InsuJet™

Inject Needle-Free

Usability summary

InsuJet™ design history

The predecessor of the InsuJet™ (SQ-Pen) was first tested on the European market in 2010. The pre-commercialized device has been continuously improved upon to reach the current market-ready InsuJet™ V5 device for Insulin administration, and the NuGen MD for general use.

Early 2010 SQ pen ——— *InsuJet™ V5 needle-free device*

The design of the InsuJet™ has evolved based on the feedback obtained during usability studies and information obtained from Post Market Surveys conducted with users of earlier generation devices as part of small scale market introductions. Some of the problems with the device highlighted in the surveys included:

1) Occasional wet injections
2) High winding torque
3) Unclear dose indication
4) Confusing interface
5) Heavy injector

These items have all been addressed and corrected in the current commercially ready InsuJet™ Injector and NuGen MD device. Design verification and user validation confirms the effectiveness of the design changes, as are summarized in this document.

InsuJet™ Usability testing

Usability testing to validate the design improvements were carried out during the device design history. In total 4 usability tests were conducted, involving 54 lay users. The results of the usability tests confirm that the InsuJet™ V5/NuGen MD device overcomes some of the most important drawbacks of previous models of the device. The positive results from usability testing should be reflected in more positive results from Post Market Surveillance Surveys going forward.

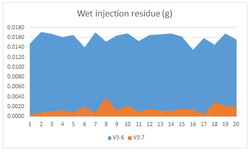
The results

1) Occasional wet injections

When liquid residue is left on the skin, it indicates not all the medication has been successfully injected into the body. Some liquid may leak out of the nozzle prior to the injection.
Design improvements have drastically reduced the volume of the residue by 90%.

Current mean leakage at 50U is 0.15 units, which is hardly observable by the naked eye and is within 6% of accepted norms for dose accuracy at this volume.

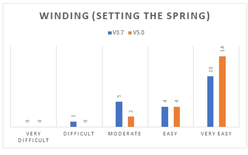
90%
Reduction of residue

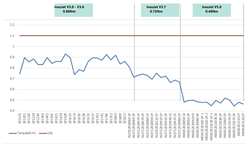


2) High winding torque

With the earlier models of the InsuJet, 21% indicated that the winding of the device was fairly heavy, and 4% found it too heavy. The use of high-performance materials and lubrication helped lower internal friction, and as a result, the torque needed to charge has been reduced by 44%.

44%
Reduction in winding torque





A user test with 20 subjects was performed to validate the suitability of the new torque. The study result shows noticeable improvement.

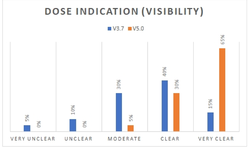
Before
70%
Easy to very easy to wind

After
90%
Easy to very easy to wind

3) Unclear dose indication

Over time, diabetes can cause damage to your eyes that can lead to poor vision or even blindness. A suitable dose indication is important for both the function and the safety of the device.
The InsuJet™ has a dose window, which magnifies the selected dose so it is more suitable for users with slightly impaired vision. With the earlier models of the InsuJet™, 25% indicated the dose indication was inconvenient, and 4% indicated it was very inconvenient.

To validate the improvement, 20 lay users were asked to compare the dose window. The legibility of the dose indication was rated as clear by 95%, where the older version scored only 55%.



Window size	V3.7	V5.0
Height (mm)	2.3	3.4
Width (mm)	3.7	5
Surface area (mm²)	8.5	17

2X size

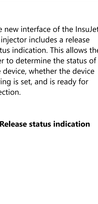
Before
55%
Clear to very clear

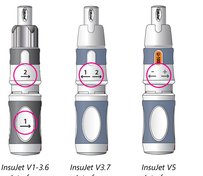
After
95%
Clear to very clear

4) Confusing interface

The two major steps in preparing the device for injection are 1) setting the spring (charging) and 2) setting the target dose.
Both steps rely on the winding of one part of the injector (front/back) relative to the other part. In previous versions, to charge the device (step 1) the back side had to be turned, where in step 2, the front side had to be turned. This occasionally lead to confusion and user error, when users adjusting the dose (step 2) rotated the back side of the device. As the lens is fixed with the backside, this resulted in a problem, as the user can now no longer observe the dose window. An improvement of the user interface design was requested.

A new and improved interface was designed which is more intuitive and results in less user errors.
In the new interface design, only the front part of the device is turned during both steps, resulting in significantly less user errors and is considered easier to use. The change in user interface was validated by a user test with 14 lay users. 93% preferred the new interface design.





For the InsuJet™ V5 a further improvement was implemented where the "1" and "2" indications were replaced by a "-" and a "+" indication.

This new indication is more intuitive whilst adjusting the dose (step 2), further reducing the risk of user errors.

The new interface of the InsuJet™ V5 injector includes a release status indication. This allows the user to determine the status of the device, whether the device spring is set, and is ready for injection.

Release status indication

5) Heavy injector

When asked what could be improved on the InsuJet™, 19% of the respondents mentioned the size & weight of the injector.

Continuous development has resulted in a significant reduction in the weight of the injector; from 150g to 115g. For reference, the iPhone 13 Pro weighs 203g.

	V1-V3.6	V3.7	V5.0
Winding torque (Nm)	0.86	0.72	0.48
Window size (mm²)	8.5	8.5	17
Dose range	4-40	4-40	4-50
Release force (N)	24.6	23.8	22.6
Weigth (g)	150	135	115

Before
150g

After
115g

Weight: 115g *Weight: 203g*

nuGen MEDICAL DEVICES