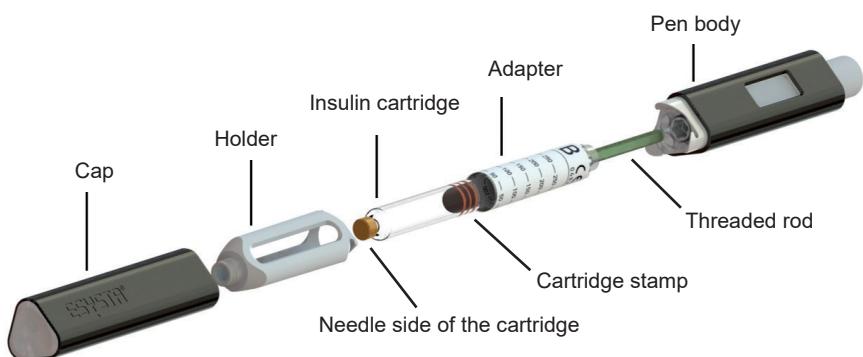




## Operating instructions ESYSTA® BT Pen





ESYSTA® BT Pen, example with adapter B and holder A/B

## Contents of the retail packaging:

- ESYSTA® BT Pen (insulin pen)
- Holder A/B
- Holder C
- Markers for colour identification
- Case
- Operating instructions

Only use the ESYSTA® BT Pen if the retail packaging is undamaged.

Any stated brand names and trade marks are the property of the respective owners.

Issue date: 01 August 2016 / V 01.00

205-40-006-02-a

# Contents

<b>1.</b>	<b>Introduction</b>	<b>6</b>
<b>2.</b>	<b>Correct use</b>	<b>7</b>
2.1	ESYSTA® BT Pen	7
2.2	ESYSTA® Adapter (disposable adapter)	7
2.3	Data transfer	8
2.4	Information for doctors and medical staff	8
<b>3.</b>	<b>Information on safe use</b>	<b>9</b>
3.1	Risks associated with its use	12
<b>4.</b>	<b>General information</b>	<b>13</b>
<b>5.</b>	<b>Components of your ESYSTA® BT Pen</b>	<b>14</b>
<b>6.</b>	<b>Commissioning your ESYSTA® BT Pen</b>	<b>15</b>
6.1	Choosing the correct ESYSTA® Adapter	16
6.2	Choosing the holder	17
6.3	Inserting the insulin cartridge	18
6.4	Marker	19
6.5	Attaching the needle	21
6.6	Switching on the ESYSTA® BT Pen	21
6.7	ESYSTA® BT Pen pre-set venting	23
6.8	Marking and carrying out additional venting	23
6.9	Setting the units for subcutaneous injections	24
6.10	Injection procedure	26
6.11	Completing the injection process	28
6.12	Cancelling the setting process	29
6.13	Temperature sensor	30

<b>7.</b>	<b>Changing the insulin cartridge</b>	<b>31</b>
7.1	Continuing with the same insulin manufacturer	31
7.2	Changing the insulin manufacturer	32
7.3	Important safety information about changing the cartridge	32
<b>8.</b>	<b>Changing the battery</b>	<b>33</b>
<b>9.</b>	<b>Enabling and disabling data transfer</b>	<b>35</b>
9.1	Enabling the Pen-smartphone connection ("bonding")	35
9.2	Disabling the Pen-smartphone connection (cancelling "bonding")	37
9.3	Data memory	38
<b>10.</b>	<b>Display and error messages</b>	<b>39</b>
<b>11.</b>	<b>Guarantee</b>	<b>43</b>
<b>12.</b>	<b>Period of use</b>	<b>44</b>
<b>13.</b>	<b>Technical data</b>	<b>45</b>
<b>14.</b>	<b>FAQs</b>	<b>46</b>
<b>15.</b>	<b>List of compatible insulin preparations</b>	<b>50</b>
<b>16.</b>	<b>List of compatible needles</b>	<b>52</b>
<b>17.</b>	<b>Index</b>	<b>53</b>
	<b>Manufacturer's contact details</b>	<b>56</b>

## 1. Introduction

Your ESYSTA® BT Pen is a device for injecting insulin. As a component of the tele-diabetological ESYSTA® product system, it automatically saves all of the insulin quantities injected, along with the associated time. This data is transferred in encrypted form via Bluetooth® radio technology<sup>1</sup> to your ESYSTA® App. The ESYSTA® App can be found in the corresponding App portals. The transfer of data to the ESYSTA® Portal is also supported.

With the ESYSTA® BT Pen, you can use all common insulin cartridges from various manufacturers. So you can continue to use the insulin preparation you have previously been prescribed.

To integrate other devices that we supply into the innovative ESYSTA® product system, visit our website:

**[www.emperra.com](http://www.emperra.com)**

Thank you for trusting our ESYSTA® devices. As you will see, the ESYSTA® BT Pen will make your treatment easier.

<sup>1</sup> The Bluetooth word mark and logo are the property of Bluetooth SIG, Inc. These brands are used by Emperra under licence.

## 2. Correct use

### 2.1 ESYSTA® BT Pen

The ESYSTA® BT Pen is a medical product. For the treatment of diabetes mellitus by trained patients or trained carers, it is used to manually inject insulin preparations from 3 ml insulin cartridges<sup>2</sup> (100 IU/ml). Up to 60 IU can be injected through human strength. You can set your insulin dose in whole units. An ESYSTA® BT Pen is only intended for treating one patient.

### 2.2 ESYSTA® Adapter (disposable adapter)

The ESYSTA® Adapter is an accessory (a consumable) required for operating the ESYSTA® BT Pen, in order to be able to use insulins from different manufacturers. There are three different designs.

The ESYSTA® Adapter is a disposable item. A new ESYSTA® Adapter must be used with each new insulin cartridge. Information on selecting the right ESYSTA® Adapters for your insulin preparation can be found in Chapter 7.

<sup>2</sup> Also referred to as a cartridge or ampoule.

