



Design Verification of Ypsomed's On Body Delivery System (OBDS) according ISO 11608 utilizing the support of ZwickRoell

Christian Esser Wiesemann, Ypsomed AG
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Agenda

1. Ypsomed company overview
2. YpsoDose a patient-centric On Body Device System (OBDS) – marketview
3. Required norms for Design Verification of electromechatrical devices
4. Which tests applied for YpsoDose based on ISO11608?
5. Support on Design Verification of OBDS 11608 based on Zwick Roell equipment?
6. Interpretation and additional tests on new 11608:6-2022
7. Outlook on Batch Release process
8. Critical reflection

Ypsomed – Vision and mission

- **Vision**
Ypsomed solutions make selfcare **simpler and easier**.
- **Mission**
With **innovative, simple-to-use and reliable products** as well as modern care concepts, we contribute significantly to the success of a therapy and thereby enable people to enjoy the best possible quality of life.
- 2'200 employees ww – HQ Switzerland
- 500m CHF turnover p.a.



Ypsomed – company overview



Deliverysystems

Preferred partner for systems to administer liquid drugs



Pen systems



Autoinjector
systems



Patch injector
systems



Smart
services



Diabetescare

Established diabetes specialist with over 35 years' experience



Infusion
systems



Blood glucose
monitoring
systems



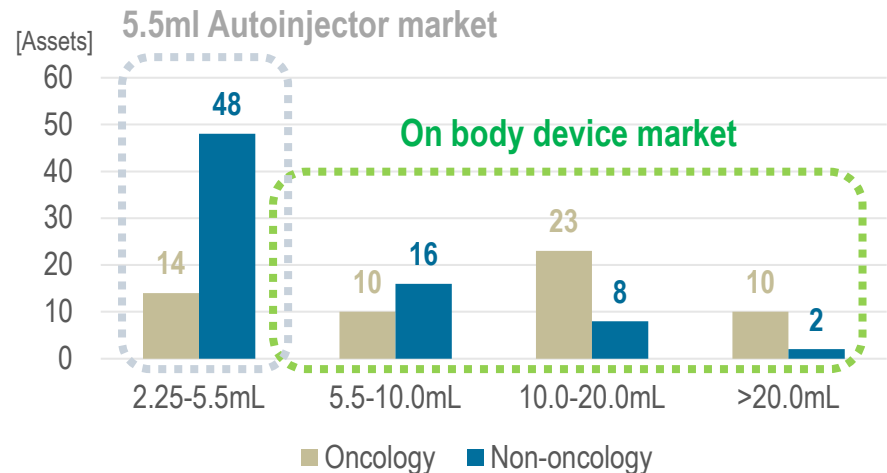
Therapy
management



Pen
needles

YpsoDose a patient centric OBDS – marketview

- Market potential **>100 assets in development** with a volume >2.25ml
- Market development of **5.5ml Autoinjectors** are influencing the OBDS market
- Demand on OBDS in today's **HCP setting** (oncology today mainly with syringe) – hometreatment?
- Highly **competitive landscape** in OBDS market shapes market situation and design



Source: Pharma big pharma pipeline Analysis
August 2023 Ypsomed internal analysis



OBDS vs. Autoinjector



Ypsomed
core
business



Difference in «functions» which needs to be proven in Design Verification according ISO 11608-2022 of a combination product

LED`s vs. No LED`s

Motor Driven vs. Spring Driven

Buzzer Sounds vs. Mechanical Clicks

Adhesion force to skin vs. Manually applied onto skin

Injection **up to 30minutes** vs. Injection under 10-30s

Ypsomed's laboratory requirements & standards to perform DV on Autoinjectors

Ypsomed performs multiple Design Verification tests with autoinjectors p.a.

