



Testing of Primary Containers and Devices

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- Background/
Experiences:
- Mechanical Engineer / Textile Engineer
 - 1997-2003: R&D ITA, RWTH Aachen University
(Biomaterials/Implants)
 - 2003-2008: R&D Paul Hartmann AG, Heidenheim
(Compression/Immobilization products)
 - Materials, production, testing, regulatory, launching, patents



Drug pens



Insulin cartridges



Hypodermic needles



Double chamber syringe



Syringes



Pen needles



Pre-filled syringes

ISO 11608-1: Needle-based injection systems for medical use - Requirements and test methods - Part 1: Pen-injectors

ISO 11608-2: Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles

ISO 11608-3: Needle-based injection systems for medical use - Requirements and test methods - Part 3: Finished cartridges

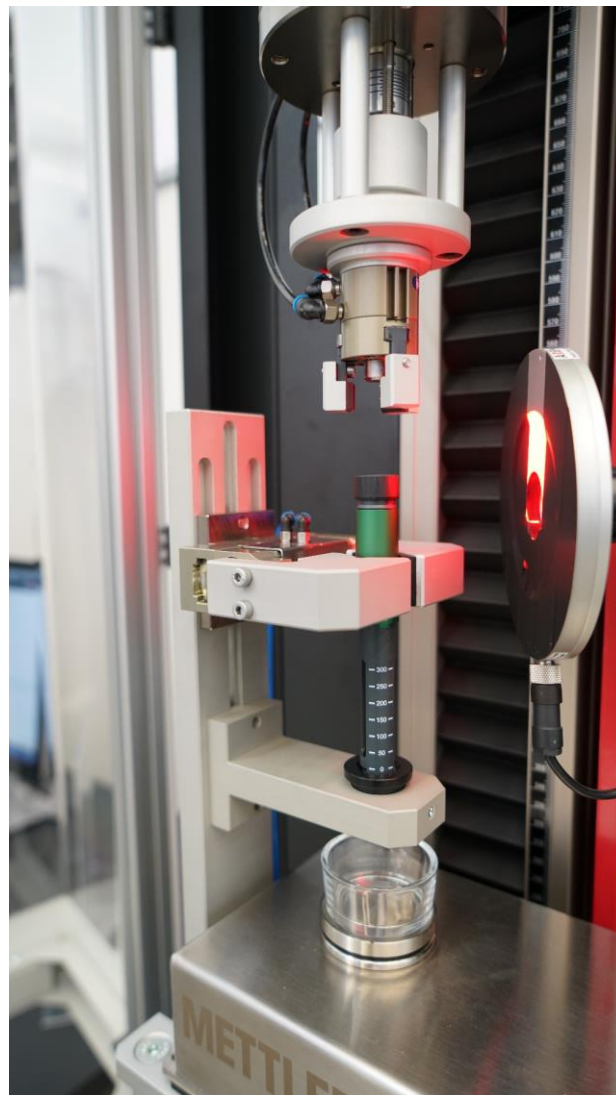
ISO 11608-4: Pen-injectors for medical use - Requirements and test methods - Part 4: Needle-based injection systems containing electronics

ISO 11608-5: Needle-based injection systems for medical use – Requirements and test methods - Part 5: Automated functions

ISO/DIS 11608-6: Needle-based injection systems for medical use – Requirements and test methods - Part 6: On-body delivery systems

Semi automated dose accuracy testing (ISO 11608-1)