## 2.3 Data transfer

The ESYSTA® BT Pen can transfer the injected quantities of insulin together with the date and time of the injection to the ESYSTA® App via a conventional smartphone using Bluetooth® radio technology.

You also have the option of registering with the ESYSTA® Portal at [www.esysta.com](http://www.esysta.com). On the Portal, you can allow your doctor to view your treatment data. For optimal use of the system, we recommend that you agree your treatment with your doctor or practice.

## 2.4 Information for doctors and medical staff

The operation of the ESYSTA® BT Pens does not essentially differ from that of other insulin pens. There are additional functions and operating steps. If you instruct patients in the use of the ESYSTA® BT Pen, or use it on patients, you should be comprehensively familiarised in advance with both the operation and these operating instructions in order to avoid making errors in use. Should you have any questions, please contact us (see p. 56).

### 3. Information on safe use

-  Before using the ESYSTA® BT Pen, you must always receive training from your doctor, pharmacist or diabetes adviser.
-  Before using your ESYSTA® BT Pen, please read all of these operating instructions carefully and follow the instructions exactly. Not following the instructions may lead to injecting a dose of insulin that is too high or too low.
-  If you need help, please contact your doctor, pharmacist, diabetes adviser or Emperra GmbH.
-  Before each use, check your ESYSTA® BT Pen for damage. In the case of damage such as cracks or breaks, or if the display or parts of the display are not functioning, do not use the ESYSTA® BT Pen.
-  Always handle your ESYSTA® BT Pen with care. Strong vibrations may damage the device. The ESYSTA® BT Pen must not be used improperly or opened using force, as this will damage the device and the guarantee will be rendered invalid.

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-  Always set the number of units correctly. The dose is increased by exactly one unit for each click when the dosing button is turned clockwise. The dose is increased by exactly one unit for each click when the dosing button is turned anti-clockwise. Do not use the ESYSTA® BT Pen if the units displayed differ from the number of units identified through the clicking and locking mechanism. In this case, contact Emperra GmbH, your doctor, pharmacist or diabetes adviser.
-  Also do not use the ESYSTA® BT Pen if you cannot see anything on the display or if the display appears faulty.
-  You must be able to clearly feel and hear the "click" when setting the dose in order to use the ESYSTA® BT Pen.
-  Always be prepared in case of loss or damage to your ESYSTA® BT Pen. We recommend always keeping an additional insulin-injecting device to hand for the relevant insulin.
-  The ESYSTA® BT Pen is not licensed for use by blind or visually-impaired people. You must be able to clearly recognise the display as well as different marker colours.

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-  In the case of impairment that prevent the safe use of the ESYSTA® BT Pens, a trained assistant should be consulted.
-  Observe the temperatures for storage and use. For example, please consider the fact that temperatures of over 70° C may occur in cars in the summer. Please also note Chapter 6.13 (Temperature sensor).
-  Protect your ESYSTA® BT Pen against dirt, moisture and the penetration of other foreign matter. Only transport and store your ESYSTA® BT Pen with the cap on, and keep it in a safe place where it cannot be confused with other things.
-  On the ESYSTA® Adapter is a scale intended for use in estimating the amount of insulin remaining in the cartridge. This scale must not be used for measuring the dose of insulin.
-  Keep your ESYSTA® BT Pen, your insulin cartridges and injection needles out of reach of unauthorised persons - and children in particular.
-  There are magnets in your ESYSTA® BT Pen. If you have a heart pacemaker, please consult your cardiologist to have confirmed in writing that it is safe for you to use the ESYSTA® BT Pen before using the ESYSTA® BT Pen.
-  There are magnets in your ESYSTA® BT Pen. It should not be stored together with magnetic cards, for example.

### 3.1 Risks associated with use

Find out about the risks and side effects of your insulin preparation. In spite of all of the safety precautions, there are residual risks from the use of the ESYSTA® BT Pen.

- Infections may occur if the injection needles are used more than once.
- Unprotected injection needles can cause injuries and transmit diseases. Third parties - particularly children - can be injured or even killed by the needles and the insulin contained within them.
- Too much or too little insulin can be injected through incorrect operation. Under-dosing through too little insulin being injected will lead to hyperglycaemia (high blood sugar), which may finally render the patient unconscious and is often associated with complications. Over-dosing by injecting too much insulin causes hypoglycaemia (low blood sugar), which can quickly become a critical condition.
- In order to prevent incorrect doses, the ESYSTA® BT Pen must be sufficiently vented before each use and particularly after each change of cartridge; see also Chapters 6.7 and 6.8.

## 4. General information

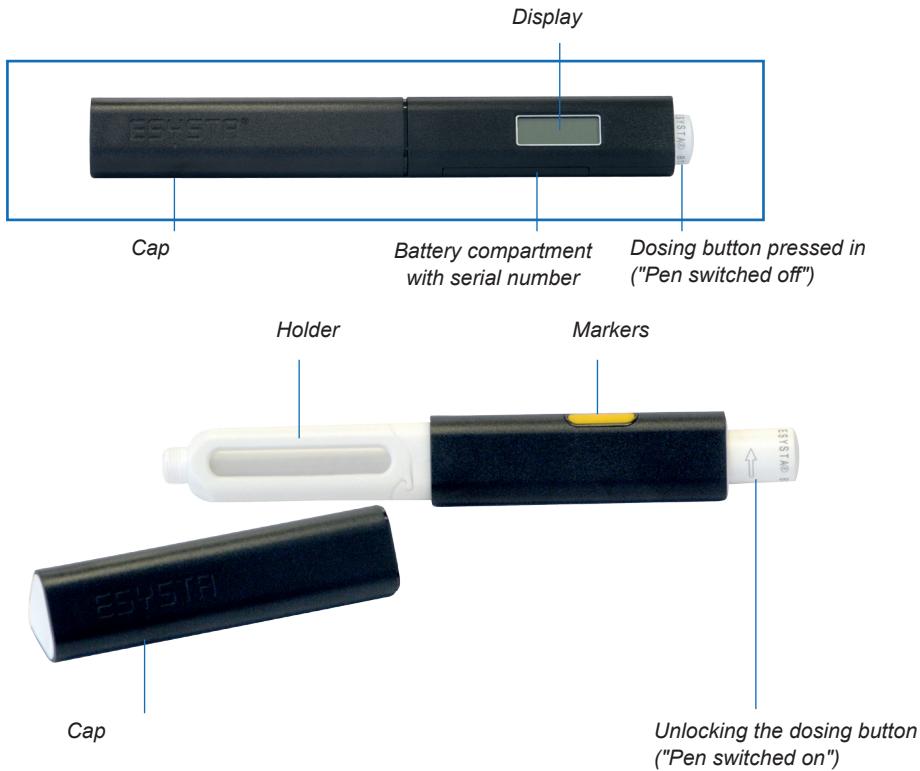
The CE mark on a medical device states that the product meets the provisions of the EU Directive on Medical Products 93/42/EEC. The ESYSTA® BT Pen insulin injection device meets the requirements of dosing accuracy under ISO 11608-1: Pen injectors for medical use – Part 1: Pen injectors – Requirements and test procedures. As part of the tele-medical ESYSTA® product system, the ESYSTA® BT Pen is equipped with a wireless interface for data. The ESYSTA® BT Pen meets the fundamental requirements of Directive 1999/5/EC for wireless installations and telecommunication transmission facilities.

