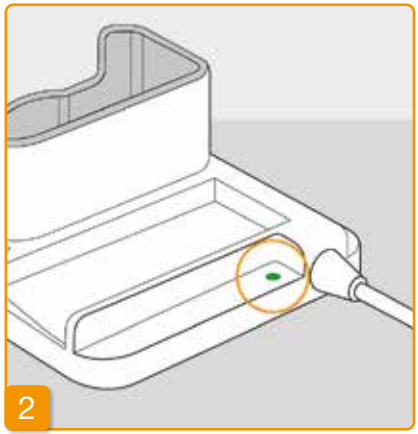
PREPARING THE PUMP FOR USE

2.1 Preparing the docking station for use

2.2 Rechargeable battery and basic settings

2

2.1 PREPARING THE DOCKING STATION FOR USE



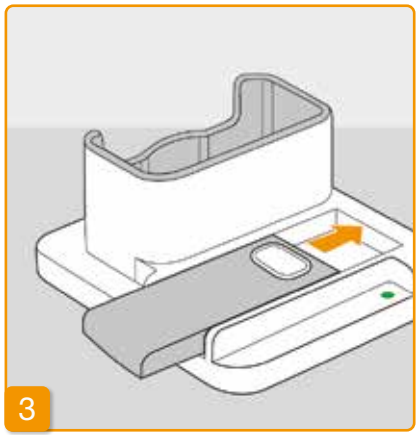
Use only the docking station supplied with the device to charge the pump and the rechargeable batteries.

Attaching the input connector to the mains adapter

Remove the docking station from the packaging. Connect the country-specific plug to the mains adapter. The input connector will snap into place with an audible click.

Connecting the docking station to a socket

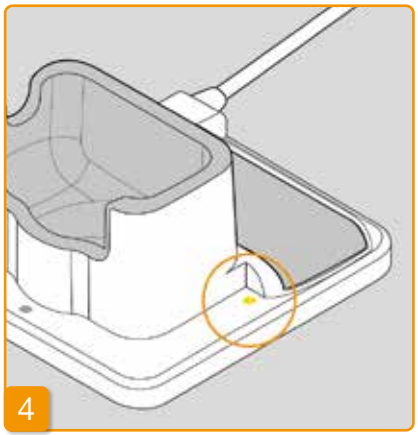
Connect the docking station to a socket. The signal light directly next to the connection will light up green.



Insert the spare rechargeable battery into the docking station

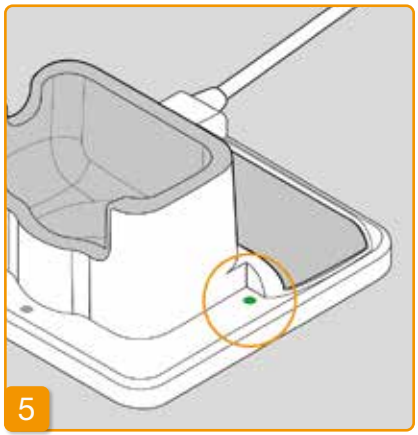
Remove one of the two rechargeable batteries from the packaging. Insert the rechargeable battery by sliding it into the docking station.

The rechargeable battery will snap into place with an audible click.



The signal light for the **spare rechargeable battery** will light up yellow. The spare rechargeable battery is charging.

ⓘ If the signal light for the **spare rechargeable battery** flashes yellow, this indicates that the docking station has detected an issue with the spare rechargeable battery. See Section 7.5.2



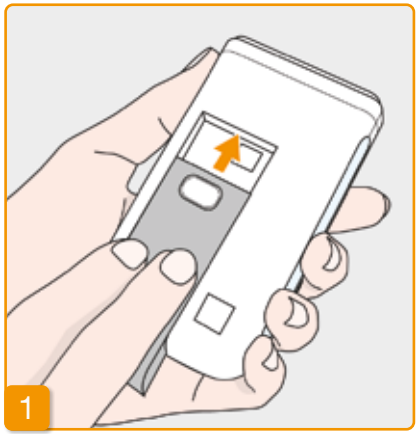
As soon as the spare rechargeable battery is fully charged, the **spare rechargeable battery** signal light will switch from yellow to green.

ⓘ Leave the spare rechargeable battery in the docking station. In this way, it will always be ready for use.

2.2 RECHARGEABLE BATTERY AND BASIC SETTINGS

⚠ The basic settings of the device can only be adjusted by medical professionals.

ⓘ If the pump has been stored for a prolonged period without a battery, then the screen could remain black when the battery is first inserted. Wait a few seconds, remove the rechargeable battery, and repeat the procedure with a charged battery.
If the pump is used for the first time or has been stored for a long time without a battery, leave the battery in the pump for at least 8 hours to fully charge the spare battery.



Inserting the rechargeable battery into the pump

Remove the pump and the second rechargeable battery from the packaging. Insert the rechargeable battery into the pump. The rechargeable battery will snap into place with an audible click. The pump will emit a short audible signal.

Greeting

Confirm the greeting with ✓.

3

Setting the language

Press the ▼ and ▲ buttons until the desired language has a blue frame around it.

Then press ✓. All texts on the screen of the pump are now displayed in the selected language.

4

Start the settings process

The pump guides you through the settings step by step. You can follow the progress by observing the points displayed in the navigation field. Press ✓ to navigate to the next step. Press ◀ to return to language selection.

5

Setting the drug

Select the name of the drug using the ▼ and ▲ buttons, then press ✓. The selected name is always displayed on the main screen.

6

Setting the hour

Press − or + until the current hour is displayed, then press ✓.

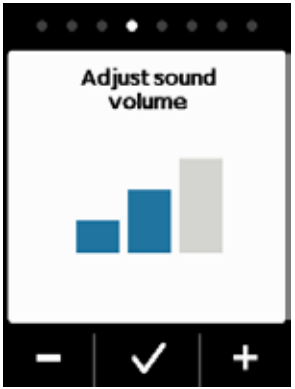
7

Setting the minutes

Repeat the process above until the current minutes are displayed.

Press ✓ when the minute value is correct.

ⓘ The same procedure is applicable for setting the date.



8

Adjust sound volume

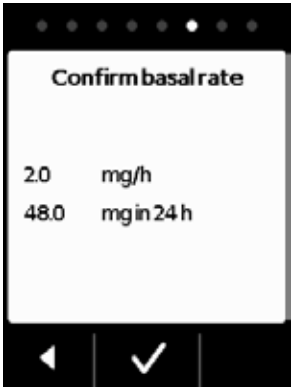
You can set the desired sound volume of the audible alerts with the − and + buttons. Press ✓ to save the setting.

ⓘ This setting only affects audible alerts. This does not change the alarms.

9

Set basal rate

You can alter the value in increments of 0.1 mg/h with the − and + buttons. Set the desired basal rate, then press ✓.



10

Confirm basal rate

Check the daily dose. Press ✓ if the value displayed is correct.

Press ◀ to return to basal rate setting.

> You can select between min. 0.0 mg/h and max. 15.0 mg/h. Please refer to the patient information leaflet and observe the maximum drug dose allowed per hour.

11

Setting the bolus dose

You can alter the bolus dose in increments of 0.1 mg/h with the − and + buttons. Set the desired bolus dose, then press ✓.

12

Setting the number of boluses

Set the number of boluses permitted using the − and + buttons, then press ✓.

ⓘ It is possible to adjust the bolus delivery amount between 0.0 mg to max. 10.0 mg. 0 to max. 20 boluses possible. Timespan is calendar day (24 hours). Lockout time of 0 min to max. 12 h possible.

13

Setting the lockout time

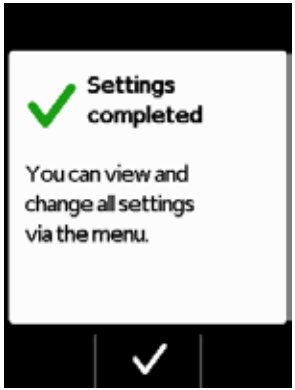
Set the desired lockout time using the − and + buttons, then press ✓.

14

Confirming the bolus settings

Check to ensure that the delivery settings displayed, and in particular the daily dose, are correct. If this is the case, press ✓.

If the settings displayed are not correct, press ◀ and return to page 38.



15

Confirming the settings

Confirm completion of the settings with ✓.

For the instructions for applying and starting the pump, see
Section 3.1

ⓘ You have now set the same basal rate for 24 hours. In the menu you can also set different basal rates for up to 5 time periods within 24 hours.

RESERVOIR AND INFUSION SET

3

3.1 Inserting the reservoir

3.2 Connecting the infusion set

3.3 Checking the readiness of the pump

3.4 Starting and stopping drug delivery

3

3.1 INSERTING THE RESERVOIR

To use the reservoir, you will need:

- a new vial of Apomine® from InterPharma Pty Ltd
- a new reservoir
- a new infusion set
- a docking station for maintaining the pump upright
- a pump

Check whether you have received the correct drug, a new reservoir and infusion set, and whether the vial is new.

⚠ Only use completely filled apomorphine vials in accordance with your prescription. The use of expired, incompletely filled or damaged vials can impair the efficacy of the therapy and endanger your health.

⚠ Never use a reservoir if its packaging is damaged. If the packaging is damaged, the reservoir is no longer sterile and could be contaminated.

⚠ Never use a reservoir more than once.

ⓘ The rechargeable battery does not have to be fully charged in order to use the reservoir.

Preparing a new reservoir

Wash your hands thoroughly before working with sterile parts.
Check to ensure that the packaging is not damaged and that the date on the package has not expired.
Remove the reservoir from the sterile packaging.

Attach the reservoir to the pump

Insert the reservoir into the opening on the pump as shown. The reservoir will snap into place with an audible click.

⚠ Do not touch the interior of the adapter when inserting the reservoir.
Risk of injury and risk of loss of sterility.

Selecting the reservoir

The pump detects that a reservoir has been inserted, but not whether the reservoir is empty.
Use the ▲ and ▼ buttons to select "New reservoir" and confirm with ✓.

ⓘ Selecting "Same reservoir" will return you to the main menu.
"Same reservoir" is not displayed when the reservoir is first inserted.

4

Self-test of the pump

The pump performs a self-test. The electronic system on the device is checked to ensure that it is functioning properly. This includes the audible signals. Therefore, pay attention during the test to determine whether you can hear two short audible signals. If you did not hear any audible signals or only one audible signal, proceed to Section 7.6.

5

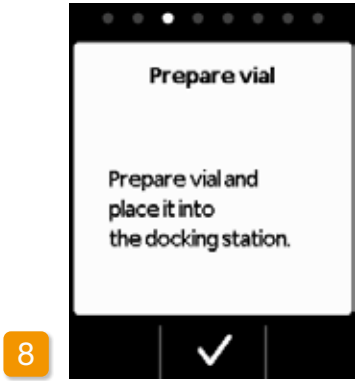
Confirming the self-test

Confirm the completion of the test with ✓.

6

Prepare vial

Take a new drug vial. Make sure that the vial contains your prescribed medication and that the date on the vial has not expired.



Remove protective cap

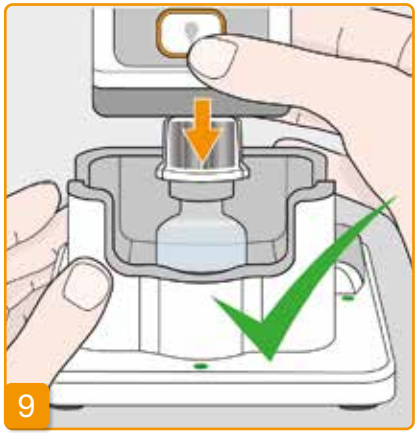
Remove the orange cap from the vial.

Insert vial

Place the vial in the space provided for this purpose in the docking station. The seal of the vial is sterilised.

If contamination is suspected, you should disinfect the cap with an alcohol swab.

Confirm with ✓.



Attaching the pump with reservoir and adapter to the vial

Turn the pump with the reservoir and tightened adapter upside down and attach it vertically to the vial from above as depicted. The adapter will snap into place on the vial with an audible click.

⚠ The vial must always be held upright when attaching the pump.

⚠ Do not touch the interior of the adapter when attaching the pump. Risk of injury on spike and risk of loss of sterility.

Confirm with ✓.

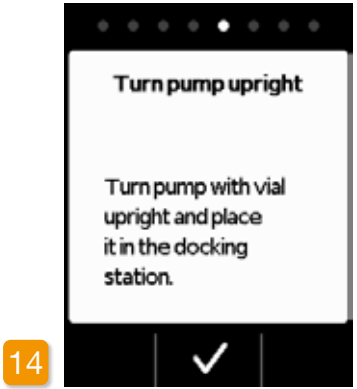
Turning the pump

Turn your pump with the vial attached and place it in the docking station. The pump must remain upright during the filling process.

Check placement of adapter

Before you start the filling process, check the placement of the adapter on the reservoir in the pump. To do so, gently turn the adapter with the vial to the right (clockwise).

If the "No vial" or "Incorrect vial" message appears instead of the level indicator, then the test of the vial has detected an error. Return to Step 6 and repeat the process with a new vial.