Movie 





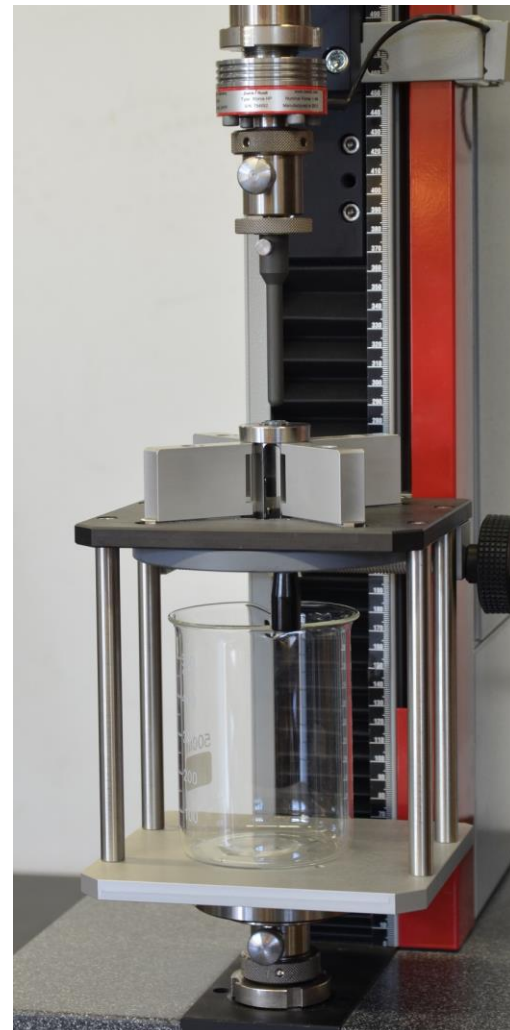
Robotic Testing System ,roboTest R' with torsion-testing machine 2.5 kN for functional-test on insulin-pen

Movie Mechanical Rear Part Test 

ISO 11608-3 Pen-Injectors for medical use: Part 3: Finished Cartridges - Requirements and test methods

Tests:

- Forces required to initiate and sustain plunger movement
- Leakage
- Resealability

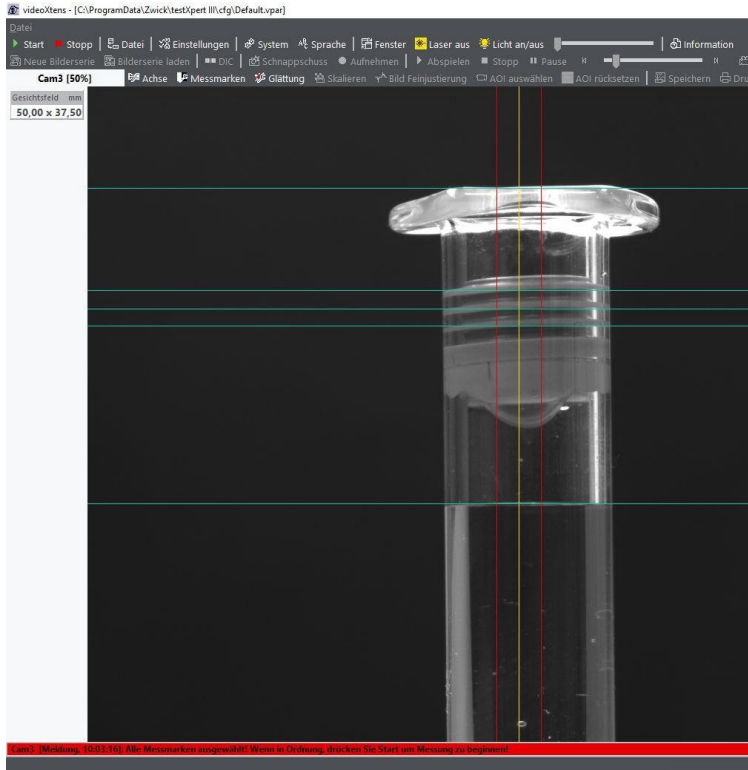




Function test following ISO 11608-5 -
Part 5: Automated functions

Customizable Testing Modules:

