mylife YpsoPump®

User Guide

Insulin Pump

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Freedom. Confidence. With mylife™.

YPSOMED
SELFCARE SOLUTIONS

Contents

Either swipe up/down or tap upper/lower value

Tap on action field or icon

Reference to the element described in the text

Note or additional information

⚠CAUTION

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury

⚠WARNING

Indicates a hazardous situation which, if not avoided, could result in death or serious injury

Read the User Guide

Ypsomed AG, CH-3401 Burgdorf, Switzerland
www.ypsomed.com

CE 0123

⚠WARNING

If you suspect you may have hypoglycaemia or hyperglycaemia, check your blood glucose more frequently for the next few hours, as recommended by your doctor or diabetes advisor, and adapt the insulin delivery settings to the changed conditions. If you are uncertain, contact your doctor or diabetes advisor immediately. Check your blood glucose as often as your doctor or diabetes advisor recommends. If you do not check your blood glucose regularly, blood glucose fluctuations will not be detected and you will not be able to adapt the insulin dosage of the pump.

If your insulin pump displays a warning or an alarm and you do not know or are uncertain how to react to it or in case an alarm cannot be solved, call our Customer Service. You find the contact details on the back of this User Guide as well as on page 10.

1 Introduction

1.1 Note about the User Guide

This User Guide contains all the information required for conducting insulin pump therapy with the mylife™ YpsoPump® safely and successfully. Make sure you read the entire User Guide carefully.

Should any problems or questions about functions or control procedures arise during insulin pump therapy, refer to the User Guide first. Should you still experience problems or if your questions have not been answered after consulting the User Guide, do not hesitate to call our Customer Service. You find the contact details on the back of this User Guide as well as on page 10.

If the male or female form is used in order to improve readability, both genders are referred to.

1.2 Warranty provisions

Warranty
Ypsomed gives you a warranty on your mylife™ YpsoPump® covering manufacturing and material defects for a period of 4 years from the date of purchase.

The warranty is restricted to free repair or replacement of possibly defective devices, at Ypsomed's own discretion. If the mylife™ YpsoPump® has been repaired or replaced, the term of the warranty is not extended.

This warranty only applies if the mylife™ YpsoPump® has been used as intended. This warranty does not apply to defects resulting from improper or careless operation, handling or cleaning, operation contrary to this User Guide or if the mylife™ YpsoPump® is operated with accessories or supplies other than those recommended by Ypsomed.

The Instructions for Use in this User Guide are only valid for the following mylife™ YpsoPump® article: REF 700015646.

You find the reference number of your mylife™ YpsoPump® on your device and on the label of your Starter Kit.

The warranty does not apply if the mylife™ YpsoPump®:

- has been altered or modified by anyone other than Ypsomed,
- has been serviced or repaired by anyone other than Ypsomed or
- has been damaged by natural wear, inappropriate use or for other reasons not linked to a manufacturing or material defect.

Warranty rights become void if the insulin pump is damaged by dropping, impact, application of force, contact with fluids listed in chapter 9.1, page 173, improper cleaning or in other cases of exposure and wear which arise from usage that is not in accordance with this User Guide.

This warranty only applies to the first user and cannot be transferred to another person or entity neither by sale, hire nor any other transfer of the mylife™ YpsoPump®.

Insofar as it is legally permissible, this warranty and the legal remedies described are exclusive and they replace all other oral, written, legal and explicitly or implicitly agreed guarantees and warranties, legal remedies and conditions, especially including the warranty of merchantability and usability for a certain purpose.

Procedure in the event of a warranty claim

Any defect in your mylife™ YpsoPump® must be reported to Ypsomed, or a service point authorised by it, in writing or on the telephone within the term of warranty.

The claim must contain the date of purchase and the serial number of your mylife™ YpsoPump® as well as a description of the defect about which the claim is being filed. The mylife™ YpsoPump® may only be returned to Ypsomed or a service point authorised by Ypsomed if prior consent has been given by Ypsomed and if the packaging is appropriate. If the complaint is justified, Ypsomed will pay any freight charges for returning the mylife™ YpsoPump® under this warranty.

Headquarters:
Ypsomed AG
Brunnmattstrasse 6
CH-3401 Burgdorf
info@ypsomed.com

Authorised service point:
Pharmaco (N.Z.) Ltd
4 Fisher Crescent, Mt Wellington
NZ-Auckland 1060

Customer Care:
0800 GLUCOSE (0800 45 82 67)
e-mail: support@pharmacodiabetes.co.nz

1.3 Indications and contraindications

The mylife™ YpsoPump® is intended for subcutaneous insulin delivery in diabetes mellitus therapy. Only rapid-acting insulin at a concentration of 100 U/ml (insulin analogue) may be used with the mylife™ YpsoPump® system. The mylife™ YpsoPump® system is designed for uninterrupted use over the entire service lifetime. The mylife™ YpsoPump® may be used at the discretion of the supervising healthcare professional after appropriate and successful training by a qualified person (physician or other qualified personnel). There is no age limit for the patient.

Contraindication

The mylife™ YpsoPump® system is not suitable for persons:

- Who are unable to perform at least four blood glucose tests a day.
- Who are unable to maintain regular contact with their medical supervisor.
- Who do not have adequate eyesight or hearing to be able to operate the mylife™ YpsoPump® system in accordance with the User Guide.

Safety instructions

Read all the instructions in this User Guide attentively. Only use the mylife™ YpsoPump® system after having received familiarisation training from your healthcare professional. If you are not able to use the mylife™ YpsoPump® in accordance with this User Guide, you may jeopardise your health and safety. In case of doubt consult your doctor, diabetes advisor or Customer Service. Should any technical problems or questions arise, refer to the User Guide first. Should you still experience problems or if your questions have not been answered after consulting the User Guide, do not hesitate to call our Customer Service. You find the contact details on the back of this User Guide as well as on page 10.

Procedure in case of serious incident

Inform Ypsomed and your local health authority in case of serious health effects (such as serious injury or hospitalisation) and/or malfunction of the mylife™ YpsoPump® insulin pump system.

1.4 Potential benefits

The mylife™ YpsoPump® insulin pump system provides the common proven benefits of standard continuous subcutaneous insulin infusion (CSII) therapy.

1.5 Potential risks

As with any medical device, there are risks associated with using the mylife™ YpsoPump®. Many of the risks are common to insulin therapy in general, but there are additional risks associated with continuous insulin infusion. Reading your User Guide and following the Instructions for Use are essential for the safe operation of your insulin pump. Consult your healthcare professional about how these risks may affect you.

Inserting and wearing an infusion set might cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring or skin discolouration).

There is a remote chance that an infusion set cannula fragment or steal needle could remain under your skin if the cannula or needle breaks while you are wearing it. If you think a cannula or needle has broken under your skin, contact your healthcare professional and call our Customer Service. You find the contact details on the back of this User Guide as well as on page 10.

Other risks associated with infusion sets include insulin leakage, occlusions and air bubbles in the tubing, which can affect insulin delivery.

Risks that could result from pump or infusion set failure include the following:

- Possible hypoglycaemia (low blood glucose) from over-delivery of insulin due to a hardware defect or use errors.
- Hyperglycaemia (high blood glucose) and ketosis possibly leading to Diabetic Ketoacidosis (DKA) due to pump failure, resulting in cessation of insulin delivery due to a hardware defect, software anomaly, insulin leakage, etc.

Monitor your blood glucose with the guidance of your healthcare professional. Patients should routinely check their glucose levels at least 4 times daily (optimally 6 to 8 times daily) in order to detect hyperglycaemia (high blood glucose) and hypoglycaemia (low blood glucose) early. Undetected hyperglycaemia or hypoglycaemia can result without proper monitoring. Consult your healthcare professional before using the mylife™ YpsoPump® to determine which features and accessories are most appropriate for you. Only your healthcare professional can determine and help you adjust your basal rate(s), insulin-to-carbohydrate ratio(s), correction factor(s), blood glucose target(s), and duration of insulin action.

1.6 Disposal

When disposing of all materials, always comply with the environmental protection regulations applicable in the particular country. Always dispose of needles and sharp or pointed objects, such as the cannula base, the tubing with adapter and the introducer needle of your mylife™ YpsoPump® Orbit infusion set, in a safety bin.

1.7 System warnings

⚠WARNING

⚠ Read the Instructions for Use in this User Guide before starting to use your mylife™ YpsoPump®. Not following the instructions in the User Guide of your mylife™ YpsoPump® or not following warnings indicated in this User Guide can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Use the mylife™ YpsoPump® insulin pump only on prescription. Never use the mylife™ YpsoPump® without prior training from your doctor or diabetes advisor. Using the mylife™ YpsoPump® without professional training can lead to incorrect dosage of insulin. When using an insulin pump, it is in your responsibility to ensure permanent access to alternative injection systems (e.g. in case of failure of the insulin pump). For more information, please contact your doctor or diabetes advisor.

⚠ Use only rapid-acting insulin at a concentration of 100 U/ml (insulin analogue) with the mylife™ YpsoPump® system. Using a different insulin can lead to incorrect dosages of insulin, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7). If you use a different insulin, change the cartridge as well as the primed infusion set and continue therapy with the correct type of insulin.

⚠ Always programme the time of day, the bolus increment, a bolus, a blind bolus, a basal rate or a temporary basal rate carefully. In all cases, incorrect programming can lead to incorrect insulin doses, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7). Therefore, only make changes to your settings after consulting your doctor or diabetes advisor.

⚠ Use your own therapy settings. The shown values on the following pages are only examples. Always make the first setting or change of the basal rate according to your doctor's or diabetes advisor's recommendations and never on your own. Programme your basal rate profile in single steps. To do this carefully enter the hourly values and make sure that the setting before each entry corresponds to your therapy recommendations.

⚠ Alarms always lead to an interruption of insulin administration. In such cases, solve the alarm according to the description in this User Guide. Disregarding the alarms can lead to incorrect insulin dosage, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Choking hazard: keep small parts out of reach of children.

1.8 System cautions

⚠ CAUTION

⚠ Avoid exposure of your mylife™ YpsoPump® to temperatures in operation above 37 °C or below 5 °C and to temperatures in storage above 40 °C or below 0 °C. Insulin solutions freeze near 0 °C and degrade at high temperatures. If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool. Do not steam, sterilise or autoclave your pump. Never expose the mylife™ YpsoPump® to radiation or light (e.g. radiators, direct sunlight). This also applies to the insulin you are using. For information about the correct insulin storage conditions and operating conditions please refer to the Instructions for Use of the insulin you are using. Do not use the mylife™ YpsoPump® in areas with very high humidity. The system may be operated within a humidity range of 20 % to 95 % RH.

⚠ Do not use your pump if it could be damaged by falling or hitting solid surfaces. Never use tools or other instruments to change the battery, cartridge or the infusion set. If the insulin pump is obviously damaged, the correct delivery of insulin might be affected. However, the damage might be microcracks that are not visible to the user and can affect dosing accuracy or watertightness. Therefore, check the outside of the insulin pump for cracks and damage and perform a self-test. An impaired functionality of the pump can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Cleaning instructions: Clean or dry the insulin pump with a damp cotton cloth. If it is not possible to remove the dirt, clean the surface with a small amount of normal cleaning liquid and a damp cotton cloth. Do not use sharp objects, chemicals, solvents or strong detergents to clean the pump.

⚠ Always monitor the self-test carefully and attentively. If you are unsure whether the self-test has been performed correctly, repeat the self-test. If, during the self-test, the visual display, tactile vibration signal or audible signal is incorrect, do not use the mylife™ YpsoPump® any more, as potential warnings or alarms on the insulin pump can no longer be displayed correctly. In this case, contact Customer Service immediately. You find the contact details on the back of this User Guide as well as on page 10.

⚠ To prevent risk of infection, never pull the stopper of the mylife™ YpsoPump® Reservoir beyond the 1.6-ml mark and do not reuse the transfer adapter or the reservoir.

⚠ In loud surroundings it may be difficult to hear alarms (e.g. lawn mowing, concerts, etc.). In such surroundings listen for alarms and check your insulin pump screen more frequently. Alarms that have not been dealt with can lead to failure of the preset insulin delivery, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Make sure the insulin pump is positioned properly while you are asleep so that you notice any alarms. Alarms that have not been dealt with can lead to failure of the preset insulin delivery, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Make sure to always carry a replacement battery with you.

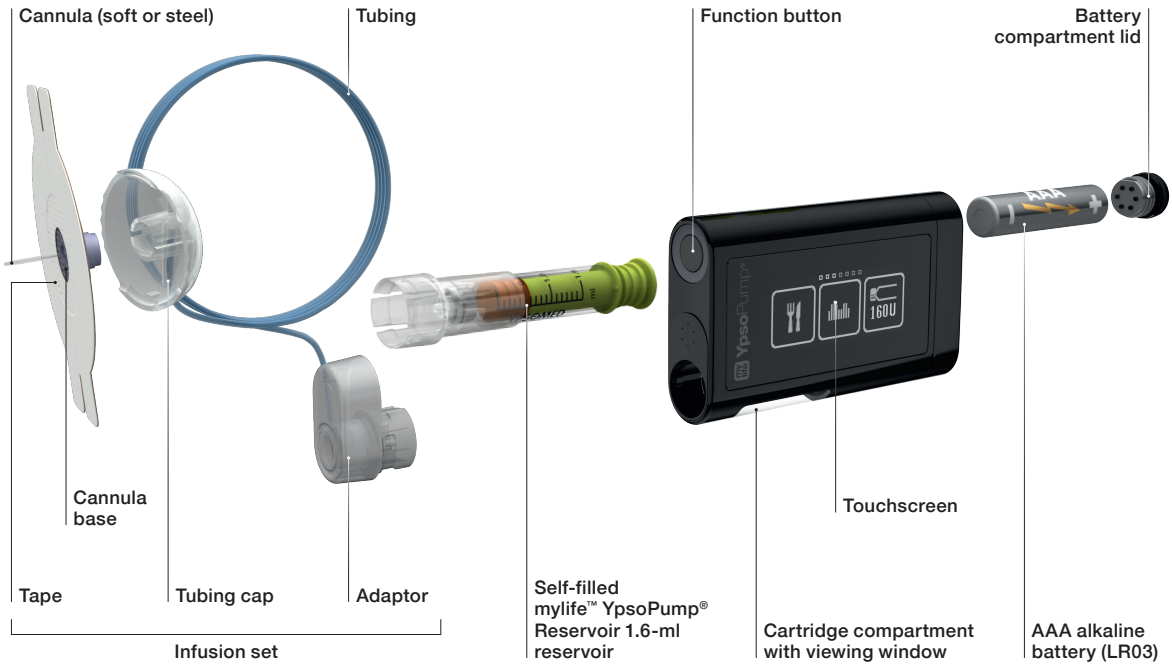
2 Operation

⚠WARNING

⚠ Use of the wrong function can lead to incorrect dosages of insulin. Refer to this User Guide for correct operation and have your doctor or diabetes advisor check the settings. If you have activated a wrong function or changed an insulin pump setting, undo it as described in this User Guide. If you are uncertain, contact Customer Service. You find the contact details on the back of this User Guide as well as on page 10. If a mix-up has caused your insulin intake to stop or change, check your blood glucose more frequently over the next few hours, as recommended by your doctor or diabetes advisor, and adjust your insulin intake to the changed conditions.

⚠ Use only AAA alkaline batteries (LR03) with your mylife™ YpsoPump®. If a different type of battery (e.g. a lithium battery or a NiMH rechargeable battery) or a damaged battery is inserted, there is no guarantee that the insulin pump will operate properly. This means that the pre-warning time up to the “Battery empty” alarm (page 163) cannot be maintained when the battery is discharged. This can lead to failure of the preset insulin delivery, which can cause hyperglycaemia (read warning in the box on page 7).

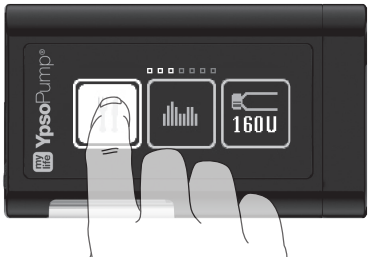
2.1 System overview

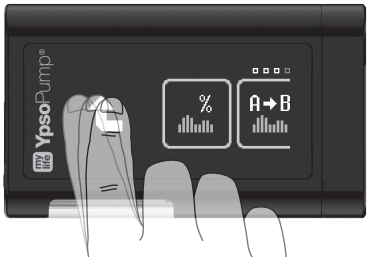


2.2 Navigation

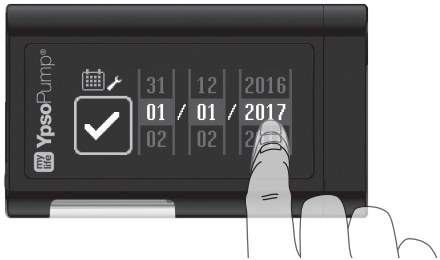
Touchscreen

The mylife™ YpsoPump® has a touchscreen (referred to below as the screen). You control the screen by using your finger to tap icons and values or swipe through menus and values. The screen of the mylife™ YpsoPump® may only be controlled with one finger. Do not use any objects to operate the screen.





Using your finger, swipe up or down through the values displayed. In this way you can increase or reduce a value. You can also tap the upper or lower value directly in order to increase or reduce it by one unit. The value selected is always displayed at the centre of the visible values and it has a grey background. Do not use the device if it shows visible signs of damage. If the device no longer responds to touch, stop using it. In such a case, contact Customer Service without delay.



Function button
The mylife™ YpsoPump® has a function button.
It is located next to the opening of the cartridge compartment at the side.

The function button has two different functionalities:
- Short press (for up to 0.8 seconds)
- Long press (for at least 2 seconds until the mylife™ YpsoPump® vibrates)

With the function button you can:
- Switch the screen on and off
- Programme a blind bolus
- Return to the status screen

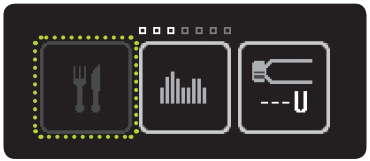
Function button

Icons

The controls on the screen are called icons. Tap an icon with your finger to select it. The brightness of icons is inverted when you touch them with your finger.

Active and inactive icons

Active icons are bright. That means the function is available and can be selected with your finger.



Inactive icons are displayed in a darker grey. This means the function is not available and cannot be selected with your finger.

Confirmation and cancellation

To confirm a value or select a function tap ☑.

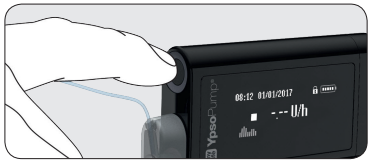
To cancel a procedure or function, tap ☒. Additionally, bolus cancellation always has to be confirmed by tapping ☑.

Back function

If you have selected a function or value by mistake or made a wrong setting, you can go back at any time by swiping to the right once until ← or ↰ appears. If ← appears, you go one step back. You do not quit the function and no set values are lost. If ↰ appears, you move up one menu level.