- **Automatization** to ensure repeatable test execution
- **High accuracy requirement** on standardized documentation of test
- **Minimized human error** potential of test procedure
- Check **multiple test attributes with one test execution** – less devices and ressources needed

Tests to be documented with limited human influence and with high accuracy

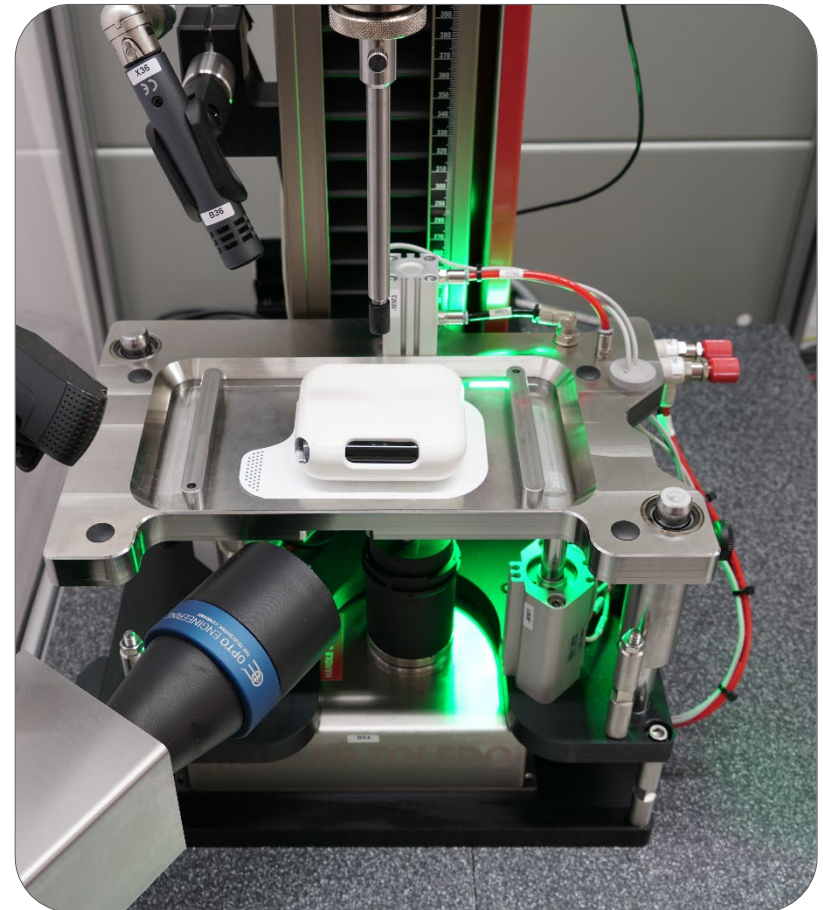
Test & raw-data of test system (video, audio) availability to ensure traceability and analysis



Support on Design Verification of OBDS 11608 based on Zwick Roell equipment?

What was the challenge to enroll YpsoDose Design Verification test with Zwick Roell equipment:

- **Primary functions** can be tested / captured in one test set-up
- Machine **perform tests autonomous** – (injection time >20minutes)
- **Partner and ability to learn from each other** – as no standard of testing from OBDS existed
- Build a **solution**, which works also **for pharma partners** to release their combination product (YpsoDose + primary packaging filled with drug product)



Norms/interpretations for Design Verification of on-body devices – ISO 11608 and FDA feedback