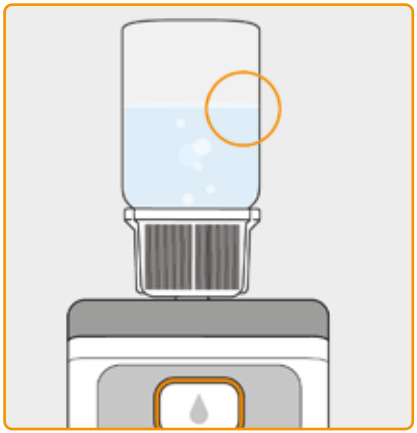


Starting the filling process

Press ✓ to start filling the reservoir. The device pumps the drug from the vial into the reservoir. This process takes a few minutes. You can follow the progress on the screen.

The pump must remain upright during the entire filling process. If not, air could get into the reservoir.

Do not remove the vial until the filling process is completely finished and confirmed with a signal.



Filling reservoir

During the filling process, you can observe how the drug is pumped out of the vial and into the reservoir. Filling the reservoir takes about six minutes.

Observing the filling process

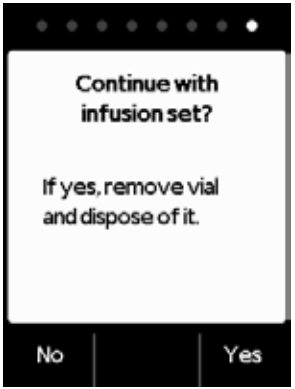
Air bubbles will form in the liquid during the filling process.

You can observe how the stopper moves in the reservoir through the viewing window.

Confirming the completion of filling

The pump will notify you with a signal as soon as the reservoir is full. Turn the pump over and check in the viewing window if the reservoir is filled with liquid, then press ✓.

ⓘ If an error message is displayed during filling, return to step 3. A small residual amount will always remain in the vial.



15

To proceed immediately with the connection of an infusion set, remove the vial and press Yes.

16

Remove and dispose of vial

Grip the vial by the adapter and remove both vial and adapter from the reservoir by turning them to the left (counterclockwise). Dispose of these components with the household waste in accordance with Section 9.5.

If you wish to connect the infusion set at a later time, then leave the vial on the pump until that time and press No. This will take you to the main screen, where you can then select "Change infusion set" in the menu in Section 4.3 to proceed.

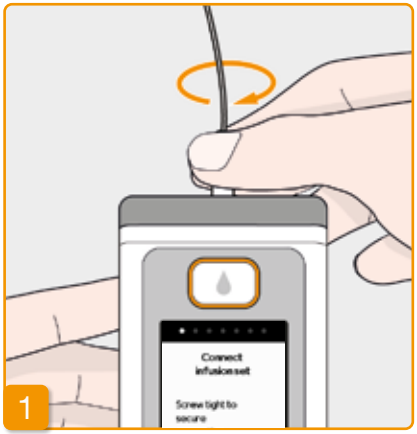
⚠ After removing the vial, the port for the infusion set is readily accessible. Avoid touching the port or any contact between the port and other objects to ensure that the port remains sterile.

3.2 CONNECTING THE INFUSION SET

CONNECTING, PREPARING, AND PRIMING THE INFUSION SET

⚠ If the port on the reservoir is soiled, replace the soiled reservoir with a new one.

⚠ Only use infusion sets with needle diameters between 28 and 31 gauge.



Connect infusion set

Check to ensure that the threaded connection on the reservoir is still clean. Remove a compatible infusion set from the packaging and connect it to the reservoir of your pump.

Tighten the threaded connection securely to ensure that the infusion set does not loosen during drug delivery.

Confirm the procedure with ✓.

⚠ If the infusion set connection is not adequately tightened, it could start leaking, leading to an incorrect dose or no delivery of the drug. Overtightening the threaded connection can damage the connection point.

2

Stand pump with the infusion set in docking station

The pump must remain upright during the next step to ensure that any air is removed from the reservoir. To do so, place your pump with the connected infusion set in the docking station.

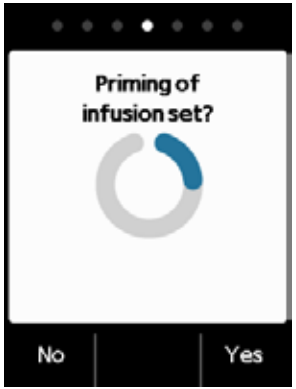
Then press ✓.

3

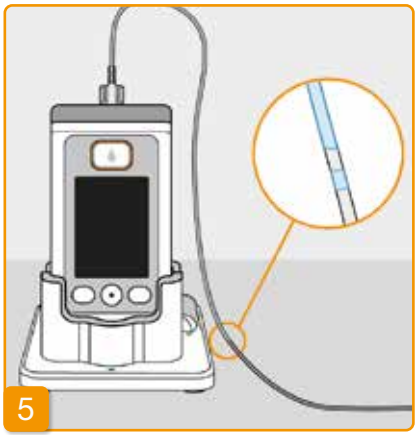
Pump is being prepared

The pump will switch on for a few seconds while the reservoir is prepared for drug delivery. At the end of this process, the liquid should be visible at the opening of the infusion set.

⚠ If the pump does not remain upright during preparation, air could remain in the reservoir, leading to incorrect dosing of the drug.



4



5

Pump ready

Pump and reservoir are now ready for use. If you wish to prime the infusion set, press Yes.

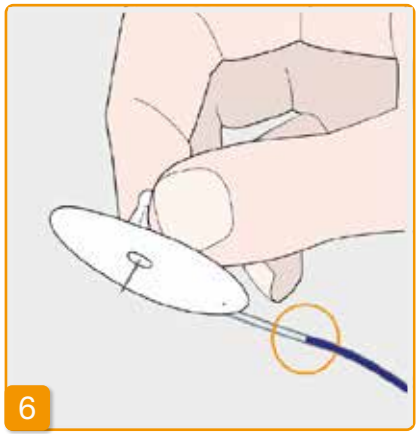
Press No to skip this step. The infusion set will not be primed.
Proceed with Step 8 "Put on infusion set".

ⓘ It may be necessary to perform multiple priming cycles until the liquid is visible in the tube.

ⓘ If no liquid is visible after multiple priming cycles, check to ensure that the reservoir has been filled properly through the viewing window. If necessary, repeat the filling process with a new reservoir and return to Step 3.1.

Observing and stopping the priming cycle

Observe the infusion set during the priming cycle. It takes a few seconds until liquid becomes visible in the tube. The drug is then slowly pushed in the direction of the needle on the infusion set.



Press Stop as soon as the liquid reaches the needle on the infusion set.

If you do not press a button, the process will stop after a few seconds.

Continuing the priming cycle

If the priming cycle stops, but the liquid is not yet visible at the needle on the infusion set, then press Yes to restart the priming cycle.

Press No to continue putting on the infusion set.

Put on infusion set

Now, connect the infusion set with your body. To do so, refer to the instructions for use of the infusion set. Press ✓.

Check from time to time to ensure that the infusion set is properly connected to the reservoir and that none of the drug solution is leaking at the t hreaded connection.

3.3 CHECKING THE READINESS OF THE PUMP

BEFORE YOU CAN START DRUG DELIVERY, THE RESERVOIR MUST BE FILLED WITH THE DRUG AND THE PUMP MUST BE CONNECTED TO YOUR BODY.

CHECKING THE READINESS OF THE PUMP

Check the following points by referring to the information on the main screen:

- The time that has been set is correct
- The battery is adequately recharged
- The device does not indicate any errors
- The displayed delivery settings are correct
- The displayed remaining amount of the drug (hours until the reservoir is empty) is sufficient for you

- The middle function key displays "Start"

3.4 STARTING AND STOPPING DRUG DELIVERY

You can start and stop delivery of the drug using the function buttons. An interruption is only necessary if you wish to

- change the reservoir
- change the infusion set
- change the rechargeable battery
- change the time
- change delivery settings
- take off the device

Starting drug delivery

Press and hold Start (approx. 3 seconds). Do not release the button until you hear an audible signal.

The display will become completely illuminated and shows a rotating blue propeller symbol.

Stopping drug delivery

Press and hold Stop and do not release the button until you hear an audible signal (approx. 3 seconds).

Your pump will stop automatically if the reservoir is empty or an error occurs. Following an alarm, you always have to restart the delivery of apomorphine.

DAILY ROUTINE

4

4.1 MENU CONTROL

1

2

From the main screen, you can access the function selection by unlocking the function buttons and opening the menu:

1 Disabling the button lock

Press to unlock.

2 Menu navigation

Press on the main screen. The pump displays the main menu. The selected function is always highlighted in blue.

Use the button to select the desired function, then press .

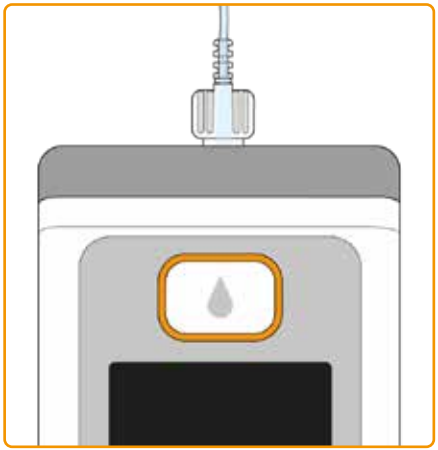
Press to return to the main screen.

In the case of an alarm, drug delivery is not possible.
In this case, all disabled functions are displayed in grey in the menu and cannot be selected.

4.2 DELIVERING A BOLUS

A separate button above the screen is provided for delivering a bolus.

You can deliver the quantity of the drug that has been set (bolus dose) in addition to the basal rate using the bolus button. Discuss with your physician how often you are permitted to deliver a bolus and in what situations you require a bolus.



The bolus function is disabled when:

- The lockout time set by your physician has not yet elapsed.
- The limited number of boluses defined by your physician has already been exceeded.

In these cases, your pump will display the 🔒 symbol next to the bolus dose.
A notice indicating the time until the next bolus can be delivered will show up if the bolus button is pressed.

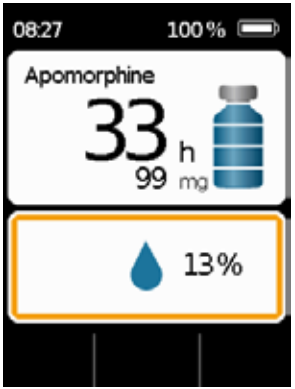
To deliver a bolus, proceed as follows:

Pressing the bolus button

A bolus can only be delivered when the pump is in the delivery mode. Press and hold the bolus button.

> If you are not in the main screen, briefly press the bolus button to return to the main screen. Then press the bolus button again to release a bolus.

Once you press the bolus button, the screen shown above will appear. Press and hold the button (for approximately 3 sec) until the audible **"OK"** signal is emitted, then release the button.



2

Bolus is delivered

The pump will emit the **"Ready"** audible signal and deliver the set bolus dose of the drug. The device will display the progression of the delivery as a percentage.

If delivery of a bolus is not possible, then the "Bolus not possible" audible signal will be emitted.

3

The pump will indicate completion by displaying 100% and emitting the **"Finished"** audible signal. Press ✓ to return to the main screen.

Once delivery of a bolus has started, it cannot be stopped. The bolus dose that has been set is always delivered in full but you will be informed to change the reservoir afterwards.

4

Following completion of the bolus delivery the function is blocked for the lockout time that has been set. The bolus lock symbol is displayed.

4.3 CHANGING THE INFUSION SET

1

2

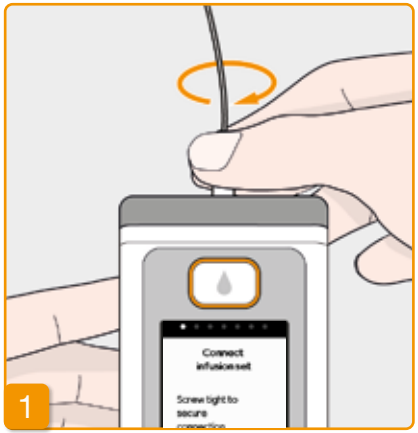
You must stop delivery before you disconnect the infusion set from your body. Section 3.4 Disable the button lock and press Stop. Then press ☰.

Select "Change infusion set" in the menu. Then proceed as described in section 3.4. Here, you can skip the placement of the pump in the docking station. Disconnect the infusion set from your body first and then from the pump. Dispose of the infusion set as recommended by the manufacturer.

Always use a new infusion set if you have had to discontinue treatment (e.g. to have a shower). Wash your hands thoroughly before working with sterile parts. When removing the infusion set, make sure not to touch the threaded connection on the reservoir and keep it clean. Do not forget to restart drug delivery after changing the infusion set! Section 3.4

ⓘ Safely dispose of the infusion set. To do so, refer to the instructions for use of the infusion set.

CONNECTING, PREPARING, AND PRIMING THE INFUSION SET



Connect infusion set

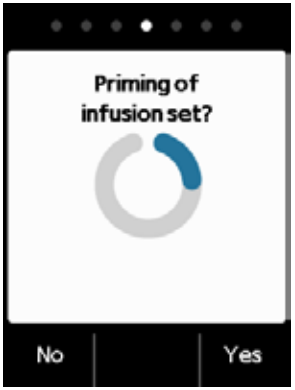
Check to ensure that the threaded connection on the reservoir is clean. Remove a compatible infusion set from the packaging and connect it to the reservoir of your pump.

