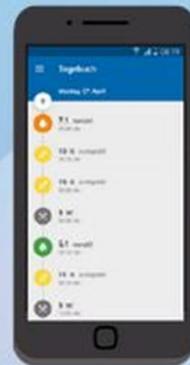


Instructions for Use for the DiGA ESYSTA[®]



ESYSTA[®] Portal



ESYSTA[®] App

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Please read the instructions for use carefully.

2 General information on the manufacturer



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Management: Dr. med. Janko Schildt

3 Classification and CE marking

ESYSTA App and ESYSTA Portal are Class I medical devices in accordance with Directive 93/42/EEC, Annex IX, Rule 12.

Rating:

The ESYSTA digital health application (DiGA), consisting of the ESYSTA App and ESYSTA Portal, is a digital diabetes diary with optional involvement of the attending physician.

The DiGA ESYSTA provides a reliable data basis to support diabetes therapy. ESYSTA thus serves to support personal diabetes management. No medical or therapeutic recommendations are given, but the emphasis is on having the data available in a better prepared, simple and uncomplicated way for therapy support.

CE marking:

Medical device DE/CA76/H000075/04 (ESYSTA App)

Medical device DE/CA76/H00075/05 (ESYSTA Portal)

4 Intended use, product description and medical benefit

The ESYSTA App and the ESYSTA Portal form the ESYSTA digital health application for supporting and monitoring the treatment of diabetes mellitus (so-called self-management).

Explanation:

The ESYSTA App and the ESYSTA Portal form a digital health application that offers users the opportunity to evaluate and analyze all data collected from connected treatment devices as well as manually entered data such as blood glucose levels, insulin levels and meals consumed and serves to monitor blood glucose levels and diabetes therapy as well as automated data evaluation to facilitate and improve therapy management. Based on the scientific evaluations, it is possible to improve the long-term sugar HbA1c in particular. The ESYSTA health application is a software that enables patients to access relevant data from digitally connected devices from other manufacturers and from the ESYSTA Portal via a smartphone to support self-management of diabetes mellitus and to supplement this data with manual entries.

ESYSTA was examined in clinical studies. According to current scientific data, a positive effect on long-term glucose levels (HbA1c) has been demonstrated. This suggests that the metabolic control of diabetes mellitus has improved. Further positive effects, e.g. on quality of life, are also medically possible.

5 Patient group, user, contraindication and indication

The target group are patients with diabetes mellitus, type 1 and type 2, who have been trained in self-management, as well as their relatives and caregivers (indications: ICD-10 codes / diagnoses E10: Diabetes mellitus, type 1, E11: Diabetes mellitus, type 2) with a minimum age of 18 years (male, female, non-binary gender identity).

There are no contraindications, but there are restrictions on use: patients with type 2 diabetes who only take oral antidiabetics and therefore do not need to inject additional insulin are not included in the patient group. Further exclusion criteria relate exclusively to the user regulations, so that potentially any diabetic can be supported. Users must be equipped with mental and physical abilities that allow them to read, operate and understand mobile applications. For this purpose, it should be possible to recognize the display without any doubt and there should be no relevant fine motoric impairment. Since the diabetics are regularly trained or checked in training processes with

hardware devices such as blood glucose meters or insulin pens, which requires significantly higher demands on vision, motor skills and understanding, these are generally also sufficient for the operation of this product. The ESYSTA Portal for doctors, among others, is already operated safely by qualified personnel and their medical certificates. There are no further exclusion criteria.

6 Type and frequency of use

ESYSTA is intended for daily use in a domestic or everyday environment.

7 Requirements and system requirements

Android:

Android version 10.0 or higher

Apple:

iOS 16.0 or higher (iPhone)

iPadOS 16.0 or higher (iPad)

Internet browser:

Firefox: 38 or higher

Chrome: 43 or higher

MS Edge 44 or higher

Opera: 31 or higher

Safari: 6 or higher

A connection to the Internet and, if necessary, a Bluetooth® or NFC connection is required to use appropriately paired treatment devices.