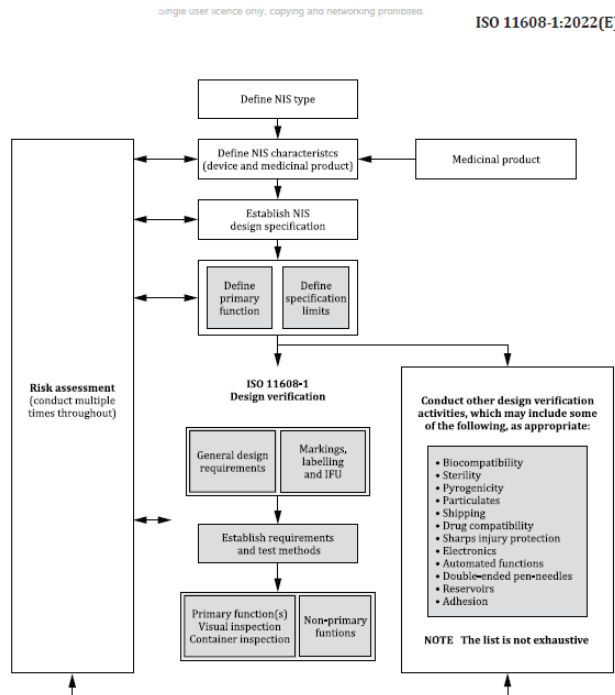
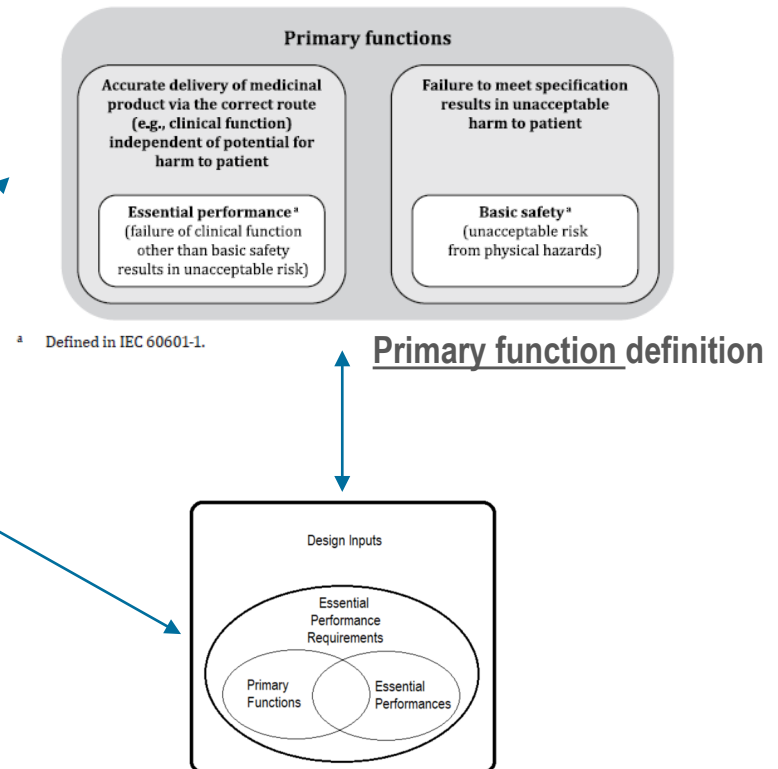


Figure 2 — Design verification flow

Design Verification flow and process

* list is not exhaustive



Ypsomed interpretation of FDA feedback on Essential Performance Requirements

Norms for Design Verification of on-body devices

Example interpretation of 11608-1:2022 for YpsoDose

Primary function

- Dose accuracy of drug delivered
- Delivery time of drug injection
- Needle extension

*

Essential Performance Requirements per FDA feedback to Ypsomed

- Dose accuracy (primary function)
- Injection Time (primary function)
- Needle Extension (primary function)
- Actuation force
- Visual / audible feedback
- Delivery profile (flow rate)
- Skin needle retraction

*

All tests conducted under all pre-conditions (warm, cold, ...)

* list is not exhaustive

Let's review the results I

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Test Report

 Competence Center Laboratory
Brunnmattstrasse 6
CH-3401 Burgdorf

YpsoDose MFT Standard atmosphere

Order

 Test order no. : 140027921
 Reference document : DTP no.
 Initiator : S. Gartmann (GASA2)
 Project/product : YpsoDose 10ml V&V übrige
 Project no. : 10004.12311

Sample(s)

 Article description : YpsoDose Z3
 Article no. : 700021492
 Lot no. : 5049242

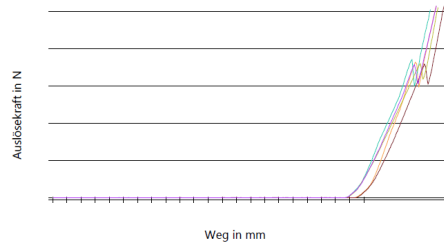
Test station

 Test equipment : 311072 Zwick/Roell MFT YpsoDose
 Load cell : 311072-793777-500N
 Load cell settings : Measurement transfer rate: 100 Hz
 Integration time traverse: 10 ms
 Integration time force: 100 ms

Test

 Zeit-Speicherintervall : 50 ms
 Preload : 5 N
 Preload speed : 50 mm/min
 Prüfungsgeschwindigkeit zum : 10 mm/min
 Auslösen des Injektors
 Date : 09.06.2023
 Prüfer : N. Filekovic (FINE1)