Tighten the threaded connection securely to ensure that the infusion set does not loosen during drug delivery.

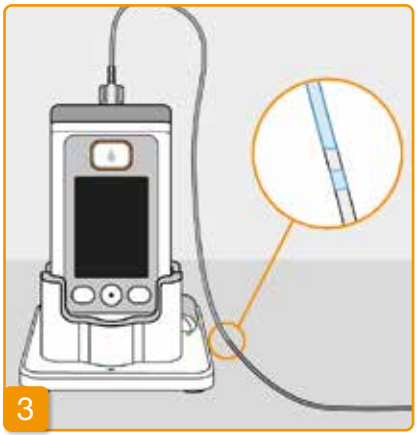
Confirm the procedure with ✓.

⚠ Make sure that the connection to the reservoir is clean and has not been touched.

⚠ If the infusion set connection is not adequately tightened, it could start leaking, leading to an incorrect dose or no delivery of the drug. Overtightening the threaded connection can damage the connection point.



2



3

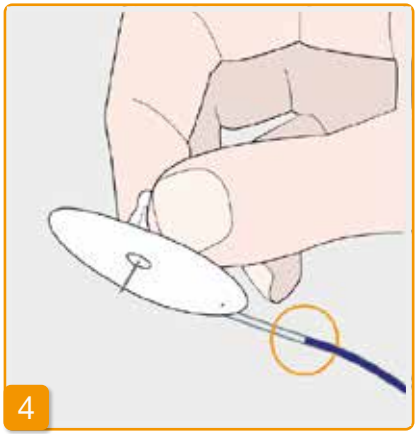
Pump ready

Pump and reservoir are now ready for use. If you wish to prime the infusion set, press Yes.

Press No to skip this step. The infusion set will not be primed.
Proceed with Step 6 "Put on infusion set".

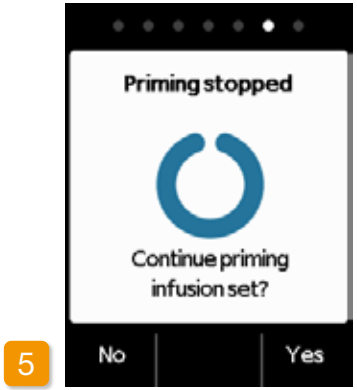
Observing and stopping the priming cycle

Observe the infusion set during the priming cycle. It takes a few seconds until liquid becomes visible in the tube. The drug solution is then slowly pushed in the direction of the tip of the needle.



Press **Stop** as soon as the liquid reaches the needle on the infusion set.

If you do not press a button, the process will stop after a few seconds.



Continuing the priming cycle

When the "Priming stopped" message is displayed, please check to ensure that the infusion set is completely filled, otherwise press **Yes** to restart the priming cycle.

Press **No** to continue applying the infusion set.

Put on infusion set

Now connect the infusion set with your body. To do so, refer to the instructions for use of the infusion set. Then press ✓.

Check from time to time to ensure that the infusion set is properly connected to the reservoir and that none of the drug solution is leaking at the threaded connection.

4.4 CHANGING THE RESERVOIR

To change the reservoir, you need:

- a new vial of Apomine® from InterPharma Pty Ltd.
- a new reservoir
- a new infusion set
- a docking station to maintain the pump upright
- a pump

Check whether you have received the correct drug and whether the vial is new.

Wash your hands thoroughly before working with sterile parts.

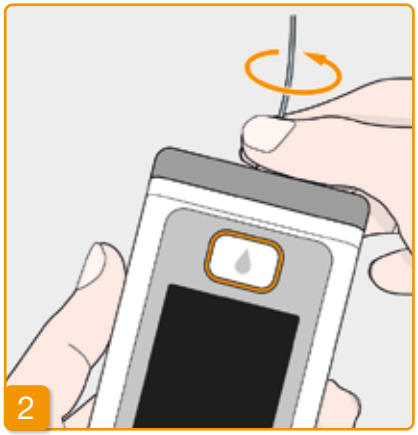
⚠ Only use completely filled apomorphine vials in accordance with your prescription. The use of expired, incompletely filled or damaged vials can impair the efficacy of the therapy and endanger your health.

ⓘ Leave the used reservoir in the pump until you insert a new one. This protects the pump from contamination and damage.

Stopping drug delivery

Press and hold Stop until you hear an audible signal. You can then release the button.

If "Start" instead of "Stop" is displayed, then delivery has already stopped.



Removing used infusion set

Remove the infusion set in use from your body and from the reservoir and dispose of it as recommended by the manufacturer.

Refer to the instructions for use of the infusion set.

Removing used reservoir

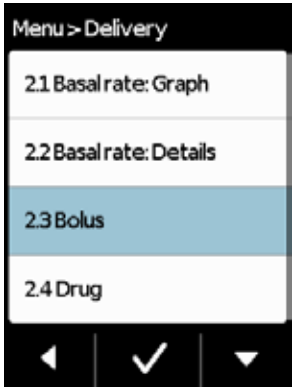
Press the release button on the pump and remove the reservoir from the device. Dispose of it with the household waste.

Proceed with Section 3.1 Inserting the reservoir

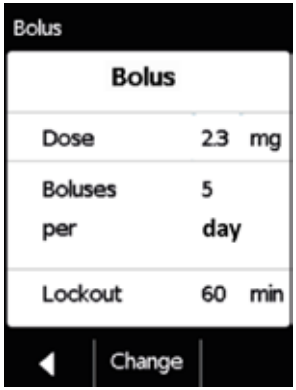
4.5 VIEWING THE DELIVERY SETTINGS

4.5.1 VIEWING THE BOLUS SETTINGS

1



2



3

Selecting delivery settings

Select **Delivery settings** in the menu and press ✓.

Bolus settings

Select **Bolus** and press ✓.

Displaying bolus settings

The pump displays the settings of the bolus function. Press ◀ to return to the delivery settings.

There are two ways of viewing your basal profile:

- as an overview in a 24h graph
- with the precise values for each time period

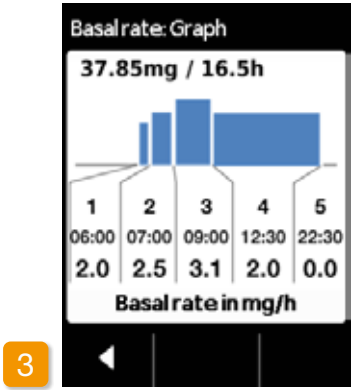
4.5.2 BASAL RATE: GRAPH

Selecting delivery settings

Select **Delivery settings** in the menu and press ✓.

Selecting the overview

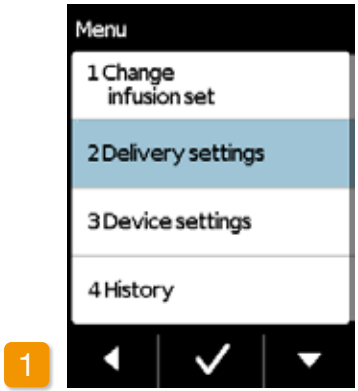
Select **Basal rate: Graph** and press ✓.



24h graph is displayed

Press ◀ to return to the delivery settings.

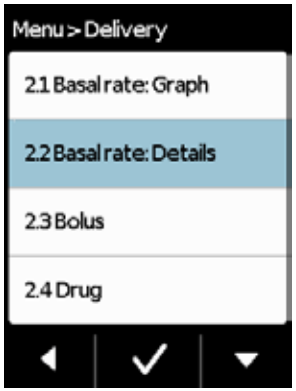
4.5.3 BASAL RATE: DETAILS



1

Selecting the delivery settings

Select **Delivery settings** in the menu and press ✓.



2

Basal rate: Details

Select **Basal rate: Details** and press ✓.

3

Selecting the basal profile time period

You can see the settings for the first time period of your basal profile. Press ▶ to view all time periods consecutively.

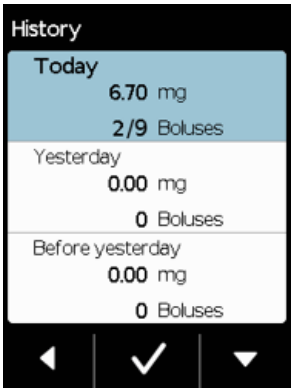
Press ◀ to return to the delivery settings.

4.6 VIEWING THE HISTORY DATA

The pump's History function allows you to review all the important events of the last three days. The following information is saved:

- Filling of the reservoir and the infusion set
- Alarms
- Warnings
- Boluses (e.g. 2/9 = 2 out of max. 9 boluses)
- Changes of the delivery settings
- Changes of the time and sound volume settings
- Insertion of the rechargeable battery

1



2

3

Selecting the history function

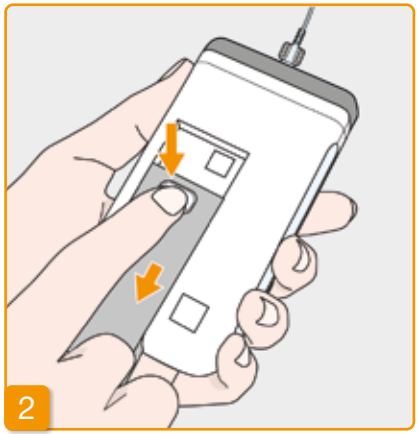
Select the **History** function in the menu and press ✓. You will see an overview of the last three days with the total amount (basal and boluses) and the number of boluses.
Select one of the days and press ✓ to get a detailed view of the day's events.

Press ◀ or the home button to return to the main menu.

4.7 CHANGING THE RECHARGEABLE BATTERY

1 Stopping drug delivery

Stop drug delivery before changing the rechargeable battery unless delivery has already stopped automatically, e.g. due to an alarm. Section 3.4



Removing an empty battery from the pump

Press and hold the button on the rechargeable battery at the back of the pump and remove the battery from the battery compartment. The pump will switch off.

ⓘ When the battery is removed, all settings are preserved.

Inserting a charged battery

Remove the charged spare battery from the docking station and insert it into the pump.

The pump will switch on.

ⓘ Insert the empty rechargeable battery in the docking station to recharge it in order to prevent a disruption in treatment the next time the rechargeable battery is replaced.

4 Greeting

The pump will display a greeting screen when switched on.
Confirm with ✓.

5 Selecting a reservoir

If a reservoir is inserted, then select "Same reservoir" and confirm with ✓.

ⓘ In case that the same reservoir will continue to be used after changing the battery and restarting the pump, then select "Same reservoir".

6 Starting drug delivery

The pump will display the main screen again. Do not forget to restart drug delivery to proceed with treatment.

4.8 REMOVING AND RECHARGING THE PUMP

1 Stopping drug delivery

Stop drug delivery.

Section 3.4

2 Remove the infusion set

Remove the infusion set from your body and from the reservoir and dispose of it in accordance with the instructions for use of the infusion set.

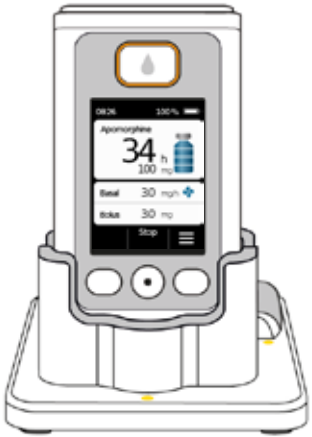
Check whether the pump is contaminated. If so, follow the cleaning instructions in Section 9.3.

3 Removing the reservoir

Remove the reservoir from your pump and dispose of it with the household waste in accordance with Section 9.5.

4 Placing the pump in the docking station

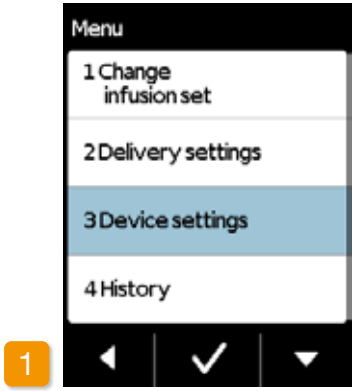
Place your pump in the docking station. The device will switch on the screen and emit a confirmation signal that the rechargeable battery is being recharged in the pump. The rechargeable battery symbol on the screen and the signal light on the docking station will light up yellow.



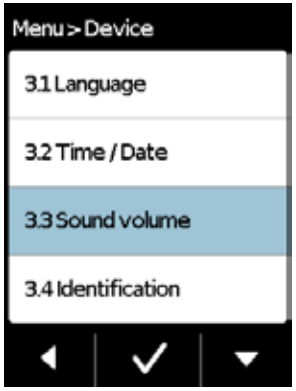
DEVICE SETTINGS

5

5.1 ADJUSTING THE SOUND VOLUME



1



2

3

The sound volume for notification signals can be adjusted with choice of three levels.

Select device settings

Select **Device settings** in the main menu and press ✓.

Select sound volume function

Select **Sound volume** in the Device settings menu and press ✓.

Adjust sound volume

You can set the desired sound volume of notice signals with the − and + function buttons. Press ✓ to save the value that has been set.

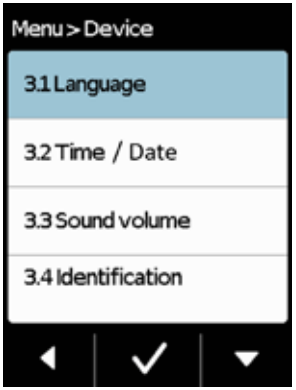
5.2 VIEWING OR CHANGING THE DEVICE SETTINGS

5.2.1 SETTING THE LANGUAGE

1

Set device settings

Select **Device settings** in the main menu and press ✓.