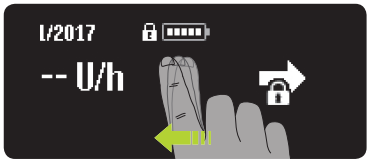
2.3 User interface

Unlock screen



1/6: The status screen of the mylife™ YpsoPump® is switched on and off by pressing the function button (short button press).

2/6: The mylife™ YpsoPump® has a screen lock. It is visualised by a padlock icon at the top right of the screen, next to the battery charge indicator.



3/6: Swipe to the left to unlock the status screen and the main menu. Three icons appear numbered 1, 2 and 3 (unlock screen).

If the mylife™ YpsoPump® is not operated on the status screen, the screen switches off after 20 seconds and the screen lock is activated. If the mylife™ YpsoPump® is not operated in the main menu or in a submenu, the screen switches off after two minutes and the screen lock is activated. Any changes that have not been saved, are lost.

4/6: Tap the currently active number successively to unlock the status screen. If the three numbers on the unlock screen are not entered in the correct sequence within 10 seconds, you return to the locked status screen. Swipe to the right to return to the locked status screen.

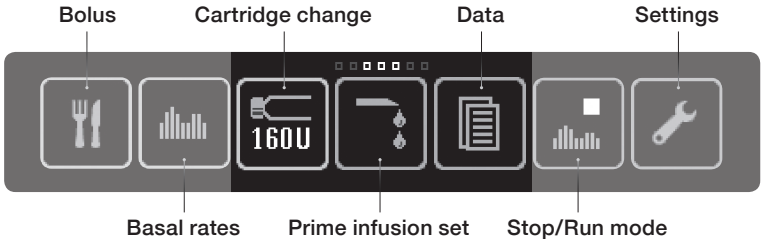
5/6: When the mylife™ YpsoPump® has been unlocked successfully, you are in the main menu. Swipe to the left to access all available menu items.

6/6: Swipe to the right to access the unlocked status screen (no padlock icon).

Make sure you switch off the screen before storing the mylife™ YpsoPump® in your trouser pocket or in a carrying system in order to avoid unintentional operation of the pump.

Overview of the main menu
On the screen you will see three menu icons at a time. To see the other menu icons, swipe to the left across the screen with your finger.

The navigation bar above the icons shows you the number of menu icons available. The small squares highlighted in white indicate where you currently are in the main menu. When operating the mylife™ YpsoPump® always make sure you use the various functions properly.



2.4 Run and stop modes

Run mode

The mylife™ YpsoPump® has two different operating modes, “Run” and “Stop”. The “Stop mode” and “Run mode” icons show the current operating status of the insulin pump in each case. Insulin delivery (e.g. basal rate) is only possible in run mode.

1/3: Open the main menu, swipe to the left and tap the “Stop mode/ switch to run mode” icon.

2/3: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly.

3/3: The status screen appears. Basal rate delivery starts according to the programmed profile.

Stop mode

To switch the mylife™ YpsoPump® from run mode to stop mode, open the main menu. Insulin delivery is not possible in stop mode.

1/3: Open the main menu, swipe to the left and tap the “Run mode/switch to stop mode” icon.

2/3: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly.

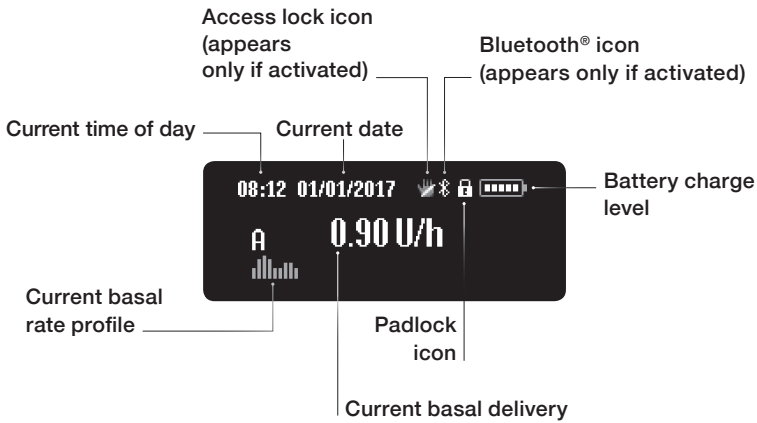
3/3: The status screen appears. Insulin deliveries are stopped immediately. This is indicated on the screen.

The screen of the mylife™ YpsoPump® shows a stop warning if the insulin pump has been in stop mode for more than one hour. The stop warning can be triggered prematurely, directly after the insulin pump has been set into stop mode, by giving the function button a long press and then confirming the warning.

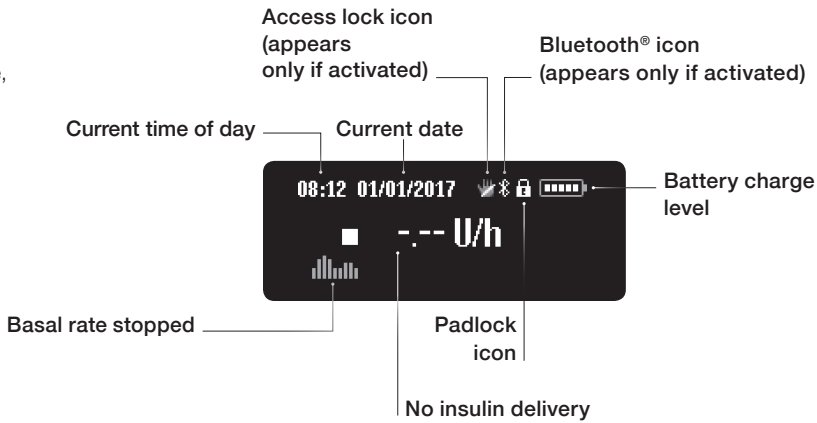
Status screen in run mode
The status screen is the main display of information and it indicates the current operating status of the mylife™ YpsoPump®. You can access the status screen at any time by giving the function button one short press. If you do not use the status screen of the mylife™ YpsoPump®, it switches off automatically after 20 seconds. The mylife™ YpsoPump® still remains active and in run mode, it delivers insulin continuously according to the programmed settings.

If the insulin pump is in run mode, the status screen indicates the current basal rate profile and the current insulin delivery.

If you are in the main menu or in a submenu and you do not operate the insulin pump for two minutes, the screen switches off automatically.



Status screen in stop mode
If the insulin pump is in stop mode, all insulin delivery is cancelled.

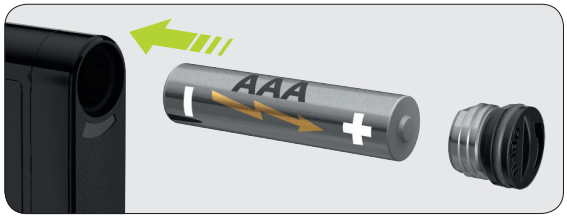


The battery charge level is indicated by rectangles in the battery icon on the status screen of the pump. The number of rectangles is proportional to the battery charge.

Battery charge level low
Battery fully charged

2.5 Putting into operation

Inserting a battery



1/11: Insert a new AAA alkaline battery (LR03). Make sure the negative pole of the battery is inserted first. On the back of the insulin pump you will see a picture showing how to insert the battery.

2/11: Lock the battery compartment by turning the groove of the battery compartment lid clockwise until it is completely closed using the edge of a coin.

Replace the battery compartment lid regularly (every three months). Otherwise, the seal of the battery compartment may no longer be intact.

Self-test

The self-test is used to check the operability of the mylife™ YpsoPump® and to give the user visual, tactile and audible feedback. A self-test is performed when putting the insulin pump into operation for the first time, after having started up the insulin pump from storage status and after the threaded rod has been returned.

3/11: As soon as the battery has been inserted, the welcome screen appears and remains until the insulin pump starts the self-test.

4/11: In addition to the mylife™ YpsoPump® logo, the serial number of the insulin pump and the software version are displayed at the top left. Confirm the start of the self-test by tapping ☑. The mylife™ YpsoPump® now performs a self-test.

5/11: Three test patterns appear on the screen one after the other. The 3 × 3 test rectangles must be displayed in full with uniform brightness.

6/11: Then the mylife™ YpsoPump® emits two vibration signals (tactile signals).

7/11: The tactile signals are followed by two audible signals.

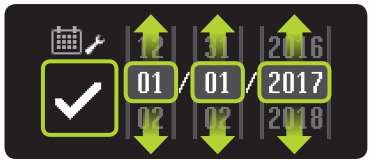
8/11: The self-test is completed. You can repeat the self-test by swiping to the right. Confirm the successful completion of the self-test by tapping ☑.

If the self-test is not confirmed within 5 minutes after having started up the insulin pump from storage status or after the threaded rod has been returned, the insulin pump indicates this with tactile and audible warnings. If the screen is now switched on using the function button, the start self-test screen appears again (Fig. 4/11). Complete the self-test and confirm.

Setting the time of day

9/11: The screen for setting the time of day appears. Set the current time of day (hours, minutes) by selecting the desired value. Confirm the values set by tapping ☑.

Setting the date

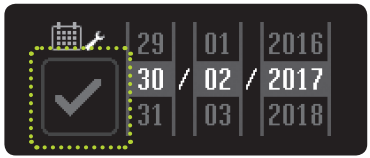


10/11: After setting the time of day, set the current date (day, month, year). Confirm your setting by tapping ☑.

11/11: The status screen appears. The insulin pump is in stop mode.

To complete the putting into operation of your insulin pump, please program both basal rate profiles following the steps on page 44, insert a cartridge following the steps on page 96, prime the infusion set following the steps on page 100, attach the infusion set to your body following the steps on page 104, prime the cannula following the steps on page 111 and switch the insulin pump into run mode following the steps on page 31.

You can adjust the time of day and the date at any time in the settings menu. If you select an impossible date (e.g. 30/02/2017), the confirmation icon will be inactive (grey) and you cannot confirm the date.



3 Basal rate

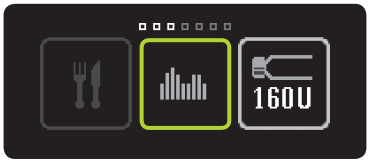
⚠WARNING

⚠ Always programme both basal rate profiles (A and B) in accordance with the recommendations from your doctor or diabetes advisor. If only one basal rate profile is needed, the second one has to be programmed in the same way as the first one. By doing so, the basal rate will continue without any interruption should you unintentionally switch the basal rate profile. Without programming a profile, your basal rate value is set to 0 and your insulin pump will not deliver any basal insulin. This can lead to hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Only switch from the present basal rate profile to a new basal rate profile when you need a second profile and only make changes to the basal rate profile in accordance with the recommendations from your doctor or diabetes advisor. A change in basal rate profile that has not been adapted to a particular situation can lead to hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

3.1 Programming basal rate profile A

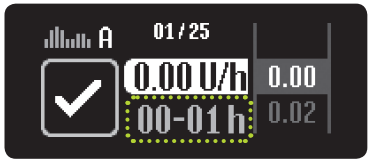
The basal rate is a basic amount of insulin that is administered continuously in order to keep the blood glucose level within the target range. You have the option to programme two different basal rate profiles (A and B). If only one basal rate profile is needed, basal rate profile B has to be programmed in the same way as basal rate profile A.



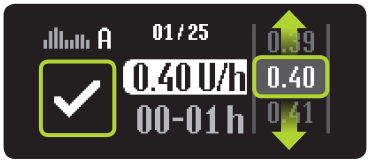
1/8: Open the main menu and tap the “Basal rates” icon.

2/8: Tap the “Basal rate profile A” icon.

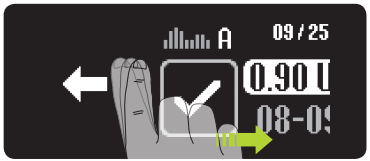
The following values are displayed on the screen of your mylife™ YpsoPump® and mentioned in this User Guide using the following abbreviations:
U = insulin units
h = hours
d = day



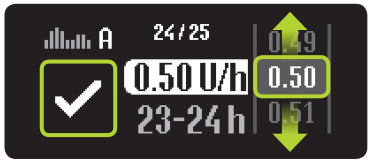
3/8: The screen to set the basal rate for the first hour appears, starting at midnight (00 – 01 h). When putting into operation for the first time (when programming a basal rate profile for the first time), an hourly value, which is set and confirmed, is applied to the next hour as a starting value.



4/8: Select the value specified for you by your doctor, between 0.00 U/h and 40.0 U/h, and confirm by tapping ☑. After each confirmation of an hourly value, you automatically move to the next hour. The basal rate values between 0.02 U/h and 1.00 U/h can be set in increments of 0.01 U/h. The basal rate values between 1.00 U/h and 2.00 U/h can be set in increments of 0.02 U/h. The basal rate values between 2.00 U/h and 15.0 U/h can be set in increments of 0.1 U/h. The basal rate values between 15.0 U/h and 40.0 U/h can be set in increments of 0.5 U/h.



5/8: By swiping to the right you can step back one hour at any time and adjust your previous entry.



6/8: Repeat step 4/8 for each individual hour segment until you have entered all 24 basal rate values.

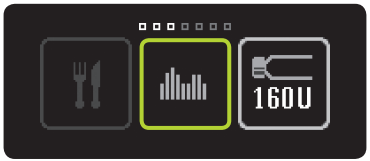
7/8: When all values have been entered, the mylife™ YpsoPump® shows you the basal rate daily dose on a chart and as a value. The basal rate values can be changed by swiping to the right until you reach the segment you want to correct. Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly. The values are saved and one event per basal rate value is written to the therapy data.

8/8: The status screen appears. The mylife™ YpsoPump® is in stop mode. To start insulin delivery switch the insulin pump into run mode. The difference between run mode and stop mode is explained on page 31.

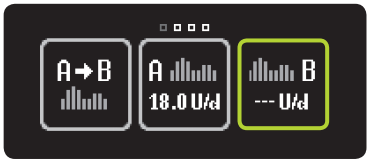
The total daily dose of the programmed basal rate profile is displayed in the basal rate submenu on the corresponding basal rate icon.

3.2 Programming basal rate profile B

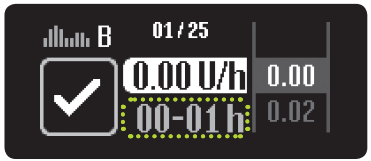
In addition to basal rate profile A, you have the option to programme a different basal rate profile B. If only one basal rate profile is needed, basal rate profile B has to be programmed in the same way as basal rate profile A. You can switch between basal rate profiles A and B at any time.



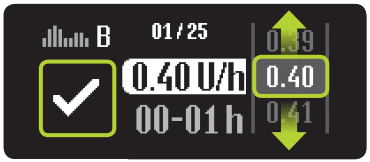
1/8: Open the main menu and tap the “Basal rates” icon.



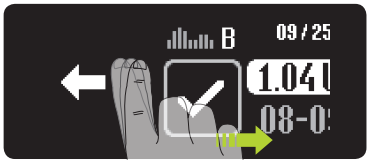
2/8: Tap the “Basal rate profile B” icon.



3/8: The screen to set the basal rate for the first hour appears, starting at midnight (00 – 01 h). When putting into operation for the first time (when programming a basal rate profile for the first time), an hourly value, which is set and confirmed, is applied to the next hour as a starting value.



4/8: Select the value specified for you by your doctor, between 0.00 U/h and 40.0 U/h, and confirm by tapping ☑. After each confirmation of an hourly value, you automatically move to the next hour. The basal rate values between 0.02 U/h and 1.00 U/h can be set in increments of 0.01 U/h. The basal rate values between 1.00 U/h and 2.00 U/h can be set in increments of 0.02 U/h. The basal rate values between 2.00 U/h and 15.0 U/h can be set in increments of 0.1 U/h. The basal rate values between 15.0 U/h and 40.0 U/h can be set in increments of 0.5 U/h.



5/8: By swiping to the right you can step back one hour at any time and adjust your previous entry.

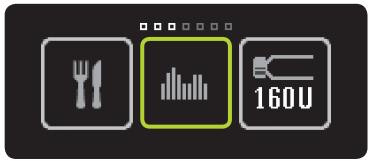
6/8: Repeat step 4/8 for each individual hour segment until you have entered all 24 basal rate values.

7/8: When all values have been entered, the mylife™ YpsoPump® shows you the basal rate daily dose on a chart and as a value. The basal rate values can be changed by swiping to the right until you reach the segment you want to correct. Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly. The values are saved and one event per basal rate value is written to the therapy data.

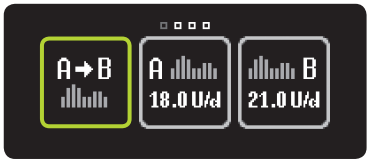
8/8: The status screen appears. The mylife™ YpsoPump® is in stop mode. To start insulin delivery switch the insulin pump into run mode. The difference between run and stop mode is explained on page 31.

The total daily dose of the programmed basal rate profile is displayed in the basal rate submenu on the corresponding basal rate icon.

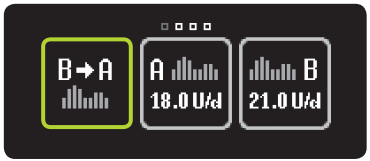
3.3 Switching basal rate profile



1/4: Open the main menu and tap the “Basal rates” icon.



2/4: If basal rate profile A is active, tap the “Switch to basal rate profile B” icon.

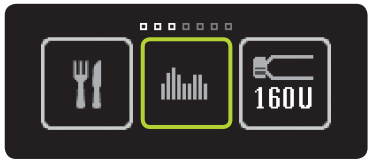


3/4: If basal rate profile B is active, tap the “Switch to basal rate profile A” icon.

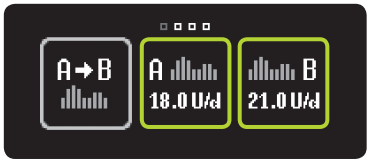
4/4: When you have made your selection, the mylife™ YpsoPump® indicates the relevant basal rate profile (A or B) with the basal rate daily dose.
Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly.

Switching basal rate profiles changes basal insulin delivery. Make sure such a change complies with your therapy recommendation. If the temporary basal rate function is activated, the switch basal rate profiles function is not available (the relevant icon is inactive).

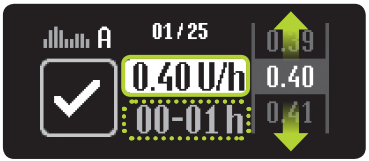
3.4 Changing a basal rate profile



1/4: Open the main menu and tap the “Basal rates” icon. The screen displays the basal rate submenu. If the “Temporary basal rate function” is activated, the basal rate profiles A and B functions are not available.



2/4: Tap the basal rate profile icon you want to change.



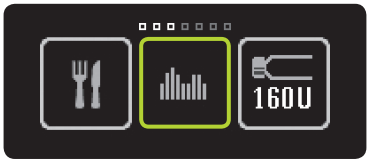
3/4: The screen to set the basal rate for the first hour, starting after midnight (00 – 01 h), is displayed – with the value you set last. You can confirm that value, or select a new value between 0.00 U/h and 40.0 U/h and also confirm by tapping ☑. Now repeat step 3/4 for each individual hour segment for all 24 basal rate values.

