ESYSTA® Bluetooth® Low Energy Insulin Pen Profile

Version 04.00

Emperra® GmbH
E-Health Technologies

Zeppelinstraße 48a
D-14471 Potsdam
Germany

Phone: +49 (0) 331 - 979 34 80 - 0
Fax: +49 (0) 331 - 979 34 80 - 19

info@emperra.com
www.emperra.com

Document History			
Version	**Date**	**Author**	**Change**
01.00	04.04.2016	MBe	Initial version
01.01	14.12.2017	FTz	Format of temperature value in context data, from sfloat to float
01.02	08.02.2018	SPr	Remove Insulin Type and Brand
	08.02.2018	SPr	Extend Insulin Dose Context Char with Device Error Event; Remove General device fault from Device Status Annunciation
02.00	06.03.2018	SPr	Final document release V02.00
02.01	19.07.2018	FTz	Add operand response codes; op code 2 not supported
02.02.	02.08.2018	FTz	Completed chapter 3.2.4 with supported (implemented) and unsupported RACP codes
03.00	04.02.2019	FTz	Final document release V03.00
04.00	09.02.2021	MBe	Remove classification as confidential

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1 General

This specification summarizes the data transfer protocol used for the communication between the ESYSTA® BT Pen and the ESYSTA® App for mobile devices. The whole data transfer operates over a Bluetooth Low Energy transport only.
The transfer procedure is similar to the official Bluetooth Generic Attribute Profile (GATT)-based Glucose Profile [1] and Glucose Service [2]. For further information regarding used terms, abbreviations, data formats etc. please refer to these ressources.

Note: All fields are shown in the order of LSO to MSO, where LSO = Least Significant Octet and MSO = Most Significant Octet.

1.1 Scope

This specification is designed to be suitable as an official standard for transferring data from any Insulin Pen that is equipped with a Bluetooth Low Energy interface. It thus covers features that might be supported by future devices, but that are currently not supported by the ESYSTA BT Pen.

1.2 Roles

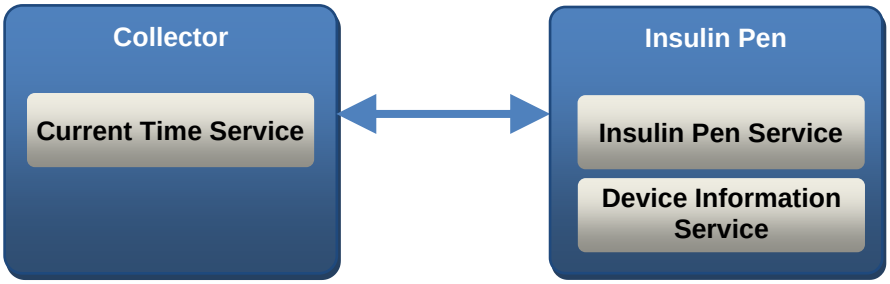
This document defines two roles: Insulin Pen and Collector. The Insulin Pen is the device that is used to inject insulin and the Collector is the device that receives the Insulin Pen application data and other related data from an Insulin Pen.
At any given time, an Insulin Pen shall be connected to only one Collector.

[1] Glucose Profile, https://www.bluetooth.com/specifications/specs/glucose-profile-1-0/

[2] Glucose Service, https://www.bluetooth.com/specifications/specs/glucose-service-1-0/

1.3 Roles and Relationships

The following diagram shows the relationships between service and profile roles.



Note: Profile roles are represented by blue boxes and the services are represented by grey boxes

An Insulin pen instantiates the Insulin Pen Service and the Device Information Service. The Collector instantiates the Current Time Service.

1.4 Requirements

The Collector shall instantiate the Current Time Service with Local Time Information, as described in the Current Time Profile (CTP).