2

Set language

Select language in the **Device settings** menu and press ✓.

3

Select language

Select the desired language using the ▼ button and confirm by pressing ✓. Press ◀ to return to Device settings.

4

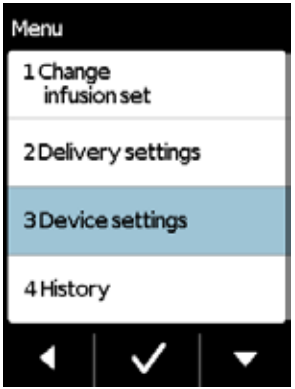
Confirm language setting

Confirm with Yes to execute the desired change.

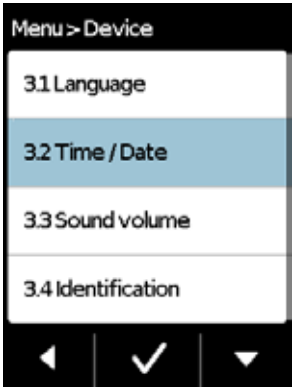
All text on the screen of your pump is now displayed in the selected language.

Press No to return to the **Device settings** menu.

5.2.2 SETTING THE TIME AND DATE



1



2

Stop drug delivery

Change the time setting during breaks in treatment only. Stop delivery first. Section 3.4

⚠ Changing the time impacts drug delivery volumes for the current day. Depending on the change, some of the daily dose might be repeated or missed.

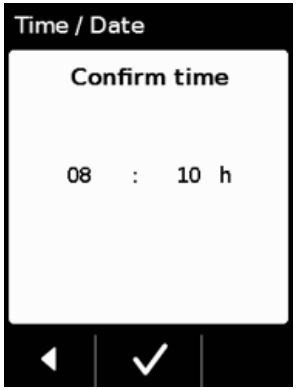
Set Time

Select **Time/Date** in the **Device settings** menu and press ✓.

3

Select hour and minutes

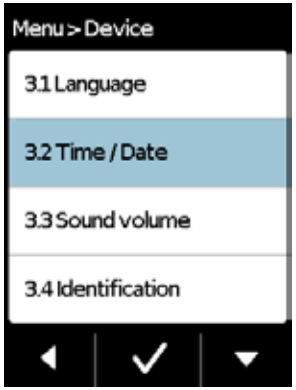
Set the current hour using the − and + buttons and confirm by pressing ✓.



4

Confirm time

Check the new time setting and confirm by pressing ✓.



5

Restart drug delivery

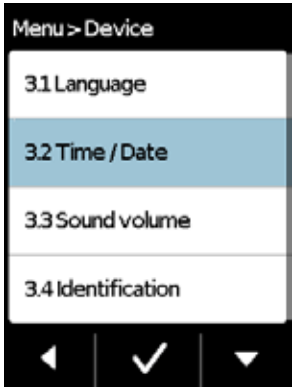
Press ◀ to return to the main screen. Restart drug delivery here.

Section 3.4

ⓘ The same procedure is applicable for setting the minutes.

ⓘ The same procedure is applicable for setting the date, see next page.

SETTING THE DATE

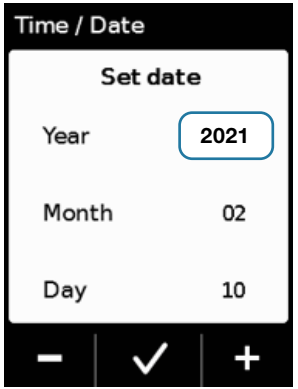


1

Set Date

Select **Time/Date** in the **Device settings** menu and press ✓.

ⓘ You can navigate to the date function after confirming the time settings.



2

Select date

Set the current year using the − and + buttons and confirm by pressing ✓. Reapeat the same procedure with month and day and confirm by pressing ✓.

3

Confirm date

Check the date settings and confirm by pressing ✓.

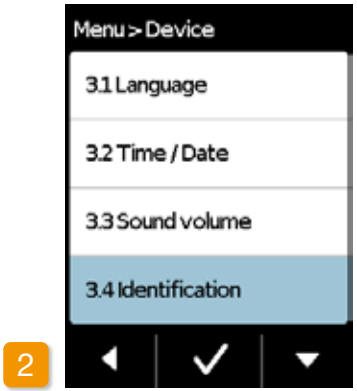
Press ◀ to return to the main screen.

ⓘ Restart drug delivery here.
See section 3.4

5.2.3 DISPLAYING THE DEVICE IDENTIFICATION

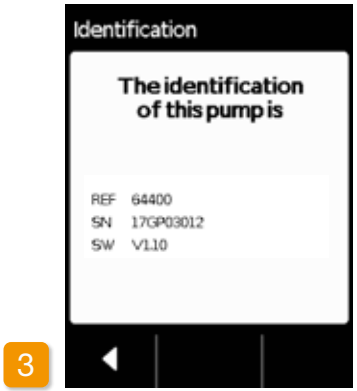
Device settings

Select **Device settings** in the main menu and press ✓.



Select identification function

Use the ▼ button in the **Device settings** menu to scroll to the **Identification** function and press ✓.



Display identification function

Press ◄ to exit the screen.

5.3 RESETTING THE SETTINGS

The basic settings should be adjusted by medical professionals.

When the settings are reset, all delivery settings and the entire history are permanently deleted. The settings cannot be restored.

1 Take off pump

Stop the pump and take it off before resetting the settings.

2

Reset function

Select the **Reset** function in the **Device settings** menu and press ✓.

The settings can only be reset if delivery has been stopped.

Section 3.4

3

Enter code

Enter the release code.

Page 161

Set the release code for changing delivery settings using buttons 1 and 2. Press ◀ to return to the delivery settings screen.

4

Confirm reset

Press Yes if you wish to permanently delete the delivery settings and the entire history. Press No to return to the Device settings menu.

6

DELIVERY SETTINGS

6.1 Programming the basal rate

6.2 Setting the bolus

6.3 Entering the name of the drug

6

The basic settings should be adjusted by medical professionals.

Use the delivery settings to control the amount of the drug that is delivered at the basal rate or with a bolus. Improper changes may have serious consequences for your health.

6.1 PROGRAMMING THE BASAL RATE

You can program the daily course of drug delivery (basal rate) in up to five freely selectable time periods (basal periods). The following is applicable here:

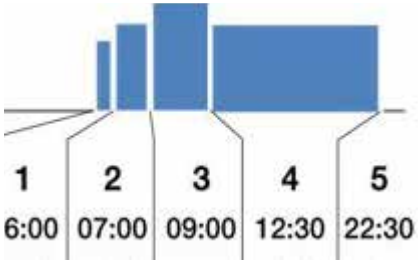
- A basal period is a time period for which you set a certain basal rate, e.g. 6:00 AM to 9:00 AM.
- The basal rate is entered in mg per hour. Example: 1.5 mg/h for 24 h = 36 mg per day.
- Basal period 1 is always the first period in the course of the day. For this basal period, you can set both the beginning and the end.
- All other basal periods automatically start as soon as the preceding period ends. You set the end for each of these periods.
- The last defined time period lasts to the start of basal period 1 in each case. No further basal periods can be entered once five time periods have been defined.

In order to program the basal rate, review your daily course from morning to evening and consecutively set the new periods and delivery amounts. Any previous values will be overwritten.

Sections 6.1.1 to 6.1.4 guide you step by step through the programming process.

The basal rate can only be set if delivery has been stopped.

6.1.1 PREPARING FOR PROGRAMMING



1	06:00 h	07:00 h	2.0 mg/h
2	07:00 h	09:00 h	2.5 mg/h
3	09:00 h	12:30 h	3.1 mg/h
4	12:30 h	22:30 h	2.0 mg/h
5	22:30 h	06:00 h	0.0 mg/h

Gather the necessary information before you start programming a basal rate profile.

The information presented in this table has been randomLy selected and is intended only as an example. Use the values applicable to you when programming your profile.

Define profile

Define the basal rate profile for an entire day. Divide the day into up to five basal periods according to the treatment plan and define the corresponding basal rate in mg/h for each basal period.

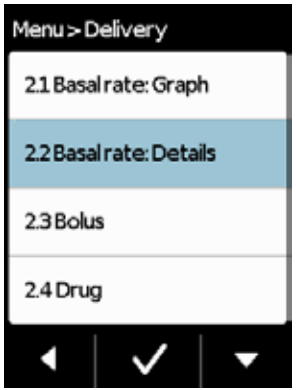
A reservoir has a volume of 20 mL which equals 100 mg of drug.

Table

It is recommended to enter the data in a table for better overview. You can then simply refer to the table when entering the values. The appendix to these instructions includes a patient form with this table.

The information in the hatched fields is automatically completed by the system and does not need to be entered.

6.1.2 SETTING BASAL PERIOD 1



1

Select Basal rate: Details

Select the Basal rate: Details item in the Delivery settings menu.

2

Select change

Basal period 1 is already automatically selected. Press Change.

> It does not matter how many periods have already been set. The subsequent time periods are adjusted per your specifications during programming.

3

Enter code

Enter the release code.

Page 161.

Set the release code for changing delivery settings using buttons 1 and 2. Press ◀ to return to the delivery settings screen.

4

Set start

Use + and − to set the start of basal period 1 (for example: 6:00 AM) and confirm with ✓.

For security reasons, the device will lock automatically after 3 minutes of inactivity. Any previous entries will be deleted. Repeat programming starting with Step 1 in this section.

5

Set end

Use + and − to set the end of basal period 1 (for example: 7:00 AM) and confirm with ✓.

If basal period 1 is also the last of the day, then the end time should be set to match the start time. Any previous basal periods will then be overwritten.

6

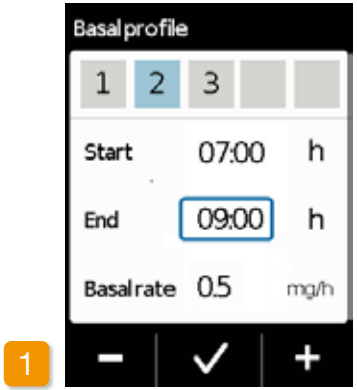
Set basal rate

Use + and − to set the basal rate for basal period 1 (for example: 2.0 mg/h) and confirm with ✓.

If the new value deviates significantly from the previous one, then the pump will display a message to this effect. Check to ensure that the value is correct and confirm the message with ✓.

6.1.3 SETTING THE REMAINING BASAL PERIODS

The end of basal period 1 is automatically the start of basal period 2. The same applies for all subsequent basal periods. You therefore only need to enter the end time and relevant basal rate for all subsequent basal periods.



1

Set end

Use + and − to set the end of the current basal period and confirm with ✓.

> If the current basal period is intended to be the last of the day, then the end time should be set to match the start time of basal period 1. Any intervening basal periods will then be overwritten.

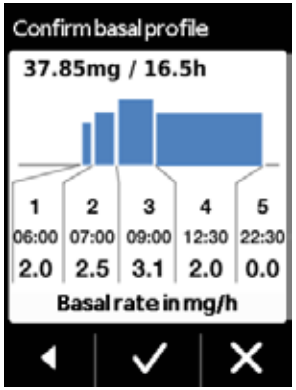
2

Set basal rate

Use + and − to set the basal rate for the current basal period and confirm with ✓.

Repeat the two steps for all other basal periods. For the last basal period of the day, the end time should be set to match the start time of basal period 1 (7:00 AM in the example).

6.1.4 FINALISING THE PROGRAMMING



Once you have covered the whole day with your entries, a diagram of the entire daily profile will appear. The new programming of the pump will not be applied until you confirm the entries.

Confirm profile

The pump will display an overview of all basal periods with your basal rates, the total of all drug deliveries, and the delivery time periods. Check all settings against your table.

If everything is correct, then press ✓ to confirm.

If not, press ◀ to return to programming or ✕ to discard the changes.

ⓘ If you discard the displayed settings, then the programming will remain unchanged. Return to "Setting basal period 1" and enter the new values to make changes.

6.2 SETTING THE BOLUS

The bolus dose will be set up for you by your PD nurse in conjunction with your physician's recommendations. The bolus comprises of three settings:

- The **bolus dose**, i.e. the amount of apomorphine delivered as an additional dose each time you press the bolus button.
- The maximum **number of boluses** allowed per calendar day.
- The minimum **lockout time** after delivery of a bolus.

ⓘ The "Change" button is only enabled when drug delivery has been stopped.

1

Navigating to the bolus settings display

Navigate to the **Delivery settings** in the menu and select **Bolus**.

Press Change and enter the release code.

Page 161

2

Define the bolus settings

Define the bolus settings in the same way as when preparing the device for the first time.

Section 4.5

3

Confirming the bolus settings

Check to ensure that the displayed bolus settings are correct. If yes, press ✓.

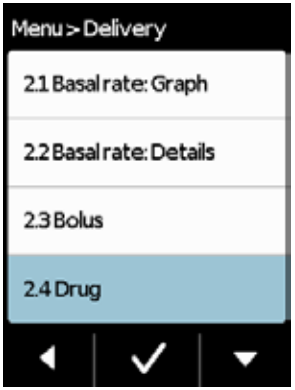
If the displayed settings are not correct, press X. This will return you to the "Delivery settings" where you can define the bolus settings again.