4/4: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly. The mylife™ YpsoPump® saves the values, writes an event to the therapy data for each changed value and indicates the basal rate daily dose.

3.5 Temporary basal rate function

Activating the temporary basal rate function

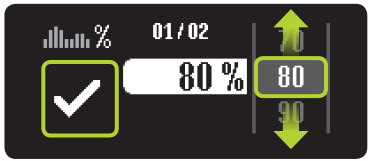
The temporary basal rate function allows you to reduce or increase the basal rate for a limited period of time. When the temporary basal rate set has finished, the programmed basal rate profile (A or B) continues. To use the temporary basal rate function the mylife™ YpsoPump® must be in run mode.



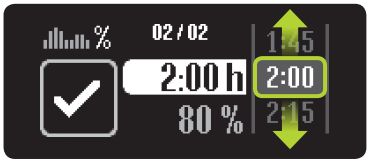
1/7 Open the main menu and tap the “Basal rates” icon.

2/7: Tap the “Temporary basal rate function” icon.

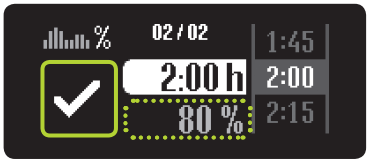
The temporary basal rate function is not available in stop mode. To use this function the insulin pump must be in run mode.



3/7: If you wish to reduce your current basal rate, select a value between 0 % and 90 %. If you wish to increase your current basal rate, select a value between 110 % and 200 %, e.g. if you choose a temporary basal rate of 80 %, the current basal rate is reduced by 20 %. 100 % means no reduction and no increase. Then confirm by tapping ☑.



4/7: Select the period of time in which you want to reduce or increase the current basal rate. The period can be set from 15 minutes to 24 hours in steps of 15 minutes.



5/7: The percentage of the current basal rate is displayed to you in grey as information under the period of time selected. The mylife™ YpsoPump® starts the temporary basal rate function after confirmation by tapping ☑. The mylife™ YpsoPump® vibrates briefly.

If the temporary basal rate function is activated, it is not possible to change a basal rate profile, to switch basal rate profiles, to change a cartridge or to prime the infusion set.

6/7: The status screen appears with the actual basal rate. A % sign next to the basal rate profile set indicates that a temporary basal rate function is active.

7/7: In addition, the period of time remaining and the selected percentage of the basal rate are displayed alternately under the basal rate value.

When the temporary basal rate set has completed, a warning appears on the screen. Confirm the warning. The programmed basal rate (A or B) also continues if you do not confirm the warning.

Cancelling the temporary basal rate function

1/4: Open the main menu and tap the "Basal rates" icon.

2/4: Tap the "Temporary basal rate function activated/cancel" icon.

3/4: Confirm cancellation of the temporary basal rate function by tapping ☑. The mylife™ YpsoPump® vibrates briefly.

4/4: The status screen appears with the basal rate originally programmed.

4 Bolus

⚠WARNING

⚠ Only change your specified bolus increment after consulting your doctor or diabetes advisor. Changing your bolus increment accidentally can lead to hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ If the bolus is cancelled prematurely, the warning “Bolus cancelled” appears. Premature cancellation occurs when there is an alarm or when the insulin pump is set to stop mode. You can check the actual duration and the amount of delivered insulin in the therapy history. If you want to continue with the bolus, programme a new bolus taking into account the amount already delivered. Bear in mind that incorrect bolus delivery can lead to hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

A bolus is an insulin dose administered in addition to the basal rate. To be able to deliver a bolus the mylife™ YpsoPump® must be in run mode.

A bolus is administered in the following situations:

- Compensation for meal carbohydrates (a meal bolus).
- Reduction of blood glucose to correct a high blood glucose level.

4.1 Setting bolus increment

The bolus increment indicates the increase or decrease in bolus amount per touchscreen gesture. It also indicates the increase in bolus amount for each press of the function button when entering a blind bolus.

1/4: Open the main menu and tap the “Settings” icon.

2/4: Tap the “Set bolus increment” icon.

3/4: Select one of the following bolus increments: 0.1 U, 0.5 U, 1.0 U, 2.0 U. Set the bolus increment value that was specified for you by your doctor. Confirm your setting by tapping ☑. The insulin pump vibrates briefly.

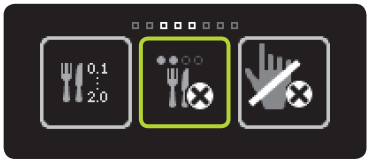
4/4: The status screen appears.

Bear in mind that the bolus increment has a direct influence on the blind bolus function. The bolus increment set equals the insulin amount increase for each press of the function button.

4.2 Activating blind bolus

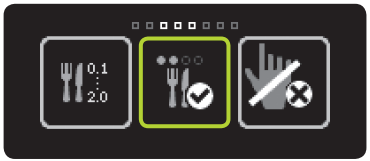
When putting the mylife™ YpsoPump® into operation for the first time the blind bolus function is always inactive. To use the blind bolus function you must activate it first.

1/4: Open the main menu and tap the “Settings” icon.



2/4: Swipe to the left and tap the “Blind bolus inactive/activate” icon.

3/4: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the blind bolus function can be used. Follow the procedure on page 78.

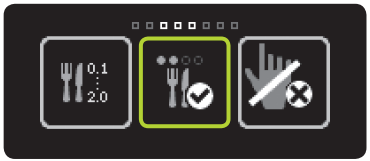


4/4: If you open the main menu again, tap the “Settings” icon and swipe to the left, the “Blind bolus active/ deactivate” icon now appears.

4.3 Deactivating blind bolus

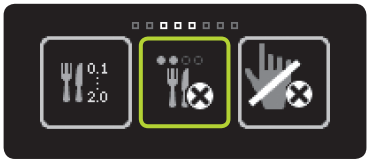
With the mylife™ YpsoPump® you have the option of deactivating the blind bolus function.

1/4: Open the main menu and tap the “Settings” icon.



2/4: Swipe to the left and tap the “Blind bolus active/deactivate” icon.

3/4: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the blind bolus function is deactivated.



4/4: If you open the main menu again, tap the “Settings” icon and swipe to the left, the “Blind bolus inactive/ activate” icon now appears.

4.4 Bolus types

The mylife™ YpsoPump® has 4 bolus types:

Standard bolus
The bolus amount entered is delivered immediately.

Extended bolus
The bolus amount entered is delivered over an adjustable extension time, spread equally.

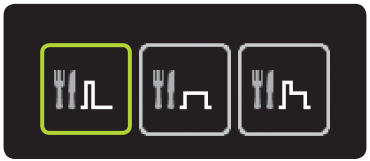
Combination bolus
The total bolus amount entered is split adjustably between a standard bolus and an extended bolus.

Blind bolus
The blind bolus is a method of standard bolus delivery that can only be programmed by pressing the function button.

It is possible to deliver a standard bolus or a blind bolus when an extended portion of a bolus is in progress. A standard or blind bolus always has priority over an extended portion of a bolus. If you deliver a standard or blind bolus when an extended portion of a bolus is in progress, the standard or blind bolus is displayed on the status screen. After its delivery, the status screen switches back to the remaining amount of the extended portion of a bolus.

Standard bolus

1/4: Open the main menu and tap the “Bolus” icon.



2/4: Tap the “Standard bolus” icon.

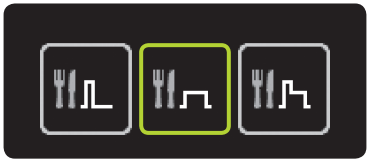
3/4: Select a bolus amount between 0.1 U and 30.0 U. Bolus delivery commences immediately as soon as you confirm by tapping ☑. If the default value of 0.0 U is confirmed, the standard bolus is cancelled. The mylife™ YpsoPump® vibrates briefly.

All bolus type functions are not available if the insulin pump is in stop mode, if the cartridge is empty, if the remaining insulin amount in the cartridge is smaller than the bolus increment setting or if the insulin pump displays an alarm or a warning. Bear in mind that entering a minimum bolus amount is directly dependent on the bolus increment setting. If the bolus increment is set to 1.0 U, for example, the minimum bolus amount that can be set for a standard bolus is also 1.0 U.

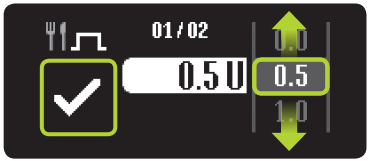
4/4: The mylife™ YpsoPump® counts down the remaining units on the status screen. You can cancel a bolus in progress at any time by tapping ☒. Cancellation must always be confirmed by tapping ☑.

Extended bolus

1/6: Open the main menu and tap the “Bolus” icon.

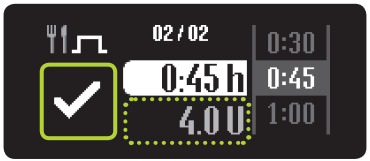


2/6: Tap the “Extended bolus” icon.



3/6: Select a bolus amount between 0.1 U und 30.0 U and confirm by tapping ☑. If the default value of 0.0 U is confirmed, the extended bolus is cancelled.

4/6: Select the extension time during which you wish to deliver the bolus amount selected. The extension time can be set from 15 minutes to 12 hours in steps of 15 minutes.

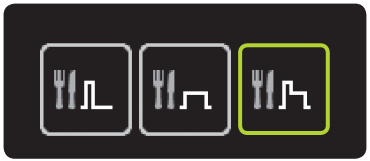


5/6: The set bolus amount is displayed in grey below the extension time selected. The mylife™ YpsoPump® starts bolus delivery after confirmation by tapping ☑. The mylife™ YpsoPump® vibrates briefly.

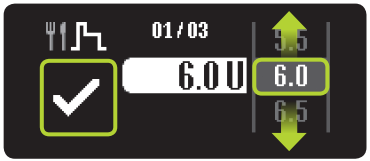
6/6: The mylife™ YpsoPump® counts down the remaining units on the status screen. In addition, the remaining extension time of the extended bolus is displayed. You can cancel a bolus in progress at any time by tapping ☒. Cancellation must always be confirmed by tapping ☑.

Combination bolus

1/8: Open the main menu and tap the “Bolus” icon.

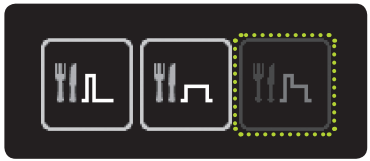


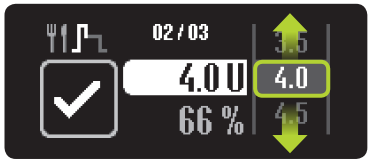
2/8: Tap the “Combination bolus” icon.



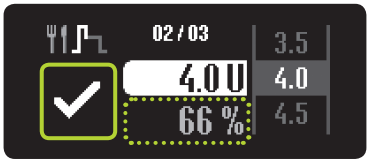
3/8: Select a total bolus amount between 0.2U and 30.0U and confirm by tapping ☑. If the default value of 0.0U is confirmed, the combination bolus is cancelled.

The combination bolus function cannot be performed if the remaining insulin amount in the cartridge is smaller than twice the bolus increment setting (minimum amount for combination bolus is twice the bolus increment).



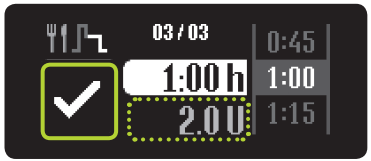


4/8: Select the bolus amount that you want to deliver directly (immediate portion).



5/8: The percentage of the immediate portion is displayed in grey under the bolus amount selected. This bolus amount must be confirmed by tapping ☑.

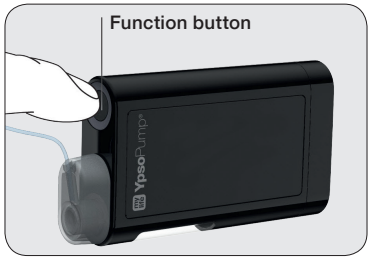
6/8: Select the extension time during which you wish to deliver the remaining portion of the bolus amount (extended portion). Extension time can be set from 15 minutes to 12 hours in steps of 15 minutes.



7/8: The bolus amount of the extended portion is displayed in grey below the extension time selected. The mylife™ YpsoPump® starts bolus delivery after confirmation by tapping ☑. The insulin pump vibrates briefly.

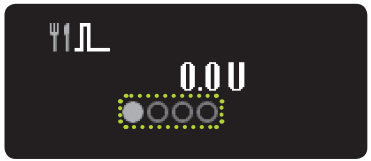
8/8: The mylife™ YpsoPump® counts down the remaining units on the status screen. The immediate portion of the bolus is delivered first. It is followed by the extended portion. In addition, the remaining extension time of the extended bolus is displayed. You can cancel a bolus in progress at any time by tapping ☒. Cancellation must always be confirmed by tapping ☑.

Blind bolus
You have the option of programming a bolus only by pressing the function button, without using the touchscreen. This means you can deliver a bolus discreetly, when the mylife™ YpsoPump® is in your trouser pocket, for example. Make sure the blind bolus function has been activated according to the procedure on page 66.



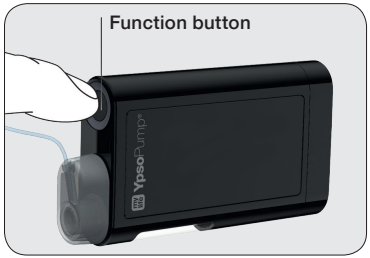
1/7: Give the function button one long press until the mylife™ YpsoPump® emits a long vibration signal.

The blind bolus function is not available in stop mode. Make sure the insulin pump is in run mode. The blind bolus function is not available if the cartridge is empty or if the insulin pump displays an alarm or a warning. To activate the blind bolus function follow the procedure on page 66. To deactivate the function follow the procedure on page 68.



2/7: You are now in the blind bolus menu. Here you can set the bolus amount required. Begin with entering an amount within 4 seconds. The elapsed time is displayed to you by dots turning grey.

If you fail to set a bolus amount within 4 seconds, the blind bolus menu disappears automatically and programming is cancelled. This is indicated by three short vibrations.



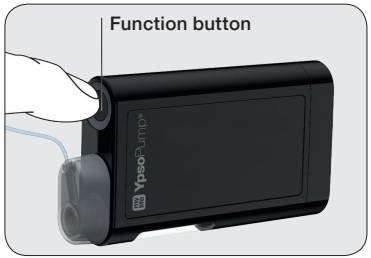
3/7: Set the bolus amount required by giving the function button a short press for each step of increase. The insulin pump confirms each function button press with a short vibration. For each function button press, the bolus amount is increased depending on the bolus increment you have set.To change the bolus increment follow the procedure on page 63. The maximum bolus amount is 30.0 U.

Giving the function button a long press may launch the blind bolus menu accidentally, if the blind bolus function was previously activated in the settings. If you do not react within 4 seconds, the blind bolus menu disappears. It is not possible to program the blind bolus in the main menu or in a submenu.

4/7: Each bolus amount set is displayed to you on the screen. When you have entered the bolus amount required, you have to wait 4 seconds. The elapsed time is displayed to you by dots turning grey.

5/7: The mylife™ YpsoPump® confirms each step of increase with a short vibration signal.

When entering a bolus that exceeds the maximum amount that can be set, blind bolus programming is cancelled with three short vibrations.



6/7: After a period of 4 seconds a long vibration signal is emitted. By giving the function button a long press, bolus delivery is confirmed. The long function button press must take place within 4 seconds after the long vibration signal. By giving the function button a short press or not reacting to the vibration signal, you have the option of quitting the blind bolus menu without any bolus delivery. This is indicated by three short vibrations.

If you are uncertain whether the blind bolus has been delivered, refer to the bolus amount in the therapy data or to the last bolus screen and respond to the delivered amount accordingly.

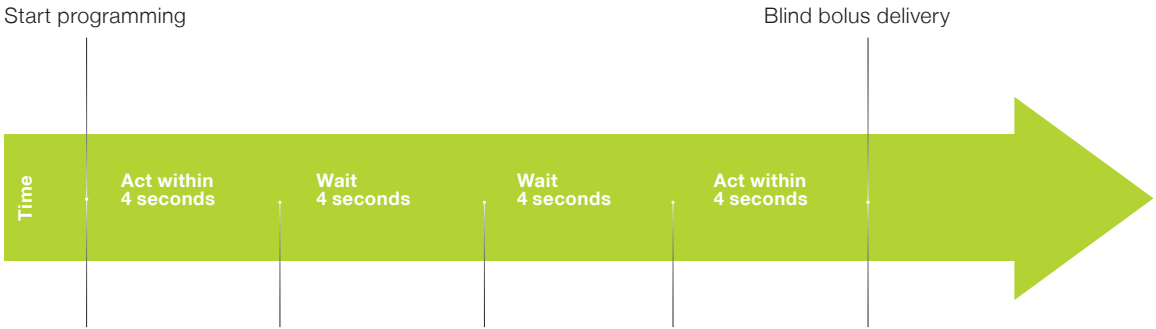
7/7: You can cancel a bolus in progress at any time by tapping ☒. Cancellation must always be confirmed by tapping ☑.

If the screen of your mylife™ YpsoPump® is switched on during blind bolus programming: the blind bolus delivery in progress is displayed on the screen.

If the screen of your mylife™ YpsoPump® is switched off during blind bolus programming: the blind bolus delivery in progress is not displayed on the screen.

Give the function button a short press to switch on the screen and see the blind bolus in progress.

Blind bolus programming at a glance



1/5: Long press of function button to start blind bolus programming.

2/5: Short press of function button for each step of bolus increase to set the bolus amount.

3/5: Awaiting confirmation from the insulin pump for each step of increase (short vibration signal).

4/5: Awaiting long vibration signal from the insulin pump.

5/5: Long press of function button to confirm bolus delivery.

4.5 Display of last bolus

1/4: Swipe to the right on the status screen to display the last bolus delivered. The last bolus delivered can only be displayed if no bolus is active.

2/4: The icon of the bolus type appears on the left of the screen, the relevant value in the middle. The delivery time and delivery date are shown at the top on a white background. By swiping to the left you can quit the display of last bolus at any time and return to the status screen.

3/4: Example of an extended bolus: if a bolus on the display of last bolus shows multiple items of information, they are displayed under each other.

When a bolus function is active, it is not possible to display the last bolus delivered.

4/4: Example of a combination bolus: the display of the percentage value of the immediate portion alternates with the display of the extension time of the extended portion at intervals of 2 seconds.

5 Changing the infusion set and cartridge

⚠WARNING

⚠ Use only the self-filled 1.6-ml reservoir (mylife™ YpsoPump® Reservoir) that is compatible with the mylife™ YpsoPump®. Using a different cartridge which is not declared by the manufacturer to be compatible with mylife™ YpsoPump® can lead to incorrect dosages of insulin, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Remove air bubbles from the reservoir while filling the mylife™ YpsoPump® Reservoir prior to insertion into the mylife™ YpsoPump®. Air bubbles can lead to incorrect dosages of insulin, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Never pull the plunger of the mylife™ YpsoPump® Reservoir further than the 1.6-ml mark. If you pull the plunger further, it may fall out or air may enter the reservoir. In addition, the reservoir will no longer be sterile. If you have pulled the plunger further, stop the filling procedure, dispose of all components of the reservoir and fill a new one.

