

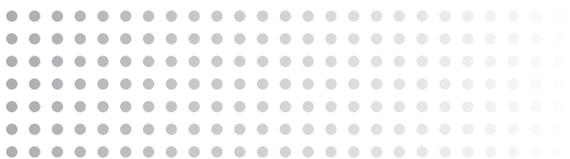


QUICK USER GUIDE
ESYSTA®

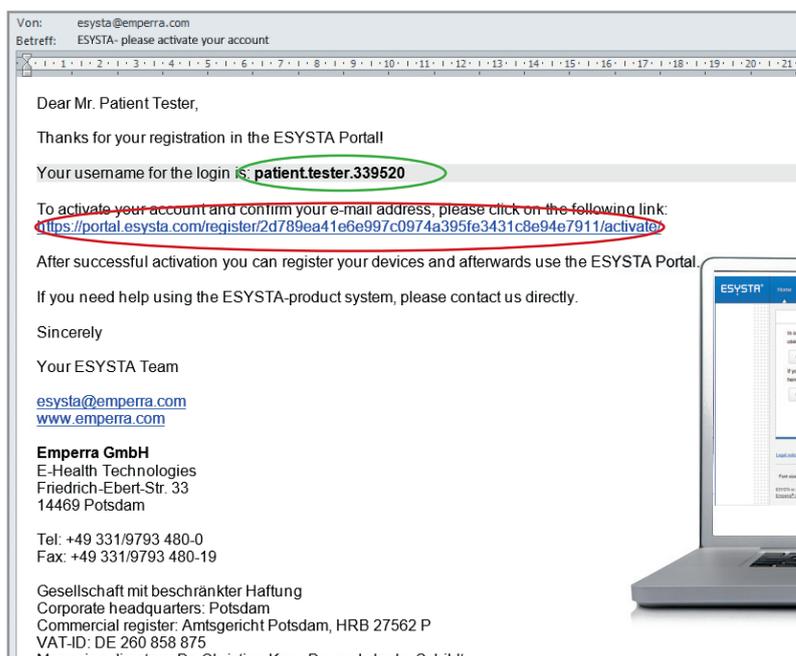


ESYSTA product system

The fully automatic telemonitoring system
for people with insulin-dependent diabetes mellitus



Quick user guide to registering with the ESYSTA® Patient Portal



Sample confirmation e-mail

1. At **www.esysta.com**, set up a user account with your personal data.
2. Click "Create user account" and enter your data. Confirm this with "Create user account".
3. You will then receive a confirmation e-mail at your specified e-mail address (see top picture). This may take a few minutes, depending on your Internet connection or e-mail provider.
4. Click on the link provided in your e-mail (framed in red in the picture for clarity). You will then be taken to the ESYSTA® website.
5. Then confirm your entry with "Register".
6. Have the serial numbers and passwords for your ESYSTA® devices ready. These can be found on the relevant device packaging. Enter the device data when you are prompted to do so.
7. Once you have registered all of your devices, you will be able to allow the doctor looking after you to access your data.

To do this, you will need:

1. The surname of your doctor
2. The town or city in which the practice is based
3. The practice's BSNR (Betriebsstättennummer / business number) **or**
4. The doctor's EFN (Einheitliche Fortbildungsnummer / standardised training number)

You will find the BSNR on any prescription or referral. Your doctor will provide you with their EFN.

In the ESYSTA® Portal, you can change your personal data at any time and also remove your doctor's permission to access your data or give permission to a new or additional doctor.

ESYSTA® APP quick user guide

If you have a tablet computer or smartphone, you can use the free ESYSTA® App. The ESYSTA® App allows all patients - but also parents or relatives and caregivers, for example - to call up personal treatment data from the ESYSTA® Portal on their mobile device. The ESYSTA® traffic lights display the status of the metabolic control at all times.

If necessary, the data (insulin values, blood glucose measurement values and bread units) can be read off in a table and in graphic form. It is also possible to enter data manually. As a result, every patient who uses ESYSTA® as part of their care can get a quick and accurate summary of their treatment status.

The ESYSTA® App is CE-registered as a medical product under DE/CA76/H00075/04.

Note

Emperra® GmbH E-Health Technologies supplies the App for tablet computers and smartphones for the current market leading operating systems (Android®, iOS®). Approval by Apple® has been obtained for iOS®.

To download the ESYSTA® App, go to the Apple App Store or to Google Play, search for "Esysta" and then install the App as normal.

Once you have installed the ESYSTA® App, you can log in using the same access data as the ESYSTA® Portal.



Quick User Guide to the ESYSTA® Basis



The ESYSTA® Basis



The ESYSTA® Basis with a 230 Volt power pack

The ESYSTA® Basis is used to automatically transfer all of the values from the ESYSTA Lab (blood glucose measuring device) and the ESYSTA® Pen (insulin pen) to the ESYSTA® Portal.

The Basis is supplied with a power pack for permanent connection to the mains (230 V / 50 Hz).