8 ESYSTA App and ESYSTA Portal functions

- Manual data entry of blood glucose, insulin and bread units via the ESYSTA App

- Automatic data entry via compatible devices. (Overview of compatible devices at: <https://esysta-diabetes.com>)
- Detailed daily display for blood glucose, insulin and bread units
- Comment function for measured values
- Fully automatic profile adjustment of limit values, insulin used and measurement units (mmol/l and mg/dl)
- Daily blood glucose curve in different views
- Permanent visibility of insulin doses in the diagram
- Automatic data synchronization between the ESYSTA App and the ESYSTA Portal
- Quick overview with the ESYSTA traffic light
- Assistance with the implementation of the therapy by the ESYSTA assistant
- Optional: Release of the data to the attending physician
- 7-day trend with weekly recommendations to improve treatment adherence
- Traffic light / daily view for daily therapy support

9 Possible undesirable side effects

No undesirable side effects of ESYSTA are known from all studies and market observation analyses to date.

10 Handling information - Quick Start Guide

10.1 Installing the ESYSTA App

The ESYSTA App can be installed on smartphones or tablets with an Android operating system from the Google Play Store. Search for "ESYSTA" in the Play Store or follow this link:

<https://play.google.com/store/apps/details?id=com.emperra.esysta>

The ESYSTA App can be installed from the App Store on Apple smartphones or tablets (iPhone or iPad). Search for "ESYSTA" in the App Store or follow this link:

<https://apps.apple.com/de/app/esysta/id521073696>

10.2 Start

To start the app, select "Open" in the App or Play Store after installation or click on the ESYSTA icon in your app menu:



10.3 Create account

After starting the ESYSTA App for the first time, you will be taken to the login screen after a few information pages. If you already have an ESYSTA account, you can log in with your username (or your email address if you entered it during registration) and your password, see the next chapter.

When you register, you choose a user name and a password. For reasons of data protection, your username is supplemented by an appendix of numbers so that it is less easy to guess. Alternatively, if you want to be able to log in with your email address, we need to save it. We need your consent for this. In this case, we recommend that you use an email address that does not contain any references to your name.

Note: If the costs are covered by health insurance, full use is only possible after entering an activation code (prescription code). You will receive this activation code from your health insurance company.

10.4 Log in to your ESYSTA account

You can log in with your username, email address (if stored) or via your health ID and authenticate yourself using a second factor (two-factor authentication). This will be explained to you during the registration process.

Log in with another ESYSTA account on the same device:

If you want to log in with a different account on the same device, this is generally possible. As switching between different accounts is cumbersome, we recommend using the app on a smartphone with the same account.

10.5 Register with a health ID

Alternatively, you can log in with your health insurance company's health ID. To do this, you must be registered with your health insurance provider and also have the relevant health insurance app installed on your smartphone/tablet. During the registration process, you will be shown how to register accordingly.

10.6 Screenshots for a simplified overview

Below you will find selected screenshots to help you use ESYSTA. ESYSTA is designed in such a way that all functions are easy to understand and self-explanatory for users. Please note that the sample images may differ slightly between Android® and iOS® (Apple) and in the web application (ESYSTA Portal). However, the functions do not differ.

