InsuJet™

Inject Needle-Free

Information deck for InsuJet™ professionals

Intended use and safety information

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InsuJet™

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Intended use and safety information

InsuJet™ Clarification of intended use

The InsuJet™ insulin-jet administration system is intended for the subcutaneous jet injection of insulin in adults and children with Diabetes Mellitus who require insulin therapy.

Insulin therapy may be used with the following patients:

• Patients with type I diabetes mellitus
• Patients with type II diabetes mellitus in whom control cannot be adequately achieved with oral hypoglycemic or diet.
• Patients with diabetes in pregnancy in whom control is inadequate with diet

The InsuJet™ insulin-jet administration system is for single patient use only.

The InsuJet™ insulin-jet administration system is suitable for U100 (100 IU/ml)

The InsuJet™ can be used to inject 4 to 50 Insulin Units per administration. Insulin is not provided with the system.

For practice purpose, saline solution and/or sterile water for injection may be injected with the device.

For the administration of other injectables, please refer to the NuGen MD device, which is approved by different regulatory agencies, including Health Canada.

InsuJet™ Intended patient populations

• Adults
• Under supervision as recommended by their physician" or diabetes specialist.
- School age children of the age 6-12 who can be injected by a caregiver
- Adolescents of the age 12-18 who can be trained to self-inject

The InsuJet™ may be used by healthcare providers who routinely administer injections.

The InsuJet may also be used by patients, at home, to self-inject, or have other individuals administer injections of prescribed medication.

⚠ Warnings

• Do not drop the InsuJet™ injector or the consumables.
• The InsuJet™ should only be used for the administration of (U-100) insulins.
• The InsuJet™ should only be used with InsuJet™ Nozzles and Adaptors.
• Check the expiration dates of your insulin. Do not use insulin past its expiration date.
• Check the expiration dates of the InsuJet™ and its consumables on the outer packaging. Do not use past its expiration date or past the indicated lifetime.
• Check the integrity of the InsuJet™ consumables packaging. Do not use if the package is breached.
• Never use the same Nozzle for different types of insulin.
• Never use the same cartridge- or vial Adaptor for different insulin cartridges or vials. Discard the Adaptor with the empty insulin cartridge or vial.
• Be careful not to touch the needle inside the Adaptor.
• Never discharge the InsuJet™ without a Nozzle attached, or air inside the Nozzle. This is called DRY-FIRING and may damage the device beyond repair.
• Do not store insulin inside the Nozzle. The Nozzle is only intended to be filled immediately before injection.
• Replace the Nozzle whenever the InsuJet™ has not been used for more than 3 days.
• Never use the same Nozzle or cartridge or vial Adaptor for different patients. Using the same device for multiple patients may result in the direct transfer of bacteria, viruses or other germs from one person to another.
• Adult supervision is highly recommended when a child uses the InsuJet™. Make sure that children are told that the InsuJet™ is not a toy.
• Keep all medications and injection devices out of the reach of children.
• Never use, or attempt to repair a damaged or broken InsuJet™ or consumable.
• In case provided hygiene practices and warnings are not followed, the consumables may be contaminated during use, possibly resulting in infections.
• The device delivers insulin using high pressure injection. The device has various safety features to ensure safe use. If any safety feature fails, stop using the device to avoid injury.
• In case a serious incident has occurred in relation to the device, this should be reported to EPG BV and the Competent Authority in your country.
• Temperature limits for use: 4-50C
• Replace the InsuJet™ injector VS in time. The same device should never be used for more than 5000 injections. Do not use the device past the indicated expiry date. Device performance and safety may be affected when using the device beyond the indicated lifetime.
• Replace the InsuJet™ Nozzle regularly. The same Nozzle should never be used for more than 56 injections, or longer than 14 days after its blister packaging is breached. It is advised to replace the Nozzle every time a new cartridge or vial is used. Using the Nozzle beyond the indicated lifetime will cause insulin leakage, may cause bacterial contamination and may result in device malfunction, with loss of warranty.

InsuJet™ Contraindications

This product is not recommended for patients who are:

• Severely visually impaired

• Physically unable to operate the system

• Not able to understand or memorize the operating instructions for using the InsuJet™

• Have a special skin type (e.g. psoriasis patients), which might impair a successful use of the InsuJet™.