The ESYSTA® BT Pen has been tested for electromagnetic compatibility in accordance with EN 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

You can set your insulin dose in whole units. The ESYSTA® BT Pen has a memory that saves all your doses, along with the date and time. The memory capacity is approx. 1,000 data records.

In combination with the ESYSTA® App, the data is transferred to a Bluetooth®-enabled smartphone.

## 5. Components of your ESYSTA® BT Pen



## 6. Commissioning your ESYSTA® Pen

Before first use, carefully pull out the film of the battery compartment that is visible from the outside.

Your ESYSTA® BT Pen must be equipped with an insulin cartridge, a matching adapter, the appropriate holder and a needle. Please mark all of your ESYSTA® BT Pens with a coloured marker. The different colours should help you to distinguish your different insulins, even in the ESYSTA® App.

**Note:**

Only use the ESYSTA® BT Pen with the insulin cartridges stated by Emperra GmbH and make sure that you use the correct ESYSTA® Adapter. If your insulin preparation is not stated in Chapter 15, please contact Emperra GmbH directly. Contact details can be found at the end of these operating instructions.

**Note:**

Before each injection of insulin, please check that the holder is straight and securely locked into the retainer. Otherwise there is a risk of incorrect dosage. If an insulin cartridge leaks and liquid enters the device, the ESYSTA® BT Pen may no longer be used.



The button is spring loaded. Please keep away from delicate areas of the body, such as the eyes!

## 6.1 Selecting the right ESYSTA® Adapters

Depending on the manufacturer, insulins are available in cartridges of various sizes. Your ESYSTA® BT Pen can be used with all of the 3 ml cartridges (100 IU/ml) named in Chapter 15, if you use the appropriate ESYSTA® Adapter. Select it from the table below.

Cartridge adapter type and colour	Suitable for 3 ml insulin cartridges (100 IU/ml) from	Holder
A 	Lilly®, Berlin-Chemie® and B.Braun®	Holder A/B
B 	Sanofi-Aventis®	Holder A/B
C 	Novo Nordisk®	Holder C

In order to always guarantee optimal dosing accuracy, the ESYSTA® Adapters are designed to be disposable products. Always change the ESYSTA® Adapter every time you change the insulin cartridge.

 Tampering with the ESYSTA® Adapter may have fatal consequences and is strictly forbidden!

## 6.2 Choosing the correct holder

Your ESYSTA® BT Pen is delivered with two different holders.

**Holder Type A/B** is for use with insulin cartridges made by the manufacturers Lilly®, Berlin-Chemie®, B.Braun® and Sanofi-Aventis®. In addition to being labelled "A/B", this holder can be distinguished by its screw thread.

**Holder Type C** is for use with insulin cartridges made by Novo Nordisk®. In addition to being labelled "C", you can recognise this holder by its lack of a screw thread, as the insulin cartridges of Novo Nordisk® have their own screw thread.



Holder A/B



Holder C

## 6.3 Inserting the insulin cartridge

First, pull off the cap and then twist off the holder. The insulin cartridge is inserted with the dosing button unlocked (see Chapter 5). When the dosing button is pushed in, you can unlock it by pressing it in, like a ball-point pen.



*Pushing the insulin cartridge into the ESYSTA® Adapter*



*Assembling the holder*

Insert the correctly selected ESYSTA® Adapter into the pen body with the threaded rod at the front. Then slide the insulin cartridge with the stamp at the front into the ESYSTA® Adapter. The needle side of the insulin cartridge now protrudes out of the open side of the ESYSTA® Adapter. Then slide the holder over the ESYSTA® Adapter filled with the insulin cartridge and assemble it by pushing and twisting until it locks into place.

## 6.4 Marker

If you regularly use more than one insulin preparation, we recommend that you use an additional ESYSTA® BT Pens for each additional insulin preparation. In order to be able to distinguish ESYSTA® BT Pens containing different insulins, identify these ESYSTA® BT Pens by using the coloured markers provided. The markers are inserted into the recess on the pen body. It is important that you can recognise the different colours beyond all doubt.



To remove an existing marker, use a pointed object and insert it between the marker and the black frame. Then carefully pry the marker out from the frame.

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**Note:**

Every time before you use your ESYSTA® BT Pen, please check the inserted insulin cartridge to ensure that you are using the correct insulin preparation type. Do not rely solely on the marker!