⚠ Using an infusion set which is not declared by the manufacturer to be compatible with mylife™ YpsoPump® can lead to incorrect dosages of insulin, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7). If you use an infusion set which is not declared by the manufacturer to be compatible with mylife™ YpsoPump®, change the infusion set.

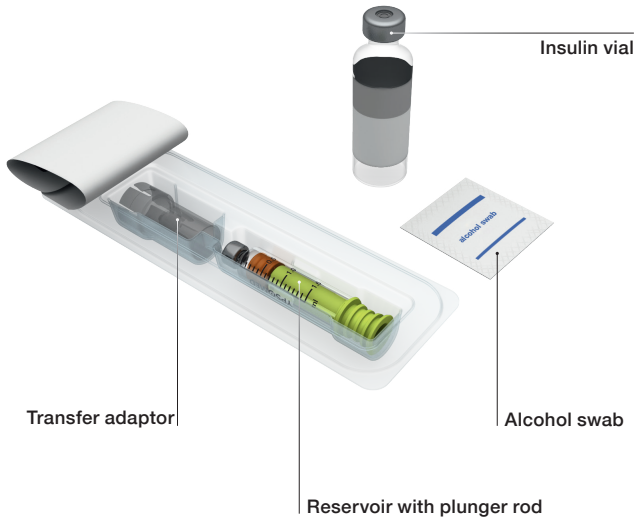
⚠ Never connect the infusion set to your body when you are performing a priming procedure. Priming with connected tubing may lead to an uncontrolled dosage of insulin, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Prime the tubing/cannula of the infusion set according to the description. If insulin emerges at the end of the tubing, it does not yet mean that it is free of air bubbles. Continuously monitor the priming process until no more air bubbles are visible. Should air bubbles be in the system, the dosage of insulin may be incorrect and the automated occlusion detection may be delayed, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

5.1 mylife™ YpsoPump® Reservoir

The mylife™ YpsoPump® Reservoir is intended to be filled with a rapid-acting insulin at a concentration of 100 U/ml and used with the mylife™ YpsoPump® insulin pump.

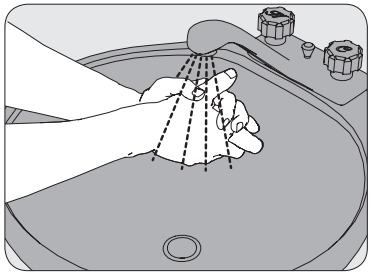
The following components are required in order to use the mylife™ YpsoPump® Reservoir:



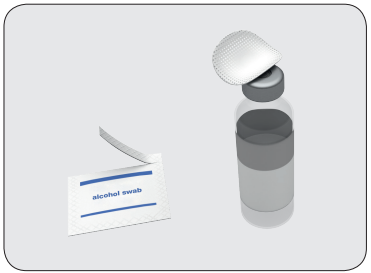
Filling the mylife™ YpsoPump® Reservoir

The mylife™ YpsoPump® Reservoir is sterile provided that the packaging has neither been opened nor damaged. If the packaging shows signs of damage, use a different reservoir. The reservoir is solely intended for single use.

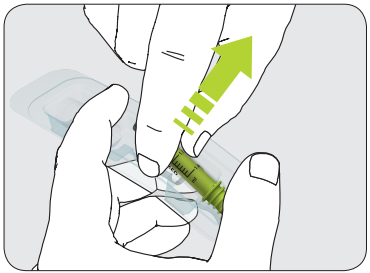
Follow the Instructions for Use of the mylife™ YpsoPump® Reservoir and the mylife™ YpsoPump® Orbit® infusion sets, especially the information in the "Warning" category and the explanations of the symbols on the packaging.



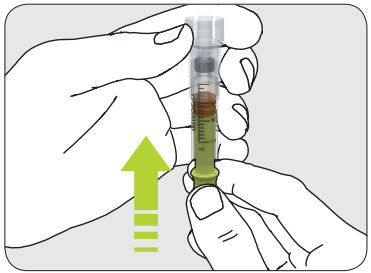
1/12: Wash your hands thoroughly with soap and water.



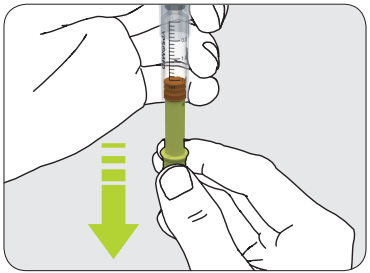
2/12: Clean the septum of the insulin vial with an alcohol swab.



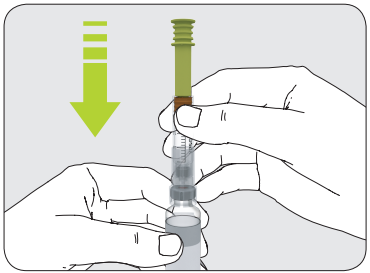
3/12: Remove the reservoir and the transfer adaptor from the packaging (see page 88) without touching the septum.



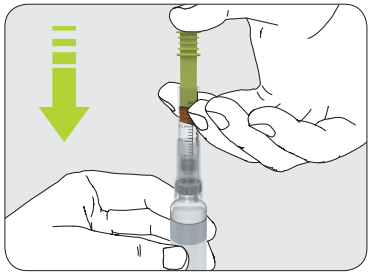
4/12: Attach the transfer adaptor to the reservoir and advance the stopper all the way forward.



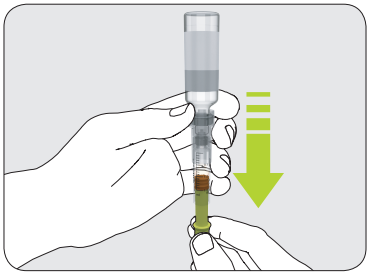
5/12: Then pull the plunger rod backwards until the entire reservoir is filled with air.



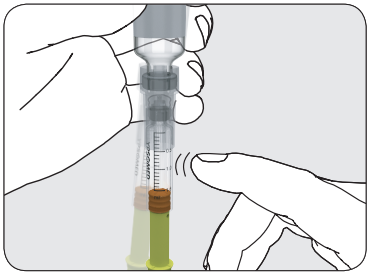
6/12: Attach the other end of the transfer adaptor to the insulin vial.



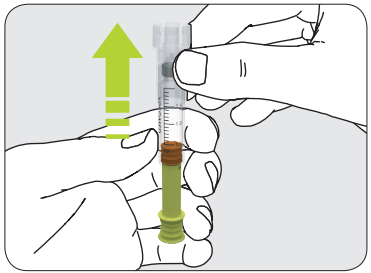
7/12: Inject all of the air into the insulin vial. This will make it easier to then withdraw insulin from the vial.



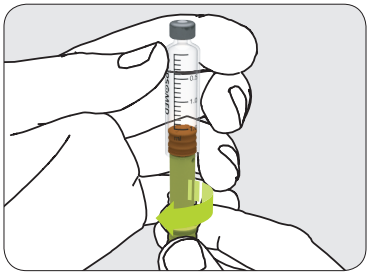
8/12: Turn the reservoir, including the insulin vial, upside down. Very gently draw the insulin into the reservoir.



9/12: Check the reservoir for air bubbles. If air bubbles are in the reservoir, carefully tap the side of the reservoir. Then press the plunger rod to push the air bubbles out of the reservoir. Repeat if necessary.



10/12: Remove the transfer adaptor from the vial. Dispose of the transfer adaptor in accordance with local laws.

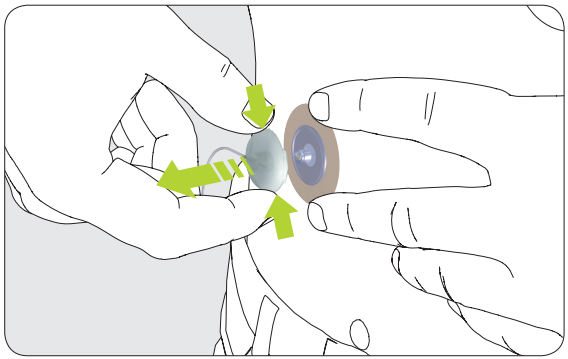


11/12: Twist off the plunger rod and dispose of it.

12/12: Follow the instructions on page 99 in order to insert the reservoir into the mylife™ YpsoPump®.

5.2 Disconnecting the infusion set

The mylife™ YpsoPump® Orbit®soft and mylife™ YpsoPump® Orbit®micro infusion sets can be easily disconnected and reconnected, offering you the option of removing the insulin pump and tubing to take a bath, a shower or do sports.



Gently press on the two marked sides of the cap and the tubing cap will disconnect from the infusion site.

5.3 Changing the infusion set

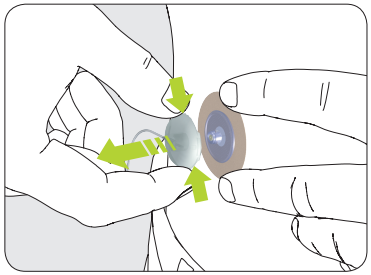
The mylife™ YpsoPump® Orbit®soft infusion set should not be used for more than 72 hours.
The mylife™ YpsoPump® Orbit®micro infusion set should not be used for more than 48 hours.

- When changing the infusion set, the insulin pump can either be in stop mode or in run mode.
- Disconnect the infusion set as described in the instructions on page 94 and carefully remove the tape from your body.
- Then follow the steps on page 99.
- Before attaching the tubing to your body, please make sure the tubing is filled with insulin without any air bubbles.
- Dispose of the introducer needle (mylife™ YpsoPump® Orbit®soft), the used cannula base and the used tubing with adaptor according to the instructions given by your doctor or diabetes advisor and in compliance with the local regulations for disposing of needles and sharp or pointed objects.

Only use the mylife™ YpsoPump® Orbit®soft and mylife™ YpsoPump® Orbit®micro infusion sets for therapy with the mylife™ YpsoPump®. All tubing and cannula lengths of these products are compatible with the mylife™ YpsoPump®.

5.4 Changing the cartridge

Removing the cartridge



1/7: Always disconnect the infusion set from your body first according to the instructions on page 94.

2/7: Open the main menu and tap the “Cartridge change and current cartridge level” icon.

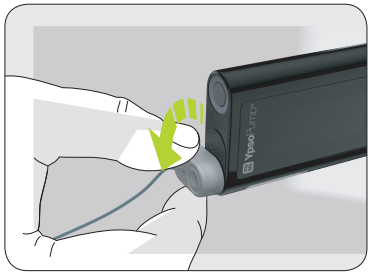
3/7: Tap the “Return threaded rod” icon.

With your mylife™ YpsoPump®, you are not required to change your infusion set every time you change your cartridge. They can be changed independently.

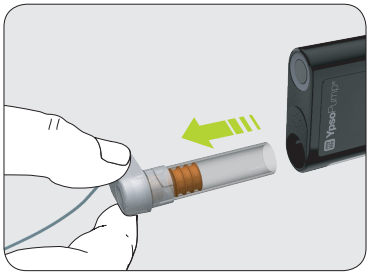
4/7: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly.

5/7: The threaded rod returns and the percentage is reduced to 0 %. Then the self-test is performed (as described on page 38).

Do not insert the new cartridge until the threaded rod has completely returned and the mylife™ YpsoPump® has successfully performed the self-test. If you insert the cartridge while the threaded rod is still returning, the insulin pump may display the message "Threaded rod return not completed". In this case repeat the cartridge change.



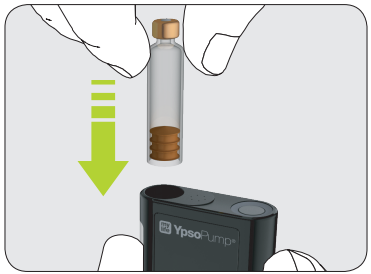
6/7: Disconnect the infusion set by turning the adaptor on the mylife™ YpsoPump® counterclockwise until it stops.



7/7: Remove the empty cartridge from the mylife™ YpsoPump® and dispose of it in accordance with your national environmental protection regulations.

Inserting the cartridge

For the mylife™ YpsoPump® you may only use a self-filled 1.6-ml reservoir (mylife™ YpsoPump® Reservoir) compatible with the mylife™ YpsoPump®.



1/2: Hold the mylife™ YpsoPump® upright with the opening of the cartridge compartment facing upwards. Insert a self-filled 1.6-ml reservoir.

2/2: Place the adaptor on the inserted cartridge upright. Turn the adaptor clockwise to the lock position. You should hear a soft click and/or feel a definite mechanical stop.

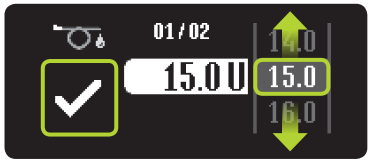
When putting the mylife™ YpsoPump® into operation for the first time or when taking the insulin pump into operation after storage status, the threaded rod must be returned prior to inserting the cartridge. Follow the procedure on page 96.

5.5 Priming the infusion set

1/6: Open the main menu and tap the “Prime infusion set” icon.

2/6: Tap the “Prime tubing” icon.

Refer to the Instructions for Use of your mylife™ YpsoPump® Orbit® infusion set for the correct priming volume. The priming volume indicated there is for guidance only. It is important that the system is primed free of air bubbles and that insulin emerges from the end of the tubing. If necessary, repeat the priming procedure with the appropriate priming volume until insulin has emerged from the end of the tubing of the infusion set.



3/6: The screen for setting the priming volume appears. For the priming volume, select a value that is suitable for your infusion set, between 1.0 U and 30.0 U. Confirm by tapping ☑.

Priming volume when only changing the cartridge: Check the cartridge for air bubbles. If the cartridge contains air bubbles, select the appropriate priming volume according to the Instructions for Use of your mylife™ YpsoPump® Orbit® infusion set, until there are no more air bubbles in the cartridge, in the adaptor and in the tubing. If the cartridge does not contain any air bubbles, prime the minimum priming volume of 1.0 U.

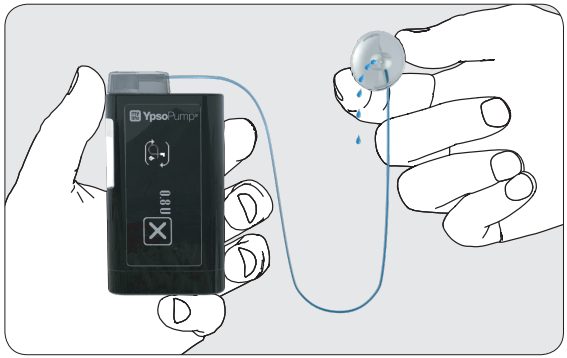
Priming volume when changing the infusion set: For the priming volume, select a value that is suitable for your infusion set according to the Instructions for Use of your mylife™ YpsoPump® Orbit® infusion set.

With your mylife™ YpsoPump®, you are not required to change your infusion set every time you change your cartridge. They can be changed independently.

4/6: Confirm that you have disconnected the infusion set from your body by removing the tubing cap from the cannula base and confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly, the threaded rod advances up to the plunger of the cartridge and the infusion set is primed with the set amount of insulin.

5/6: During the priming procedure, keep the insulin pump in an upright position, with the adaptor facing upwards and tap the insulin pump lightly on your open palm to remove the air bubbles from the infusion set. The screen counts the delivered priming volume upwards until the set value has been reached. You can cancel the priming procedure at any time by tapping ☒.

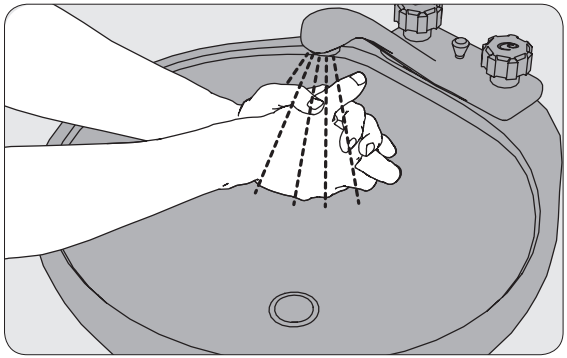
If the temporary basal rate function or a bolus is activated, the prime infusion set function is not available. The prime infusion set function also cannot be executed if the cartridge is empty.



6/6: Repeat the priming procedure with the appropriate priming volume until there are no more air bubbles in the cartridge, in the adaptor or in the tubing and until insulin has emerged from the end of the tubing of the infusion set.

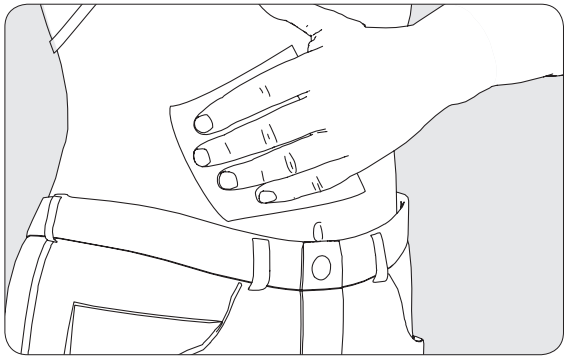
5.6 Attaching the infusion set to your body

If insulin has emerged from the end of the tubing and there are no more bubbles of air in the cartridge, in the adaptor or in the tubing, attach the infusion set to your body.

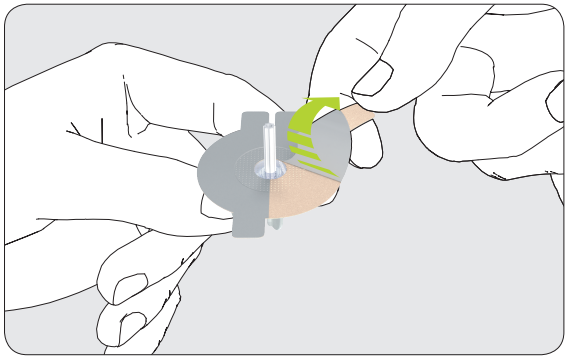


1/12: Wash your hands thoroughly.

These abridged instructions are intended to be a recommendation. For detailed information, notes and warnings please refer to the Instructions for Use of the relevant mylife™ YpsoPump® Orbit® infusion set (mylife™ YpsoPump® Orbit®soft and mylife™ YpsoPump® Orbit®micro).

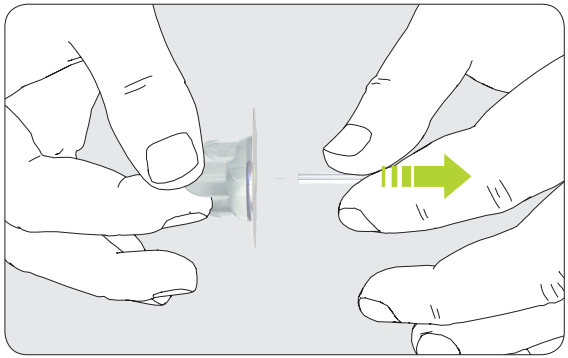


2/12: Clean and disinfect the infusion site with an isopropyl alcohol swab (70 %). Before continuing, make sure there are no hairs on the site and that the infusion site is dry.