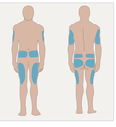
• In case of doubt please consult your Diabetes Care Specialist.

• Patients who bruise or bleed easily (e.g. people using antithrombotic drugs) may use the device with caution.

• If you experience any prolonged or severe bruising or bleeding, it is recommended to stop and consult your doctor.

InsuJet™ Administration site selection guide

NOTE: It is advised that your first InsuJet™ insulin administration takes place under the supervision of a Diabetes Care Specialist.



Any of the sites that are normally recommended for your insulin administration can be used with the InsuJet™. Choose an area with some fatty tissue. Avoid areas with low fat, or high muscle content.

Abdomen: Use the areas on the same level or slightly below your belly button, as illustrated above. If you are unable to find a suitable administration site in the abdominal area, please consider another area.

Legs: Sit on a chair with the back of your legs supported and both feet flat on the floor. Relax your thigh muscle. The administration should take place on the front or outer portion of the thigh.

Buttocks: Find a sitting position that allows you to reach the buttocks. The administration should take place in the upper outer portion of your buttock.

NOTE: For relatively soft or sensitive administration areas, it is recommended to use a Comfort Ring during administration. See page 37 for instructions to install a Comfort Ring on the Nozzle.

InsuJet™ Safety information

For diabetes management, the application of insulin by the InsuJet™ results in a complete administration of medicinal product in the subcutaneous layer. Tolerability, total insulin absorption, total insulin action and total blood glucose lowering effects are equivalent to conventional needle injections.

Clinical benefits

• Greater patient acceptance among patients with needle-phobia, or patients who wish to administer insulin without needle

• Administration of insulin by jet injection enhances insulin absorption and reduces the duration of glucose-lowering action. This profile resembles more closely the pattern of endogenous insulin secretion and may help to achieve better meal insulin coverage and correction of postprandial glucose excursions

• The removal of needle sharps helps reduce the occurrence of needle stick injuries and cross contamination, making the InsuJet™ suitable for the treatment of patients from high-risk categories.

• The InsuJet™ targets the subcutaneous tissue just below the dermis reducing the chance of intramuscular injection.

Possible InsuJet™ Side effects

Always read the patient information leaflet of your prescribed insulin. The possible side effects are listed in this leaflet. Side effects which you may experience with the use of the InsuJet are listed in this section:

Bleeding - Common
A tiny pinprick bleed following administration is not unusual for some people and can simply be wiped off. If a larger amount of blood is present you may have hit a capillary, this should be a random observation from time to time. Apply pressure to the administration site. This will stop the bleeding in most cases.
If you experience any prolonged or severe bleeding, it is recommended to consult your doctor

Bruising - Common
If you tend to bruise easily with a needle-based device, you may bruise with the InsuJet™ as well. Consult your doctor, as various injection locations may provide to either improve to decrease or eliminate bruising.
Also, consider using a Comfort Ring to reduce the pressure of the Nozzle on your skin and consult your doctor, as various injection locations may provide to either improve, decrease or eliminate bruising.
If you require a relatively large amount of insulin, it may be worth splitting your dose;
E.g. 2 doses of 25 units each instead of 50 units at once.
If you experience any prolonged or severe bruising, consult your doctor.

Infection - Very rare
Although very rare, infections potentially can be caused by microbial contamination being introduced into the body at the injection site.

Using an alcohol swab on the site you're going to inject, and timely replacement of the consumables will help to prevent infections.
If you notice (signs of) an infection at the injection site, please consult your doctor.

Irritation – Rare
Individuals may develop slight red swelling and irritation at the site of an injection. This most commonly occurs when someone first begins insulin therapy and usually resolves over time. If the itching is troublesome, notify your health care provider.

Raised white bump - Common
This may indicate that, while successful, your administration did not penetrate sufficiently into your skin. If this happens, practice your administration technique.
If you require a relatively large amount of insulin, it may be worth splitting your dose; E.g. 2 doses of 25 units each instead of 50 units at once.