Start button activation force



140027921_Test mit MediLiz2

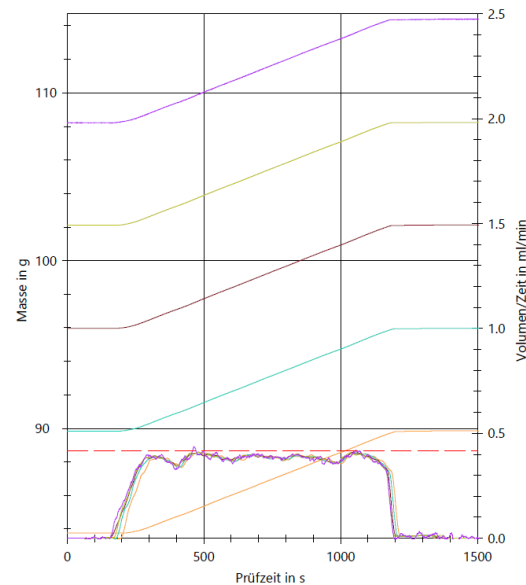
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Test Report

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Dose delivery rate



Legend

 Vol Needle accuracy of drug delivered
 Lne Needle extension
 Del. time Delivery time of drug injection
 dVol/dt_{max} Maximal dose delivery rate
 Fb Start Button Activation force
 Lne_{Ende} Skin Needle retraction

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Test Report

 Competence Center Laboratory
Brunnmattstrasse 6
CH-3401 Burgdorf

Test results

Legende	Nr	Datum/Zeit	Fb N	Lne mm	dVol/dt _{max} ml/min	Vol. ml	Del. time min	t _{ges} min	Lne _{Ende}
	1	09.06.2023 07:39:45	3.6	6.08	0.411	6.096	16.344	21.91	Ok
	2	09.06.2023 08:17:23	3.7	6.08	0.408	6.113	16.476	21.88	Ok
	3	09.06.2023 09:00:36	3.6	6.16	0.410	6.171	16.672	21.60	Ok
	4	09.06.2023 09:56:10	3.6	6.16	0.410	6.132	16.427	22.14	Ok
	5	09.06.2023 10:44:10	3.6	6.22	>0.436	6.180	19.324	22.17	Ok

Statistics

Serie	Fb N	Lne mm	dVol/dt _{max} ml/min	Vol. ml	Del. time min	t _{ges} min
n = 5						
x	3.6	6.14	0.415	6.138	17.049	21.94
min	3.6	6.08	0.408	6.096	16.344	21.60
max	3.7	6.22	0.436	6.180	19.324	22.17
s	0.0	0.06	0.012	0.036	1.278	0.23

Expanded statistics

	Buttonforce	Injektionstiefe	Flowrate	Volume	Delivery Time	Overall Injection Time
p	99.0%	97.5%	95.0%	97.5%	97.5%	97.5%
k	6.598	5.774	4.203	4.909	4.909	6.015
Ø+k-s	3.915 N	6.486 mm	0.464 ml/min	---	---	23.213 min
Ø-k-s	3.325 N	5.794 mm	---	5.96 ml	10.776 min	---

Comments:

	ID:	Date:	Signature:
Created:			
Inspected:			

Let's review the results II

Essential Performance Requirements per FDA feedback to Ypsomed

- Dose accuracy (primary function) **1**
- Injection Time (primary function) (first-drop to last) **2**
- Needle Extension (primary function) **3**
- Actuation force **4**
- Visual / audible feedback **5**
- Delivery profile (flow rate) **6**
- Skin needle retraction **7**

*

additionally to the test-report each injectionvideo (LED feedback, buzzer sound) is captured and stored to the test

YpsoDose DV Tests are tested on Zwick-Roell equipment and capture 98% of all relevant tests according ISO 11608 incl. FDA relevant Essential Performance Requirements






* list is not exhaustive

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Test Report

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Brunnmattstrasse 6
CH-3401 Burgdorf