ⓘ If X will be pressed a notice will be displayed: "Reject Settings: All settings remain unchanged".

ⓘ Start drug delivery on the main screen to continue the therapy.

ⓘ It may be advisable to select a bolus dose that will bridge any planned breaks in continuous medication.
Example: basal rate 3 mg/h, bolus dose 1.5 mg, lockout time 30 min. A bolus delivery replaces the amount during a break of 30 minutes, e.g. to have a shower.

6.3 ENTERING THE NAME OF THE DRUG



1

2

Selecting the drug

Select the "Drug" function in the "Delivery settings" menu and press ✓.

Setting the drug

Press Change and enter the release code. Page 161

Select Apomorphine using the ▲ and ▼ buttons, then press ✓. The selected name is always displayed on the main screen. Apomine® is the brand name of apomorphine supplied by InterPharma Pty Ltd.

7

ERROR MESSAGES AND NOTICES

7.1 OVERVIEW

Your pump continuously monitors the system operation and automatically informs you of important changes in the operating state. One of the following four types of messages can be triggered, differing in terms of urgency:

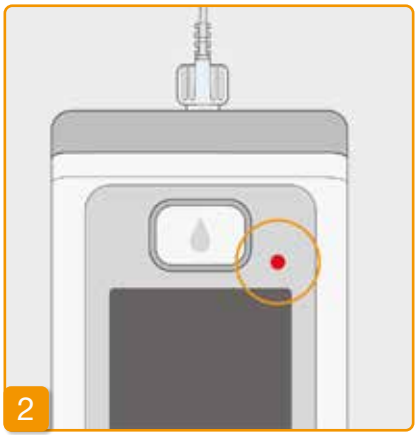
1 **Alarm with error message**
Signal sequence: two consecutive, equally short audible signals that repeat every 16 seconds

2 **Device error**
Signal sequence: same as the sequence for ERRORS,at slightly higher pitch

3 **Warning**
Signal sequence: four short audible signals, two each in alternation

4 **Notice**
No audible signal

1


2

3

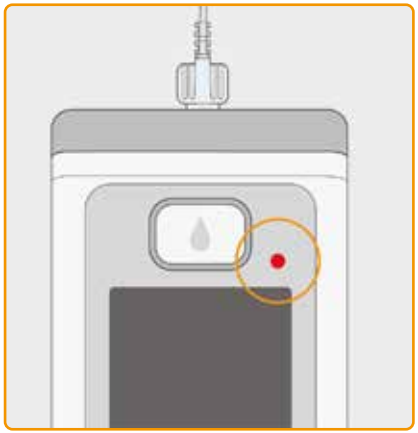
4

7.2 ALARMS

The pump will trigger an alarm if a user response is required in order to ensure the continued, safe delivery of the drug.

The pump will immediately stop drug delivery in the case of an alarm and emit an alarm signal to indicate the interruption.

The tables on the following pages describe the various alarms and troubleshooting measures to resolve each issue.



Device error

The red signal light above the display will flash red for all alarms. The device will emit an audible signal.If the screen remains blank, then a device error has occurred.

The device error message will remain displayed for three minutes. For additional instructions concerning device errors, see page 109.

Alarm with error message

The pump will display a known error message with a text message. The screen will provide the reason for the interruption and corresponding instructions to resolve the issue.
The alarm will remain displayed on the screen until you acknowledge the message with ✓.

Alarm	Reason for alarm	What should I do?
 **Reservoir empty**	The amount of drug remaining in the reservoir is less than the set basal rate or bolus dose.	Press ✓ to acknowledge the alarm and change the infusion set and reservoir in accordance with the instructions in Section 4.4.
 **No reservoir**	The reservoir has been removed during operation.	Press ✓ to acknowledge the alarm and reinsert the reservoir. Then start the delivery of the basal rate. If you wish to connect a new reservoir, follow the instructions in Section 4.4.
 **Rechargeable battery empty**	The rechargeable battery is empty and needs to be recharged.	Press ✓ to acknowledge the alarm and replace the rechargeable battery in accordance with the instructions in Section 4.7.

Alarm	Reason for alarm	What should I do?
 **Occlusion**	The infusion route (reservoir, infusion set, cannula) is blocked.	Press ✓ to acknowledge the alarm and remove the infusion set from your body. Connect a new infusion set to the pump, as described in Section 4.3, and use the priming function. Treatment can be continued once the drug is visible in the tube or comes out the end of the tube during the priming cycle. If the tube becomes blocked again during priming or at a later point, dispose of the reservoir with the household waste as described in Section 9.6 and start filling a new reservoir. Proceed here in accordance with the instructions in Section 4.4.

Alarm	Reason for alarm	What should I do?
Device error  The red signal light to the right above the screen will flash.	The internal pump monitoring system has detected a technical error (e.g., sensor failure, etc.). Drug delivery has stopped.	**1. Replace the rechargeable battery** An empty or defective battery is the most likely root cause of a device error. Therefore, replace the rechargeable battery first and check to ensure that the new battery is adequately charged and properly connected. **2. Contact your ANSSER Nurse** If the device error is unable to be resolved by replacing the rechargeable batter, then contact your ANSSER nurse on 1800 276 646.

7.3 WARNINGS

Warnings on the pump require the user to respond within a defined time period. In the event of a warning, drug delivery continues unchanged. The pump will emit an audible signal to notify the user of the message. The warning will remain displayed until you acknowledge the message with ✓.

Warning	Reason for alarm	What should I do?
Battery low	The "Battery low" warning will appear when the remaining battery capacity falls below 20%.	Press ✓ to acknowledge the warning and replace the rechargeable battery at the next opportunity in accordance with the instructions in Section 4.7.
Reservoir low	The "Reservoir low" warning will appear when the amount of drug remaining in the reservoir reaches 60 min, 30 min and 10 min.	Press ✓ to acknowledge the warning and change the reservoir as soon as possible in accordance with the instructions in Section 4.4.

7.4 NOTICES

Notices are messages concerning the condition of the pump. They have no impact on the progression of the delivery used earlier. Therefore, the device will only display them on the screen and will not emit any audible signals.

The tables on the next pages describe the various notices and troubleshooting measures.

Notices appear only once. If you do not acknowledge a notice, the notice is only displayed until the screen is switched off.

Notice	Why did it occur?	What should I do?
USB connection	The "USB connection" notice will appear when the pump is connected to a PC and the data is being exported.	Wait until the data is ready to be exported.
Delivery is zero	The "Delivery is zero" notice will appear when the delivery settings for the basal rate and bolus settings are both set to zero.	Press ✓ to acknowledge the notice and enter the complete delivery settings (medical professionals only). Section 6 provides corresponding instructions.
Bolus amount is zero	The "Bolus amount is zero" notice will appear when the set bolus dose is zero.	Press ✓ to acknowledge the notice and enter the delivery setting (medical professionals only). Section 6 provides corresponding instructions.
Bolus not ready	The "Bolus not ready" notice will appear when the bolus is triggered while the basal rate is being administered.	Press ✓ to acknowledge the notice and repeat the bolus delivery at a time when the basal rate is not being administered (motor is not turning). Section 4.2 provides corresponding instructions.
Reset	The "Reset" notice will appear when the pump parameters are reset to the factory default settings.	Then re-enter the settings. To be performed by medical professionals only. Section 6 provides corresponding instructions.

Notice	Why did it occur?	What should I do?
Pump not ready	You have attempted to start the pump before executing the "Prepare the infusion set" function.	Press ✓ to acknowledge the notice and prepare the infusion set in accordance with the instructions in Section 4.3.
Battery too low for filling	The "Battery too low for filling" notice will appear when the rechargeable battery is not adequately charged to complete the filling process.	Press ✓ to acknowledge the notice and place the pump in the docking station for filling in accordance with the instructions in Section 3.1.
Bolus lockout active	You have attempted to deliver another bolus while bolus lockout time is enabled. The remaining lockout time is indicated on the screen.	Press ✓ to acknowledge the notice and wait until the lockout time has elapsed. You can then deliver another bolus.
Reservoir empty	The "Reservoir empty - Incomplete Bolus delivered!" notice will appear when the amount of drug remaining in the reservoir is less than the set bolus dose.	Press ✓ to acknowledge the notice and change the infusion set and reservoir in accordance with the instructions in Section 4.4.
No reservoir	The "No reservoir" notice will appear when you attempt to execute the "Prepare the infusion set" function, but no reservoir has been inserted.	Press ✓ to acknowledge the notice and insert a new reservoir in accordance with the instructions in Section 3.1.

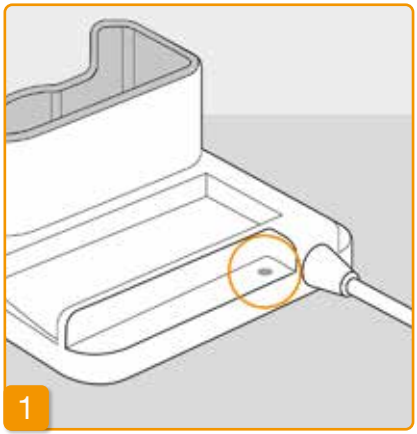
Notice	Why did it occur?	What should I do?
Bolus maximum reached	The "Bolus maximum reached" notice will appear when the maximum possible number of boluses to be delivered per day has been reached.	Press ✓ to acknowledge the notice and wait until the lockout time has elapsed. You can then deliver another bolus.
Bolus button pressed too long	The "Bolus button pressed too long" notice will appear when the bolus button is pressed and held for longer than 30 seconds.	Press ✓ to acknowledge the notice and follow the instructions for bolus delivery in Section 4.2.
Function not available	Drug delivery is switched on and you attempt to execute one of the following functions: – Reset – Set time – Prime infusion set	Stop delivery and then execute the desired function. Do not forget to then restart drug delivery!
Value will increase	The "Value will increase" notice will appear when the original value is exceeded by at least 100% when setting a value.	Check to ensure that you have entered the correct value and confirm the notice with ✓.
Value will significantly decrease	The "Value will significantly decrease" notice will appear when the set value falls below the original value by at least 50%.	Press ✓ to acknowledge the notice and check to ensure that you have entered the correct value.

Notice	Why did it occur?	What should I do?
Vial incorrect	The "Vial incorrect" notice will appear when an invalid or previously used vial is detected by the pump.	Press ✓ to acknowledge the notice, dispose of the vial with the household waste, and fill the reservoir with a new vial in accordance with the instructions in Section 3.1.
No vial	The "No vial" notice will appear when an invalid or previously used vial is detected by the pump.	Press ✓ to acknowledge the notice and fill the reservoir with a new vial in accordance with the instructions in Section 3.1.
Code incorrect	The "Code incorrect" notice will appear when an incorrect code has been entered for a password-protected pump function.	Press ✓ to acknowledge the notice and enter the correct code on page 161.
Reject settings	The "Reject settings" notice will appear when pump programming has not been confirmed with ✓.	All changes are discarded. Press ✓ to acknowledge the notice.
Start button pressed too long	The "Start button pressed too long" notice will appear when the start button has been pressed and held for longer than 30 seconds.	Press ✓ to acknowledge the notice and follow the instructions for starting the pump on page 57.

Notice	Why did it occur?	What should I do?
Stop button pressed too long	The "Stop button pressed too long" notice will appear when the stop button has been pressed and held for longer than 30 seconds.	Press ✓ to acknowledge the notice and follow the instructions for stopping the pump in Section 3.4.
Filling aborted	The "Filling aborted" notice will appear when you remove the reservoir during the filling process.	Press ✓ to acknowledge the notice, reinsert the reservoir, and continue the filling process in accordance with the instructions in Section 3.1.
Error while filling	The "Error while filling" notice will appear when an alarm is triggered during filling and the filling process is cancelled.	Press ✓ to acknowledge the notice. Remove the reservoir and repeat the filling process with a new reservoir in accordance with the instructions in Section 3.1.
Preparation interrupted	The "Preparation interrupted" notice will appear when you remove the reservoir during the preparation process.	Press ✓ to acknowledge the notice, reinsert the reservoir, and continue the preparation process in accordance with the instructions in Section 3.2.

7.5 ERROR SIGNALS ON THE DOCKING STATION

7.5.1. THE MAINS CONNECTION SIGNAL LIGHT ON THE DOCKING STATION IS NOT LIT



No mains connection

If the mains connection signal light on your docking station is not lit, this means that either there is no mains voltage or the docking station is defective.

Check mains connection

Check the mains connection of the docking station.

See Section 2.1

If the power supply to the docking station is not functioning, then contact your ANSSER Nurse on 1800 276 646.

7.5.2 SIGNAL LIGHT ON THE DOCKING STATION IS FLASHING

If one of the signal lights on the docking station is flashing, one of the following errors has occurred:

Signal light	Colour	Meaning	What should I do?
Rechargeable battery for pump	flashes yellow	The pump is not completely inserted into the docking station or the rechargeable battery is not connected to the pump or the rechargeable battery is defective	Check whether the pump has been placed correctly in the docking station. Insert the rechargeable battery into the pump. If necessary, replace the rechargeable battery in the pump as quickly as possible.
Spare rechargeable battery	flashes yellow	Rechargeable battery defective	Replace the rechargeable battery in the pump as quickly as possible and replace the defective rechargeable battery with a new one. Contact the ANSSER nurse service on 1800 276 646

7.6 TROUBLESHOOTING

If you have any questions or problems relating to your D-*mine*® Pump, your ANSSER nurse will be available at the toll-free number below to help.