Possible InsuJet™ Side effects

Intramuscular (IM) injection - Uncommon
The InsuJet™ is intended for the delivery of insulin to the subcutaneous layer of the skin. Accidental intramuscular injection, may occur at injection sites without fat, causing the insulin to be injected in the muscle instead. Intramuscular injections may considerably increase the variability of insulin absorption and may impair glycemic control in insulin-dependent diabetic patient.

Uncomfortable administration - Common
Similar to administration with a needle, an uncomfortable administration can occur if you administer insulin close to a nerve ending. This cannot be foreseen, although some people may find that particular areas are more sensitive and should be avoided. Note: Administration of cold insulin can be painful. Remove the insulin from the refrigerator some time before administration.

Scar-tissue / skin hardening - Common
Rotating your injection sites is crucial in preventing the build-up of scar tissue. If you inject into the same area of your body over and over every day, your body will build-up a harder fibrous tissue every time it heals from the injury of that injection.
Over time that build-up of scar tissue may interfere with your body's ability to properly absorb the insulin you injected.
By making an effort to inject in different areas of the body (thigh, belly, back of the arm, buttocks, etc.) and different parts of each area (upper thigh vs. lower thigh, etc.) you can prevent the rapid build-up of scar tissue.

Possible side effects of insulin injection
Insulin side effects amongst diabetics are rare, but when they occur, allergic reactions can be severe and pose a significant risk to health.
Always read the patient information leaflet of your prescribed insulin. The possible side effects are listed in this leaflet.
If you are in doubt, contact your Diabetes Care Specialist for medical advice about the side effects of insulin injection.

Hyperglycemia / Hypoglycemia - Common
Hyperglycemia, or high blood sugar is a condition in which an excessive amount of glucose circulates in the blood.
Hypoglycemia, also known as low blood sugar, is when blood sugar decreases to below normal levels. Too much insulin can lead to Hypoglycemia. Too little insulin may result in Hyperglycemia.
Refer to the drug safety information or consult your diabetes care specialist for more information on how to recognize symptoms of hyperglycemia and hypoglycemia and how to maintain normal blood glucose levels.

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Clinical summary

For diabetes management, the application of insulin by the InsuJet™ results in a complete administration of medicinal product in the subcutaneous layer. Tolerability, total insulin absorption, total insulin action and total blood glucose lowering effect are equivalent to conventional needle injections.

Injections by the InsuJet results in a complete administration of medicinal product in the subcutaneous layer and a faster uptake and thus an earlier pharmacologic effect.

Due to the faster absorption of insulin an (semi) endogenous pharmacokinetic insulin profile is created. A low and delayed peak of insulin could lead to hyperglycaemia while eating and to hypoglycaemia shortly after the meal due to remaining high systemic insulin concentration.

More suitable for the treatment of patients with needle-phobia, or patients who wish to administer insulin without needle

Needle phobia is common, many patients with diabetes perceive insulin injections as painful or experience some form of anxiety with injections[1], the presence of which is strongly associated with nonadherence and poorer glycemic. The absence of the needle in the InsuJet may in the treatment of patients with needle-phobia. This is supported by Post Market Surveys, where 91% of the users is choosing the InsuJet as a treatment method out of fear for needles.

More rapid insulin absorption with faster time to maximum insulin concentration and faster offset of action.

Subcutaneous (SC) administration of multiple daily insulin injections is effective for achieving tight glycemic control but is associated with some limitations. Current rapid insulin analogs when administered subcutaneously do not replicate the normal pancreatic response and are often associated with immediate postprandial hyperglycaemia and delayed post-meal hypoglycaemia.

This is mainly due to slower onset and offset of action of subcutaneously absorbed insulin. Faster insulin action to mimic endogenous insulin physiology is therefore desired to minimize postprandial glycaemic excursions.
Faster insulin action using the InsuJet is reported in varies clinical investigations of the InsuJet[2,3].

Reduce obesity dependent insulin absorption variability

For achieving tight glycemic control (especially postprandial), it is important that insulin absorption is stable, and does not depend on factors such as patient obesity.
Obesity has been reported to be associated with delayed insulin absorption[4]. Injection with the InsuJet does not result in obesity dependent absorption variability as observed with needle injections[5].