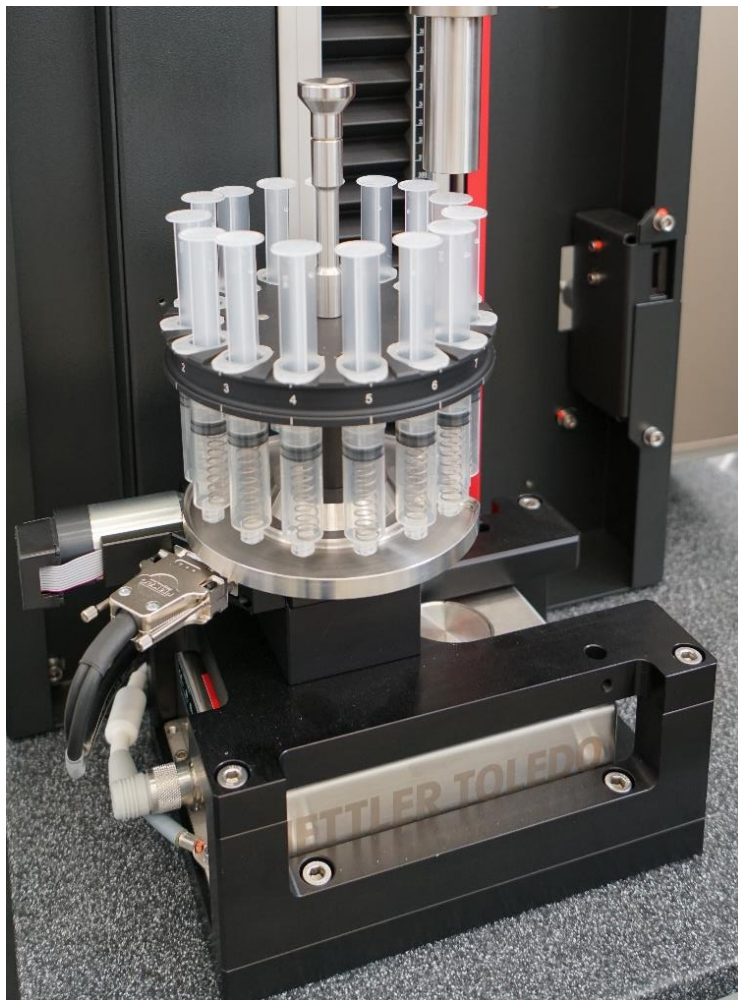
- Special low pressure grips
- Integrated high-precision scale
- Activation forces
- Sensor Needle length with removal last drop
- Sensor Ejection Time
- Sound detection via microphone
- Camera for needle tip/fluid stream recording



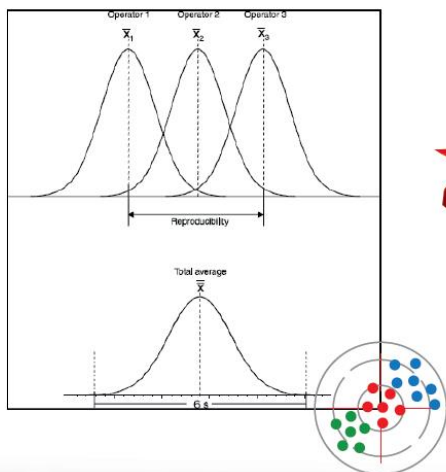
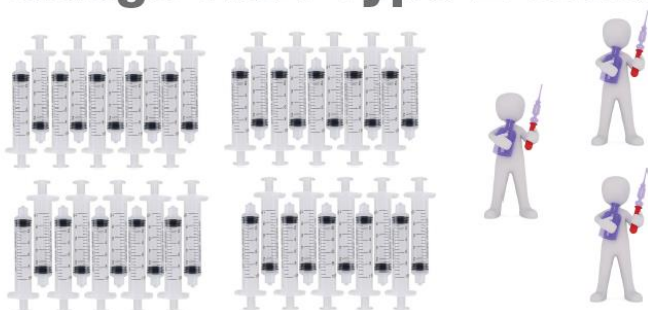
Measurement of plunger position



Plunger movement measurement

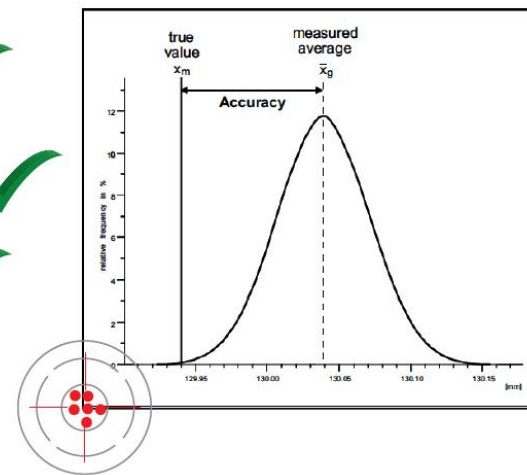
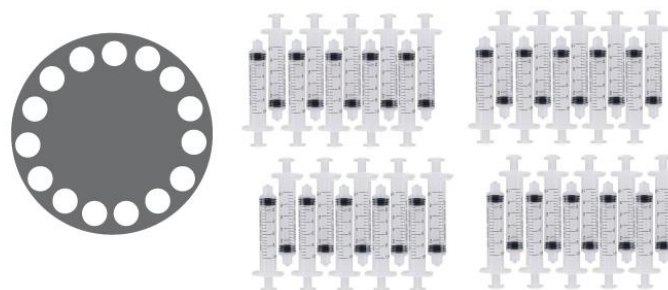