2 Services and Characteristics

2.1 Overview

Service	UUID	
Generic Access	00001800-0000-1000-8000-00805f9b34fb	
Generic Attribute	00001801-0000-1000-8000-00805f9b34fb	
Device Information	0000180a-0000-1000-8000-00805f9b34fb	
Battery Information	0000180f-0000-1000-8000-00805f9b34fb	
Insulin Pen	c2f00001-1466-4478-b6dc-88c865226d5f	
Insulin Pen Custom	c2f00c01-1466-4478-b6dc-88c865226d5f	

2.2 Insulin Pen Service

To receive insulin dose values, the Collector needs to use the RACP.

All insulin dose entries are delivered through the Insulin Dose characteristic and optional with the Insulin Dose Context characteristics. The Collector needs to subscribe the Client Characteristic Configuration for “Insulin Dose”, “Insulin Dose Context” and “Record Access Control Point” characteristics.

Characteristic	Assigned Number	Properties
Insulin Dose	c2f0000d-1466-4478-b6dc-88c865226d5f	Notify
Insulin Dose Context	c2f0000c-1466-4478-b6dc-88c865226d5f	Notify
Insulin Pen Feature	c2f0000f-1466-4478-b6dc-88c865226d5f	Read
RACP	00002a52-0000-1000-8000-00805f9b34fb	Indicate, Write

2.2.1 Insulin Dose Characteristic

The “Insulin Dose” is used to deliver all base information for a given entry using the following structure. Each entry is delivered through a notification.

<table>
<tr><th>Name</th><th>Field Requirement</th><th>Format</th><th>Additional Information</th></tr>
<tr><td>Flags</td><td>Mandatory</td><td>8bit</td><td>
<table>
<tr><th>Bit</th><th>Name</th><th>Key</th><th>Value</th><th>Requires</th></tr>
<tr><td rowspan="2">0</td><td rowspan="2">Time Offset Present</td><td>0</td><td>False</td><td></td></tr>
<tr><td>1</td><td>True</td><td>C.1</td></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Local Time Present</td><td>0</td><td>False</td><td></td></tr>
<tr><td>1</td><td>True</td><td>C.2</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Insulin Dose, Type and Injection Location Present</td><td>0</td><td>False</td><td></td></tr>
<tr><td>1</td><td>True</td><td>C.3</td></tr>
<tr><td rowspan="2">4</td><td rowspan="2">Insulin Dose Unit</td><td>0</td><td>IU</td><td></td></tr>
<tr><td>1</td><td>L</td><td></td></tr>
<tr><td rowspan="2">5</td><td rowspan="2">Device Status Annunciation Present</td><td>0</td><td>False</td><td></td></tr>
<tr><td>1</td><td>True</td><td>C.4</td></tr>
<tr><td>6</td><td colspan="4">reserved for further use</td></tr>
<tr><td rowspan="2">7</td><td rowspan="2">Context Information Follows</td><td>0</td><td>False</td><td></td></tr>
<tr><td>1</td><td>True</td><td></td></tr>
</table>
</td></tr>
<tr><td>Sequence Number</td><td>Mandatory</td><td>uint16</td><td></td></tr>
<tr><td>Base Time</td><td>Mandatory</td><td></td><td></td></tr>