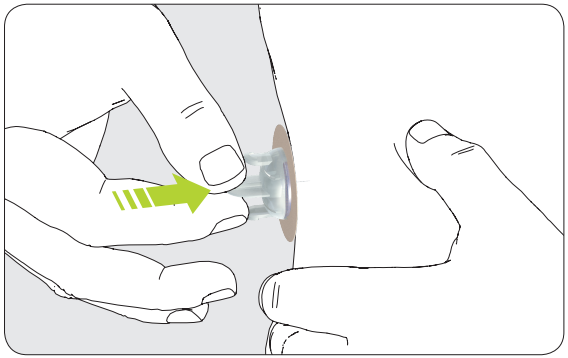


3/12: Peel the protective foil off the tape carefully. Make sure you do not touch the adhesive film.

We recommend you to use a 70 %-isopropyl-alcohol pad. The use of 70 % isopropyl supports the optimal adhesion of the tape. The use of other alcohol pads has not been tested and may result in premature tape failure and interruption of insulin delivery.

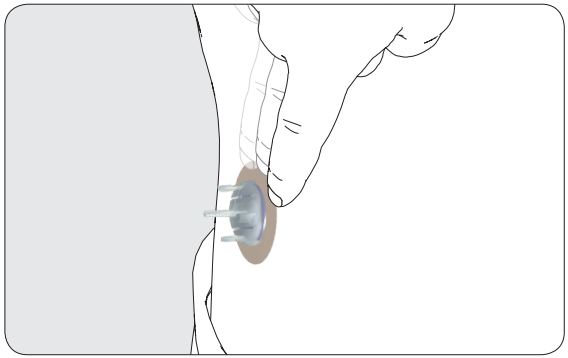


4/12: Remove the cannula protector from the cannula carefully.

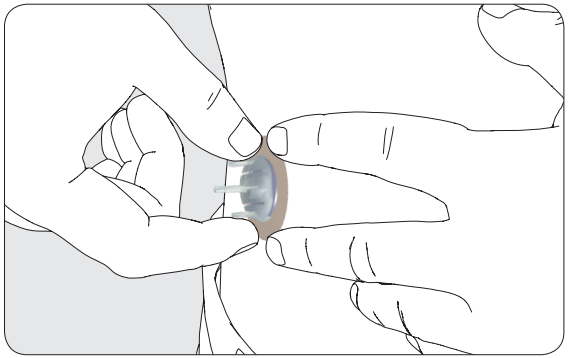


5/12: Stabilise the infusion site and insert the cannula at an angle of 90° or alternatively use the appropriate inserter for the infusion set.

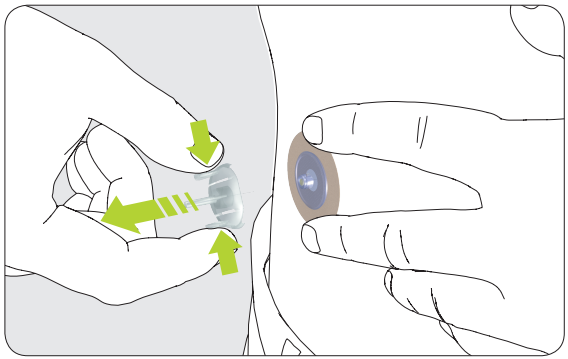
The mylife™ YpsoPump® Orbit®micro has a steel cannula that can be applied to the body without any additional introducer needle. To facilitate skin penetration with the mylife™ YpsoPump® Orbit®soft and mylife™ YpsoPump® Orbit®micro infusion sets use the mylife™ Orbit®Inserter.



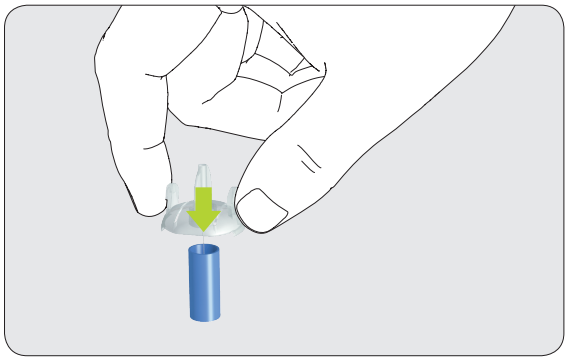
6/12: Press the tape onto the skin and run your fingers over the tape for a few seconds to optimise adhesion.



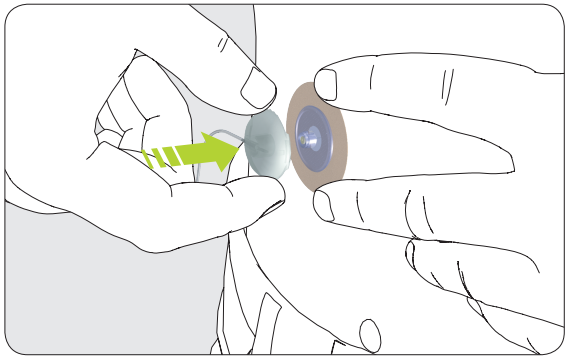
7/12: Press the tape onto the skin with one hand and grasp the introducer cap with two fingers of your other hand.



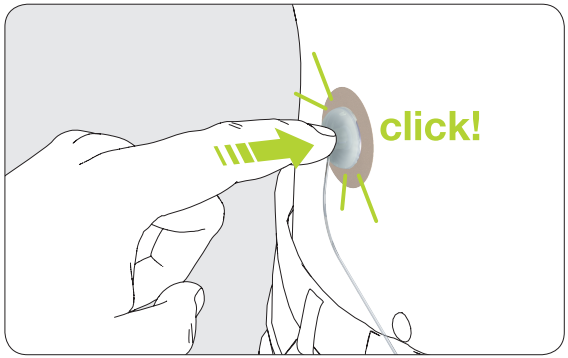
8/12: Carefully remove the introducer needle (mylife™ YpsoPump® Orbit®soft) or the introducer cap (mylife™ YpsoPump® Orbit®micro) by pressing on the two outer wings of the introducer cap and pull it from the infusion site.



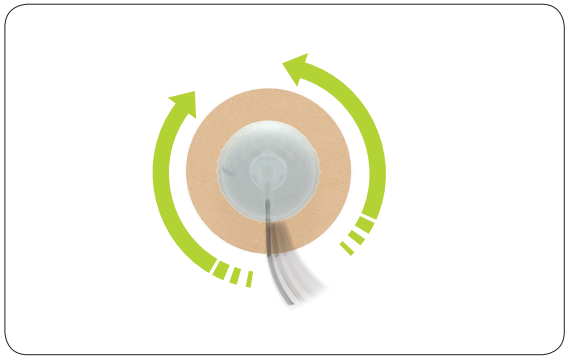
9/12: Cover the removed introducer needle with the blue protection cap and dispose of it in a safety bin.



10/12: Attach the tubing cap straight to the cannula base of the infusion set.



11/12: Make sure you hear it click into place.

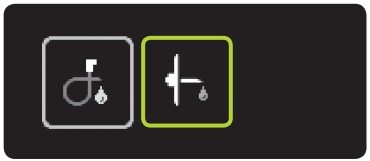


12/12: Rotate the tubing left and right, at least one full turn in each direction while pulling upward on the cap, to ensure the tubing cap is fully engaged and the fluid path is opened.

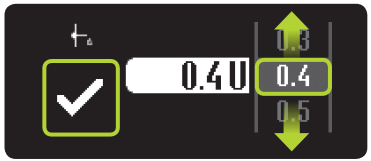
5.7 Priming the cannula

After having attached the infusion set to your body, the cannula has to be primed with insulin.

1/4: Open the main menu and tap the “Prime infusion set” icon.



2/4: Tap the “Prime cannula” icon.



3/4: The screen for setting the priming volume appears. For the priming volume, select a value that is suitable for your cannula, between 0.1 U and 1.0 U, according to the Instructions for Use of your mylife™ YpsoPump® Orbit® infusion set. Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the cannula is primed with the set amount of insulin.

4/4: During the priming procedure, the screen counts the delivered priming volume upwards until the set value has been reached. You can cancel the priming procedure at any time by tapping ☒.

6 Data/History

You can view the saved events in the data menu.

The mylife™ YpsoPump® has a data backup that typically covers at least 6 months. A distinction is made between “Therapy data” and “Alarm history”. Therapy data comprise records of all therapy-relevant events such as bolus delivery, priming procedure or change in basal rates.

Alarm history lists all the alarms that have taken place. If the number of events exceeds the maximum number, the oldest events are overwritten.

Therapy data: 500 events displayed (total of 3000 stored in the insulin pump).
Alarm history: 100 events displayed (total of 200 stored in the insulin pump).

6.1 Therapy data

1/6: Open the main menu and tap the “Data” icon.

2/6: Tap the “Therapy data” icon.

3/6: For each event, the time of day and date are displayed inverted. As a result you can distinguish the event from a current display.

The icon for the event appears on the left of the screen, the relevant value in the middle. By swiping to the right you can quit therapy data at any time. All the possible events are listed in the table on page 117.

In the therapy data, functions still in progress are marked by the triangular symbol under the icon.

Example: combination bolus
Three screens each containing different information are displayed one after the other at intervals of 2 seconds:

4/6: Display of total bolus amount.

5/6: Display of immediate portion.

6/6: Display of extended portion and extension time.

Remember to back up your therapy data regularly to prevent any loss of events.

Possible events in therapy data

	Battery removed
	Bolus increment changed
	Combination bolus
	Date changed
	Extended bolus
	Hourly value from basal rate profile A changed (1 event for each hourly value changed)
	Hourly value from basal rate profile B changed (1 event for each hourly value changed)
	Primed cannula
	Primed tubing
	Standard bolus or blind bolus
	Switched from basal rate profile A to basal rate profile B
	Switched from basal rate profile B to basal rate profile A
	Switched to run mode
	Switched to stop mode

	Temporary basal rate function
	Threaded rod returned
	Time of day changed
	Total insulin amount per day (basal and bolus)

6.2 Alarm history

1/3: Open the main menu and tap the “Data” icon.

2/3: Tap the “Alarm history” icon.

3/3: For each event, the time of day and date are displayed inverted. As a result you can distinguish the event from a current display.

The icon for the event appears on the left of the screen. By swiping to the right you can quit the alarm history at any time. All the possible events are listed in the table on page 120.

Possible events in alarm history

 Auto stop	 No insulin
 Battery empty	 Occlusion
 Battery not suitable	
 Cartridge empty	
 Charge internal rechargeable battery	
 Electronic error	
 No battery	

7 Functions and settings

⚠WARNING

⚠ For patients who do not self-manage their diabetes, the access lock function should always be activated when the insulin pump is not being used by a caregiver. The access lock function is intended to prevent inadvertent operation that may lead to insulin delivery or changes in the insulin pump settings. Inadvertent operation can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

7.1 Changing the time of day

1/3: Open the main menu and tap the “Settings” icon.

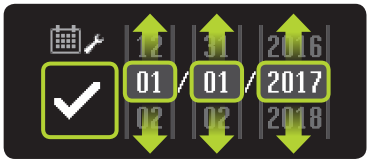
2/3: Tap the “Time of day” icon.

3/3: Set the current time of day, confirm by tapping ☑ and the mylife™ YpsoPump® will vibrate briefly. The time of day set is entered in the therapy settings.

7.2 Changing the date

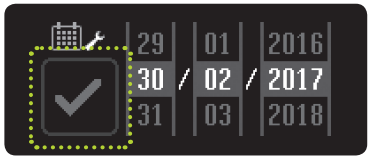
1/3: Open the main menu and tap the “Settings” icon.

2/3: Tap the “Date” icon.



3/3: Set the current date (day, month, year). Confirm your setting by tapping ☑.

The values displayed are only examples. Always use your own settings. You can adjust the time of day and the date at any time in the settings menu. If you select an impossible date (e.g. 30/02/2017), the confirmation icon will be inactive (grey) and you cannot confirm the date.



7.3 Access lock

The access lock function offers access protection (e.g. for children).

When the access lock function is activated, only the following mylife™ YpsoPump® functions can be operated:

- Data: View therapy data and alarm history
- Settings: Rotate screen
- Settings: Deactivate access lock function

The following mylife™ YpsoPump® functions cannot be operated when the access lock function is activated:

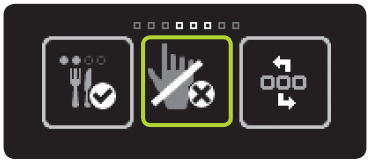
- All types of bolus delivery
- Temporary basal rate function
- Programming and switching basal rate profiles
- Returning threaded rod for cartridge change
- Priming infusion set and cannula
- Switch to run or stop mode
- Time and date settings
- Bolus increment settings
- Activate/deactivate blind bolus
- Activate/deactivate Bluetooth®
- Bluetooth® pairing

The icons for these functions are shaded grey in the menu.

Basal rate delivery continues when the access lock is activated.

Activating access lock

1/5: Open the main menu and tap the “Settings” icon.



2/5: Swipe to the left and tap the “Access lock inactive/activate” icon.

3/5: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the access lock function is activated.

4/5: The status screen appears. The activated access lock function is visualised by an access lock icon at the top of the screen.

5/5: If you open the main menu again, tap the “Settings” icon and swipe to the left, the “Access lock active/ deactivate” icon now appears.

When the access lock function is activated, all inactive icons are displayed in a darker grey. This means the function is not available and cannot be selected.

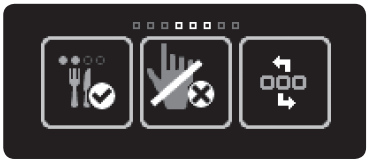
Deactivating access lock

1/5: Open the main menu and tap the “Settings” icon.

2/5: Swipe to the left and tap the “Access lock active/deactivate” icon.

3/5: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the access lock function is deactivated.

4/5: The status screen appears. The access lock icon at the top of the screen disappears. All icons are now active and the functions can be operated again.



5/5: If you open the main menu again, tap the “Settings” icon and swipe to the left, the “Access lock inactive/ activate” icon now appears.

7.4 Rotating the screen by 180°

You have the option of rotating the screen of the mylife™ YpsoPump® by 180°.

1/3: Open the main menu and tap the “Settings” icon.

2/3: Swipe to the left and tap the “Rotate screen” icon.

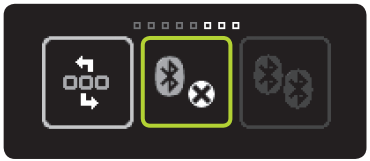
3/3: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the orientation of the screen is rotated by 180°.

7.5 Bluetooth®

Activating Bluetooth®

Use the Bluetooth® function to transfer your therapy data from your mylife™ YpsoPump® to another supported Bluetooth® enabled device. If you want to use the Bluetooth® connection to a Bluetooth® enabled device, the Bluetooth® interface must firstly be activated on the mylife™ YpsoPump®.

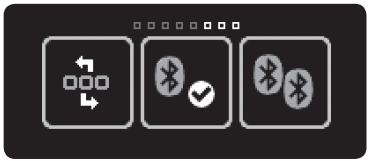
1/5: Open the main menu and tap the “Settings” icon.



2/5: Swipe to the left and tap the “Bluetooth® inactive/activate” icon.

3/5: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the Bluetooth® function is activated.

4/5: The status screen appears. The activated Bluetooth® function is visualised by a Bluetooth® icon at the top of the screen.

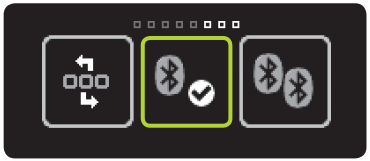


5/5: If you open the main menu again, tap the “Settings” icon and swipe to the left, the “Bluetooth® active/deactivate” icon now appears.

Deactivating Bluetooth®

If you do not want to use any Bluetooth® enabled devices with the mylife™ YpsoPump®, the Bluetooth® interface can be deactivated.

1/5: Open the main menu and tap the "Settings" icon.

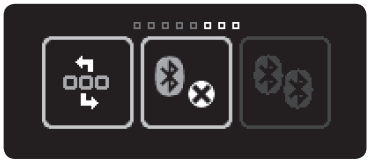


2/5: Swipe to the left and tap the "Bluetooth® active/deactivate" icon.

When Bluetooth® is not used, it is recommended to deactivate the function. This will prevent that your location is tracked by means of Bluetooth® tracker devices that detect your mylife™ YpsoPump®.

3/5: Confirm by tapping ☑. The mylife™ YpsoPump® vibrates briefly and the Bluetooth® function is switched off.

4/5: The status screen appears. The Bluetooth® icon at the top of the screen disappears.



5/5: If you open the main menu again, tap the “Settings” icon and swipe to the left, the “Bluetooth® inactive/ activate” icon now appears.

Bluetooth® pairing

The first time you establish Bluetooth® connectivity between the mylife™ YpsoPump® and another Bluetooth® enabled device, you have to enter an identification code to allow Bluetooth® connection between the two devices. To use the Bluetooth® pairing function, the Bluetooth® function must be activated. It is possible to pair a maximum of 5 Bluetooth® enabled devices with mylife™ YpsoPump®.

1/6: Open the main menu and tap the “Settings” icon.

2/6: Swipe to the left and tap the “Bluetooth® pairing” icon.

3/6: The mylife™ YpsoPump® is ready for Bluetooth® pairing and waits for the pairing request of the Bluetooth® enabled device.

If the release does not take place within 2 minutes, the screen lock is activated and the Bluetooth® pairing function must be restarted.

4/6: A six-digit number code appears on the screen of the mylife™ YpsoPump® and the arrows rotate. Enter this code on your Bluetooth® enabled device.

The identification code must be entered within 30 seconds. If the time is exceeded or a wrong identification code is entered, the warning “Bluetooth® connection failed” appears. Confirm the warning and repeat the procedure on page 135.

5/6: If Bluetooth® pairing was successful, the display automatically changes back to the status screen.

6/6: If you open the main menu again, tap the “Settings” icon, swipe to the left and tap the “Bluetooth® pairing” icon, the active connection is shown by the rotation of the arrows.

An active Bluetooth® connection to a Bluetooth® enabled device is indicated by rotating arrows. Only one Bluetooth® enabled device at a time can have an active connection with the mylife™ YpsoPump®.

7.6 Preparing for storage

If you will not be using the mylife™ YpsoPump® for a longer period, set your insulin pump into stop mode and remove the battery from the insulin pump to avoid any damage caused by a leaking battery. That puts the insulin pump in storage status. In the storage status the settings remain intact (basal rate, bolus increment, etc.).

After a restart all you have to do is perform the self-test and reset the time of day and date. After that, the insulin pump is in stop mode. A threaded rod return followed by priming has to be performed to put the insulin pump back into operation. Follow the procedure on page 37.

