



ESYSTA® Data Export Standard

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1 Introduction

ESYSTA is a digital health application designed for supporting and monitoring the treatment of diabetes mellitus. It consists of two components, the ESYSTA Portal and the ESYSTA App. ESYSTA stores treatment data in a central database, which is a part of the ESYSTA Portal. ESYSTA allows patients to export these data as human-readable PDF¹ reports as well as files in the interoperable JSON^{2,3} format.

PDF reports serve for the patient's personal documentation and as a backup for situations in which they have neither access to their smartphone with the ESYSTA App or to the ESYSTA Portal. They are just mentioned here for completeness' sake and are not further dealt with in this document.

JSON files are meant to be imported into other IT systems. This document describes the structure of these files.

2 JSON Export Format

The data exported from the ESYSTA Portal adhere to the following JSON schema⁴:

<http://portal.esysta.com/esysta-data-export-schema.json>

This schema is designed as a generic data structure for treatment data relating to diabetes mellitus, including, but not limited to, all data included in a typical diabetes diary. It defines an object with 10 top-level properties, which are shown in Listing 1 and briefly described in the following chapters. For the full description please refer to the JSON schema.

¹ The application/pdf Media Type, 2017, RFC 8118, <https://tools.ietf.org/html/rfc8118>

² JSON, <https://www.json.org/json-en.html>

³ ECMA-404: The JSON Data Interchange Format, https://www.ecma-international.org/wp-content/uploads/ECMA-404_2nd_edition_december_2017.pdf

⁴ JSON Schema, <https://json-schema.org/>

```
{
  "export_metadata": {
    <ExportMetadata>
  },
  "patient": {
    <Patient>
  },
  "devices": [
    <elements of type Device>
  ],
  "diary": {
    <Diary>
  },
  "statistics": {
    <Statistics>
  },
  "evaluation_description": {
    <EvaluationDescription>
  },
  "evaluations": [
    <elements of type Evaluation>
  ],
  "doctors": [
    <elements of type Doctor>
  ],
  "medical_findings": [
    <elements of type MedicalFindings>
  ],
  "messages": [
    <elements of type Message>
  ],
}
```

Listing 1: Top level structure

2.1 Export Metadata

The property `export_metadata` contains a short list of attributes of the data export proper, most importantly the time the export was initiated at, and the date range of the exported data.

2.2 Patient

The property `patient` contains attributes of the patient whose data are exported, these include the first name, last name and contact data.

2.3 Devices

For a most convenient and reliable diabetes documentation, ESYSTA is compatible with various devices that automatically transmit therapy-relevant data, e.g. via Bluetooth[®] Low Energy⁵. This comprises blood glucose meters as well as the ESYSTA Pen. The property `devices` is an array containing details like `manufacturer`, `model`, `serial_number` and `device_type` of the devices registered for the patient's account. If `device_type` is given, it indicates the type of data interface of the device, with the possible values listed in the following table:

⁵ Bluetooth Radio Versions, <https://www.bluetooth.com/learn-about-bluetooth/radio-versions/>

device_type	Interface	Note
ism	ISM band ⁶ radio interface	Used by the ESYSTA Lab and ESYSTA Pen
ble	Bluetooth [®] Low Energy	Used by the ESYSTA BT Pen and various blood glucose meters
nfc	Near field communication	Currently not supported by ESYSTA
usb	Universal Serial Bus	
serial	Legacy serial interface	

Table 1: possible values of `device_type`

2.4 Diary

The property `diary` is a structure that contains 4 arrays, one for each possible type of diary entry; the labels of which are:

- `blood_glucose`
- `continuous_blood_glucose`
- `insulin`
- `carbohydrate`
- `events`

Listing 2 shows this as JSON structure:

```
{
  "blood_glucose": [
    <elements of type DiaryItemBloodGlucose>
  ],
  "continuous_blood_glucose": [
    <elements of type DiaryItemContinuousBloodGlucose>
  ],
  "insulin": [
    <elements of type DiaryItemInsulin>
  ],
  "carbohydrate": [
    <elements of type DiaryItemCarbohydrate>
  ],
  "events": [
    <elements of type DiaryItemEvent>
  ]
}
```

Listing 2: structure of type `Diary`

2.4.1 Blood glucose

The array `blood_glucose` lists all the patient's recorded blood glucose measurements within the exported time range. Each element of the array is of the type `DiaryItemBloodGlucose` and represents one blood glucose measurement. This may have been either manually entered or measured and directly imported from a blood glucose meter without any manual step involved, as indicated by the flag `manually_entered`. This distinction is important, as manually entered data may be less reliable. The flag `locked` indicates, whether the user is disallowed to change the value, which is usually the case for values imported from a device. the Blood glucose