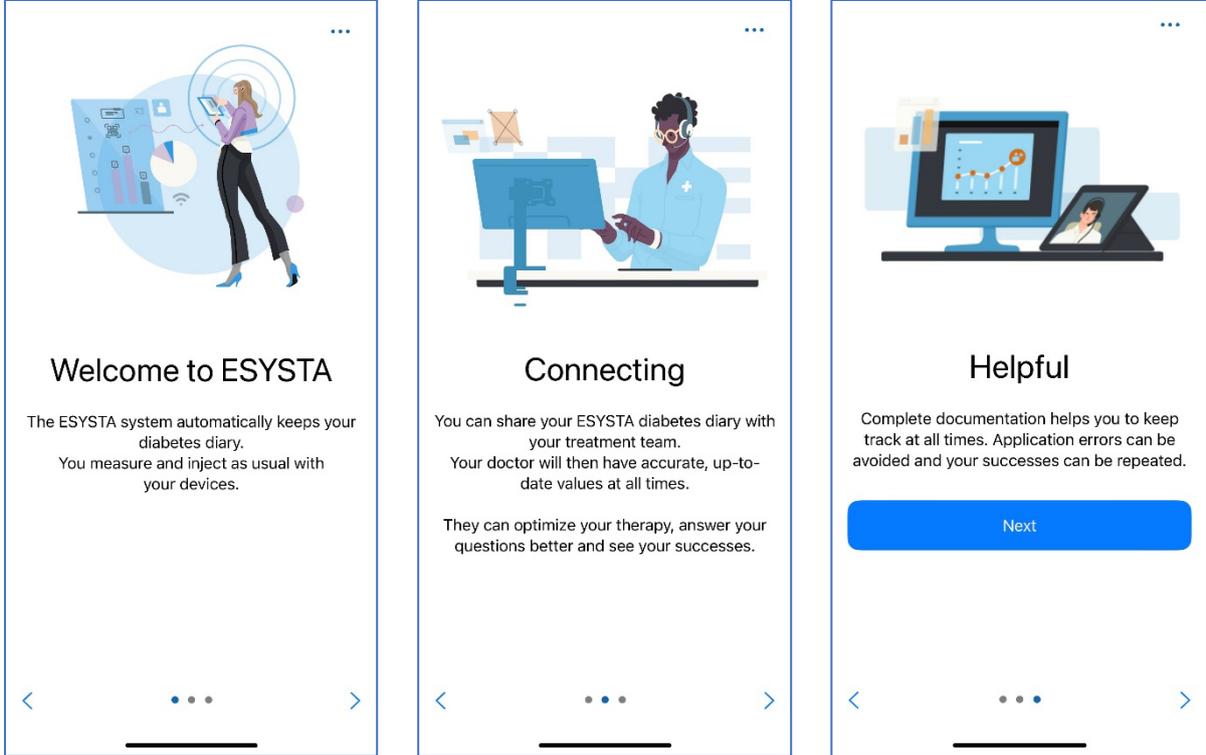
First step - registration in the app and portal

The most important settings are made during registration. If you have entered an email address, you will receive a confirmation to the email address you provided. Click on the link to activate your account.

The image displays three sequential screenshots from the ESYSTA registration process:

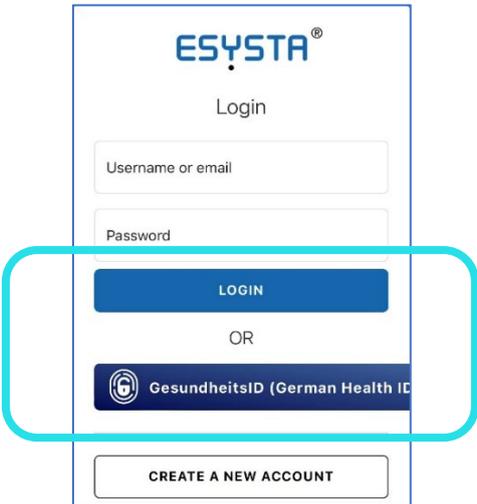
- Screen 1: Create a new account**
 - Header: ESYSTA®
 - Text: Create a new account
 - Section: **User data** (highlighted with a red box)
 - Field: Name (Nickname)
 - Field: Email (optional)
 - Checkbox: I consent to the storage of my email address.
 - Section: **Credentials**
 - Field: Password
 - Field: Confirm password
- Screen 2: Consents and conditions**
 - Section: **Consents and conditions**
 - Checkbox: I agree to the [Terms and Conditions of Emperra GmbH](#) and consent to the collection, processing, and storage of my personal data for the intended use of ESYSTA. This is required for the use of ESYSTA, billing, and documentation purposes. More information can be found in our [Privacy Policy](#).
 - Checkbox: I am aware that the ESYSTA Portal serves as addition to my diabetes mellitus monitoring and that it is recommended to discuss this with my doctor. I will always discuss any adjustments to my medical treatment and detailed medical questions with my doctor.
 - Section: **Optional consents**
 - Checkbox: I consent to the data processing and data analysis to permanently guarantee the technical functionality, the user-friendliness and the further
- Screen 3: Optional consents**
 - Section: **Optional consents**
 - Checkbox: I consent to the data processing and data analysis to permanently guarantee the technical functionality, the user-friendliness and the further development of the digital health application.
 - Checkbox: I consent to the storage of my data for days after my DiGA activation period expires. Note: If you do not consent to this, we are legally obligated to permanently delete your ESYSTA account and all associated data at the end of the DiGA activation period. We recommend the extended storage so your ESYSTA account remains available until the next prescription if you enter a new valid voucher within 30 days after the expiration.
 - Buttons: **CREATE NEW ACCOUNT AND PROCEED** (highlighted with a red box) and **BACK**

To make it easier to get started with the ESYSTA system, we have included a product tour in the app that provides a brief overview of the functions. On the portal page you will also find video links for explanation.