ANSSER nurse free telephone support service: 1800 APOMINE (1800 276 646).

This section gives some common examples of when a pump might not function correctly. We also provide recommendations concerning how to safely continue operating your pump.

ⓘ Please contact your ANSSER nurse if the information in this section is not sufficient to continue operating your pump safely.

Description	What should I do?
The pump was dropped	Stop drug delivery and disconnect the infusion set from your body. Remove the reservoir and the infusion set. Remove the rechargeable battery from the device. Inspect the outside of the pump and rechargeable battery for cracks or damage. Restart the device and monitor the start-up process. The full display must always appear. If there is no visible damage on the pump and rechargeable battery, then you can fill a new reservoir and continue treatment with a new infusion set. If the pump is damaged, contact your ANSSER Nurse.
There is drug solution in the reservoir compartment	Stop drug delivery and disconnect the infusion set from your body. Remove the reservoir and the infusion set and dispose of both. Remove the rechargeable battery from the device. Clean the pump and rechargeable battery with a paper towel and inspect both for cracks or damage. Restart the device and monitor the start-up process. The full display must always appear. If there is no visible damage, then you can restart treatment. Always use a new reservoir and new infusion set. If the pump is damaged, contact your ANSSER Nurse.
Vial not emptied	If the vial has not been emptied completely during filling, then repeat the filling process with a new reservoir and a new vial. A small amount will always remain in the vial after the filling process.
Self-test, no signal	Remove the reservoir and reinsert it, select "New reservoir", and follow the instructions in Section 3.1. If you still don't hear an audible signal or only one audible signal during the self-test, then the pump is defective. Contact your ANSSER Nurse.

Description	What should I do?
The reservoir compartment or other parts of the pump are contaminated or contain water	Stop drug delivery and disconnect the infusion set from your body. Remove the rechargeable battery from the device. Remove any contaminants (grains of sand, dust particles, etc.) from the reservoir compartment by gently tapping the pump against the palm of your hand or another soft object. Never strike the device against a hard surface. Inspect the connection to the reservoir for contaminants as well. Then clean the device with a damp cotton cloth. Dry any dampened areas with a dry cotton cloth or paper towel. Inspect the pump and rechargeable battery for cracks or damage. Restart the device and monitor the start-up process. The full display must always appear. If there is no visible damage on the pump and rechargeable battery, then you can restart treatment. Always use a new reservoir and new infusion set. If the pump is damaged, contact your ANSSER Nurse.
Incorrect language set	Press  (lower right) to switch to the menu and consecutively select the following: - Number 3 - Number 3.1 Then select the desired language setting in Section 5
Pump will not start	If the pump will not start, this may be due to the following: The reservoir has not been changed or was changed incorrectly. Follow the corresponding instructions in Section 3.1. The pump has not yet been prepared. Follow the instructions in Section 4.3 to correct the error. The "Start" button was held and pressed too long or not long enough. Follow the corresponding instructions in Section 3.4.

Description	What should I do?
Pump will not stop	If the pump will not stop, this may be due to the following: The "Stop" button was held and pressed too long or not long enough. Follow the corresponding instructions in Section 3.4.
Reservoir is not fully filled with liquid	The fit of the adapter was not checked before the filling process. If it is too loose, air can be drawn in during the filling process. Take a new reservoir and a new vial. Before you start the filling process, check the placement of the adapter on the reservoir in the pump. To do so, gently turn the adapter with the vial to the right (clockwise). Repeat the filling process according to the instructions in Section 3.1.
Bolus cannot be delivered	If the bolus cannot be delivered, this may be due to the following: Drug delivery has stopped and must be restarted. Follow the corresponding instructions in Section 3.4. The bolus lock is currently enabled. It is not possible to deliver a bolus before the lockout time has elapsed. The available number of delivered boluses has been reached. Another bolus delivery is therefore not possible until after the lockout time has elapsed.

Description	What should I do?
The rechargeable battery is empty or not fully charged	If the rechargeable battery is empty or not fully charged, this may be due to the following: The rechargeable battery was removed prematurely from the docking station. Make sure not to remove the rechargeable battery from the docking station until it is completely charged. Follow the corresponding instructions in Section 4.7 The lifetime of the rechargeable battery has expired or the docking station is damaged and is no longer charging the battery. Observe the signal lights on the docking station as described in Section 1.2 and notify ANSSER nurse on 1800 276 646 concerning any displayed errors.
New reservoir not able to be filled	If the new reservoir is not able to be filled, this may be due to the following: "Same reservoir" has been incorrectly selected on insertion of a new reservoir. Remove the reservoir and reinsert, select "New reservoir" and follow the instructions in Section 3.1.
Incorrect entry during insertion of the reservoir	"Same reservoir" instead of "New reservoir" has been incorrectly selected on insertion of a new reservoir. Please proceed as follows: Remove the reservoir and reinsert, make the correct selection and follow the instructions in Section 3.1.

Description	What should I do?
The infusion set has been primed correctly, delivery has started but the display is not completely illuminated and shows no rotating blue propeller symbol.	First, check whether the threaded connection between the pump and infusion set is tightened firmLy and the infusion set is properly connected to the body. If this is the case, but the problem persists, stop drug delivery and disconnect the infusion set from your body. Remove the reservoir and the infusion set and dispose of both. Remove the rechargeable battery from the device. Inspect the pump and rechargeable battery for cracks or damage. Restart the device and monitor the start-up process. Each step must be properly displayed on the screen. If there is no visible damage on the pump and rechargeable battery, then you can continue treatment with a new reservoir. Change the reservoir and infusion set in accordance with the instructions in Section 3.1. If the pump is defective, contact your ANSSER nurse on 1800 276 646
Incorrect screen display	If the buttons cannot be unlocked, briefly remove the rechargeable battery from the pump and reinsert. If the pump is defective, contact your ANSSER nurse on 1800 276 646.
Air in the reservoir visible after filling	Check the filling level of the reservoir in the viewing window after the filling process. Air bubbles can be removed from the reservoir by a priming process via the connected infusion set. To do this, follow the instructions for priming in Section 3.2
No liquid in the infusion set	Check the filling level of the reservoir before connecting the infusion set with the body. If no liquid reaches the infusion set even after priming process, repeat the process with a new reservoir and new vial. Instructions in Section 3.1

YOUR EVER PHARMA D-*mine*® PUMP IN EVERYDAY LIFE

8.1 Travelling

8.2 Electromagnetic danger zones

8.3 Contact with water or dust

8.4 Regular testing

8

8.1 TRAVELLING

It is not a problem to take your pump with you when travelling. But please observe the following aspects when doing so:

- When you change the time on the pump to a different time zone, this immediately affects drug delivery. Depending on the time difference, a portion of the daily dose is repeated or omitted. Therefore, discuss any time change with your medical professional before travelling.
- Make sure that you have the required disposable accessories with you or that you can get them on the journey.
- If taking extra disposable accessories with you, observe the required storage conditions, especially for the reservoir and vial.
- Be sure to make enquiries as to the availability of your usual medical team at home or an appropriate medical team at your destination.
- Take the entire system, including pump and accessories, with you. Never forget the docking station with the second rechargeable battery.
- Make sure that you can recharge the batteries at your destination. Depending on the country, you may need a suitable adapter to be able to connect the docking station to the local power supply.
- Your pump does not emit radio signals and meets the regulations for unintentional electromagnetic interference. Safety systems for security checks at airports should not impair the functionality. If this is not the case, contact your ANSSER nurse on 1800 276 646.

If you have trouble with your D-Mine pump while traveling outside of Australia, please contact the ANSSER nurse service by E-mail: ansser@ansser.com.au.

8.2 ELECTROMAGNETIC DANGER ZONES

The EVER Pharma D-*mine*® Pump conforms to all standards and regulations that apply to operation in the home environment or the public environment. The pump is not influenced by household appliances, trains, electrical building installations, safety systems or other electronic equipment in this environment. Conversely, the pump will not interfere with the equipment mentioned either. Avoid areas with very strong electromagnetic fields though, such as:

- radar or antenna facilities
- magnetic resonance tomography (MRT) scanners
- computed tomography (CT) scanners
- X-ray or high voltage sources

Excessive electromagnetic radiation can impair the function of your pump (e.g. by reducing the delivery precision by +/-15%) or cause a device error Section 7.2.

⚠ Never take your EVER Pharma D-*mine*® Pump near a magnetic resonance tomography (MRT) scanner.

8.3 CONTACT WITH WATER, DUST, HEAT, HUMIDITY

⚠ The EVER Pharma D-*mine*® Pump is protected against splashing water and dust when the reservoir is inserted (protection class IP 42).
But the pump should not be exposed directly to water or used in a dusty environment.

Therefore, take off your pump when you:
- bathe or go swimming
- have a shower

If water gets into the pump, this can impair the function of your pump and cause a device error Section 7.2.

⚠ Be careful not to expose the EVER Pharma D-*mine*® Pump directly to light, radiation, and heat sources (e.g. radiators, fireplaces).
Keep your pump away from condensing humidity (e.g. humidifiers, boiling water).

8.4 REGULAR TESTING

The EVER Pharma D-*mine*® Pump is maintenance-free and requires no annual safety inspection.

The EVER Pharma D-*mine*® Pump must be inspected regularly to ensure that it is clean, complete, and undamaged.
The pump performs a self-test prior to each filling of a new reservoir.
Section 3.1 .

9

USEFUL INFORMATION ON THE USE AND MAINTENANCE OF YOUR PUMP

9.1 Disposable accessories

9.2 Accessories/Replacement parts

9.3 Cleaning

9.4 Storage

9.5 Warranty

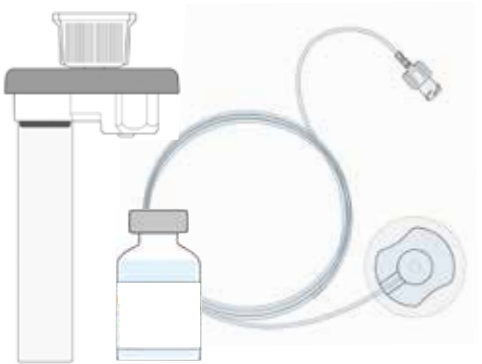
9.6 Disposal

9

9.1 DISPOSABLE ACCESSORIES

You can obtain your Apomine® vials for your EVER Pharma D-*mine*® Pump from your pharmacy with a prescription from a medical professional.
Speak to your ANSSER nurse about how to order new reservoirs and infusion sets.

Only use infusion sets with a needle diameter between 28 and 31 gauge.



9.2 ACCESSORIES/ REPLACEMENT PARTS

You can obtain the accessories for your EVER Pharma D-*mine*® Pump directly from your ANSSER nurse.

- Carrying bag
- Rechargeable battery
- Docking station

9.2.1. CARRYING BAG

EVER Pharma D-*mine*® Pump carrying bag

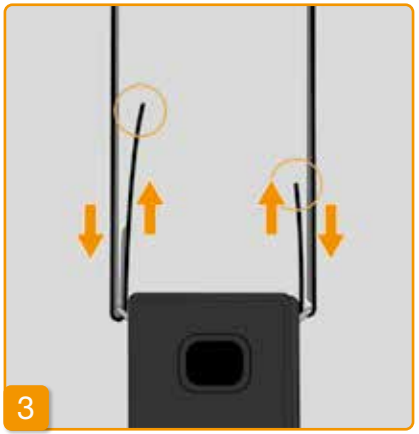
The carrying bag enables you to carry your pump conveniently on your belt or around your upper body.

CARRIER OPTION A

Carrier option A enables you to carry the pump across your upper body.

Pull both ends of the strap through the hook with each loop side facing outward.

Secure the strap by pressing the hook side of the strap to the loop side of the strap.

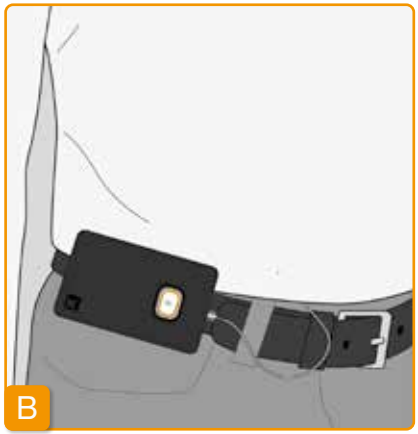


You can adjust each side to the carrying length that is optimal for you. Ensure hook-and-loop fastening is fully pressed together so none on strap sticks out.

Place the pump in the carrying bag. Make sure that the infusion set is pointing up.

Completely close the carrying bag. Check to ensure that the opening for pressing the bolus button is completely accessible.

CARRIER OPTION B



Carrier option B enables you to carry the pump secured to your belt.

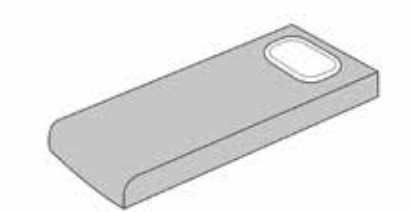
Slide the hooks all the way back to prepare the carrier. Protruding hooks could impair carrying comfort.