Test results

Legende	Nr	Datum/Zeit	Fb N	Lne mm	dVol/dt _{max} ml/min	Vol. ml	Del. time min	t _{ges} min	Lne _{Ende}
	max								7
	min								
	1	09.06.2023 07:39:45	3.6	6.08	0.411	6.096	16.344	21.91	Ok
	2	09.06.2023 08:17:23	3.7	6.08	0.408	6.113	16.476	21.88	Ok
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Statistics

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s	0.0	0.06	0.012	0.036	1.278	0.23

Expanded statistics

	Buttonforce	Injektionstiefe	Flowrate	Volume	Delivery Time	Overall Injection Time
p	4 99.0%	3 97.5%	6 95.0%	1 97.5%	2 97.5%	97.5%
k	6.598	5.774	4.203	4.909	4.909	6.015
Ø+k-s	3.915 N	6.486 mm	0.464 ml/min	---	---	23.213 min
Ø-k-s	3.325 N	5.794 mm	---	5.96 ml	10.776 min	---

Comments:

—	ID:	Date:	Signature:
Created:			
Inspected:			

How to interpret ISO11608:6-2022 – OBDS section

ISO11608:6 refers especially on the Design Verification of OBDS specialties:

Adhesive

Freedom of Orientation

Dose Delivery Profiles if
clinically relevant

GAP interpretation of chapter 6 according to the Ypsomed processhouse on ISO11608 shows following additional considerations on combination product level:

1. Orientational worst-case testing
2. Adhesive testing
3. Exposure to typical fluids
4. Dose delivery profiles (only if clinically relevant)

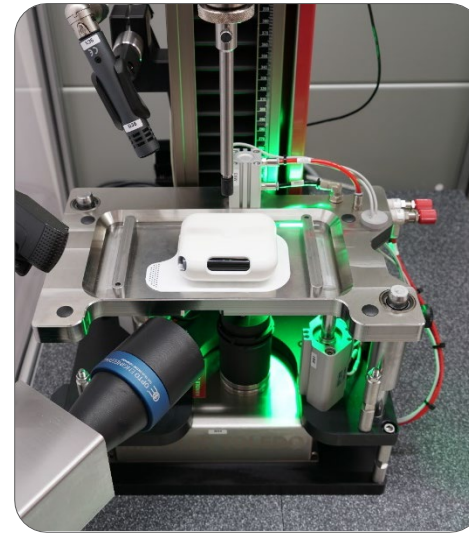
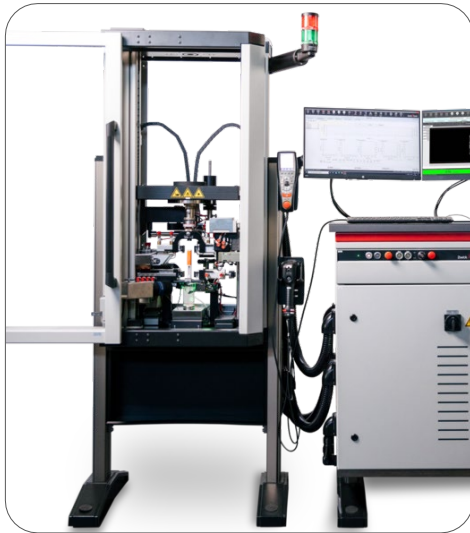
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* list is not exhaustive

Outlook on Batch Release process

Pharma Companies are required to test the **primary function** of the combination product for every **batch release**.

Ypsomed believes, that the the joined development will support pharma companies in their release process of combination products of OBDS.



* list is not exhaustive

Critical reflection on Design Verification of Ypsomed's on-body-injector according ISO 11608 utilizing the support of ZwickRoell

Ypsomed can provide evidence to pharma companies about majority of conducted tests on 11608 using support of ZwickRoell.

Minority of required tests remain manually performed due to orientation and other test requirements.

Handling of Testequipment is manual (loading, etc.) which shows potential for automatisisation for high volume.

Generated test reports from support of ZwickRoell are used not only for 11608 Design Verification tests also within Feasibility studies to ensure reproducible testing results.

Joined testing strategy at Ypsomed and pharma partners supports quality of combination product.

Thanks Zwick Roell for the great collaboration!



More confidence. More success. With Ypsomed Delivery Systems.



Pen
systems



Autoinjector
systems



Patch injector
systems



Smart
services