Second step - Registration

After registering, you can log in with your account in the app and in the portal. You can then decide whether you also want to use biometric or authenticator apps (e.g. Google Authenticator). Alternatively, you can use your health ID.



Third step - Enter your activation code, which you will receive from your health insurance company (e.g. via your health insurance app).
In the case of reimbursement by a health insurance company, please enter the activation code you have received.

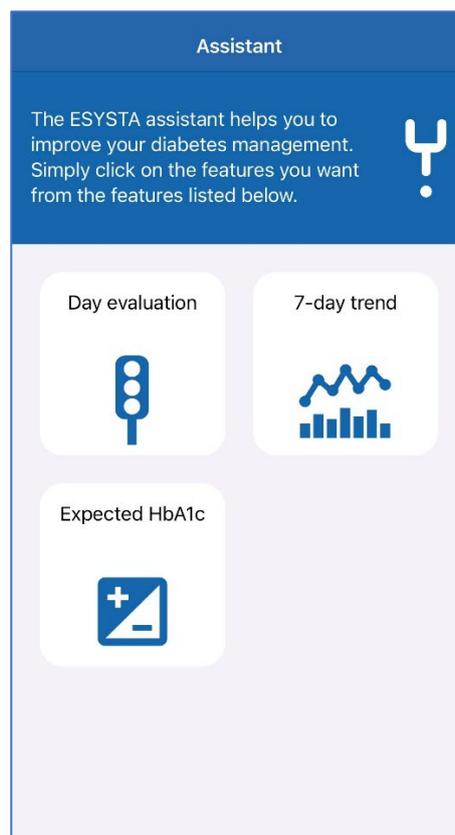
Functions at a glance:

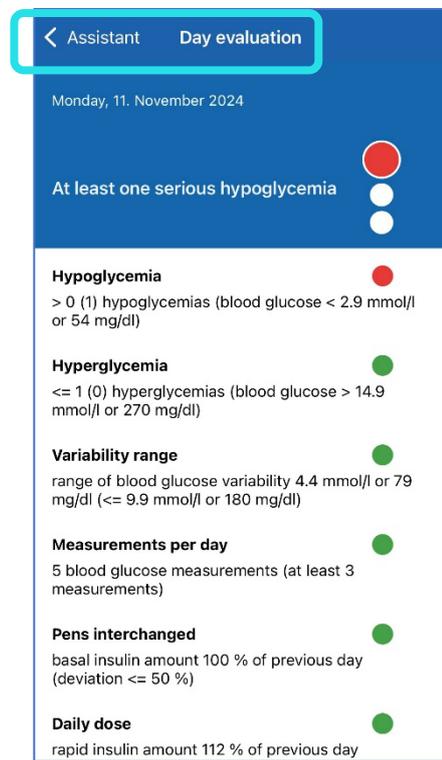
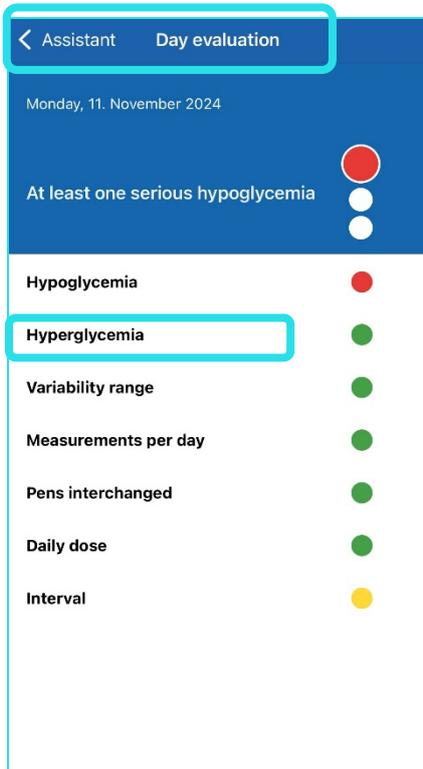
What is the ESYSTA Assistant? By regularly entering your values (insulin doses and blood glucose), the ESYSTA Assistant provides an overview of your therapy progress.