## 6.5 Attaching the needle

Align the needle onto the thread of the holder (or, in the case of insulin cartridges made by the company Novo Nordisk® onto the thread of the insulin cartridge) and screw the needle tight. To do this, hold the pen firmly by the holder so that it does not come loose from the pen body. Always check that the needle is firmly seated to be sure that the inner side of the needle has sufficiently penetrated the insulin cartridge cap and that the insulin can thus flow freely through the needle. You can first remove the outer and then - if present - the inner protective cap on the needle.

### Note:

Regarding the handling of needles, please also follow the instructions for use of the respective manufacturer.

## 6.6 Switching on the ESYSTA® BT Pen

To switch on ESYSTA® BT Pen, press on the dosing button as you would a ball-point pen, so that the dosing button pops out.

If the dosing button is to be unlocked when the display is switched off ("stand-by mode" after a long period of disuse with the dosing button unlocked), push it in and unlock it again.

Once the ESYSTA® BT Pen is switched on, a display test initially appears. The following display appears:



This display test is for your security. Check whether all of the segments to be displayed here are present. If individual segments of the display are not working or if the display is blank, you may not use the ESYSTA® BT Pen. In this case, please contact Emperra GmbH. After approx. 2 seconds, the ESYSTA® BT Pen indicates how many hours have passed since the last injection of insulin and how many units you injected. On the left are displayed the time (smaller figures) with the unit "H" for hours, and on the right the insulin units "IU". Please be aware that the time display rounds to whole hours.

Up to half an hour is displayed as "0H", half an hour to one and a half hours is displayed as "1H", etc. If the last injection of insulin was more than 99.5 hours ago, the display shows " - -".

On first commissioning and on first use after changing the battery, the hours are displayed as " - -". For the last dose of insulin, "0 IU" is displayed in this case.

## 6.7 Venting specified by the ESYSTA® BT Pen

If the display shows "Pr" ("priming"), the ESYSTA® BT Pen requires venting, e.g. after inserting a new insulin cartridge, in order to remove any air contained in the insulin cartridge and to fill the injection needle with insulin.

To do this, unlock the dosing button and set at least 2 units (2 ratchet positions) by turning the dosing button in the direction of the arrow (the display shows "Pr" in the left-hand section and in the right-hand section the display will flash with the venting dose set). Hold the ESYSTA® BT Pen with the needle pointing upwards so that the air can collect at the needle. Then push the dosing button in until it locks into place. The display now goes out and the units set are saved as venting units. If no insulin visibly emerges from the tip of the needle after this venting procedure (irrespective of the insulin preparation and the fill level of the insulin cartridge), you will need to carry out further venting until the insulin preparation emerges from the needle. These venting procedures will be shown in the ESYSTA® Portal as venting only if you proceed according to Chapter 6.8.

## 6.8 Marking and carrying out additional venting

To carry out further venting and to have this identified as such in the ESYSTA® Portal, unlock the dosing button again so that the ESYSTA® BT Pen is switched on (see Chapter 5). Now set one ratchet position (1 IU) by turning the dosing button in the direction of the arrow - without pushing the dosing button in - and then turn it against the direction

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of the arrow back to zero (0 IU). The display now shows "Pr" in the left-hand section. Set the required number of venting units by turning the button in the direction of the arrow. Hold the ESYSTA® BT Pen with the needle pointing upwards so that the air can collect at the needle. Now press the dosing button in fully until it locks into place. Once the dosing button has been pushed in, the display will go out. Insulin will now emerge from the needle. If this does not happen, you must repeat this procedure until insulin emerges from the tip of the needle. All units are marked and saved as venting units. Unlocking the dosing button again prepares the ESYSTA® BT Pen for a subcutaneous dosage of insulin, as described below.

## **6.9 Setting the units for subcutaneous injections**

Once the ESYSTA® BT Pen is sufficiently vented and you have switched it on by unlocking the dosing button (see Chapter 5), you can now set the insulin units. You can set the required dose of insulin by turning the dosing button clockwise in steps of one unit (1 IU). A maximum of 60 IUs is possible as a single dose. On each increase of the dose by one unit, you will hear a "click" and at the same time feel a ratcheting action and see the dose indicated on the display increase by exactly one unit.

**Note:**

Only use the ESYSTA® BT Pen for injection if you receive the following responses:

- Display of the set units
- Audible click for each unit set
- Ratcheting action felt for each unit set

**If you inadvertently set too high a dose, you can correct (reduce) this by turning the dosing button against the direction of the arrow.**

It is not possible to set a dose that is greater than the quantity of insulin present in the cartridge. For technical reasons, a small residual amount of insulin will always remain in the cartridge. If the insulin cartridge contains less insulin than the required dose, you will only be able to inject an incomplete dose. Once you switch on your ESYSTA® BT Pen again after inserting a new insulin cartridge, it will display the amount of insulin last injected. You can use this information for calculating the follow-up dose of insulin to be injected. This avoids unnecessary disposal of the remaining insulin and saves money.

 If you have a clear sense of resistance when turning the dosing button, never try to forcefully twist the dosing button beyond this stopping point. Otherwise your ESYSTA® BT Pen may be damaged. This stopping point signals

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that the maximum dose of insulin that can be used with the existing cartridge has been reached and prevents a higher dose of insulin being set.

**Note:**

Each time you change the insulin cartridge, you must vent sufficiently (see Chapter 6.7 and 6.8). Then select the remaining dose that is required (see Chapter 6.9) and proceed according to these operating instructions.

To protect the batteries, the ESYSTA® BT Pen switches off automatically after three minutes without any activity. To switch the ESYSTA® BT Pen back on again, you must first push in the dosing button. Insulin may emerge under certain circumstances. When you next switch on, the ESYSTA® BT Pen will request venting (see also Chapter 6.7).