Reduce the risk of needle stick injuries and cross contamination

The use of the InsuJet™ reduces the risk of needle-stick injuries and cross contamination for patients and health care providers.
The absence of needle sharp that can impose biological hazards to the patient, caregivers, healthcare providers and others in the direct environment or involved in the disposal of the contaminated needles is a meaningful benefit.

Reduce the risk of intramuscular injections.

The InsuJet targets the subcutaneous tissue just below the dermis reducing the chance of intramuscular injection. Patients wish to avoid intramuscular injections, as they considerably increase the variability of insulin absorption and may impair glycemic control in insulin-dependent diabetic patients[6].
For conventional insulin therapy, accidental intramuscular (IM) injections are very common, and can be caused by incorrect injection technique, low fat percentage and incorrect needle length.

Improved early postprandial glucose control

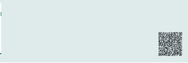
The overview summarizes the various clinical investigations conducted with the InsuJet device, both on healthy volunteers as well as diabetic patients, to support the above clinical claims. Links to the studies are provided, and the studies have been published in credible journals, meaning that they have been peer reviewed.

The studies show that the application of insulin by the InsuJet results in a complete administration of medicinal product into the subcutaneous layer. The effects on postprandial glucose levels, insulin absorption, tolerability, are similar to better following administration of insulin by InsuJet compared with conventional needle injection. The varies studies also show that many patients would prefer the device if they were asked to choose.

Insulin administered by needle-free jet injection corrects marked hyperglycaemia faster in overweight or obese patients with diabetes

Adult, overweight or obese (BMI ≥25 and ≤40 kg/m2) patients with type 1 diabetes (n=10) or insulin-treated type 2 diabetes (n=10) were enrolled in a randomized, controlled, crossover study. On two separate occasions, patients were instructed to reduce insulin dose(s) to achieve marked hyperglycaemia (18–23 mmol/l). Subsequently, insulin aspart was administered either by jet injection or by conventional pen, in a dose based on estimated individual insulin sensitivity. Pharmacodynamic and pharmacokinetic profiles were derived from plasma glucose and insulin levels, measured for 6 h after injection.

It was concluded that administration of rapid-acting insulin by jet injection results in faster correction of marked hyperglycaemia in overweight or obese patients with insulin-requiring diabetes.

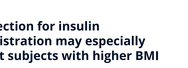


Improved Early Postprandial Glucose Control

Clamp studies have shown that the absorption and action of rapid-acting insulin are faster with injection by a jet injector than with administration by conventional pen. To determine whether these pharmacokinetic changes also exist in patients with diabetes and benefit postprandial glucose control, a comparison was made of the pharmacologic profiles of insulin administration by jet injection versus conventional insulin pen, after a standardized meal in patients with type 1 or type 2 diabetes.

Results showed that insulin administration by jet injection resulted in shorter time until peak plasma insulin level and reduced hyperglycemic burden during the first hour compared with conventional administration. Jet injection did not, however, significantly reduce the hyperglycemic burden during the 5-h period thereafter. There was no indication that the jet injector performed differently in patients with type 1 and type 2 diabetes.

It was concluded that the considerably more rapid insulin absorption after administration by jet injector translated to a significant if modest decrease in postprandial hyperglycemia in patients with type 1 and type 2 diabetes. The improved early postprandial glucose control may specifically benefit patients who have difficulty in limiting postprandial glucose excursions.



Jet injection for insulin administration may especially benefit subjects with higher BMI

In a euglycaemic glucose clamp study with healthy volunteers it was showed that using jet injectors, rather than conventional pens, significantly improved the time-action profiles of rapid-acting insulin analogs. Here, it was investigated whether such profiles were modified by body mass index (BMI) and related weight parameters by comparing insulin administration by jet injection to that by conventional pen in subgroups defined by BMI, waist-to-hip ratio, waist circumference and insulin dose.

After conventional administration, times to peak insulin levels (T-INSmax) occurred 31.1 [95% confidence interval (CI) 13.7–48.5] minutes later and time to maximum glucose requirement (T-GIRmax) 56.9 (95%CI 26.6–87.3) minutes later in more obese (BMI > 23.6 kg/m2) than in lean subjects (BMI < 23.6 kg/m2). In contrast, T-INSmax and T-GIRmax were similar in subjects with high and low BMI, when insulin was administered by jet injection.