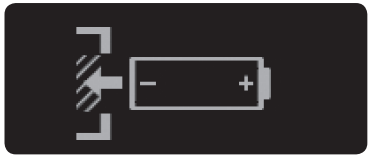
When preparing your mylife™ YpsoPump® for storage, remove the cartridge and the infusion set and dispose of the tubing and cannula base in a safety bin.

1/2: Set the mylife™ YpsoPump® to stop mode (see page 33). Remove the cartridge and the infusion set as described on page 96.

2/2: Open the battery compartment lid and remove the battery. Close the battery compartment lid and store the mylife™ YpsoPump® in a safe place.

7.7 Internal rechargeable battery

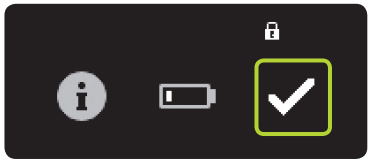
The mylife™ YpsoPump® has an internal rechargeable battery that is charged by the inserted alkaline battery. If the alkaline battery is removed, all functions still work. If the insulin pump is in run mode and a new battery is not inserted within 5 minutes, the “No battery” alarm is displayed. In stop mode the insulin pump is put in storage status 5 minutes after removal of the alkaline battery. If the alkaline battery is removed, the battery orientation screen appears:



To change the alkaline battery please follow the instructions on page 141.

If the internal rechargeable battery is subjected to a heavy load, it may run down. In this situation the “Charge internal rechargeable battery” alarm appears. The internal rechargeable battery is now charged by the inserted alkaline battery which is indicated by arrows rotating round the hourglass. The charging process can take up to 20 minutes. An alarm cancels any boluses in progress and any temporary basal rate function that is active.

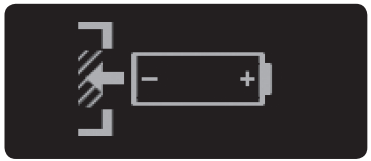
7.8 Changing the battery



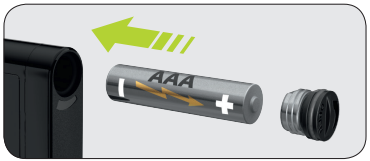
1/5: If the “Battery charge level low” warning appears, the insulin pump can still be operated for at least two days. Replace the battery as soon as possible.

2/5: Open the battery compartment by inserting a coin in the groove of the battery compartment lid and turn counterclockwise. Remove the empty battery from the battery compartment and dispose of it in accordance with your national environmental protection regulations.

If the battery compartment has remained open for more than 5 minutes and the mylife™ YpsoPump® is in run mode, an alarm is triggered. After inserting a new battery, all insulin pump settings are saved and do not have to be entered again.
If the battery compartment remains open for more than 5 minutes and the mylife™ YpsoPump® is in stop mode, the insulin pump is automatically put into storage status. When changing the alkaline battery, make sure you do not lose the battery compartment lid.



3/5: The battery orientation screen shows the orientation of the AAA battery for insertion. It appears on the status screen. If the insulin pump is in run mode and the battery is not inserted for more than 5 minutes, an alarm is triggered.



4/5: Insert a new, size AAA, alkaline battery (LR03). Make sure the negative pole of the battery is inserted first. On the back of the insulin pump you will see a picture showing how to insert the battery. You can obtain replacement batteries from the usual battery sales outlets.

When changing the alkaline battery, check the battery compartment, the battery itself and the battery compartment lid for any damage. If you discover any damage (e.g. battery leak), contact Customer Service.

5/5: Lock the battery compartment by inserting a coin in the groove of the battery compartment lid and turning it clockwise until it stops. When the battery has been inserted, the mylife™ icon appears first, followed by the status screen or welcome screen. The latter appears if the battery has been removed during a threaded rod return or during a self-test after starting up from the storage status. Change the battery compartment lid every three months to minimise signs of wear.

If you remove the battery while you are in the main menu or in a submenu, all the current settings, which have not yet been confirmed, will be discarded and the battery orientation screen appears.

After removal of the battery the following functions are completed first before the battery orientation screen appears:

- Return of the threaded rod
- Priming in progress
- Standard bolus in progress
- Immediate portion of the combination bolus in progress
- Blind bolus in progress

If you remove the battery while any of the following functions are in progress, the battery orientation screen appears and the function continues in the background for 5 minutes until the alarm is triggered (alarms lead to a discontinuation of insulin delivery):

- Basal rate delivery
- Temporary basal rate function in progress
- Extended bolus in progress
- Extended portion of the combination bolus in progress

8 Troubleshooting

⚠WARNING

⚠ Simultaneously triggered alarms are displayed in the order of their priority. If you have handled an alarm, it is possible that further alarms are pending. Unsolved alarms may result in failure of the preset insulin delivery, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

⚠ Disconnect the infusion set immediately from your body after an occlusion alarm in order to prevent insulin from being delivered to the body when the occlusion is suddenly eliminated. Not disconnecting the infusion set can lead to incorrect dosages of insulin, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7).

8.1 Incidents

Air bubbles in the cartridge or in the infusion set	Check your blood glucose level. Disconnect the infusion set from your body and prime the infusion set without any air bubbles in accordance with the procedure on page 100.
“Basal rate profile A” and “Basal rate profile B” icons are not available (shown in grey)	If the temporary basal rate function is activated, the basal rate profile A and basal rate profile B functions are not available and it is not possible to change the basal rate profiles. To cancel the temporary basal rate function, follow the instructions on page 59.
Blind bolus function is not available	Make sure the blind bolus function is activated and the mylife™ YpsoPump® is in run mode. The blind bolus function is not available in stop mode. To put the insulin pump into run mode, follow the instructions on page 31. The blind bolus function cannot be performed if the cartridge is empty. To change the cartridge follow the instructions on page 96. If the remaining insulin amount in the cartridge is smaller than the bolus increment setting, the blind bolus function is not available. Nor is the blind bolus function available if a threaded rod return has been performed without any subsequent priming or if the priming function has not been completed properly.

“Bluetooth® pairing” icon is not available (shown in grey)	If the Bluetooth® function is not activated, the Bluetooth® pairing function cannot be activated. To activate the Bluetooth® interface refer to the instructions on page 131.
“Bolus” icon is not available (shown in grey)	Make sure the mylife™ YpsoPump® is in run mode. The bolus function is not available in stop mode. To put the insulin pump into run mode, follow the instructions on page 31. The bolus function cannot be performed if the cartridge is empty. To change the cartridge follow the instructions on page 96. If the remaining insulin amount in the cartridge is smaller than the bolus increment setting, the bolus function is not available. Nor is the bolus function available if a threaded rod return has been performed without any subsequent priming or if the priming function has not been completed properly.
“Cartridge change” icon is not available (shown in grey)	If the temporary basal rate function is activated and/or if an extended bolus or combination bolus is active, the cartridge change function is not available. To cancel the temporary basal rate function, follow the instructions on page 59. To cancel an extended or combination bolus in progress, follow the instructions on page 73 or page 75.
“Combination bolus” icon is not available (shown in grey)	The combination bolus function cannot be performed if the remaining insulin amount in the cartridge is smaller than twice the bolus increment setting (minimum amount for combination bolus is twice the bolus increment).

Dirt in the cartridge compartment	Set the insulin pump into stop mode. Disconnect the infusion set from your body. Remove the cartridge from the cartridge compartment. To clean the insulin pump, follow the cleaning instructions on page 16.
Dirt on the surface	To clean the insulin pump, follow the cleaning instructions on page 16.
Infusion set blocked (occlusion)	Disconnect the infusion set from your body and check your blood glucose level. Eliminate the occlusion in accordance with the procedure on page 166.
Insulin in the cartridge compartment	Check your blood glucose level frequently. Set the insulin pump to stop mode. Disconnect the infusion set from your body. Remove the cartridge from the cartridge compartment and check it for cracks and damage. If necessary, replace the cartridge and clean the cartridge compartment following the cleaning instructions on page 16. If the insulin pump has not suffered any apparent damage, you can continue insulin pump therapy – otherwise contact Customer Service. You find the contact details on the back of this User Guide as well as on page 10.

Insulin pump dropped	Check your blood glucose level frequently. Set the insulin pump to stop mode. Disconnect the infusion set from your body. Remove the cartridge and the infusion set and replace them. The insulin pump (as well as the cartridge) may contain undiscovered microcracks that are not visible to the human eye and might influence delivery dose accuracy. Check the exterior of the insulin pump for cracks and damage. Pay close attention to the self-test after the threaded rod has returned after a cartridge change. If the insulin pump has not suffered any apparent damage, you can continue insulin pump therapy. If the insulin pump is damaged, contact Customer Service. You find the contact details on the back of this User Guide as well as on page 10.
Most icons are not available (shown in grey)	If the access lock function is activated, all therapy related functions are not available. To deactivate the access lock function, follow the instructions on page 127.
“Prime cannula” icon is not available (shown in grey)	The tubing of the infusion set has not yet been primed. To prime the tubing, follow the instructions on page 100.
“Prime infusion set” icon is not available (shown in grey)	If the temporary basal rate function is activated and/or if an extended bolus or combination bolus is active, the prime infusion set function is not available. To cancel the temporary basal rate function, follow the instructions on page 59. To cancel an extended or combination bolus in progress, follow the instructions on page 73 or page 75. The prime infusion set function cannot be executed if the cartridge is empty. To change the cartridge follow the instructions on page 96. If a previous threaded rod return has not yet been completed properly, the prime infusion set function cannot be executed either.

“Switch basal rate profile” icon is not available (shown in grey)	If the temporary basal rate function is activated, the switch basal rate profile function is not available. To cancel the temporary basal rate function, follow the instructions on page 59.
Water in the battery compartment	Set the insulin pump into stop mode. Disconnect the infusion set from your body. Remove the battery from the battery compartment. To clean the insulin pump, follow the cleaning instructions on page 16.
Water in the cartridge compartment	Set the insulin pump into stop mode. Disconnect the infusion set from your body. Remove the cartridge from the cartridge compartment. To clean the insulin pump, follow the cleaning instructions on page 16.

8.2 Displayed warnings

The mylife™ YpsoPump® has a safety system that constantly monitors all functions. If there is a deviation from the defined operating status, the insulin pump triggers a warning or an alarm, depending on the situation. You will find a description of the alarms on page 160. Displayed warnings are not saved in the alarm history.

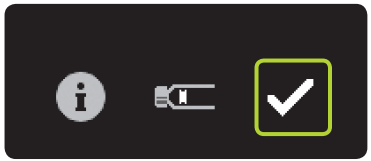
All the displayed warnings are described on the following pages. The warnings are arranged in order of priority. This means:

- The “Cartridge level low” warning always appears with priority over all the warnings below if multiple events occur at the same time.
- The “Battery charge level low” warning always has priority over all the warnings below it, except if the “Cartridge level low” warning occurs at the same time.
- Unconfirmed alarms always appear with priority over warnings.

Displayed warnings are primarily tactile and audible and there are 4 escalation levels. The levels escalate at intervals of 30 minutes. The warnings appear on the status screen and have to be confirmed. For this purpose the screen can be switched on with the function button. The warnings do not cause any cancellation in insulin delivery. When all the warnings have been confirmed, the original status screen reappears.

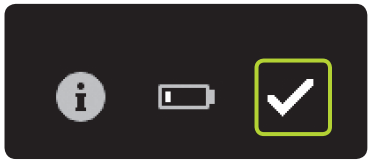
Escalation levels warnings:
Level 1: Tactile
Level 2: Tactile and low audible signal
Level 3: Tactile and high audible signal
Level 4: Tactile and higher audible signal

Cartridge level low



The “Cartridge level low” warning is triggered if the programmed basal rate (including the temporary basal rate function) for the next 12 hours, together with the remaining amount of any bolus in progress, is greater than or equal to the remaining contents of the cartridge. Confirm by tapping ☑ and change the cartridge as soon as possible in accordance with the procedure on page 96. The “Cartridge level low” warning escalates to the “Cartridge empty” alarm if the cartridge is not changed in the meantime.

Battery charge level low



If the “Battery charge level low” warning appears, the mylife™ YpsoPump® can still be operated for at least two days. Confirm by tapping ☑ and insert a new AAA alkaline battery (LR03) as soon as possible. Follow the procedure on page 141. Having confirmed the warning you will still see the low battery charge on your status screen. The “Battery charge level low” warning escalates to the “Battery empty” alarm if the battery is not changed in the meantime.

Threaded rod return not completed

The “Threaded rod return not completed” warning appears if it has not yet been possible to perform the threaded rod return function properly. The warning can occur on account of dirt (sand, dried insulin, etc.) in the cartridge compartment or generally if the drive has a mechanical fault. This fault can also be triggered by touching the threaded rod with an object when the threaded rod is returning.

Confirm by tapping ☑ and perform the threaded rod return function again. Make sure the cartridge is removed from the cartridge compartment first and that there is no dirt in the cartridge compartment – do not touch the threaded rod with objects. You will find further information about the threaded rod return function on page 96.

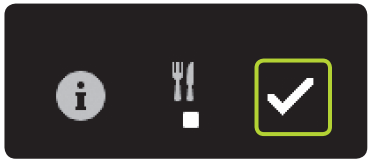
Priming not completed

The “Priming not completed” warning appears if:

- the drive is fully extended (cartridge empty) without a plunger having been detected.
- the priming procedure is cancelled by the user during plunger detection.
- the priming procedure is cancelled by an alarm.
- the force on the plunger holder decreases during the priming procedure, for example because the cartridge has been removed or a wrong cartridge has been inserted.

Confirm by tapping ☑ and perform the priming function again. Make sure the cartridge has been inserted properly and that the adaptor is connected to the insulin pump properly. Follow the procedure on page 100.

Bolus cancelled



The “Bolus cancelled” warning appears if a bolus is cancelled prematurely. Premature cancellation happens if there is an alarm or if the insulin pump is put into stop mode. Confirm by tapping ☑.

If your bolus in progress is cancelled prematurely, you can obtain the actual duration and the insulin amount delivered by referring to the therapy data or to the last bolus screen. If you wish to continue the bolus, you must reprogram it. Follow the procedure on page 61.

Temporary basal rate function completed or cancelled

The “Temporary basal rate function completed or cancelled” warning appears if the temporary basal rate function has been completed or if it is cancelled prematurely. Premature cancellation happens if there is an alarm or if the insulin pump is put into stop mode. Confirm by tapping ☑.

If your temporary basal rate function is cancelled prematurely, you can obtain the actual duration and the percentage setting by referring to the therapy data. If you wish to continue the temporary basal rate function, you must reprogram it. Follow the procedure on page 56.

Insulin pump stopped

The “Insulin pump stopped” warning appears if the insulin pump has been in stop mode for more than one hour. Confirm by tapping ☑. The warning now no longer appears unless the insulin pump is set to run mode again and then back to stop mode. To restart the insulin pump, follow the steps on page 31.

The screen of the mylife™ YpsoPump® shows a stop warning if the insulin pump has been in stop mode for more than one hour. The stop warning can be triggered prematurely, after the insulin pump has been set in stop mode, by giving the function button a long press and then confirming.

Bluetooth® connection failed

The “Bluetooth® connection failed” warning appears if:

- the 30-second time limit to enter the identification code is exceeded during the pairing process.
- a wrong identification code is entered during pairing process.
- an active Bluetooth® connection is accidentally disconnected.

Confirm by tapping ☑. Do pair the insulin pump again to the required device in accordance with the procedure on page 135.

8.3 Alarms

The mylife™ YpsoPump® has a safety system that constantly monitors all functions. If there is a deviation from the defined operating status, the insulin pump triggers an alarm, depending on the situation. You will find a description of the warnings on page 151. All the alarms are written to the alarm history, where they can be called up.

All the alarms are described on the following pages. The alarms are arranged in order of priority. This means:

- The “No battery” alarm always appears with priority over all the alarms below if multiple events occur at the same time.
- The “Battery empty” alarm always appears with priority over all the alarms below, but not if the “No battery” alarm occurs at the same time.
- Unconfirmed alarms always appear with priority over warnings.

Alarms always lead to cancellation of insulin delivery.

Alarms given are primarily tactile and audible and there are 4 escalation levels. The levels escalate at intervals of 5 minutes. If an alarm is confirmed but not dealt with, it is given again by audible and tactile means after 30 minutes. An electronic error is the exception. That is indicated directly and permanently by audible and tactile means.

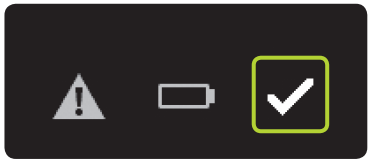
Alarms that do not involve an electronic error appear on the status screen and have to be confirmed. To do so, the screen has to be switched on first using the function button. Alarms always lead to cancellation of insulin delivery. The alarm remains on the status screen until the actions to deal with the alarm have been performed on the pump. An electronic error is the exception. It is dealt with in accordance with the procedure on page 171.

Escalation levels alarms:
Level 1: Tactile
Level 2: Tactile and low audible signal
Level 3: Tactile and high audible signal
Level 4: Tactile and higher audible signal

No battery

The “No battery” alarm appears if you remove the alkaline battery from the battery compartment for more than 5 minutes when the insulin pump is in run mode. Confirm by tapping ☑ and insert a new AAA alkaline battery (LR03). Follow the procedure on page 141. The “No battery” alarm only appears if the battery was removed while the insulin pump was in run mode. If the battery is removed in stop mode, the insulin pump adopts storage status after 5 minutes.

Battery empty



The “Battery empty” alarm appears if the battery no longer has sufficient power and has to be changed. Confirm by tapping ☑ and insert a new AAA alkaline battery (LR03). Follow the procedure on page 141.

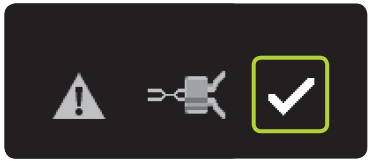
Battery not suitable

The “Battery not suitable” alarm appears if you insert a battery whose voltage is too high. Confirm by tapping ☑. Remove the unsuitable battery from the battery compartment and insert a new AAA alkaline battery (LR03). Follow the procedure on page 141.

Charge internal rechargeable battery

The “Charge internal rechargeable battery” alarm appears if the internal rechargeable battery of the mylife™ YpsoPump® is depleted on account of a high load. All the insulin deliveries in progress are cancelled: boluses, temporary basal rate and basal rate. Confirm by tapping ☑. The internal rechargeable battery is now charged by the alkaline battery which is indicated by arrows rotating round the hourglass. The charging process can take up to 20 minutes. When you have confirmed the alarm, any cancelled boluses and the cancelled temporary basal rate function are indicated with appropriate warnings. Then the status screen is displayed, but not if the “Charge internal rechargeable battery” alarm has appeared after the threaded rod has returned or during a self-test after starting the insulin pump from storage status. In these cases the welcome screen appears.