**To preserve the life of the battery for as long as possible, you should always store your ESYSTA® BT Pen with the dosing button pushed in and the ESYSTA® Adapter inserted.**

## **6.10 Injection process**

Before each injection, check that the ESYSTA® BT Pen contains the correct insulin preparation. Tilt the ESYSTA® BT Pen back and forth to sufficiently mix the liquid in the cartridge and carry out a visual inspection on the insulin preparation (see also the instruction leaflet for the insulin preparation). Stick the needle through the skin in a suitable position. Slowly press the dosing button until it reaches the stop and locks into place. A counter on the left-hand section of the display counts down in seconds from 8 to 1. Please leave

the needle in the skin for this length of time and only withdraw from the skin once the countdown is complete. In this way, you can guarantee that the set insulin dose has been injected completely. Then, for five seconds, the display indicates the dose administered and then goes out.

**Note:**

The ESYSTA® BT Pen is equipped with a mechanism that guarantees that the insulin emerges evenly during the injection procedure. However, pushing the dosing button too fast may lead to the insulin being injected too quickly. This may lead to an alteration in the cells (hardening or lumps in the fatty tissue, also called lipodystrophy or lipohypertrophy). Please press slowly until the dosing button locks into place.

You should also systematically change your injection sites.

The dosing button is equipped with a strong spring to guarantee complete and correct administration of the insulin. If the dosing button is not pressed in far enough, this may lead to the dosing button not locking into place during the injection, and popping back out again.

In this case, you must leave the needle in the skin and press the dosing button in again – without twisting it – until it locks completely into place. Even if this happens several times or the ESYSTA® BT Pen displays "3 Er" (see Chapter 10), only the previously set dose of insulin will be injected in total. The injection process is only completed correctly once the dosing button locks and you have held the needle in the skin for at least 8 seconds.

If you inadvertently pull the ESYSTA® BT Pen out of the skin before the dosing button has locked into place, stick the needle back into the skin – without twisting the dosing button. Inject the remaining quantity by completely pushing in the dosing button until it locks into place. If you suspect that the set dose has not been fully injected, please do not inject any additional units, but instead check your blood-sugar values after a suitable period of time. The next application of insulin should only occur after a sufficient length of time and with the knowledge of the current blood-sugar value, so that you can be sure that you are not injecting too much insulin and thereby triggering a dangerous state of hypoglycaemia.

## **6.11 Completing the injection**

Once you have injected the insulin, remove the disposable needle by carefully placing the outer cover over the needle and then screwing the needle off, using the protective cover. Dispose of the needle along with the outer cover, in order to prevent injuries. For proper handling and disposal of needles, please also follow the instructions for use of the respective manufacturer. To avoid the risk of painful infections, use each needle only once. After each injection of insulin, put the cap on the ESYSTA® BT Pen and store it in the case provided, in order to prevent damage and contamination.

## 6.12 Cancelling the setting process

Even if you have already set the units, you can cancel this setting procedure without wasting insulin. Reset the ESYSTA® BT Pen back to zero by turning the dosing button against the direction of the arrow and then pushing in the dosing button. Please proceed as in Chapter 6.11.

### **Note:**

**Do not turn the dosing button of the ESYSTA® BT Pen into the negative range!** (This may happen by turning the dosing button beyond zero against the direction of the arrow.) However, if this does happen, carefully turn clockwise again until units are again displayed. Check the ESYSTA® Adapter and cartridge for damage, and make sure that you carry out the correct venting procedure and function test (see Chapters 6.7 and 6.8).

## 6.13 Temperature sensor

The ESYSTA® BT Pen is equipped with a temperature sensor that regularly measures the ambient temperature and indicates the results on the display. Extreme ambient temperatures can reduce the effectiveness of the insulin or even render it ineffective.

If the temperature range above 40 °C is exceeded, the message "Ht" ("High temperature") appears in the display. If the temperature falls below around 2 °C, the message "Lt" ("Low temperature") appears in the display. In these instances, it should be assumed that the insulin will no longer have an adequate effect. We therefore recommend switching to a new insulin cartridge that has been stored in the temperature range specified by the insulin manufacturer. An injection can still be carried out by adjusting the selected dose. When the selected insulin units are set, the warning message disappears and reappears next time the pen is switched on. When the insulin cartridge is changed, including a new adapter, the temperature warning display is reset.

### **Note:**

Please note that the temperature sensor has a certain tolerance range and the values stated above are only guideline figures. Please also regularly check the storage and usage temperatures for your insulin with the insulin manufacturer. Information from the temperature sensor is also transferred to the ESYSTA® App and the ESYSTA® Portal.

## 7. Changing the insulin cartridge

If you change the insulin cartridge, check whether you are staying with the insulin preparation you previously used or if you are changing to another insulin preparation. Both cases are described below.

### **Note:**

Insulin cartridges are changed and inserted with the dosing button unlocked (see Chapter 5). Please also always note the relevant designation of the insulin type in the ESYSTA® App. You may need to modify it if necessary.

### **7.1 Continuing with the same insulin manufacturer**

First, pull off the cap. To change the cartridge, remove the needle if this has not yet been done. Remove the holder by twisting anti-clockwise. Remove the used ESYSTA® Adapter with the insulin cartridge and dispose of them both. Take a new ESYSTA® Adapter for the new insulin cartridge of the same type and assemble them both as described in Chapter 6.3.

## 7.2 Changing the insulin manufacturer

If you are changing the type of insulin preparation, then in addition to the steps described in Chapter 7.1, you must select the correct holder and the correct ESYSTA® Adapter (see Chapters 6.1 and 6.2). Never make changes to the holder or ESYSTA® Adapter.

Change the details of the insulin in the ESYSTA® App and if necessary in the ESYSTA® Portal.

## 7.3 Important safety information about changing the cartridge

 After changing the insulin cartridge, you must carry out a venting procedure. You may frequently have to carry out several venting procedures after changing the cartridge (see Chapters 6.7 and 7.8).

 You must use a new suitable ESYSTA® Adapter with each new insulin cartridge!

 Even if your last insulin cartridge was not completely emptied, because your doctor changed your treatment, for example, a new ESYSTA® Adapter must also be used with the new insulin cartridge.

## 8. Battery change

Your ESYSTA® Pen is powered by three CR 1225 format batteries (button cells).

With proper use, depending on the behaviour of the user, these batteries guarantee a sufficient energy supply for up to six months.