It was concluded that using jet injection for insulin administration may especially benefit subjects with higher body weight.

Jet injection advances the pharmacodynamics of regular insulin to that of an analogue

Rapid-acting insulin analogues are generally preferred over regular human insulin because of their more immediate onset of action and shorter time-action profile. However, these analogues may not always be tolerated by or universally available for people with insulin-requiring diabetes. Jet injection has been demonstrated to facilitate faster insulin absorption. We determined whether administration of regular human insulin by jet injection achieves the same pharmacological properties as that of a rapid-acting insulin analogue in 20 healthy volunteers.

Regular human insulin by jet injection had a faster onset of glucose-lowering effect compared to aspart by conventional pen (T-GIR50%, 30.8 ± 2.9 versus 43.1 ± 3.2 min, P < 0.01). There were no differences in time to maximal GIR (106.1 ± 11.9 versus 95.8 ± 9.2 min, P = 0.50), maximal GIR (8.6 ± 0.7 versus 7.7 ± 0.7 mg/kg/min, P = 0.0.33), total glucose-lowering effect (101.0 ± 9.8 versus 87.6 ± 7.0 g, P = 0.28), and time until 50% of glucose disposal (144.8 ± 5.6 versus 151.3 ± 5.1 min, P = 0.39).

Jet-injected regular human insulin had a pharmacological profile that was essentially not dissimilar from that of aspart insulin administered by conventional pen, and can therefore be used as an alternative for conventionally administered rapid-acting insulin analogues and may help to achieve better meal insulin coverage and correction of postprandial glucose excursions.

Needle-Free Jet Injection Technology improves Pharmacokinetic and Pharmacodynamic Profile of Rapid-Acting Insulin

InsuJet™ 's clinical trials, performed by a renowned Dutch academic hospital, were performed to compare the pharmacologic profile of administration of insulin aspart by jet injection to that by conventional insulin pen.

Results showed that the time to maximal GIR was significantly shorter when insulin was injected with the jet injector, compared with conventional pen administration. The time to peak insulin concentration was similarly reduced and peak insulin concentrations were increased. Jet injector insulin administration reduced the time to 50% glucose disposal. No differences were measured in maximal GIR, total insulin absorption, or total insulin action between the two devices.

Conclusions were drawn that administration of insulin aspart by jet injection enhances insulin absorption and reduces the duration of glucose-lowering action. This profile resembles more closely the pattern of endogenous insulin secretion and may help to achieve better meal insulin coverage and correction of postprandial glucose excursions.

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References:

1. Peyrot M, Rubin RR. Levels and risks of depression and anxiety symptomatology among diabetic adults. Diabetes Care 1997; 20:585–590

2. Improved pharmacokinetic and Pharmacodynamic profile of rapid-acting insulin using needle-free injection technology. E.E.C Engwerda, E.J. Abbink, C.J. Tack, B.E. de Galan. Diabetes Care Publish Ahead of Print, published online June 29, 2011

3. Needle-Free Jet Injection of Rapid-Acting Insulin Improves Early Postprandial Glucose Control in Patients With Diabetes technology. E.E.C Engwerda, E.J. Abbink, C.J. Tack, B.E. de Galan. Diabetes Care Publish Ahead of Print, published online October 2, 2013

4. Factors Affecting the Absorption of Subcutaneously Administered Insulin: Effect on Variability", Journal of Diabetes Research, vol. 2018, Article ID 1205121

5. Insulin administered by needle-free jet injection corrects marked hyperglycaemia faster in overweight or obese patients with diabetes. Helana M. de Wit, Elsemiek E.C. Engwerda, Cees J. Tack, B.E.de Galan, Diabetes, Obesity and Metabolism 2015

6. Diabetes Care 1988 Jan; 11(1): 41-45

InsuJet™

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Post Market Surveillance (PMS) summary

InsuJet™ market history

Previous versions of the InsuJet™ have been test marketed in various countries in Europe and Asia. Post Market Surveillance data was gathered to evaluate the suitability of the design. This limited soft market launch allowed for critical end user feedback.

These surveys were done in countries where the devices were initially introduced; the Netherlands and the United Kingdom.

This document summarizes the data obtained from cross-sectional surveys, which provided critical real market input and the feedback was instrumental to focus on key improvement that were introduced in the latest version: the InsuJet™ V5.