Occlusion



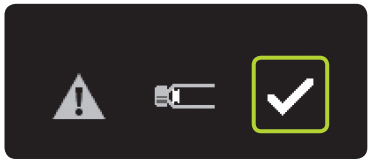
The “Occlusion” alarm appears if the infusion path is blocked (e.g. adaptor, infusion set, cannula).
Confirm by tapping ☑ and disconnect the infusion set from your body. Then perform the following actions:

- Change the infusion set in accordance with the procedure on page 95.
- Prime the tubing with the priming volume specified for the tubing according to the Instructions for Use of your mylife™ YpsoPump® Orbit® infusion set.
- If priming of the new infusion set can be completed without an occlusion alarm, therapy can be continued.
- If an occlusion alarm occurs again while the new infusion set is being primed, the cartridge must be changed in accordance with the procedure on page 96. If subsequent priming can be completed without an occlusion alarm, therapy can be continued.
- If an occlusion alarm occurs again while priming after having changed the cartridge, the insulin pump is faulty and Customer Service must be consulted. You find the contact details on the back of this User Guide as well as on page 10.

No insulin

The “No insulin” alarm appears if after a threaded rod return no priming procedure is performed within 5 minutes or if the priming procedure failed. The “No insulin” alarm only appears if the insulin pump is in run mode.
Confirm by tapping ☑. Insert a cartridge and perform a priming procedure. Follow the procedure on page 100.

Cartridge empty



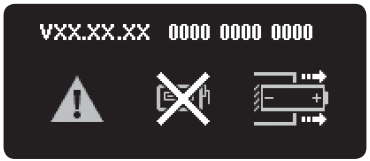
The “Cartridge empty” alarm appears if the cartridge contains 0.0 U insulin. Confirm by tapping ☑.
Change the cartridge in accordance with the procedure on page 96.

Auto stop

The “Auto stop” alarm appears if the mylife™ YpsoPump® is in run mode and has not been operated within 24 hours. Insulin delivery in progress is stopped. Confirm the alarm by tapping ☑. After confirmation of the alarm, insulin delivery restarts.

Electronic error

If the mylife™ YpsoPump® detects an internal malfunction, an electronic error is displayed. All the functions of the insulin pump are cancelled. In the event of an electronic error the insulin pump displays two different screens alternately which show you how to restart the insulin pump in a few steps.



Disconnect the infusion set from your body and remove the alkaline battery from the battery compartment.

Then press the function button for 2 seconds. The insulin pump is now devoid of a battery and in storage status. To put the insulin pump back into operation perform the steps on page 37 and check your therapy settings. Change the cartridge and the infusion set in accordance with the steps on page 95.

If the electronic error remains after the insulin pump has been put into operation again or if it reoccurs after a certain time, stop using the pump, remove the alkaline battery and contact Customer Service. You find the contact details on the back of this User Guide as well as on page 10.

9 Everyday situations

⚠WARNING

⚠ Sport and physical activity which involve physical contact and hard knocks (e.g. hockey, football, etc.) can cause damage to the mylife™ YpsoPump®. Extreme sports (e.g. parachuting, diving, amateur flying, etc.) must not be performed with the mylife™ YpsoPump®. Heavy work (e.g. construction work, removal work, etc.) can also cause damage to your insulin pump and lead to a change in your insulin requirement, which can cause hypoglycaemia or hyperglycaemia (read warning in the box on page 7). In case of doubt consult your doctor, diabetes advisor or Customer Service. You find the contact details on the back of this User Guide as well as on page 10.

9.1 General

- Always wear the mylife™ YpsoPump® in your trouser pocket or use a carrying system offered by Ypsomed. Position the tubing in a way that strangulation is impossible, especially at night. Make sure the insulin pump is not subjected to any jolts, hard knocks or other mechanical interference. Make sure the insulin pump is not soiled (particles of dust, sand, etc.).

- The mylife™ YpsoPump® and the infusion set must not come into contact with medical products or care products such as antiseptics, antibiotic creams, soaps, perfumes, deodorants, body lotions or any other cosmetics because this can discolour the mylife™ YpsoPump® or cause the touchscreen to turn dull. Sweat and saliva cannot damage the mylife™ YpsoPump®. However, there is a risk of damage to the insulin pump housing if the mylife™ YpsoPump® comes into contact with other liquids or chemicals such as detergents, alcohol, beverages, oil or grease.

9.2 Watertightness

- The mylife™ YpsoPump® has the water protection classification IPX8 according to EN 60529 (immersion to a depth of 1 m for up to 60 minutes). For water sports that cannot comply with these specifications (e.g. diving), disconnect the insulin pump from your body following the instructions on page 94 and measure your blood glucose regularly.

9.3 Travelling

- Consult your doctor or diabetes advisor to find out what preparations have to be made in order to travel with the mylife™ YpsoPump®. Make sure you take sufficient supplies for your mylife™ YpsoPump® and blood glucose meter with you on your journey. Make sure you will be able to continue your therapy in an emergency (insulin pen, glucose, etc.).
- If you will be travelling through different time zones, consult your doctor or diabetes advisor about how best to adapt your therapy to the changes in time of day.
- The mylife™ YpsoPump® has only been tested for use at altitudes of up to 5 500 metres above sea level. If you are travelling to a region that is higher than 5 500 metres above sea level, you should stop the mylife™ YpsoPump® and take it off.
- Disconnect the infusion set from your body while the aircraft is taking off and landing. In pressurised aircrafts, you do not need to switch off the mylife™ YpsoPump® during flight.
- On airfields your mylife™ YpsoPump® may be exposed to strong radar radiation. To avoid possible interferences of radar with your insulin pump we recommend switching off the Bluetooth® function on your mylife™ YpsoPump® during boarding, deboarding, in aircrafts on airfields, or in aircrafts approaching airfields.

9.4 Sources of interference

- The mylife™ YpsoPump® meets the required standards for electromagnetic interference immunity. The functions of the mylife™ YpsoPump® should not be affected by security systems at airports or anti-theft systems in department stores.
- However, malfunctions cannot be ruled out because numerous electrical appliances, e.g. mobile phones, emit electromagnetic waves. For this reason it is advisable to maintain a minimum distance of 25 cm between the mylife™ YpsoPump® and such an electrical appliance.
- The mylife™ YpsoPump® must not be used in the vicinity of electromagnetic fields of radar and antenna systems, high-voltage sources, X-ray sources, medical diagnostic imaging equipment, such as Magnetic Resonance Imaging (MRI), Computer Tomography (CT), Positron Emission Tomography (PET), or any other sources of heavy electric current. Such hazardous areas can cause the mylife™ YpsoPump® to stop delivering insulin or damage the insulin pump.
- Examples of other hazardous areas are hyperbaric chambers and areas exposed to flammable gases or vapours. Before you enter such areas you must stop the mylife™ YpsoPump® and take it off.

9.5 Sport

- Consult your doctor or diabetes advisor to find out what preparations have to be made in order to do sports with the mylife™ YpsoPump®. Make sure you take sufficient supplies for your mylife™ YpsoPump® and blood glucose meter with you. Make sure you will be able to continue your therapy in an emergency (insulin pen, glucose, etc.).

- Sports which involve physical contact and hard knocks (e.g. hockey, football, basketball, volleyball, etc.) can cause damage to the mylife™ YpsoPump®. Extreme sports (e.g. parachuting, diving, amateur flying, etc.) must not be performed with the mylife™ YpsoPump®. Heavy work (e.g. construction work, removal work, etc.) can also cause damage to your insulin pump.

10 Annex

10.1 Product specifications

Insulin pump dimensions:	7.8 × 4.6 × 1.6 cm
Touchscreen dimensions:	4.1 × 1.6 cm
Weight:	83 g (including battery and filled cartridge)
Temperature range:	Operation: from + 5 °C to + 37 °C Storage: from 0 °C to + 40 °C
Humidity range:	Operation: 20 % to 95 % RH, non-condensing Storage: 20 % to 95 % RH, non-condensing
Air pressure range:	Operation: 500 hPa to 1060 hPa Storage: 700 hPa to 1060 hPa
Battery:	1.5 V alkaline battery (LR03), size AAA
Service life of the battery:	Typically 30 days of average use (54 U/day; temperature 23 °C ± 2 °C) with activated Bluetooth® function
Duration of data storage:	360 (three hundred and sixty) months
Non-pyrogenic:	Liquid path only
Protection against electric shock:	Type BF applied part (EN 60601-1), internally powered ME device
Alarm generation:	Audible, tactile and visual
Cartridge capacity:	1.6 ml (160 U)
Insulin concentration:	100 U/ml
Water protection classification:	IPX8 according to EN 60529 (immersion to a depth of 1 m for up to 60 minutes)
Basal rate:	2 profiles (A and B), freely programmable by the user
Basal rate setting range:	0.00 U/h to 40.0 U/h

Minimum basal rate greater than 0.00 U/h:	0.02 U/h
Basal rate increments:	Range 0.02 U/h to 1.00 U/h: increment 0.01 U/h Range 1.00 U/h to 2.00 U/h: increment 0.02 U/h Range 2.00 U/h to 15.0 U/h: increment 0.1 U/h Range 15.0 U/h to 40.0 U/h: increment 0.5 U/h
Bolus types:	Standard bolus, extended bolus, combination bolus and blind bolus
Minimum bolus:	0.1 U
Bolus setting range:	0.1 U to 30.0 U
Bolus increments:	0.1 U, 0.5 U, 1.0 U and 2.0 U
Basal rate accuracy from 0.30 U/h to 40.0 U/h:	± 5 % at 23 °C ± 2 °C
Bolus delivery accuracy for 0.1 U:	± 10 % at 23 °C ± 2 °C
Bolus delivery accuracy for 6.0 U:	± 5 % at 23 °C ± 2 °C
Bolus delivery accuracy for 30.0 U:	± 5 % at 23 °C ± 2 °C
Communication interface:	Bluetooth® 4.0 Low Energy 2400 to 2483.5 MHz
Occlusion alarm threshold:	≤ 3.0 bar
Maximum infusion pressure:	3.0 bar
Occlusion bolus volume at 1.00 U/h:	max. 5.0 U
Typical time until occlusion alarm at 1.00 U/h:	4 hours
Typical time until occlusion alarm at 0.02 U/h:	350 hours
Delivery rate during bolus delivery:	0.555 U/second
Maximum delivery volume in the case of a single fault:	5.0 U

10.2 Electromagnetic compatibility (EMC)

Essential performance

The mylife™ YpsoPump® maintains accuracy of basal rate delivery, accuracy of bolus delivery, accuracy of occlusion detection, and functioning of alarm indication during its expected lifetime.

Wireless communication

- Quality of service, wireless coexistence

  The mylife™ YpsoPump® is designed to work safely and effectively in the presence of nearby wireless devices typically found at home, work, retail shops, and places of leisure where daily activities occur, and will not affect their performance. To improve quality of service when other devices operating in the 2.4 GHz band are around, the mylife™ YpsoPump® uses the built-in coexistence features provided by Bluetooth® technology. However, as with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication.

- Radiofrequency communications specifications

Radiofrequency communication interface	Bluetooth® 4.0 Low Energy with an Ypsomed proprietary data format
Operating frequencies	2400 MHz – 2483.5 MHz
Channel spacing	2 MHz
Type of the modulation	Gaussian Frequency Shift Keying (GFSK)
Effective radiated power	0.00086 Watts (= 0.86 mWatts)

- FCC notice

  This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.

  Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  – Reorient or relocate the receiving antenna.
  – Increase the separation between the equipment and receiver.

  Important: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Ypsomed. Doing so could interfere with your ability to operate the equipment.

- Data security
  The mylife™ YpsoPump® insulin pump is designed to only accept radio frequency (RF) communications from paired and authenticated devices. “Pairing and authentication” means to set up a connection between the two devices using Bluetooth® Low Energy (BLE) wireless technology. This is a secure connection, and there is no risk of your pump receiving signals from any other device. The mylife™ YpsoPump® ensures data security via encryption and ensures data integrity using error checking processes, such as cyclic redundancy checks.

Precautions regarding electromagnetic compatibility

- This mylife™ YpsoPump® can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI). The mylife™ YpsoPump® maintains essential performance in the specified environmental conditions.

- On airfields your mylife™ YpsoPump® may be exposed to strong radar radiation. To avoid possible interferences of radar with your insulin pump we recommend switching off the Bluetooth® function on your mylife™ YpsoPump® during boarding, deboarding, in aircrafts on airfields, or in aircrafts approaching airfields.

- The safety system of the mylife™ YpsoPump® is able to detect an internal malfunction due to electromagnetic disturbances. In such a case it cancels any insulin delivery and emits an “electronic error”. It is dealt with in accordance with the procedure on page 171.

EMC separation distances

To provide the mylife™ YpsoPump® with optimal protection against electromagnetic fields the following precautions concerning electromagnetic compatibility must be taken:

- The mylife™ YpsoPump® must be put into operation in accordance with the instructions in this User Guide.
- Wireless communication devices such as wireless computer network devices (Wi-Fi), mobile phones, cordless telephones and their base stations, walkie-talkies, etc., can influence the mylife™ YpsoPump® by emitting electromagnetic waves. The mylife™ YpsoPump® should therefore be kept at sufficient distance from such devices.

	Separation distance in m		
Nominal power of the transmitter in watts	**150 kHz to 800 MHz**	**800 MHz to 2.5 GHz**	**Mobile phones[1] 800 to 900 MHz and 1700 to 1990 MHz**
0.01	0.04	0.07	0.03
0.1	0.11	0.22	0.08
1	0.35	0.70	0.25
2	0.49	0.99	0.35
10	1.11	2.21	0.79
100	3.50	7.00	2.50

[1] Owing to the widespread use of mobile phones the interference immunity of the mylife™ YpsoPump® was measured at those frequencies with a higher field strength (28 V/m).

Examples:

- A Wi-Fi router has a transmitting power of 0.1 W limited by law and it operates in the frequency range of 2400 MHz. According to the table that means a recommended safety distance of 22 cm.
- A DECT cordless telephone has a peak power of 0.25 W and it operates in the frequency range of 1880 to 1900 MHz. According to the table that means a recommended safety distance of approx. 13 cm.
- A mobile phone has a peak power of 2 W and it operates in the frequency range of 900 MHz (GSM900). According to the table that means a recommended safety distance of approx. 35 cm.
- A mobile phone has a peak power of 1 W and it operates in the frequency range of 1880 to 1900 MHz. According to the table that means a recommended safety distance of approx. 25 cm.

Guidance and manufacturer's declaration – electromagnetic emissions

The mylife™ YpsoPump® is intended for use in the electromagnetic environment specified below. Always make sure that the mylife™ YpsoPump® is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11/EN 55011	Group 1	The mylife™ YpsoPump® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11/EN 55011	Class B	The mylife™ YpsoPump® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions FCC Part 15	Class B	
Harmonics emissions EN 61000-3-2	N/A	
Voltage fluctuations/flicker EN 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity

The mylife™ YpsoPump® is intended for use in the electromagnetic environment specified below. Always make sure that the mylife™ YpsoPump® is used in such an environment.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact ± 15 kV air	± 15 kV contact ± 30 kV air	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Requirement does not apply to this battery powered device.
Surge EN 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	Requirement does not apply to this battery powered device.
Conducted disturbances EN 61000-4-6	3 Vrms	N/A	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions and voltage variations on power supply lines EN 61000-4-11	0 % U_T 0.5 Cycle 0 % U_T 1 Cycle 70 % U_T 25/30 Cycles 0 % U_T 250/300 Cycles	N/A	Requirement does not apply to this battery powered device.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	400 A/m (EN 60601-2-24)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radio frequency susceptibility (radiated) RTCA DO-160G, Section 20	Category R (airport radar)	Category R (airport radar)	On airfields your mylife™ YpsoPump® may be exposed to strong radar radiation. To avoid possible interferences of radar with your insulin pump we recommend switching off the Bluetooth® function on your mylife™ YpsoPump® during boarding, deboarding, in aircrafts on airfields, or in aircrafts approaching airfields.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The mylife™ YpsoPump® is intended for use in the electromagnetic environment specified below. Always make sure that the mylife™ YpsoPump® is used in such an environment.

Immunity test	Proximity field from wireless transmitters	Compliance level
Radiated RF EN 61000-4-3	10 V/m @ 80 MHz to 2.5 GHz	10 V/m @ 80 MHz to 3 GHz
Proximity fields from RF wireless communications equipment EN 60601-1-2, table 9	385 MHz: 27 V/m @ 18 Hz pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation 2450 MHz: 28 V/m @ 217 Hz pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation	385 MHz: 27 V/m @ 18 Hz pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation 2450 MHz: 28 V/m @ 217 Hz pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation

Immunity test	Proximity field from wireless transmitters	Compliance level
Radiated RF electromagnetic field AIM Standard 7351731, table 3	65 A/m @ 134.3 kHz 7.5 A/m @ 13.56 MHz 7.5 A/m @ 13.56 MHz 5 A/m, 12 A/m @ 13.56 MHz 3 V/m @ 433.92 MHz 54 V/m @ 860 – 690 MHz 54 V/m @ 2.45 GHz	65 A/m @ 134.3 kHz 7.5 A/m @ 13.56 MHz 7.5 A/m @ 13.56 MHz 5 A/m, 12 A/m @ 13.56 MHz 3 V/m @ 433.92 MHz 54 V/m @ 860 – 690 MHz 54 V/m @ 2.45 GHz

Continuation of the table

Electromagnetic environment – guidance

Portable and mobile RF communications equipment should be used no closer to any part of the mylife™ YpsoPump®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance: $d = 1.2\sqrt{P}$ @ 80 MHz to 800 MHz, $d = 2.3\sqrt{P}$ @ 800 MHz to 3 GHz

Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Continuation of the table

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

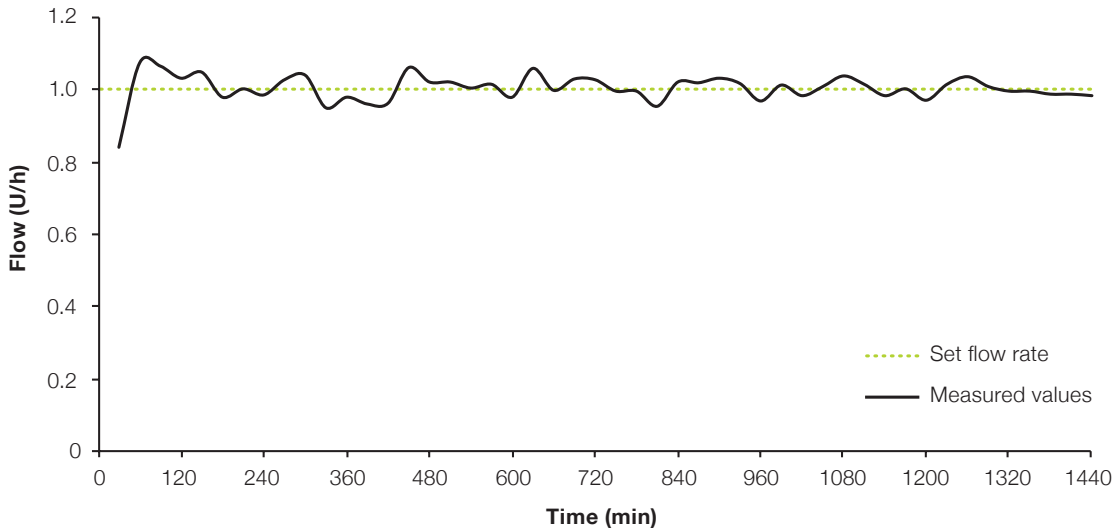
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1 Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the mylife™ YpsoPump® is used exceeds the applicable RF compliance level above, the mylife™ YpsoPump® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the mylife™ YpsoPump®.