⁶ https://en.wikipedia.org/wiki/ISM_band

values are always given in both units **mmol/l** and **mg/dl**. Some blood glucose meters also allow to specify the metabolic situation in which this measurement was made, e.g. **fasting**, **before_meal** (aka pre-prandial), **after_meal** (aka post-prandial) etc. If a measurement has been annotated this way, this is indicated by the field **mark**. The flag **mark_locked** indicates, whether the user is disallowed to change this annotation. The field **measurement_status** states whether the blood glucose meter indicated that the measured value was within the valid range, in which case this item is set to **valid**. Other possible values of this item are **high** and **low**, both indicating a measurement result that was outside the valid range of the device. The property **device** is given when the value was imported from a device.

2.4.2 Continuous blood glucose

The array **continuous_blood_glucose** lists all the patient's recorded samples from a continuous glucose monitor (CGM)⁷ within the exported time range. Its elements are of the type **DiaryItemContinuousBloodGlucose**. The data may have been imported as CSV⁸-data that had previously been exported from a CGM manufacturer's web portal. Such "continuous" blood glucose data are typically sampled at regular intervals (e.g. 5 minutes) and never entered manually.

2.4.3 Insulin

The array **insulin** lists all the patient's recorded insulin applications within the exported time range. Its elements are of the type **DiaryItemInsulin**. The flags **manually_entered** and **locked** have the same meaning as described in chapter 2.4.1 for Blood glucose. When registering insulin pens with ESYSTA, the user may specify additional attributes for that pen, like the type and brand of the insulin used. Some insulin pens like the ESYSTA Pen can be marked with a colored marker for easy distinction of different pens. This color can also be specified. It is then indicated by the field **insulin_pen_marker_color**. If supported by the device, various other attributes may be given, like **aeration**, which indicates that the associated amount of insulin was not injected but discarded for "priming" the device (i.e. to make sure that no air is injected in the following application), temperature warnings, and whether the insulin carpule was changed prior to this application of insulin.

2.4.4 Carbohydrate

The array **carbohydrate** lists all the patient's recorded meal intakes in terms of the specified carbohydrate unit within the exported time range. Its elements are of the type **DiaryItemCarbohydrate**. The Carbohydrate values are always entered manually, either directly via the ESYSTA App's user interface, or via some device like the ESYSTA Lab, in which case the flag **locked** is set (otherwise, if the user would be allowed to change the values in the ESYSTA App or the ESYSTA Portal, the data would diverge from the history kept in the device (which cannot be altered)).

2.4.5 Events

The array **events** lists all the patient's additionally recorded events within the exported time range. Its elements are of the type **DiaryItemEvent**. Events allow the

⁷ https://en.wikipedia.org/wiki/Continuous_glucose_monitor

⁸ https://en.wikipedia.org/wiki/Comma-separated_values

patient to record anything that is relevant for the diabetes therapy which is not included in the other diary items. Typical note-worthy events are such that affect the metabolic status, like physical exercise, illness, alcohol consumption etc.

2.5 Statistics

The structure **Statistics** comprises 3 groups of data, providing aggregate values derived from the recent values contained in the diary for

- blood glucose measurements,
- insulin amounts, and
- meal intakes.

2.6 Evaluation Description

The structure **EvaluationDescription** is special in that it consists of constant strings only. It explains the meaning of the data found in the structure **Evaluation** described below.

2.7 Evaluation

ESYSTA uses an evaluation algorithm that analyzes each day's diary data according to 7 criteria. These are titled:

- "Hypoglycemia",
- "Hyperglycemia",
- "Measurements per day",
- "Pens interchanged",
- "Daily dose",
- "Interval"

If the diary contains sufficient data for evaluation, for each of these criteria, a numeric value and an evaluation is given, the latter in form of one of the well-known traffic-light colors "red", "yellow"⁹ and "green". If the diary does not contain sufficient data for evaluation, no numeric value is given for the respective criterion, and the color is set to "grey". The criteria are described in detail in the structure **EvaluationDescription** contained in every exported JSON file and also in the following subchapters.

From the evaluations of these criteria, a summary evaluation for the day is derived, which is also given as one of the colors mentioned above. Days for which no data at all are suitable for evaluation are excluded from the export.

The first 4 of the 7 items mentioned above refer to the results of the patient's blood glucose measurements. Sometimes, measurement results can be wrong, e.g. because the blood volume applied to the test strip was insufficient. Some blood glucose meters are able to detect this more or less reliably, others don't and display a value that is too low. Experienced diabetics often realize this and perform another measurement to check the previous result. Therefore, the evaluation algorithm excludes blood glucose measurements that have a successor within 5 minutes.