Pull the belt through the belt loop on the back of the carrying bag. Make sure that the top of the carrying bag can be opened on your body.

Place the pump in the carrying bag and close the bag. Check to ensure that the infusion set is pointing toward the middle of the abdomen and the opening for pressing the bolus button is completely accessible.

⚠ The opening on the carrying bag should never point downward because the pump could fall out and become damaged.

9.2.2 RECHARGEABLE BATTERY



Rechargeable battery set for
EVER Pharma D-*mine*® Pump

Follow the instructions below when handling the rechargeable battery:

⚠ Only charge the EVER Pharma D-*mine*® Pump rechargeable battery with a docking station designed specifically for this purpose.

⚠ Never damage or take apart a rechargeable battery.
Leaking rechargeable battery contents can result in chemical burns on the skin.

⚠ Do not heat the rechargeable battery to over 70 degrees Celsius (158 degrees Fahrenheit).

⚠ Never throw the rechargeable battery into fire.

⚠ Defective rechargeable batteries must never be discarded with household waste. Always take defective batteries to the local collection point provided for this purpose.

9.3 CLEANING

A cloth moistened with water is sufficient to clean the EVER Pharma D-*mine*® Pump. Do not use alcohol or solvent-based cleaning agents. Recommended: Foam disinfectant for wipe-disinfection of alcohol-sensitive surfaces. You can also use a washing up liquid or mild cleaning agent. Do not perform cleaning and disinfection without a reservoir inserted. Protect all device openings against the penetration of liquids.

Before cleaning and disinfecting the pump, remove the infusion set and battery.

- Discard the infusion set.
- First clean the pump, charging station, charging cable, mains plug and battery with a damp cloth to remove dirt or contamination.
- Then disinfect all components with a recommended disinfectant.

Notice:

- Only use recommended disinfectants. The use of non-recommended disinfectant may damage the pump.
- Make sure that all surfaces are completely moistened with the disinfectant without liquid penetrating into the openings and connections. Let the disinfectant dry completely, do not wipe the pump and accessories dry.
- Check all pump components (pump, battery, charger, power cable with plug) for damage and replace them if necessary.

The EVER Pharma D-*mine*® Pump must be inspected regularly to ensure that it is clean, complete, and undamaged. Handle the pump in accordance with the instructions for use. The pump automatically performs a self-test each time the reservoir and vial are changed, see Section 3.1.

9.4 STORAGE

Store your EVER Pharma D-*mine*® Pump and its accessories under normal indoor ambient conditions, see Section 10.2. Take the pump off as described in Section 4.8 and remove the rechargeable battery from the pump. You can safely store all pump components in the packaging until you restart the pump.

9.5 WARRANTY

EVER Pharma GmbH grants – notwithstanding any statutory or contractual warranty you may have under any agreement with your authorized dealer – a limited guarantee on materials and/or workmanship for two years from date of delivery to the first end consumer (evidenced by invoice).
This guarantee shall be subject to Austrian law with the exception of its choice of law rules. Guarantee is excluded for defects caused by either improper handling and/or force, operational errors, overuse, lack of or improper maintenance, disassembled product, and/or normal wear and tear. The guarantee does not extend to consumable parts. Within the period of guarantee any defects subject to guarantee will, at EVER's sole choice and discretion, either be repaired or replaced.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Cease using the goods when a fault arises and contact your Apomine® Nurse Support Service (ANSSER -phone: 1800 276 646) or InterPharma on +61 2 9846 1950. Arrangements will be made to collect your pump and a replacement pump sent to you free of charge.

Name	Warranty period
D-*mine*® Pump without reservoir	2 years
Docking station/power supply	2 years
Rechargeable battery	2 years
D-*mine*® Reservoir	2 years

9.6 DISPOSAL

The EVER Pharma D-*mine*® Pump and rechargeable batteries are accepted by authorised dealers for disposal. The applicable hygiene and disposal regulations must be followed when disposing of disposable articles and drugs.

- Dispose of reservoirs, vials, and adapters with the household waste.
- Defective rechargeable batteries must never be discarded with the household waste. Always take defective batteries to the local collection point provided for this purpose.

10 APPENDIX

10

10.1 SYMBOLS ON THE SCREEN

Reservoir
Filling level 100%

Reservoir
Filling level 75%

Reservoir
Filling level 50%

Reservoir is filling
Filling level 25%

Reservoir (not during filling)
Filling level below 25%

Alarm
Reservoir empty

No reservoir
or
reservoir is filling
Filling level 0%

Rechargeable battery
OK

Rechargeable battery
is being charged

Warning
Rechargeable battery
almost empty

Alarm
Rechargeable battery
empty

Place pump upright in
docking station

Alarm

Notice

Warning message

Unlock buttons

Bolus currently disabled

Ongoing delivery

SYMBOLS ON THE PRODUCT

Marking for conformity with standards in the USA and Canada

MEDICAL –
CARDIO, VASCULAR AND PULMONARY EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)
CAN/CSA-C22.2 No. 60601-1 (2014)
IEC 60601-1-6 (2013)
ANSI/AAMI HA60601-1-11 (2015)
IEC 60601-2-24 (2012)
E363201

UL recognized component mark

Manufacturer

Date of manufacture

Equipment type BF according to standard IEC 60601-1. Protection against electric shock

Observe warnings in the instructions for use.

Follow instructions for use.

CE 0044 — Conformity marking in accordance with the European Medical Device Directive and number of the notified body

REF — Item number

SN — Serial number

LOT — Batch number

IP 42 — Symbol for protection against particles and water in accordance with IEC 60529

Do not discard with household waste

Pyrogen-free

MD — Medical Device

GTIN — Global Trade Item Number

UDI — Unique device identification

Air humidity limitation

Protect from moisture

Protect from heat and sunlight

Temperature limit

For single use only

Do not use if packaging is damaged

STERILE R — Sterilisation by irradiation

Use by

Single Sterile Barrier System

Single Patient - multiple use

Distributor

10.2 TECHNICAL DATA

Dimensions (with reservoir, without adapter)	Length	114.3	mm
	Width	61.4	mm
	Depth	29.9	mm
Weight	Pump	140	g
	Reservoir empty	22	g
Temperature	In operation (including rechargeable battery charging)	+5 to +40	°C
	Storage (including transport)	-25 to +70	°C
Air humidity	In operation	15 to 90	% RH
	Storage	up to 93	% RH
Atmospheric pressure	In operation	700 to 1060	hPa
	Storage	n/a	hPa
Power supply	Rechargeable battery	Lithium polymer CP5/26/54 3.7 650 2.4	 V mAh Wh
	Docking station	100-240 50-60 0.6	V Hz A
Pump mechanism	Micro-piston pump	10µl/stroke	
Device adjustment time	Warm-up time	30	min
	Cooling time	30	min

Service life of a rechargeable battery	Typical operating time with one charge	7	days
	Number of charging cycles	300	cycles
History	View	3 800	days Entries per day
	Export	up to 12,500	entries
Protection against electric shock	Class II ME Equipment		
Operating mode	Suitable for continuous operation and internally supplied with power		
Protection class	IP 42		
Sterilisation method for reservoir	Gamma		
Use in oxygen-rich environment	No		
Maximum infusion pressure		4	bar
Occlusion alarm threshold		4	bar
Maximum time period to occlusion alarm		10	min

Applied part	Infusion set	Type	BF
Unintended bolus	Basal rate 4.8 mg/h	< 70	µL
Maximum delivery volume able to be infused under single fault conditions	Basal rate 4.8 mg/h	50	µL
RFID	Transmission frequency	13.56	MHz
	Effective radiated power	200	mW

10.3 SOURCES OF INTERFERENCE

- The EVER Pharma D-*mine*® Pump has been tested as a class B, group 1 medical device in accordance with IEC 60601-1-2: 2014. It is intended for use in clinics, hospitals and domestic environments.
- The EVER Pharma D-*mine*® Pump delivers apomorphine. Using the device in the vicinity of strong electromagnetic fields can impair or impede performance. In such cases, the EVER Pharma D-*mine*® Pump may signal that an error has occurred.
- Avoid using the EVER Pharma D-*mine*® Pump in the vicinity of active electrosurgical instruments and within RF shielded rooms for MRT at medical facilities where the electromagnetic wave intensity is high.
- The use of the EVER Pharma D-*mine*® Pump in the vicinity of or in connection with other devices should be avoided because this can lead to malfunctions.
- The use of accessories, converters or cables that are not intended for or supplied with the EVER Pharma D-*mine*® Pump can result in increased electromagnetic emissions, reduced electromagnetic immunity, and malfunctioning of the pump.

- Portable RF communications equipment (including peripheral devices, such as antenna cables and external antennae) should not be used at a distance of less than 30 cm or 12 inches from any part of the EVER Pharma D-*mine*® Pump, including cables. Such equipment includes mobile phones, wireless phones, and wireless computer devices. Otherwise the performance of the EVER Pharma D-*mine*® Pump may be reduced.

ELECTROMAGNETIC EMISSIONS

RF emissions CISPR 11	Group 1	Class B
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	dmax < 4%	dmax < 4%

ELECTROMAGNETIC IMMUNITY

	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-2 kV, +/-4kV, +/-8kV +/-15kV air	+/- 8 kV contact +/-2 kV, +/-4kV, +/-8kV +/-15kV air
High-frequency electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz -2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz -2.7 GHz 80% AM at 1 kHz
	27 V/m 385 MHz PM 18Hz	27 V/m 385 MHz PM 18Hz
	28 V/m 450 MHz PM 18Hz	28 V/m 450 MHz PM 18Hz
	9 V/m 710 MHz PM 217 Hz 745 MHz PM 217 Hz 780 MHz PM 217 Hz	9 V/m 710 MHz PM 217 Hz 745 MHz PM 217 Hz 780 MHz PM 217 Hz
	28 V/m 810 MHz PM 18 Hz 870 MHz PM 18 Hz 930 MHz PM 18 Hz	28 V/m 810 MHz PM 18 Hz 870 MHz PM 18 Hz 930 MHz PM 18 Hz
	28 V/m 1720 MHz PM 217 Hz 1845 MHz PM 217 Hz 1970 MHz PM 217 Hz	28 V/m 1720 MHz PM 217 Hz 1845 MHz PM 217 Hz 1970 MHz PM 217 Hz

	IEC 60601 test level	Compliance level	Recommended separation distance
RF interference currents IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	3 Vrms 150 kHz - 80 MHz	$d = 1.2\sqrt{P}$
Radiated RF disturbances IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz	10 V/m 80 MHz - 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz - 800 MHz $d = 2.3\sqrt{P}$ 800 MHz - 2.5 GHz

High-frequency electromagnetic fields IEC 61000-4-3	28 V/m 2450 MHz PM 18Hz	28 V/m 2450 MHz PM 18Hz
	9 V/m 5240 MHz PM 217 Hz 5500 MHz PM 217 Hz 5785 MHz PM 217 Hz	9 V/m 5240 MHz PM 217 Hz 5500 MHz PM 217 Hz 5785 MHz PM 217 Hz
Fast transient electrical disturbances/bursts IEC 61000-4-4	+/- 2kV 100 kHz repetition rate	+/- 2kV 100 kHz repetition rate Signal input/output +/-1 kV 100 kHz repetition rate
Surge IEC 61000-4-5	+/-1 kV line-to-line +/-2 kV line-to-ground	+/-0.5 kV line +/-1 kV line-to-line +/-2 kV line-to-ground
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle at 0° and 70% UT; 25 cycles (50 Hz) / 30 cycles (60Hz) at 0° Power failure 0% UT 250 cycles (50Hz), 300 cycles (60Hz)	Voltage dips: 0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle at 0° and 70% UT; 25 cycles (50 Hz) / 30 cycles (60Hz) at 0° Power failure 0% UT 250 cycles (50Hz), 300 cycles (60Hz)
Power frequency magnetic fields (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m

Recommended separation distance between portable and mobile RF communications equipment and the Ever Pharma D-*mine*® Pump

Separation distance according to frequency of transmitter [m]			
Rated maximum output of transmitter [W]	**150 kHz to 80 MHz outside the ISM bands**	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
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

The EVER Pharma D-*mine*® Pump is suitable for use in an electromagnetic environment in which radiated RF disturbances are controlled. Customers and users of the EVER Pharma D-*mine*® Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EVER Pharma D-*mine*® Pump according to the maximum output power of the communications equipment.