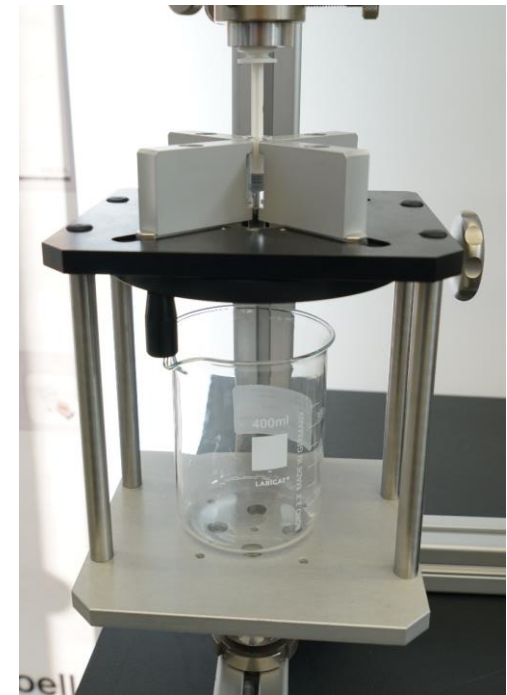
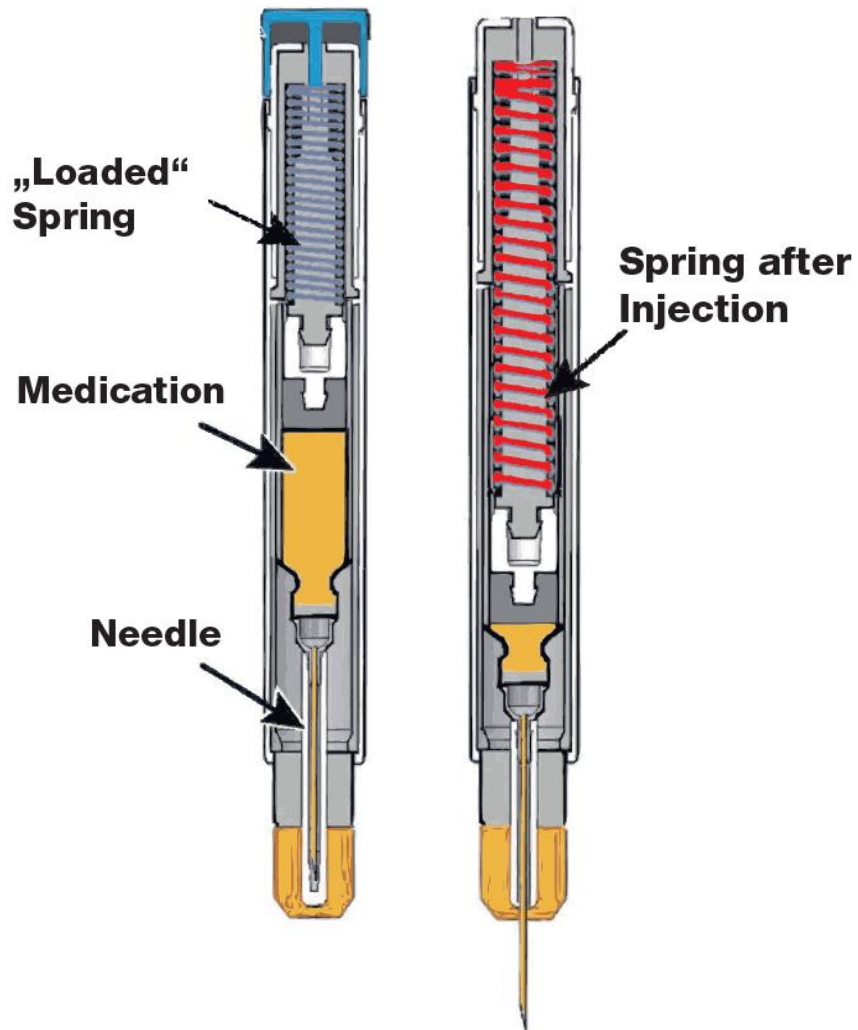
Gauge R&R Type 2 Study