### **Note:**

The life of the batteries may be reduced by environmental influences (e.g. serious temperature fluctuations) and by being stored when switched on (unlocked dosing button).

The batteries are not rechargeable. Do not burn batteries. Dispose of old batteries correctly - never in your domestic waste. Battery collection points can be found in all shops that sell batteries. Only open the battery compartment to change the batteries, as otherwise foreign bodies may possibly penetrate the open battery compartment, which may negatively affect the function of the ESYSTA® BT Pen. If the battery voltage is low, then "bL" (battery low) will be displayed when you switch on the ESYSTA® BT Pen. You should now replace the batteries within the next few days.

When selecting batteries, please make sure that they are safe against explosion accidents. This can best be found out from the battery manufacturer.

To change the batteries, open the battery compartment by pulling it out like a drawer. To maintain child safety, quite a lot of strength is required. Always remove all three batteries and replace them with new batteries of type CR 1225.



Observe polarity! The positive pole of all three batteries must point upwards. Incorrectly inserted batteries may damage the device. Once all three batteries are correctly inserted, push the battery compartment back in completely. Then check the function of the ESYSTA® BT Pen by venting as described in Chapter 6.7.

#### **Note:**

We advise changing the batteries near your smartphone with the ESYSTA® App and with Bluetooth® transfer switched on and then importing the data, so that your ESYSTA® BT Pens can be optimally time-synchronised with the ESYSTA® App.

## 9. Enabling and disabling data transfer

### 9.1 Enabling the Pen-smartphone connection (“bonding”)

The data captured from the ESYSTA® BT Pen is transferred automatically via Bluetooth® radio technology to your Bluetooth®-enabled smartphone. To do this, you must configure your ESYSTA® App (see Chapter 1) as follows.

Open the ESYSTA® App on your smartphone. Select the function marked "Add device".

1. In accordance with the prompts, enter which marker colour and which preparation you have used for the ESYSTA® BT Pen. Use the selection options after the arrows. "Next" confirms your entries and takes you to the next menu item.
2. Put the ESYSTA® BT Pen in transfer mode by following the instructions on the smartphone display. "Next" takes you to the next menu item after each command.
3. Establish a connection between the ESYSTA® BT Pen and your smartphone. Read the explanatory notes on the smartphone display carefully and then click "Next". From the list that then appears in the smartphone display, select the device that you want your smartphone to connect to. A 2-digit code prefixed by "A", "b" and "c" then appears three times in succession in the Pen display. This, together, creates the 6-digit security code (PIN) which you should enter into your smartphone when prompted to do so.

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- Once you have successfully bonded your devices, this will be shown in the smartphone's display. The ESYSTA® BT Pen display shows "bond". "Done" takes you out of configuration mode.

Your devices are now connected to each other. The Pen data can be imported via your smartphone into the ESYSTA® App.

If you use several ESYSTA® BT Pens for your treatment and want to integrate them into the ESYSTA® App, select the "Add device" function again and repeat steps 1 to 4 for each individual Pen.

**Note:**

Ideally, you should always keep transfer mode active so that your current treatment data is always available in the ESYSTA® App. The ESYSTA® BT Pen can only exchange data with a smartphone. Any attempt to connect to other devices will not work. Even if you are using the ESYSTA® App on a second smartphone and search for the Pen, you will not find it there. If however you want or have to do this anyway, for example because you have a new phone, then you must cancel the connection ("bonding") between the previous smartphone and the ESYSTA® BT Pen (see Chapter 9.2).

## 9.2 Disabling the Pen-smartphone connection (cancelling "bonding")

If you want to cancel the connection between the previous smartphone and the ESYSTA® BT Pen ("bonding"), for example because you have changed your smartphone, carry out the following steps on the ESYSTA® BT Pen.

Put the pen in transfer mode by pulling out the dosing button and pushing it back in again. Then use the ESYSTA® App to establish a connection to the Pen and enter the security code displayed.

To cancel bonding, carry out the following steps on the Pen:

1. Push the dosing button out.
2. Turn the button for 2 units and then back to 0 units.
3. Push the button in.
4. The display now shows "dE bo" (standing for "delete bond").
5. Repeat steps 1 to 4 two more times. In the top left section of the display, 1-2 dots indicate how often this process has already been carried out.
6. Once the action has been completed for the third time, "no bo" (stating "not bonded") appears in the Pen display.

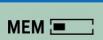
The Pen is now not assigned to any smartphone exclusively. It can be re-linked with another smartphone. To do this, follow the instructions in Chapter 9.1.

### 9.3 Data memory

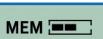
The approximate quantity of the data to be transmitted can be seen by the number of bars in the top section of the display:



There is no data in the memory awaiting transmission.

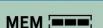


There is data in the memory awaiting transmission.



There are over one hundred data records in the memory that have not yet been transferred.

There is still sufficient free memory available.



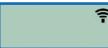
There is a high number of records in the memory that have not yet been transferred. The memory is full.

The oldest data will be overwritten by current data.

#### Note:

The insulin application function of the ESYSTA® BT Pen will not be affected by a full memory.

## 10. Display and error messages

Display	Designation	Explanation
	Display test	Please check whether all the elements of each figure are displayed, in order to prevent errors when reading due to partial failure of the display.
	Display of the last insulin injection	Thirty units were injected around 1 hour ago.
	Setting the units	Currently, 17 insulin units are set.
	Time counter for Administration of insulin	Counts every second from 8 to 1. Leave the needle in the skin until the countdown has completed.
	Administration of insulin complete	Seventeen units have just been injected.
	Wireless mode flashing	The ESYSTA® BT Pen is searching for contact with the smartphone. Once contact is made, it sends the saved data.
	Radio mode constant	The ESYSTA® BT Pen is bonded to the smartphone and transferring data.