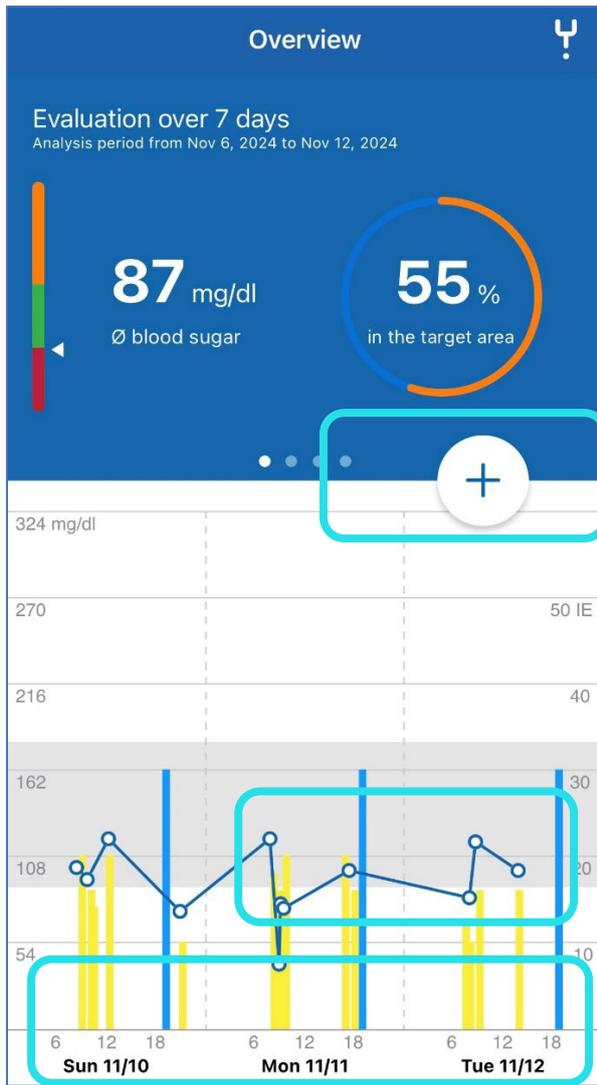
Please note! We do not make a diagnosis - whenever you feel unwell or your values change, please always contact your doctor first.

However, we use the wizard to give you a detailed overview of your values and also tell you how the current week compares to the previous one. The traffic light (daily evaluation) uses color codes to show you which range your values are currently in (see illustrations below).

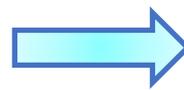




The daily evaluation gives you a quick overview of the day thanks to the traffic light display. If you click on the individual points, you will get more details on the respective topics.