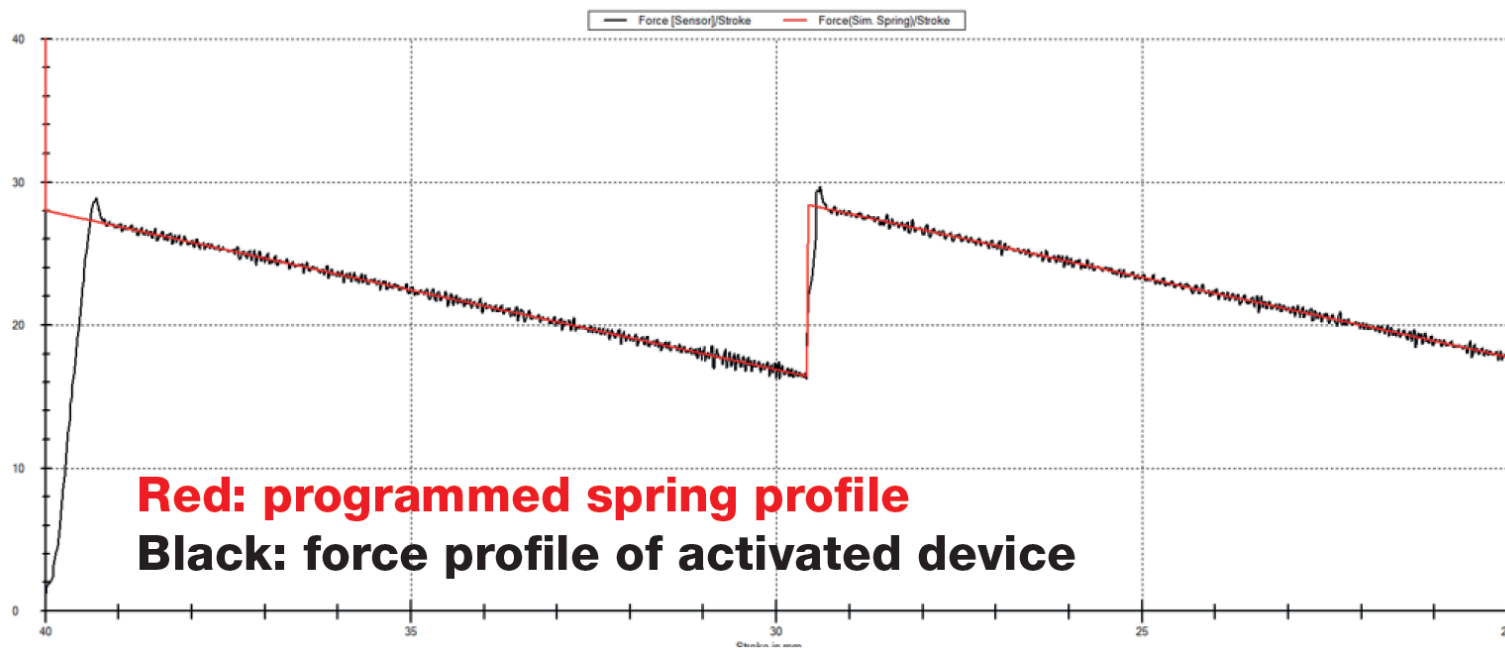


- ~~X~~ Operator influence ✓
- ~~X~~ Complexity of R&R study ✓
- ~~X~~ Reliable test results ✓

Gauge R&R Type 3 Study









Questions?