Display	Designation	Explanation
	Negative units set	Caution, serious error! Turn the dosing button clockwise until zero or a higher figure appears.
	More than 60 units set	The pen is intended for injecting up to 60 units of insulin. Turn the dosing button <u>against the direction of the arrow</u> until a number appears again.
	Time of the last injection cannot be determined	The last injection was more than 99 hours ago, or the batteries have been changed.
	The batteries are flat	Please change the batteries as soon as possible.
	Temperature exceeded	The temperature range $> 40^{\circ}\text{C}$ was exceeded (in this case, the measured maximum was $45^{\circ}\text{C}$ )
	Minimum temperature not met	The temperature range $< 2^{\circ}\text{C}$ was fallen below (in this case, the measured minimum was $-6^{\circ}\text{C}$ )

Display	Meaning	Explanation
	Error with dosing sensor	<p>This error may occur when the ESYSTA® BT 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 Emperra GmbH.</p>
	Button was pressed with the dose set in the negative range	<p>For the next injection, the actual dose injected may be lower than the dose displayed. This is why your ESYSTA® BT Pen must be vented before the next injection until insulin visibly emerges from the needle.</p>
	Application not completed correctly	<p>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. (see Chapter 6.10).</p>
	No ESYSTA® adapter in the ESYSTA® BT Pen	<p>There is no ESYSTA® adapter in the ESYSTA® BT Pen.</p>

Display	Meaning	Explanation
5 Er	The ESYSTA® BT 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® BT Pen from this point in time.
6 Er	The end of the life of the Pen will be reached in 6 weeks	This message will be displayed on every operation during the last two weeks of the period of use. Please replace your pen promptly!
7 Er	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.
MEM 	Memory full	The data memory is full. The insulin application function of the pen will continue to exist. Please transfer the data (see Chapter 9).
Pr	Venting	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 (see also Chapters 6.7 and 6.8).

Display	Meaning	Explanation
	Ready to bond with a smartphone	See Chapter 9
  	Security code (PIN)	<p>The three indicators appear on the display in sequence. Together they create the 6-digit security code which is needed to bond the ESYSTA® BT Pen with a smartphone.          (As an example here: 123456)</p>

## 11. Guarantee

Emperra GmbH accepts no liability for problems with the ESYSTA® BT Pen resulting from improper handling of the device. Devices damaged in this way are excluded from the right to exchange.

## 12. Period of use

Your ESYSTA® BT Pen is designed for a period of use of up to two years from the date of initial use.

6 Er

In the six weeks before expiry of the period of use, the adjacent display will appear on each operation. Please remember to get a new ESYSTA® BT Pen in good time.

5 Er

After 24 months of use, the adjacent display will appear on operation. You must not continue to use the ESYSTA® BT Pen from this time.

## 13. Technical data

Insulin pen

Dimensions (with dosing button pushed in):

approx. 180 mm x 23 mm x 25 mm

Weight without insulin cartridge: 62 g

Battery

Power supply: 3 x button cells, CR 1225

Nominal voltage: 3.0 V

Nominal capacity: 50 mAh

Height: 2.5 mm ± 0.2 mm

Diameter: 12.5 mm ± 0.3 mm

Storage temperature without batteries and without insulin cartridge: -30 °C to 60 °C

Storage temperature without batteries and without insulin cartridge: -20 °C to 60 °C

Once the insulin cartridge is inserted, please follow the prescribed storage temperature of your insulin preparation (instructions enclosed by the insulin manufacturer).

Temperature for use: 18 °C to 28 °C

Period of use: 2 years

## 14. FAQs

**Question:** What does "Pr" mean on the display?

**Answer:** "Pr" stands for "priming".

Please read Chapters 6.7 and 6.8.

**Question:** Why does the ESYSTA® BT Pen show "Pr" so often?

**Answer:** There are various reasons for this. One possibility is incorrect handling of the ESYSTA® BT Pen. For example, if you store the ESYSTA® BT Pen with an unlocked dosing button, it will switch itself off after a few minutes. If you switch it back on by pushing the dosing button in and out, the ESYSTA® BT Pen will demand to be vented by displaying "Pr". Other possible causes include: turning the dosing button when pushed in, unlocking the cartridge holder, such as when changing the insulin cartridge, changing the battery, turning the unlocked dosing button to "1" and back to "0" (see also Chapter 6.8).

**Question:** How can I identify venting as such?

**Answer:** See Chapter 6.8 for more information.

**Question:** Why can't I attach the holder?

**Answer:** The holder, adapter and insulin cartridge may possibly not suit each other. Please make sure that you always use the holder and ESYSTA® Adapter that suit your insulin preparation. Various manufacturers use insulin cartridges with different dimensions, and you will have to select the right ESYSTA® Adapter for this. You will find a table in Chapter 6.1 and on the packaging of the ESYSTA® BT Pen and ESYSTA® adapters.

**Question:** Why are there markers with different colours?

**Answer:** If you use several ESYSTA® BT Pens for different insulin preparations (e.g. basal or quick-acting insulin), you can identify these ESYSTA® BT Pens by colour. Ensure that you use the same identification system in the ESYSTA® App. The change of coloured marker is described in Chapter 6.4.

**Question:** Why is no insulin coming out of the ESYSTA® BT Pen?

**Answer:** You may possibly have not screwed the needle on far enough. Check the correct position of the needle and turn it to tighten if necessary. If the needle is blocked, replace it with a new needle in its original packaging. The ESYSTA® BT Pen may possibly be insufficiently vented (see Chapters 6.7 and/or 6.8).

**Question:** Why do I have to use a new ESYSTA® Adapter each time?

**Answer:** In order to guarantee dosing accuracy, the ESYSTA® Adapters are disposable products and must be replaced with each new cartridge of insulin (see Chapters 6.1, 6.3 and 7).

**Question:** Which ESYSTA® Adapter must I use?

**Answer:** There are suitable ESYSTA® Adapters for the different insulin cartridges from various manufacturers. Various manufacturers use insulin cartridges with different dimensions, and you will have to select the right ESYSTA® Adapter for this. There is a table in Chapter 6.1 and on the packaging of the ESYSTA® BT Pen and the ESYSTA® Adapters.