⁹ As described in the detailed descriptions, some criteria never evaluate as "yellow".

2.7.1 Evaluation criterion "Hypoglycemia"

The numeric value is the number of severe hypoglycemiae, i.e. blood glucose values < 3 mmol/l (< 54 mg/dl), on the evaluated day. From this value, the evaluation color is derived as follows:

- "red": At least one severe hypoglycemia was recorded.
- "green": No severe hypoglycemia was recorded.
- "grey": There are not enough data to evaluate this criterion.

2.7.2 Evaluation criterion "Hyperglycemia"

The numeric value is the number of severe hyperglycemiae, i.e. blood glucose values > 15 mmol/l (> 270 mg/dl), on the evaluated day. From this value, the evaluation color is derived as follows:

- "red": More than two severe hyperglycemiae were recorded.
- "yellow": Two severe hyperglycemiae were recorded.
- "green": At most one severe hyperglycemia was recorded.
- "grey": There are not enough data to evaluate this criterion.

2.7.3 Evaluation criterion "Variability range"

The numeric value is the difference between the highest and the lowest blood glucose value recorded on the evaluated day. From this value, the evaluation color is derived as follows:

- "red": The variability range was > 10 mmol/l (> 180 mg/dl).
- "green": The variability range was ≤ 10 mmol/l (≤ 180 mg/dl).
- "grey": There are not enough data to evaluate this criterion.

2.7.4 Evaluation criterion "Measurements per day"

The numeric value is the number of recorded blood glucose measurements on the evaluated day. From this value, the evaluation color is derived as follows:

- "red": Less than two blood glucose measurements were recorded.
- "yellow": Two blood glucose measurements were recorded.
- "green": More than two blood glucose measurements were recorded.
- "grey": There are not enough data to evaluate this criterion.

2.7.5 Evaluation criterion "Pens interchanged"

The numeric value is the total amount of applied basal insulin in relation to the amount recorded for the previous day in %. A basal insulin amount that strongly deviates from the one of the previous day might be due to an accidental use of the wrong insulin pen. From this value, the evaluation color is derived as follows:

- "red": The deviation in comparison to the previous day was $> 50\%$.
- "green": The deviation in comparison to the previous day was $\leq 50\%$.
- "grey": There are not enough data to evaluate this criterion.

2.7.6 Evaluation criterion "Daily dose"

The numeric value is the total amount of applied rapid-acting insulin in relation to the amount recorded for the previous day in %. A rapid-acting insulin amount that strongly deviates from the one of the previous day can be a hint on metabolic irregularities. From this value, the evaluation color is derived as follows:

- "red": The deviation in comparison to the previous day was $> 50\%$.

"yellow": The deviation in comparison to the previous day was > 30%, but <= 50%.
"green": The deviation in comparison to the previous day was <= 30%.
"grey": There are not enough data to evaluate this criterion.

2.7.7 Evaluation criterion "Interval"

The numeric value is the fraction of rapid-acting insulin applications without blood glucose measurement in the preceding 30 minutes, in %. Injecting rapid-acting insulin without knowing the current blood glucose value is dangerous, so this criterion encourages you to measure your blood glucose level prior to injecting such insulin. From the numeric value, the evaluation color is derived as follows:

"red": To > 75% of the injections of rapid-acting insulin there was no preceding blood glucose measurement within the last 30 minutes.

"yellow": To > 50% (but <= 75%) of the injections of rapid-acting insulin, there was no preceding blood glucose measurement within the last 30 minutes.

"green": To <= 50% of the injections of rapid-acting insulin, there was no preceding blood glucose measurement within the last 30 minutes.

"grey": There are not enough data to evaluate this criterion.

2.8 Doctors

ESYSTA allows patients to share their data with their doctors, who can access these data via the ESYSTA Portal. This enables the doctors to evaluate the patient's situation at any time. The array `doctors` contains data of all doctors to whom the patient has granted data access.

2.9 Medical Findings

To complete the patient's diabetes-related therapy data, doctors can enter medical findings such as HbA1c¹⁰ values. The array `medical_findings` lists all these data entered within the exported time range.

2.10 Messages

Doctors can allow patients to send them messages via the ESYSTA portal. They can also respond to such messages. This provides a safe communication medium between patients and doctors. The array `messages` lists all these messages entered within the exported time range.

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¹⁰ cf. Glycated hemoglobin, https://en.wikipedia.org/wiki/Glycated_hemoglobin