<tr><td>Year</td><td></td><td>unit16</td><td></td></tr>
<tr><td>Month</td><td></td><td>unit8</td><td></td></tr>
<tr><td>Day</td><td></td><td>unit8</td><td></td></tr>
<tr><td>Hour</td><td></td><td>unit8</td><td></td></tr>
<tr><td>Minute</td><td></td><td>unit8</td><td></td></tr>
<tr><td>Second</td><td></td><td>unit8</td><td></td></tr>
<tr><td>Time Offset</td><td>C.1</td><td>sint16</td><td></td></tr>
<tr><td>Local Time</td><td>C.2</td><td></td><td></td></tr>
<tr><td>Time Zone</td><td></td><td>sint8</td><td></td></tr>
<tr><td>DST Offset</td><td></td><td>uint8</td><td></td></tr>
<tr><td>Insulin Dose</td><td>C.3</td><td>sfloat</td><td></td></tr>
<tr><td>Dose Type</td><td>C.3</td><td>nibble</td><td>
<table>
<tr><th>Key</th><th>Values</th></tr>
<tr><td>0</td><td>Reserved for future use</td></tr>
<tr><td>1</td><td>Regular injection</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>2</td><td>Priming defined by user</td></tr>
<tr><td>3</td><td>Priming enforced by pen after power up</td></tr>
<tr><td>4</td><td>Priming enforced by pen the carpule was changed</td></tr>
<tr><td>5</td><td>Priming enforced by pen because the cannula was change</td></tr>
<tr><td>6</td><td>Priming enforced by pen because of an unclear device state</td></tr>
<tr><td>15</td><td>Insulin application type not available</td></tr>
</table>
</td></tr>
<tr><td>Injection Location</td><td>C.3</td><td>nibble</td><td>
<table>
<tr><th>Key</th><th>Values</th></tr>
<tr><td>0</td><td>Reserved for future use</td></tr>
<tr><td>1</td><td>Abdomen</td></tr>
<tr><td>2</td><td>Buttocks</td></tr>
<tr><td>3</td><td>Hips</td></tr>
<tr><td>4</td><td>Upper arm</td></tr>
<tr><td>5</td><td>Lower arm</td></tr>
<tr><td>6</td><td>Upper leg</td></tr>
<tr><td>7</td><td>Lower leg</td></tr>
<tr><td>15</td><td>Injection location not available</td></tr>
</table>
</td></tr>
<tr><td>Device Status Annunciation</td><td>C.4</td><td>int16</td><td>
<table>
<tr><th>Bit</th><th>Name</th><th>Key</th><th>Value</th></tr>
<tr><td rowspan="2">0</td><td rowspan="2">Device battery low at time</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Device lifetime exceeded at time</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Device lifetime near at time</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td rowspan="2">3</td><td rowspan="2">Entered dose higher than the device can deliver</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td rowspan="2">4</td><td rowspan="2">Entered dose lower than the device can deliver / negative dose</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td>5</td><td></td><td>0</td><td>False</td></tr>
</table>
</td></tr>
</table>