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**Question:** Why is the ESYSTA® BT Pen not transmitting data to my smartphone?

**Answer:** There may be various reasons for this.

1. Your ESYSTA® BT Pen BT Pen is not bonded with your smartphone (see Chapter 9).

2. The Bluetooth® connection on your smartphone is disabled.

3. Your smartphone is outside the range of the ESYSTA® BT Pen (approx. 10 m).

To transfer data, insulin injections must have been already stored in the ESYSTA® BT Pen. You can identify this in the upper section of the display. Should data continue not to be sent, please contact Emperra GmbH.

**Question:** Why does the ESYSTA® BT Pen go out immediately after injecting?

**Answer:** The ESYSTA® BT Pen may have been in venting mode (see Chapters 6.7 and/or 6.8).

**Question:** How many ESYSTA® BT Pens can I use?

**Answer:** You can use any number of ESYSTA® BT Pens. Each ESYSTA® BT Pen will be displayed in the ESYSTA® App along with the insulin preparation stated during its registration. You should always use the same marker colour for one insulin preparation (e.g. an ESYSTA® BT Pen marked in blue for your basal insulin, and an ESYSTA® BT Pen marked in yellow for your mealtime insulin). Please also discuss this with your doctor.

**Question:** Why is no data being synchronised between the ESYSTA® App and the ESYSTA® Portal?

**Answer:** There may be various reasons for this.

1. Data transfer on your smartphone is disabled.
2. You are in an area with inadequate GSM network coverage.

**Question:** What should I do if I can't switch on the ESYSTA® BT Pen?

**Answer:** If you have switched on the ESYSTA® BT Pen according to these operating instructions and there is nothing on the display, please change the batteries. If this does not help, then you should always keep a replacement injection device to hand, and also contact Emperra GmbH directly.

**Question:** What should I do if parts of the display fail or are continually on display?

**Answer:** Do not use this ESYSTA® BT Pen under any circumstances. In this case, you should always keep a replacement injection device to hand, and also contact Emperra GmbH.

## 15. List of compatible insulin preparations

### ***Novo Nordisk®***

NovoRapid® Penfill® 100 IU/ml injection solution in a cartridge

NovoMix® 30 Penfill® 100 IU/ml injection suspension in a cartridge

Levemir® Penfill® 100 IU/ml injection solution in a cartridge

Actrapid® Penfill® 100 IU/ml injection solution in a cartridge

Actraphane® 30/-50 Penfill® 100 IU/ml injection suspension in a cartridge

Protaphane® Penfill® 100 IU/ml injection suspension in a cartridge

### ***Sanofi-Aventis®***

Lantus® 100 IU/ml injection solution in a cartridge

Apidra® 100 IU/ml injection solution in a cartridge

Insuman® Rapid 100 IU/ml injection solution in a cartridge

Insuman® Comb 15 100 IU/ml injection suspension in a cartridge

Insuman® Comb 25 100 IU/ml injection suspension in a cartridge

Insuman® Comb 50 100 IU/ml injection suspension in a cartridge

Insuman® Basal 100 IU/ml injection suspension in a cartridge

<sup>5</sup> In the case of insulins that are not on this list, please contact Emperra GmbH directly.

**Lilly®**

Huminsulin® Normal 100/ for pen 3 ml/pen injection solution

Huminsulin® Profil III for pen 3 ml/-pen injection suspension

Huminsulin® Basal (NPH) 100/-for pen 3 ml/-pen injection suspension

Humalog® 100 IU/ml injection solution/pen 100 IU/ml

Humalog® Mix 25 100 IU/ml injection suspension/-Pen

Humalog® Mix 50 100 IU/ml Injection suspension/ pen

Abasaglar® 100 IU/ml injection solution in cartridge / pen

**Berlin-Chemie®**

Berlinsulin® H Normal 3 ml pen injection solution

Berlinsulin® H 30/70 3 ml pen injection suspension

Berlinsulin® H Basal 3 ml pen injection suspension

Liprolog® Mix 25 Pen 100 IU/ml injection suspension

Liprolog® Mix 50 Pen 100 IU/ml injection suspension

Liprolog® 100 IU/ml injection solution in cartridge/pen

**B.Braun®**

Insulin B. Braun Rapid® 100 IU/ml

Insulin B. Braun Comb® 30/70 100 IU/ml cylinder ampoules with injection suspension

Insulin B. Braun Basal® 100 IU/ml cylinder ampoules with injection suspension

## 16. List of compatible needles

All needles in the list below are available in various lengths. Compatibility with the ESYSTA® BT Pen depends on the length of the needles (e.g. 8 or 10 mm). If your product is not listed in the table below, please contact Emperra GmbH.

Manufacturer	Type
BECTON DICKINSON GMBH	BD MICRO FINE®
BERLIN-CHEMIE AG	BERLIFINE®
YPSOMED GMBH	CLICKFINE® OPTIFINE®
BERENBRINKER SERV.GMBH	INSUPEN Pen Nadel Effective® INSUPEN Pen Nadel Original® INSUPEN Pen Nadel Ultrafin®
NOVO NORDISK PHARMA	NOVOFINE®
B.Braun	Omnican Fine®

## 17. Index

	Page
Adapter .....	7, 16, 32
App .....	6, 30, 35-37
Battery .....	33-34
Bonding .....	35-37
Transferring data .....	35-38
Display .....	22, 39, 43
Dosing button .....	10, 14, 21-29
Dosing .....	24-26
Venting .....	23
Disposal .....	28, 33
Error messages .....	39-43
Questions .....	46-49
Function test .....	22
Guarantee .....	43
Holder .....	17
Injection .....	26-29
Insulin .....	31-32, 50-51
Needle .....	21, 52
Marker .....	19
Portal .....	6, 8, 30
Safety .....	9-13
Temperature sensor .....	30
Period of use .....	44





FCC Certification

FCC ID: 2AHMS-BTPEN1

This device complies with part 15 of 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.

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