10.4 DRUG DELIVERY

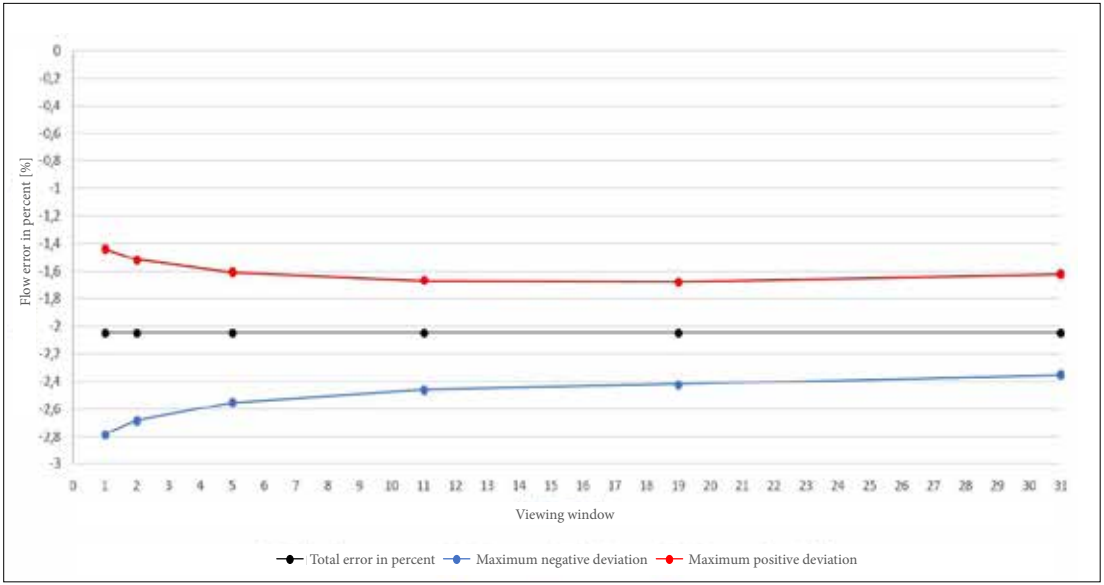
Programming of the basal rate	Up to 5 time periods over the course of 24 hours Time periods adjustable in increments of 30 minutes
Delivery of the basal rate	The programmed profile is repeated every day Delivery amount 0.1 to 15 mg/h Delivery at intervals of 1 to 30 minutes based on the set basal rate. Delivery precision +/- 5%*
Bolus delivery	Immediately upon detection of the bolus command Delivery rate 0.25 mg/s Precision +/- 5%*
Precision of delivery (trumpet curve after end of the stabilising phase)*	Page 157
Start-up diagram (delivery during the stabilising phase)*	Page 158

*As measured according to the EN 60601-2-24 standard

10.5 SETTINGS

Reservoir warning time	Reservoir Warning time Fixed settings at 60 min, 30 min and 10 min.
Bolus dose	0.0 to 10 mg adjustable in increments of 0.1 mg
Bolus lock	Number of boluses: 0 to 20 per time period: one calendar day Lockout time: 0 min to 12 h

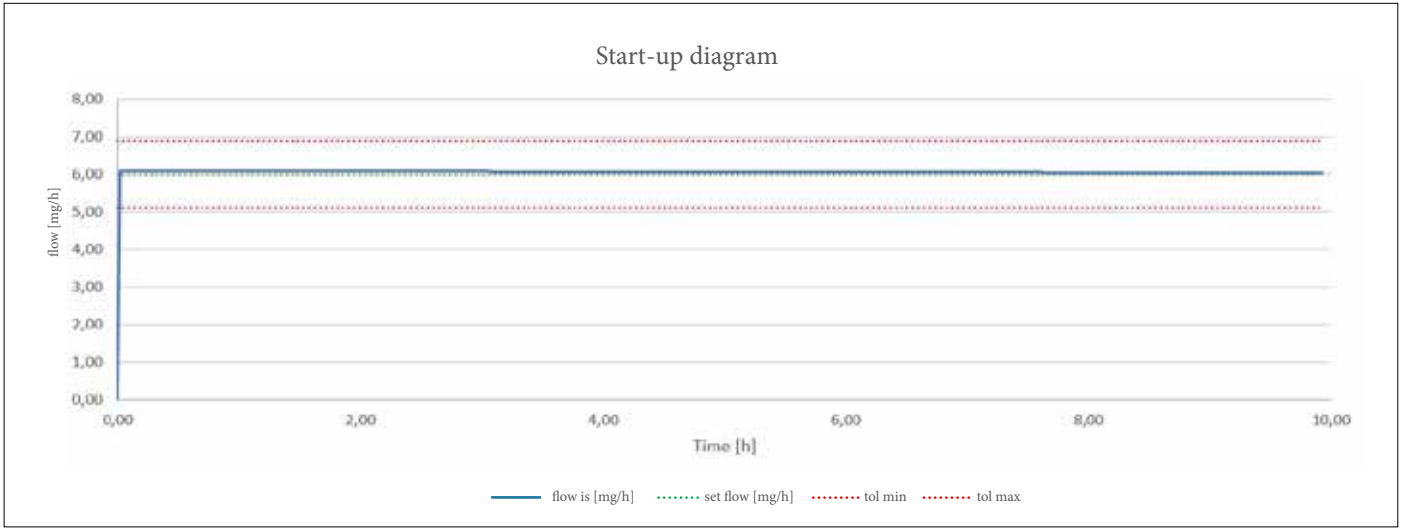
TRUMPET CURVE



Equipments and conditions:

- Delivery rate 6.0 mg/h
- Orbit administration set
- Ambient conditions: 22°C, unregulated relative humidity

START-UP DIAGRAM



Start-up diagram with delivery rate of 6.0 mg/h

Equipment and conditions:

- Orbit administration set
- Ambient conditions: 22°C, unregulated relative humidity

10.6 ABBREVIATIONS AND GLOSSARY

Apomorphine	Name of the active pharmaceutical ingredient used for treatment of Parkinson's disease. The brand name of your drug is Apomine®. If you are not sure you are using the correct drug, discontinue the treatment and contact your physician immediately.
Basal rate	Continuously delivered quantity of apomorphine, which can be programmed on the pump.
Bolus	Additional delivery of apomorphine.
Bolus lock	Locking of the bolus function to prevent delivery in excess of the prescribed drug amount or an overdose.
Function button	Button for operating the menu functions. The meaning of the function buttons is always indicated in the function button section at the bottom of the screen.
Luer connection	Standardised connecting piece between infusion set and reservoir that provides an air-tight connection when connected properly.
Menu	Selection of functions.

10.7 LICENCE TERMS - Fonts

Licence terms Font "DejaVu": Copyright (c) 2003 by Bitstream, Inc. All Rights Reserved. Bitstream Vera is a trademark of Bitstream, Inc.
Permission is hereby granted, free of charge, to any person obtaining a copy of the fonts accompanying this license ("Fonts") and associated documentation files (the "Font Software"), to reproduce and distribute the Font Software, including without limitation the rights to use, copy, merge, publish, distribute, and/or sell copies of the Font Software, and to permit persons to whom the Font Software is furnished to do so, subject to the following conditions: The above copyright and trademark notices and this permission notice shall be included in all copies of one or more of the Font Software typefaces. The Font Software may be modified, altered, or added to, and in particular the designs of glyphs or characters in the Fonts may be modified and additional glyphs or characters may be added to the Fonts, only if the fonts are renamed to names not containing either the words "Bitstream" or the word "Vera". This License becomes null and void to the extent applicable to Fonts or Font Software that has been modified and is distributed under the "Bitstream Vera" names. The Font Software may be sold as part of a larger software package but no copy of one or more of the Font Software typefaces may be sold by itself. THE FONT SOFTWARE IS PROVIDED "AS IS", WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT OF COPYRIGHT, PATENT, TRADEMARK, OR OTHER RIGHT. IN NO EVENT SHALL BITSTREAM OR THE GNOME FOUNDATION BE LIABLE FOR ANY CLAIM, DAMAGES OR OTHER LIABILITY, INCLUDING ANY GENERAL, SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, WHETHER IN AN ACTION OF CONTRACT, TORT OR OTHERWISE, ARISING FROM, OUT OF THE USE OR INABILITY TO USE THE FONT SOFTWARE OR FROM OTHER DEALINGS IN THE FONT SOFTWARE. Except as contained in this notice, the names of Gnome, the Gnome Foundation, and Bitstream Inc., shall not be used in advertising or otherwise to promote the sale, use or other dealings in this Font Software without prior written authorization from the Gnome Foundation or Bitstream Inc., respectively. For further information, contact: fonts at gnome dot org.

License Terms - Font "Noto Sans CJK TC", Font "Noto Naskh Arabic"
Noto is a trademark of Google Inc. Noto fonts are open source. All Noto fonts are published under the SIL Open Font License, Version 1.1. This license is copied below, and is also available with a FAQ at: http://scripts.sil.org/OFL; SIL OPEN FONT LICENSE Version 1.1 - 26 February 2007; PREAMBLE: The goals of the Open Font License (OFL) are to stimulate worldwide development of collaborative font projects, to support the font creation efforts of academic and linguistic communities, and to provide a free and open framework in which fonts may be shared and improved in partnership with others. The OFL allows the licensed fonts to be used, studied, modified and redistributed freely as long as they are not sold by themselves. The fonts, including any derivative works, can be bundled, embedded, redistributed and/or sold with any software provided that any reserved names are not used by derivative works. The fonts and derivatives, however, cannot be released under any other type of license. The requirement for fonts to remain under this license does not apply to any document created using the fonts or their derivatives. DEFINITIONS: "Font Software" refers to the set of files released by the Copyright Holder(s) under this license and clearly marked as such. This may include source files, build scripts and documentation. "Reserved Font Name" refers to any names specified as such after the copyright statement(s). "Original Version" refers to the collection of Font Software components as distributed by the Copyright Holder(s). "Modified Version" refers to any derivative made by adding to, deleting, or substituting -- in part or in whole -- any of the components of the Original Version, by changing formats or by porting the Font Software to a new environment. "Author" refers to any designer, engineer, programmer, technical writer or other person who contributed to the Font Software. PERMISSION & CONDITIONS: Permission is hereby granted, free of charge, to any person obtaining a copy of the Font Software, to use, study, copy, merge, embed, modify, redistribute, and sell modified and unmodified copies of the Font Software, subject to the following conditions: 1) Neither the Font Software nor any of its individual components, in Original or Modified Versions, may be sold by itself. 2) Original or Modified Versions of the Font Software may be bundled, redistributed and/or sold with any software, provided that each copy contains the above copyright notice and this license. These can be included either as stand-alone text files, human-readable headers or in the appropriate machine-readable metadata fields within text or binary files as long as those fields can be easily viewed by the user. 3) No Modified Version of the Font Software may use the Reserved Font Name(s) unless explicit written permission is granted by the corresponding Copyright Holder. This restriction only applies to the primary font name as presented to the users. 4) The name(s) of the Copyright Holder(s) or the Author(s) of the Font Software shall not be used to promote, endorse or advertise any Modified Version, except to acknowledge the contribution(s) of the Copyright Holder(s) and the Author(s) or with their explicit written permission. 5) The Font Software, modified or unmodified, in part or in whole, must be distributed entirely under this license, and must not be distributed under any other license. The requirement for fonts to remain under this license does not apply to any document created using the Font Software. TERMINATION: This license becomes null and void if any of the above conditions are not met. DISCLAIMER: THE FONT SOFTWARE IS PROVIDED "AS IS", WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT OF COPYRIGHT, PATENT, TRADEMARK, OR OTHER RIGHT. IN NO EVENT SHALL THE COPYRIGHT HOLDER BE LIABLE FOR ANY CLAIM, DAMAGES OR OTHER LIABILITY, INCLUDING ANY GENERAL, SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, WHETHER IN AN ACTION OF CONTRACT, TORT OR OTHERWISE, ARISING FROM, OUT OF THE USE OR INABILITY TO USE THE FONT SOFTWARE OR FROM OTHER DEALINGS IN THE FONT SOFTWARE.

10.8 DECLARATION OF CONFORMITY

EVER Pharma GmbH hereby declares that the device conforms to the pertinent provisions of EU Medical Device Directive 93/42/EEC (MDD 93/42/EEC) and Directive 2014/53/EU (RED 2014/53/EU) for radio equipment. Please contact the following address to request the complete declaration of conformity:

EVER Neuro Pharma GmbH
Oberburgau 3
A- 4866 Unterach / Austria

SETTINGS

REMOVABLE PATIENT FORM FOR PHYSICIANS

Patient name _____

Date of settings adjustment _____

Patient contact details _____

Drug name _____

Serial no. of the pump _____

Code for changing the settings ___ ___ ___ ___ ___ ___

Basal rate for basal period 1	Start h	End h	Basal rate mg/h
Basal rate for basal period 2	Start h	End h	Basal rate mg/h
Basal rate for basal period 3	Start h	End h	Basal rate mg/h
Basal rate for basal period 4	Start h	End h	Basal rate mg/h
Basal rate for basal period 5	Start h	End h	Basal rate mg/h

BOLUS SETTINGS

Bolus dose	mg
Number of boluses	
Time period	h
Lockout time	min

REMOVABLE PATIENT FORM

FOR PHYSICIANS

Australian Sponsor:

InterPharma Pty Ltd
Suite 103, 39 East Esplanade
Manly, NSW 2095 Australia

Medical information: 1300 308 213
Email for Medinfo: medinfo@interpharma.com.au

ANSSER Apomine® Nurse Support Service: 1800 276 646

EVER Neuro Pharma GmbH
Oberburgau 3
A-4866 Unterach / Austria

Phone: +43 7665 20555 0
Fax: +43 7665 20555 910
Email: office@everpharma.com
www.everpharma.com
www.d-minecare.com

CE 0044

REF 64263

EVER Pharma D-*mine*® Pump instructions for use D-mine_IFUPump_64263_AUS_V04
Revision: 08/2023 Software Version 1.1x