2 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

10.3 Delivery accuracy according to EN 60601-2-24

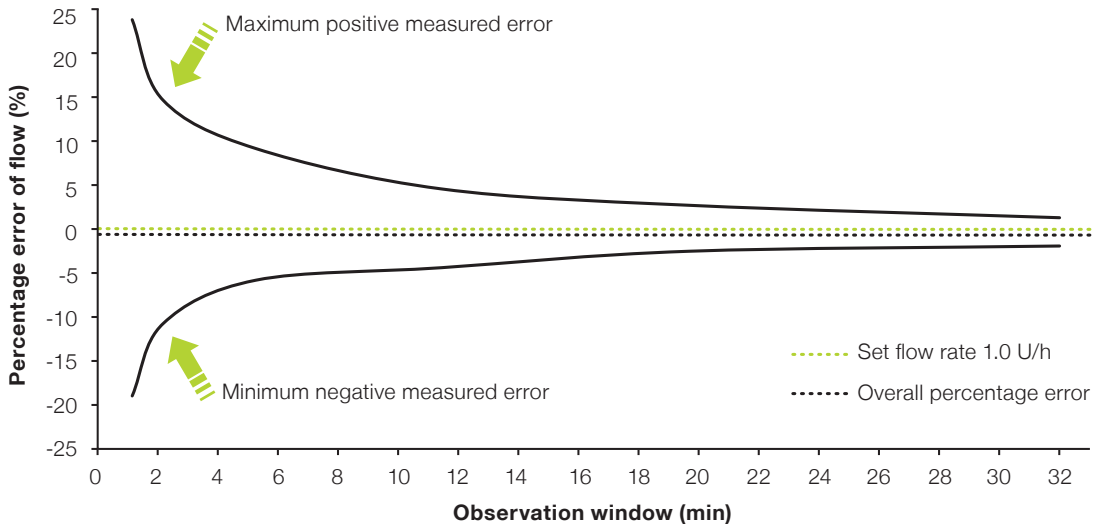
Start-up graph



Material and conditions

- mylife™ YpsoPump® Orbit®soft, 110 cm tubing length
- Ambient conditions 22 °C (± 2 °C), humidity uncontrolled (25 % to 75 %)

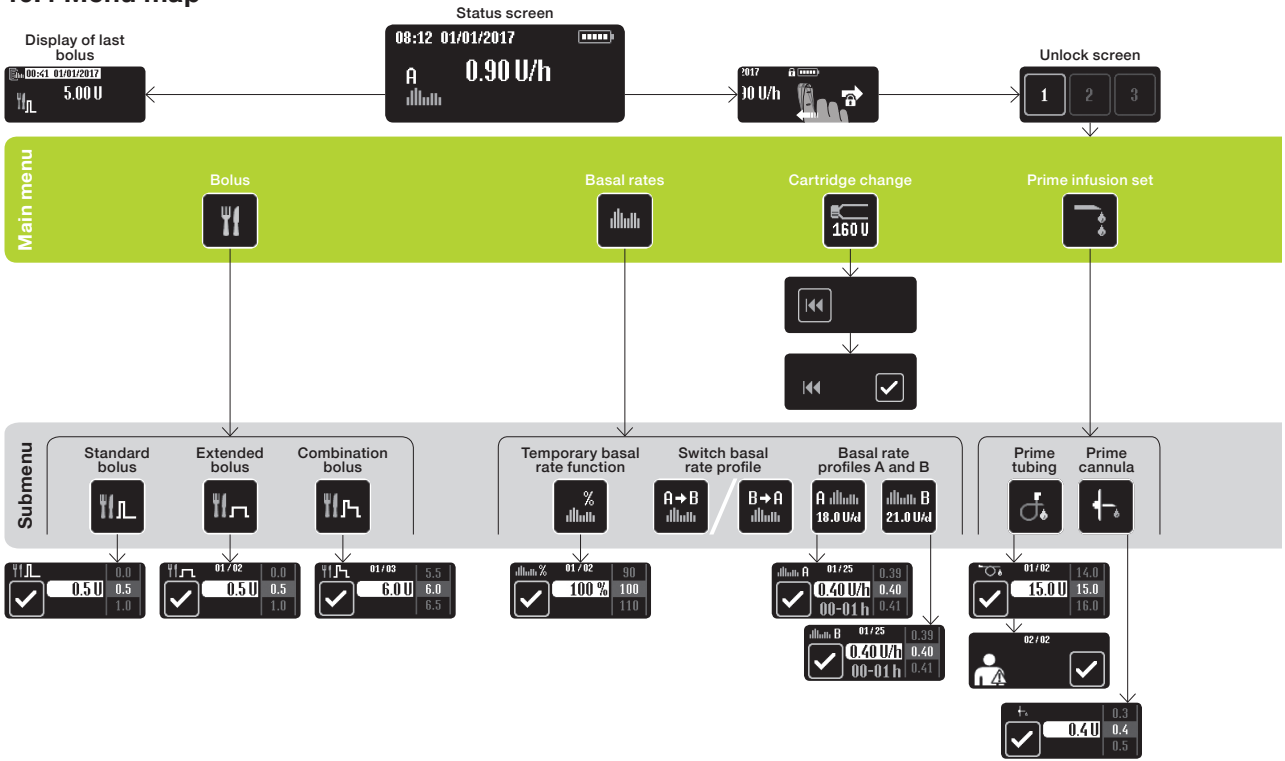
Trumpet curve

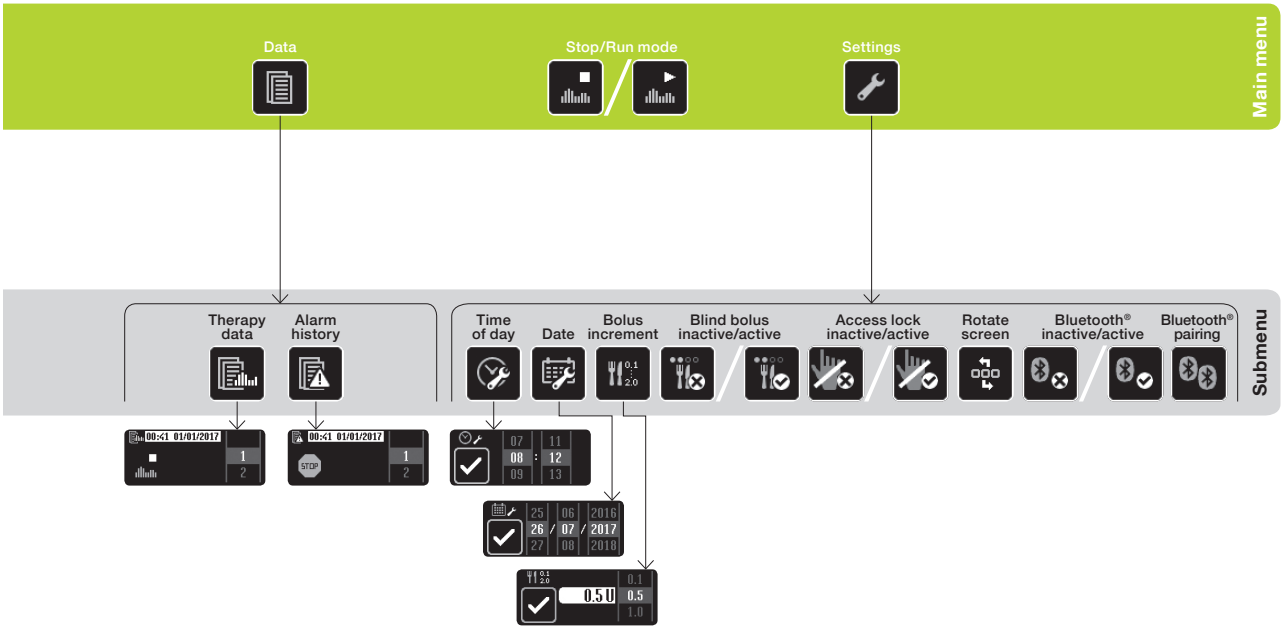


Material and conditions

- mylife™ YpsoPump® Orbit®soft, 110 cm tubing length
- Ambient conditions 22 °C (± 2 °C), humidity uncontrolled (25 % to 75 %)

10.4 Menu map





10.5 Icon overview

Navigation aids

	Cancel
	Confirm
	Forward to unlock
	Forward
	One menu level up
	One step back

General icons

	Warning
	Alarm
	Audible signal
	Vibration signal
	Battery charge level
	Battery removed
	Remove battery
	Threaded rod returning

	Prime tubing in progress
	Prime cannula in progress
	Disconnect infusion set from body
	Ready for Bluetooth® pairing
	Bluetooth® pairing in progress
	Press function button for 2 seconds
	Total insulin amount per day (basal and bolus)

Icons in main menu and submenus

	Bolus
	Standard bolus
	Extended bolus
	Combination bolus
	Basal rates
	Basal rate profile A
	Basal rate profile B
	Switch to basal rate profile A

	Switch to basal rate profile B		Data
	Temporary basal rate function		Therapy data
	Temporary basal rate function activated/cancel		Alarm history
	Cartridge change and current cartridge level		Run mode/switch to stop mode
	Return threaded rod		Stop mode/switch to run mode
	Prime infusion set		Settings
	Prime tubing		Time of day
	Prime cannula		Date

	Set bolus increment
	Blind bolus active/deactivate
	Blind bolus inactive/activate
	Access lock active/deactivate
	Access lock inactive/activate
	Rotate screen
	Bluetooth® active/deactivate
	Bluetooth® inactive/activate

	Bluetooth® pairing

Alarm icons

	No battery
	Battery empty
	Battery not suitable
	Charge internal rechargeable battery
	Occlusion

	No insulin
	Cartridge empty
	Auto stop
	Electronic error

Warning icons

	Cartridge level low
	Battery charge level low
	Threaded rod return not completed
	Priming not completed
	Bolus cancelled
	Temporary basal rate function completed or cancelled
	Insulin pump stopped
	Bluetooth® connection failed

10.6 Explanation of symbols

mylife™ YpsoPump® symbols

CE 0123	The product was designed and manufactured in accordance with the relevant standards/directives and may be sold within the EU (European Union) and in EFTA countries.
	Warning/Caution! Refer to accompanying document.
	Read the User Guide
MD	Medical Device
IPX8	IPX8 according to EN 60529 (immersion to a depth of 1 m for up to 60 minutes)
	Applied part type BF according to EN 60601-1 (protection against electric shock)
	Symbol for the separate collection of batteries/devices with a built-in battery
	1.5 V alkaline battery (LR03), size AAA and polarity
	Customer Service number

	Device with built-in Bluetooth® technology The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth® SIG, Inc., and any use of such marks by Ypsomed is under license. Other trademarks and trade names are those of their respective owners.
	Device emits electromagnetic RF energy
	Manufacturer
REF	Catalogue number
SN	Serial number
GTIN	Global trade item number
	Date of manufacture
	Begin use by
	Temperature limit
	Keep dry
	Keep away from sunlight

mylife™ YpsoPump® Orbit® and mylife™ YpsoPump® Reservoir symbols

CE 0123	The product was designed and manufactured in accordance with the relevant standards/directives and may be sold within the EU (European Union) and in EFTA countries.
	Warning/Caution! Refer to accompanying document.
	Consult Instructions for Use
MD	Medical Device
℞ Only	Restriction of sale and prescription by doctors of medicine (USA)
STERILE EO	Sterilised using ethylene oxide
STERILE EO	Single sterile barrier system. Sterilised using ethylene oxide.
	Non-pyrogenic
	Do not reuse
	Do not use if package is damaged

	Manufacturer
REF	Catalogue number
LOT	Batch code
GTIN	Global trade item number
	Date of manufacture
	Use by date
	Temperature limit
	Keep dry
	Keep away from sunlight
	Distributor

10.7 Glossary

Adaptor
The adaptor fixes the cartridge in place in the mylife™ YpsoPump® and at the same time pierces the septum of the cartridge.

Basal rate
The basal rate is a basic amount of insulin that is continuously administered subcutaneously in order to keep the blood glucose level within target range. The basal rate is determined according to your requirement together with your doctor and programmed accordingly in the mylife™ YpsoPump®.

Basal rate profile
The mylife™ YpsoPump® has 2 programmable basal rate profiles, A and B. A basal rate profile consists of 24 programmable hourly basal rates. Insulin delivery can thus be optimally adapted to your metabolism.

Blind bolus
The blind bolus is a method of bolus delivery that can only be programmed and triggered by pressing the function button. This can be done without viewing the touchscreen.

Bolus
A bolus is a programmed amount of insulin that is delivered in addition to the basal rate administered continuously (over a period of 24 hours). A bolus is used to correct an increased blood glucose level or to compensate for the carbohydrates in a meal.

Bolus increment
The bolus increment relates to all four bolus types. It indicates by how many units the bolus amount is increased/reduced when pressing the respective controls on the touchscreen/ function button.

Cannula
The cannula is located on the cannula base. It introduces the insulin to the subcutaneous tissue of the body.

Cannula base
The cannula base is an element of the mylife™ YpsoPump® Orbit® infusion set. It consists of the cannula, the tape and the septum. It can be disconnected from the infusion set tubing and is located on the patient side of the infusion set.

Cartridge
The cartridge contains the insulin. The cartridge of the mylife™ YpsoPump® has a capacity of 1.6 ml (160 U) insulin with a concentration of 100 U/ml.

Combination bolus
The combination bolus is a type of bolus in which the total bolus amount entered is split up between an immediate portion and an extended portion.

Disconnectable infusion set
The disconnectable infusion set makes it possible to remove the infusion set to take a shower or bath or do sports.

Extended bolus
An extended bolus is delivered by the mylife™ YpsoPump® over the period of time you select.

Icon
Icons are graphic symbols on the touchscreen of the mylife™ YpsoPump®. The entire control system of the mylife™ YpsoPump® is based on language-independent icons.

Infusion set
The infusion set is the connection between the mylife™ YpsoPump® and the patient's body.

Infusion site
An infusion site is the part of the body in which the infusion set is applied and the cannula is inserted through the skin.

Insulin
Insulin is a hormone that is made in the beta cells of the pancreas in healthy human beings. Insulin is a key hormone in carbohydrate metabolism.

Internal rechargeable battery
The mylife™ YpsoPump® has an internal rechargeable battery that is charged by the inserted alkaline battery.
If the alkaline battery is removed, all functions still work.

Priming procedure
The priming procedure is the procedure in which the infusion set is filled with insulin.

Run mode
In run mode, insulin is delivered according to the settings. Normally, all the functions of the mylife™ YpsoPump® can be performed. All operable icons are active.

Self-test
The self-test is the procedure that is automatically performed when the device is put into operation for the first time and after every return of the threaded rod. The insulin pump tests the functions and the operability of the visual signal (screen), the vibration signal and the audible signal.

Standard bolus
The standard bolus is a type of bolus in which the bolus amount entered is delivered immediately.

Status screen
The status screen indicates the current operating status of the mylife™ YpsoPump® (current time of day, current date, battery charge, current function and current insulin delivery). To access the status screen the function button has to be given one short press.

Stop mode
No insulin is delivered in stop mode. Certain functions (bolus delivery, temporary basal rate, switch basal rate profile) are inactive in stop mode. The relevant icons are displayed in grey and are disabled.

Swipe
Swipe is the action taken on the screen of the mylife™ YpsoPump® with which values are set. Set a value by swiping up or down with your finger until the required value is at the centre of the screen. You can also tap the upper or lower value directly in order to increase or reduce it by one unit each time.

Temporary basal rate
A temporary basal rate is set to reduce or increase the basal rate for a limited period of time. When a set temporary basal rate has finished, the programmed basal rate profile (A or B) continues.

Threaded rod
The threaded rod is a mechanical drive component of the mylife™ YpsoPump® which pushes the plunger of the cartridge forward in order to deliver insulin.

Threaded rod return
Threaded rod return is the procedure in which the threaded rod of the mylife™ YpsoPump® returns to the starting position so that a new cartridge can be inserted.

Touchscreen
Touchscreen means a screen that is sensitive to touch. The touchscreen of the mylife™ YpsoPump® responds to touch and is controlled by tapping and swiping.

100 U/ml
100 U/ml indicates the concentration of the insulin.
100 units of insulin in every millilitre of liquid.

10.8 My pump settings

Basal rate profile A		Daily total _____ U/day	
00:00 to 01:00	_____ U/h	12:00 to 13:00	_____ U/h
01:00 to 02:00	_____ U/h	13:00 to 14:00	_____ U/h
02:00 to 03:00	_____ U/h	14:00 to 15:00	_____ U/h
03:00 to 04:00	_____ U/h	15:00 to 16:00	_____ U/h
04:00 to 05:00	_____ U/h	16:00 to 17:00	_____ U/h
05:00 to 06:00	_____ U/h	17:00 to 18:00	_____ U/h
06:00 to 07:00	_____ U/h	18:00 to 19:00	_____ U/h
07:00 to 08:00	_____ U/h	19:00 to 20:00	_____ U/h
08:00 to 09:00	_____ U/h	20:00 to 21:00	_____ U/h
09:00 to 10:00	_____ U/h	21:00 to 22:00	_____ U/h
10:00 to 11:00	_____ U/h	22:00 to 23:00	_____ U/h
11:00 to 12:00	_____ U/h	23:00 to 24:00	_____ U/h

Basal rate profile B			Daily total _____ U/day
00:00 to 01:00	_____ U/h	12:00 to 13:00	_____ U/h
01:00 to 02:00	_____ U/h	13:00 to 14:00	_____ U/h
02:00 to 03:00	_____ U/h	14:00 to 15:00	_____ U/h
03:00 to 04:00	_____ U/h	15:00 to 16:00	_____ U/h
04:00 to 05:00	_____ U/h	16:00 to 17:00	_____ U/h
05:00 to 06:00	_____ U/h	17:00 to 18:00	_____ U/h
06:00 to 07:00	_____ U/h	18:00 to 19:00	_____ U/h
07:00 to 08:00	_____ U/h	19:00 to 20:00	_____ U/h
08:00 to 09:00	_____ U/h	20:00 to 21:00	_____ U/h
09:00 to 10:00	_____ U/h	21:00 to 22:00	_____ U/h
10:00 to 11:00	_____ U/h	22:00 to 23:00	_____ U/h
11:00 to 12:00	_____ U/h	23:00 to 24:00	_____ U/h

Temporary basal rate function	Value	Duration
e.g. soccer training	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours
	_____ per cent	_____ hours

Notes

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