With the “plus” you can Enter values manually

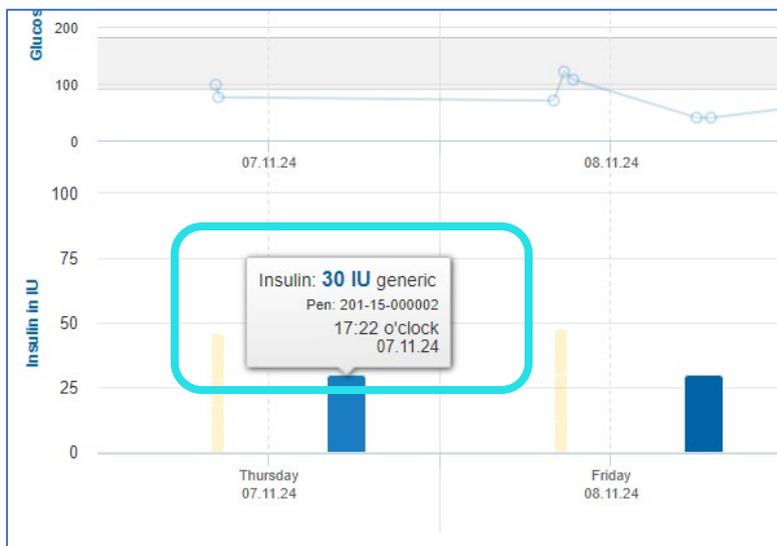
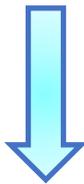
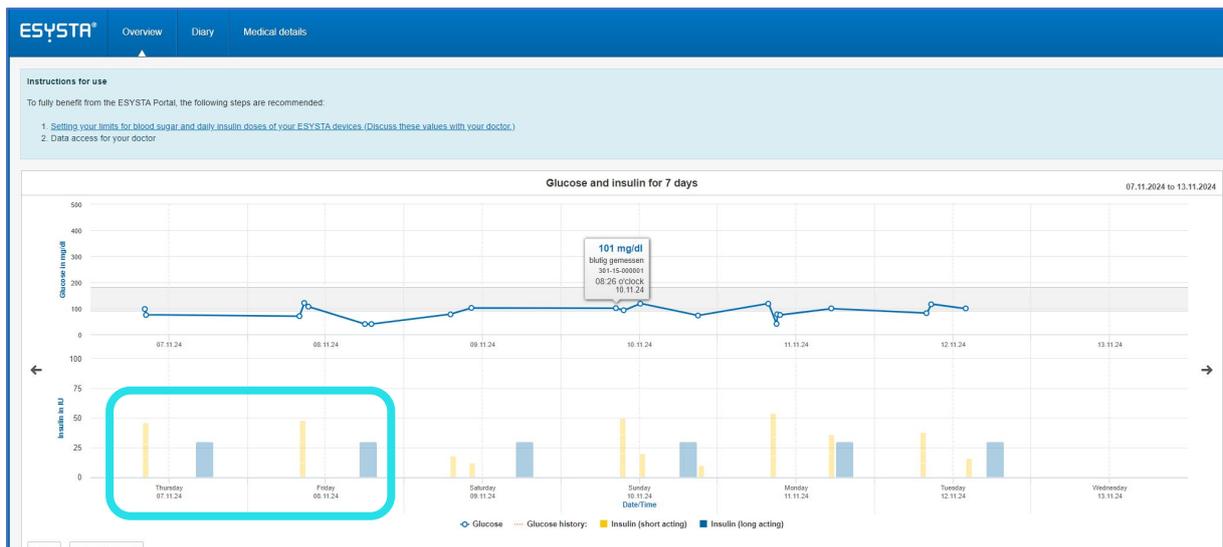


Blood glucose levels over time



Insulin injections

If you are logged into the ESYSTA Portal, an overview of your values for the current week will appear at the beginning. Move your mouse over the insulin level bars and see the detailed information.



Under the menu item "Overview" on the left-hand side, you will find all the functions of your ESYSTA Portal at a glance. In addition to the progressions and diagrams, you can also conveniently:

- Enter events manually
- Download and print reports (e.g. for the doctor)
- Export data

ESYSTA data evaluation

The ESYSTA traffic light evaluation analyzes the data according to the currently selected type of therapy ICT. To change this calculation basis go to [Adjust traffic light evaluation](#) for selecting the type of therapy.

Legend:
 Green = The evaluation of your data does not reveal any irregularities.
 Yellow = The evaluation of your data reveals irregularities.
 Red = The evaluation of your data reveals serious irregularities.
[more information about the ESYSTA data evaluation](#)

← [previous week](#)

	Thursday 07.11.2024	Friday 08.11.2024	Saturday 09.11.2024	Sunday 10.11.2024	Monday 11.11.2024
Day evaluation	Red	Red	Yellow	Red	Red
Hypoglycemia	Green	Red	Green	Green	Red
Hyperglycemia	Green	Green	Green	Green	Green
Variability range	Green	Green	Green	Green	Green
Measurements per day	Yellow	Green	Yellow	Green	Green
Pens interchanged?	Green	Green	Green	Green	Green
Daily dose	Red	Green	Yellow	Red	Green
Interval	Yellow	Green	Green	Yellow	Yellow

10.7 Download (export) ESYSTA data

Export data from ESYSTA

Important note

⚠ You have the option of exporting and downloading your therapy data - including blood sugar, insulin and meals - collected by the ESYSTA product system. To do so, you can use the following export functionality by specifying a time period for the desired data or selecting that all of your data should be exported. Depending on the amount of data to be exported, this process can take several minutes.

Start date:
 Format: DD.MM.YYYY

End date:
 Format: DD.MM.YYYY

or

I would like to export the complete data for the entire period of my ESYSTA use.

Click on "Export data" to start the export. After a few minutes, the data export is prepared and ready for download.

ESYSTA was developed by doctors and diabetics to make your life with diabetes mellitus easier. We want to give you the opportunity to integrate your therapy into your everyday life in the best possible way and to obtain a reliable database without having to resort to a multitude of accessories.

If you have any problems with the handling or would like more functions, please contact us. We are always there for you.