				Application Procedure was interrupted	1	True
			6	Application Procedure timed out	0	False
					1	True
			7	A carpule change preceded the application	0	False
					1	True
			8	The carpule was missing at the time of the application	0	False
					1	True
			9	A carpule of wrong type was inserted at the time of the application	0	False
					1	True
			10	A cannula change preceded the application	0	False
					1	True
			11	The cannula was missing at the time of the application	0	False
					1	True
			12	The device temperature was too high since the last carpule change	0	False
					1	True
			13	The device temperature was too low since the last carpule change	0	False
					1	True
			15	Time fault has occurred and time may be inaccurate	0	False
			14	reserved for further use		

2.2.2 Insulin Dose Context Characteristic

The “Insulin Dose Context” is only used to deliver concrete temperature values for a given time. Each entry is delivered through a notification.

<table>
<tr><th>Name</th><th>Field Requirement</th><th>Format</th><th>Additional Information</th></tr>
<tr><td>Flags</td><td>Mandatory</td><td>8bit</td><td>
<table>
<tr><th>Bit</th><th>Name</th><th>Key</th><th>Value</th><th>Requires</th></tr>
<tr><td rowspan="2">0</td><td rowspan="2">Temperature Value Present</td><td>0</td><td>False</td><td></td></tr>
<tr><td>1</td><td>True</td><td>C.1</td></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Temperature Unit</td><td>0</td><td>Celsius</td><td></td></tr>
<tr><td>1</td><td>Fahrenheit</td><td></td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Device Error Event Present</td><td>0</td><td>False</td><td>C.2</td></tr>
<tr><td>1</td><td>True</td><td></td></tr>
</table>
</td></tr>
<tr><td>Sequence Number</td><td>Mandatory</td><td>uint16</td><td></td></tr>
<tr><td>Temperature Value</td><td>C.1</td><td>float</td><td></td></tr>
<tr><td>Device Error Event</td><td>C.2</td><td>uint8</td><td>
<table>
<tr><th>Bit</th><th>Name</th><th>Key</th><th>Value</th></tr>
<tr><td rowspan="2">0</td><td rowspan="2">General device fault has occurred at time</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Bluetooth transmission fault has occurred at time</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Device sensor error at time</td><td>0</td><td>False</td></tr>
<tr><td>1</td><td>True</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>3-7</td><td colspan="3">reserved for further use</td></tr>
</table>
</td></tr>
</table>

2.2.3 Insulin Pen Feature Characteristic

The “Insulin Pen Feature” characteristic is used to determine all features supported by device.

Name	Field Requirement	Format	Additional Information
Flags	Mandatory	8bit	

Bit	Name	Key	Value	Requires
0	Low Battery Detection Supported	0	False	
		1	True	
1	End of Life Detection Supported	0	False	
		1	True	
2	Priming Detection Supported	0	False	
		1	True	
3	Dose High-Low Detection Supported	0	False	
		1	True	
4	Insulin Temperature High-Low Detection Supported	0	False	
		1	True	
5	Application Interrupt Detection Supported	0	False	
		1	True	
6	Application Interrupt Detection Supported	0	False	
		1	True	
7	Carpule Change Detection Supported	0	False	
		1	True	
8	Cannula Change Detection Supported	0	False	
		1	True	
9	Insulin Type Detection Supported	0	False	
		1	True	
10	Insulin Brand Detection Supported	0	False	
		1	True	

			11	General Device Fault Supported	0	False
					1	True
			12	Time Fault Supported	0	False
					1	True
			13	Multiple Bond Supported	0	False
					1	True
			14	Carpule Error Detection Supported	0	False
					1	True
			15	Carpule Error Detection Supported	0	False
					1	True

2.2.4 RACP Characteristic

The “Record Access Control Point” characteristic provides basic management functionality for the Insulin Pen record database. This enables functions including counting records, transmitting records and clearing records based on filter criterion.

Name	Field Requirement	Format	Additional Information
Op Code	Mandatory	uint8	**Key** / **Description** 0 – Reserved for future use (Operator: N/A) 1 – Report stored records 3 – Abort Operation 4 – Report number of stored records 5 – Number of stored records response 6 – Response Code
Operator	Mandatory	uint8	**Key** / **Description** 0 – Null 1 – All records 3 – Greater than or equal to

			5 First record (i.e. oldest record). 6 Last record (i.e. most recent record).
Operand Filter Type	Mandatory	uint8	**Key** / **Description** 0 N/A 1 Filter Sequence Number
Operand Filter Parameter	Mandatory	variable	Filter operand, e.g. sequence number
Operand Response Code	Mandatory	uint8	**Key** / **Description** 0 N/A 1 Success 2 Op Code not supported 3 Invalid Operator (received operator does not meet the requirements of service) 4 Operator not supported 5 Invalid Operand (received operand does not meet the requirements of service) 6 No records found 7 Abort unsuccessful 8 Procedure not completed 9 Operand not supported

2.3 Insulin Pen Custom Service

To terminate the connection, the Collector needs to write a 1 to the value.

Characteristic	Assigned Number	Properties
Insulin Dose Custom Value	c2f00c0a-1466-4478-b6dc-88c865226d5f	Read, Write

2.3.1 Insulin Pen Custom Value

Name	Field Requirement	Format	Additional Information
Value	Mandatory	8bit	When a Collector no longer needs the connection, is shall write a value of 1 into this field to terminate the connection and save power on both devices.