First remove both parts (ESYSTA® Basis and power pack) from the packaging and connect the round 6 Volt DC plug of the power pack into the jack provided on the ESYSTA® Basis. Then connect the 230 Volt plug on the power pack to a 230 Volt power socket. The ESYSTA® Basis switches on automatically. The ESYSTA® Basis control lights flash initially. After a few minutes, they light up continuously and the ESYSTA® Basis is now ready for operation.

Ideally, position the ESYSTA® Basis close to where you normally keep the devices you use to treat your diabetes. If this area has a poor mobile signal, we recommend setting up the ESYSTA® Basis in the same room close to the window.



1 ESYSTA® Basis • 2 ESYSTA® Pen • 3 ESYSTA® Lab

Quick User Guide to the ESYSTA® PEN

Note

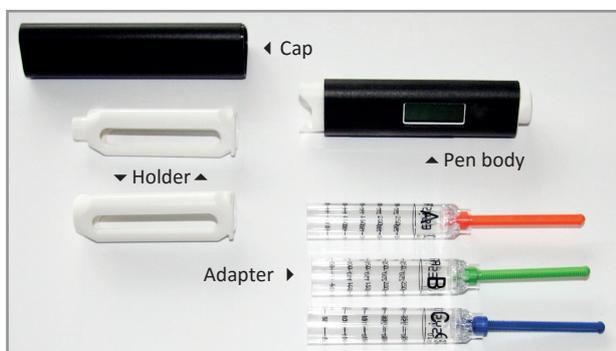
The ESYSTA® Pen can accept any conventional insulin cartridge using an ESYSTA® adapter. The ESYSTA® adapters are single-use products. Please always use a new ESYSTA® adapter of the correct type with each new insulin cartridge. Choose the correct adapter for your needs from the table shown.



Manufacturer	Adapter colour	Adapter type	Holder
Lilly Berlin-Chemie B.Braun	● orange	A	A/B
Sanofi Aventis	● green	B	A/B
Novo Nordisk	● blue	C	C

ESYSTA® adapter for the ESYSTA® Pen

Instructions



1. Please first remove the locking cap and then the ESYSTA® Pen holder.
2. Plug the adapter suitable for your insulin cartridge into the body of the pen with the threaded rod going in first.



3. The holder is then pushed using the adapter filled with the insulin cartridge and made to engage by pushing it and turning it.
4. The Pen is now ready for use. You can use it just like any other insulin pen.

Notes

- Please always use the ESYSTA® Pen with a cannula (needle) screwed onto it.
- Switch the ESYSTA® Pen on by pressing the dosing button to unlock it. The display shows "88 88" (display test).
- Only use the Pen if you are able to see all of the segments in this display.



Venting

Before you are able to use the Pen for injection after an insulin ampoule change, the Pen asks you to vent it ("Pr" = priming).



1. Turn the dosing button at least 2 units in the direction of the arrow ("Pr" flashes), hold the pen vertically with the needle tip pointing upwards and then press the dosing button until it engages.
2. If no insulin comes out, set the Pen to 1 insulin unit and turn the dosing button back to 0 ("Pr" flashes), then turn the button at least 2 insulin units in a clockwise direction. Then press the dosing button. Repeat step 2 until insulin is expelled from the needle. Your Pen is ready to deliver insulin.

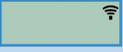
Administration of insulin

Set the required number of insulin units by turning the unlocked dosing button in the direction of the arrow. The set number of units appears in the display. When injecting the insulin, push the dosing button in until it engages and leave the needle in the skin until the countdown in the display has gone from 8 to 0. The quantity of insulin injected is saved in the Pen and automatically forwarded at regular intervals via the ESYSTA® Basis to the ESYSTA® Portal.

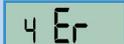
Summary of displays on the ESYSTA® PEN



Display	Designations	Explanation
	Display test	Please check whether all elements of the digits are displayed in order to detect any possible display errors caused by a partial failure of the display.
	Venting, Priming	This display urges you to vent the pen. It is triggered by various conditions and guarantees safe function of the pen. Make sure that the venting procedure is always carried out correctly until insulin emerges. Possible triggers of this display are: Turning the dosing button outside the readiness for operation mode by setting the units for application, unlocking the cartridge holder, e.g. to change the insulin cartridge, change the batteries, marking of the venting procedure.
	Display of the last insulin injection	30 units of insulin were injected around 1 hour ago.
	Setting the units	Currently, 17 insulin units are set.
 	Countdown on insulin administration	Counts down in seconds from eight to zero. Leave the needle in the skin until the countdown has completed.