Your Emperra Team

11 Emergency information (notes and contact details)

Important notes

-  ESYSTA may only be used if you have sufficient visual acuity (visual acuity, visual acuity). If you are considering using the device in barrier-free mode, you must consult your doctor in advance.

-  ESYSTA is not an alarm system. The traffic light reflects automatically recorded or manually entered values. As ESYSTA does not take permanent measurements and does not make diagnoses, a doctor must always be contacted or an emergency doctor called in the event of any kind of deterioration in well-being or a deterioration in the values.

-  Protect your data! ESYSTA is backed by an ISO 27001-certified information security system. This means that our product and our processes always have the protection of your data as their top priority. When using ESYSTA, please ensure that you only use it on your personal smartphone or personal computer. If you make an exception and you want to use ESYSTA on a public computer (internet browser), for example, please log off immediately after use (log out) and delete any history in the internet browser.

-  Always ensure that the operating system used is up to date and meets the requirements. If in doubt, please contact ESYSTA customer service. (Contact details follow in the next chapter).

-  If the ESYSTA software application malfunctions, please contact ESYSTA customer service (contact details are provided in the following section).

-  ESYSTA is not a substitute for a medical diagnosis or therapy. In any case, a change in the treatment regime must be agreed with a doctor.

-  If you have any problems with activation, registration or using ESYSTA, you can contact ESYSTA customer service. We will also be happy to go through the processes step by step with you.

-  If the data from the app and/ or portal differs from that displayed by your devices, please contact your doctor (especially if this has been

approved by you). Also note the values on and consult our customer service.



If you, as the attending physician bzw. , notice that the values in the portal show an anomaly, please check the real-time glucose value with the patient bzw. in order to rule out or detect system errors.



If you no longer wish to use ESYSTA, you can delete your ESYSTA account at any time. You will find this function under the Settings field. Alternatively, please contact our customer service. The ESYSTA app (program) can be uninstalled on the smartphone using the uninstall function. The ESYSTA Portal (website application) was not previously installed on the computer. Deleting the account is sufficient for this.

12 Contact details and important phone numbers

ESYSTA customer service:

Hotline: +49 (0) 800 / 367 37 72 (free of charge)

Phone: +49 (0) 331 / 979 3480 50

Fax: +49 (0) 331 / 979 3480 59

E-Mail: esyستا@emperra.com

Emergency call: 112 (Germany)

Police: 110 (Germany)

13 Data protection

Only the data required for the secure use of ESYSTA is collected. The legal data protection requirements are met. All content and processes are subject to the German Federal Data Protection Act and the General Data Protection Regulation (GDPR). More detailed information on the processing of personal data can be found in our privacy policy at:

<https://www.emperra.com/de/datenschutzerklaerung/>

Contact our external data protection officer:

Gunther Kohn

intersoft consulting services AG

Beim Strohhouse 17, 20097 Hamburg

Phone: +49 (0)331/979 34 80-0

E-Mail: Datenschutz@Emperra.com

V03.00 © 11.2024 Emperra® GmbH E-Health Technologies Art.-Nr. 404-40-001-02-c

Responsible state authority:
**The State Commissioner for Data Protection and the Right of Access to
Files Brandenburg**
Stahnsdorfer Damm 77
14532 Kleinmachnow
Phone: +49 (0) 33203/356-0
Fax: +49 (0) 33203/356-49
E-Mail: Poststelle@LDA.Brandenburg.de

14 Software status at the time of creation

App Android: 2.7.0
App iOS: 2.5.0
Portal: 2.13.0

15 Date of creation, version

November 2024, Version 03.00
Index: 404-40-001-02-c

Product component	Basic UDI-DI
ESYSTA App iOS	4260227091373
ESYSTA App Android	4260227091380
ESYSTA Portal	4260227091397

Note: In order to further improve product quality and functionality, we have implemented appropriate quality assurance processes within the company. This also includes reporting serious medical incidents that are observed in connection with ESYSTA at any time, even if they were not directly caused by ESYSTA itself.

In this case, you as the user or we as a company must notify the competent authority (e.g. Federal Institute for Drugs and Medical Devices/BfArM or State Office for Occupational Safety, Consumer Protection and Health Brandenburg/LAVG or "Notified Body" DNV Medcert GmbH Hamburg).

If you have any questions, you can also contact our ESYSTA customer service at any time (see page 16 for contact details).