Display	Designations	Explanation
	Insulin injection complete	Seventeen units have just been injected.
	Wireless mode	The ESYSTA® Pen sends data.
	Negative units set	Caution, serious error! Turn the dosing button in the direction of the arrow until zero or a higher number is displayed.
	More than 60 units set	The Pen is designed for the administration of between 2 and 60 units of insulin. Turn the dosing button against the direction of the arrow until a number appears again.
	Time of the last injection cannot be determined	The last injection is more than 99 hours ago or the batteries have been changed in the interim.
	The batteries are flat	Please change the batteries as soon as possible.
	Error with dosing sensor	This error may occur when the ESYSTA® Pen is defective or if the dosing button has been turned too quickly. If the ESYSTA® Pen displays this error, do not use it for an injection under any circumstances! Press the dosing button in, in order to discard the insulin amount previously set. Once the display has switched itself off, push the dosing button back out again and start to reset the units again. Should this error occur repeatedly, please contact Empera® GmbH.
	The button has been pressed in with a dose set in the negative range	The next time the Pen is used, the actual dose injected may be lower than the one displayed because a negative dose was set. This is why your ESYSTA® Pen must be vented before the next injection until insulin visibly emerges from the needle.
	Injection not completed correctly	The dosing button was not pushed in all the way or became unlocked again during the injection process (countdown not yet finished). It is possible that not all of the quantity set has been administered.

Summary of displays on the ESYSTA® PEN

Display	Designations	Explanation
	No adapter in the ESYSTA® Pen	There is no ESYSTA® adapter in the ESYSTA® Pen.
	The ESYSTA® Pen has reached the end of its useful life	This message is displayed during switch-on after 24 months of use. Discontinue the use of the ESYSTA® Pen from this point in time.
	The end of the life of the pen will be reached in 14 days	This message will be displayed on every operation during the last two weeks of the period of use. Please replace your pen promptly!
	Memory error	A problem has occurred with the internal data memory. Injected doses cannot be saved and will not be transferred to your ESYSTA® Portal. Please contact Emperra® GmbH.
	Memory full	The data memory is full. The insulin application function of the pen will continue to exist. Please transfer data.

Quick User Guide to the ESYSTA® LAB (blood glucose measuring device)

Note

The measurement values can be displayed in mg/dL or mmol/L. You can learn more about this in the ESYSTA® Lab's operating instructions.

If there is still a contact protection film on the battery compartment cover on the back of the ESYSTA® Lab, please remove it. The device must be coded before the first measurement is taken.



Coding

The code number on the coding strip and test strip socket must match. Slide the coding strip (grey) with the writing facing upwards into the test strip port on the device. The measuring device switches on automatically. If the correct code appears in the display, remove the coding strip. Your ESYSTA® Lab is now coded.

Blood glucose measurement

Insert a blood glucose measuring strip into the ESYSTA®Lab. The device switches on automatically. Hold the test strip against the droplet of blood until a beeping sound is heard. After five seconds, the message "Ok" appears in the display to indicate that the measurement has been carried out correctly. The blood glucose value measured is then displayed and stored in the device.

Entering bread units (BU)

Pressing the scroll wheel when the blood glucose measuring device is switched on takes you to BU mode. Turning the scroll wheel allows the BU value to be set. Pressing the scroll wheel



again confirms this value and "Ok" appears in the display. The data is then stored in the device if you then press the button or if the device switches itself off automatically after 30 seconds.

Note

If the device is not yet switched on, you must hold the scroll wheel down for two seconds.

Miscellaneous

You can also carry out the following functions and/or change the following settings on the device:

- Trigger the sending of data manually
- Switch the beeping sound on and off
- Change the unit from mg/dL to mmol/L and vice versa
- Switch the illumination on or off
- Set the size of the BU increments

For more information, please take a look at the ESYSTA® Lab operating instructions or contact the Service Hotline on: **+49 (0)800 / 367 37 72 (free of charge from German landlines).**

Summary of displays on the ESYSTA® LAB



Display	Designations	Explanation
	Error 4 bAt	The batteries are flat. Please replace the batteries.
	Code FAL	This message appears if the coding strip cannot be read. Please remove the coding strip and insert it into the device again (with the writing facing upwards). If "FAL" appears again, please contact Emperra® GmbH.
	Error 202	If this error message appears, switch the device off and on again. If the error continues to occur, please contact Emperra® GmbH.
	Error 303	Please first change the batteries. If the error message appears again, please contact Emperra® GmbH.
	Error 3 Old	The test strip has already been used or has become damp. Please use a new test strip.

Display	Designations	Explanation
	HI	High measured value (> 630 mg/dL or 35.0 mmol/L). Please repeat the measurement. If the result does not change, please contact your doctor immediately.
	LO	Low measured value (< 20 mg/dL or 1.1 mmol/L). Please repeat the measurement. If the result does not change, please contact your doctor immediately.
	Ht & thermometer symbol	If the surrounding / operating temperature is above 40°C, the measurement results may be incorrect. Move the measuring device to an ambient temperature of between 10°C and 40°C and wait until the warning message no longer appears when you attempt to take a further measurement.
	Lt & thermometer symbol	If the surrounding / operating temperature is below 10°C, the measurement results may be incorrect. Move the measuring device to an ambient temperature of between 10°C and 40°C and wait until the warning message no longer appears when you attempt to take a further measurement.
	Error ts	The time displayed is incorrect. This may occur in isolated cases after the battery compartment is opened. Please only open the battery compartment if a battery change is needed and carry out the change close to the ESYSTA® Basis.



Emperra® Service Hotline.
Free of charge from German landlines.

+49 (0)800 3673772
+49 (0)800 Emperra
Mon - Fri 08.30 - 17.00

esysta@emperra.com

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