The new InsuJet™ V5 is marketed since 2021, so limited Post Market data is available for this device. Instead, usability test data will be provided that validates the latest design. The usability test results are presented in the Usability Summary.

The new InsuJet™ V5 injector

InsuJet™ user survey feedback and key findings

InsuJet™ has and continues to run a multi-year survey study for InsuJet™ end-users. The surveys confirm the suitability of the InsuJet™ and its labeling information for its target groups. Around a 100 end-users participated in 4 cross-sectional surveys, conducted globally with the majority coming from The Netherlands and The United Kingdom.

Besides survey data, this document will summarize the data obtained through complaint handling.

Key findings are separated into categories below:
(i) End-users demographics,
(ii) Types of insulin commonly used by the InsuJet™ test groups,
(iii) The ease of use of the InsuJet™ Injector and consumables,
(iv) Interesting study findings, and
(v) Overall usability and preference

(i) End-user demographics

The survey study's initial results show that the end-users predominantly are 40 to 70 years old and 62% male. The vast majority (83%) had type-2 diabetes, where they contracted diabetes later in life.

End-users age:

15-80

The InsuJet™ is also approved for pediatric use, however, in historical end-user surveys, no children younger than 15 years old participated. To close this gap, in 2022 a Post Market Clinical Follow up study is started, specifically into this target group, as the InsuJet™ is used in different markets for pediatrics. Results are pending, but will be added to this document by late 2022.

At 91%, the most significant driver to look for an alternative for their insulin treatments is a fear of needles[1].

91%

Solution for fear of needles

44% of the end-users are patients actively looking and informing their medical professionals for an alternative to needle insulin therapy[2]. 80% of the participants must administer insulin multiple times a day[3].

(ii) Types of insulin commonly used by the InsuJet™ end-users

Many types of insulins are used in combination with the InsuJet™, include rapid acting, regular insulins and long-acting insulins. It was noticeable that the type of insulin most commonly used was the long-acting insulin, at 42%[4].

42%

Use long-acting insulin

Many patients administer a mixture of rapid/short-acting and long-acting insulin.

(iii) The ease of use of the InsuJet™ Injector and consumables

Overall, over 81%[5] of participants find the InsuJet™ Injector and consumables simple to use from the first time.

81%

No problems using InsuJet™

Suitability for lay users

Although the survey shows that participants would like to have a introduction/training from a medical professional, most participants did not have any introduction, but were able to use the device without problems with the instructions for use provided.

The end-users stated that the InsuJet™ Injector manual as very clear, with over 75% immediately understanding what to do[6].

When using the system and drawing the insulin from various cartridges or vials, the clear display for the number of insulin units you draw feels more controlled and is seen as very easy by the majority of the end-users.

Ease of use of consumables

The consumables are divided into the InsuJet™ Nozzle and the InsuJet™ Adaptors. The InsuJet™ Nozzle is seen to be very easy to use and reuse. Where 88% of the end-users found it convenient to, and sanitary to change the InsuJet™ Nozzle every 1 to 2 weeks after use[7]. Changing of consumables including installing adaptor for each new cartridge or vial of insulin is seen as easy by over 79%[8].

(iv) Interesting findings regarding the InsuJet™

One of the benefits of the InsuJet™ reported in clinical investigations is faster insulin absorption and onset of insulin action. In the survey, 70% of the users reported that they noticed faster insulin absorption[9].

70%

Noticed faster absorption

One of the findings in the survey is that 40%[10] reported using less insulin with the InsuJet™ compared to their previous insulin administration system.

40%

Reported using less insulin

Although currently not supported by data from clinical investigations, this could potentially be an important benefit of the InsuJet™. However, clinical investigations performed did not study the long term benefits using InsuJet™, but this finding could be an important target for long term Post Market Clinical Follow up.

(v) Overall usability and preference

96% of the respondents found the InsuJet™ pleasant, user friendly or mostly and efficient method[11], and over 78% would recommend the InsuJet™ systems to others[12].

78%

Would recommend InsuJet™

Several suggestions were provided on how to further improve the device, summarized in the chapter "InsuJet PMS follow-up"

InsuJet™ PMS follow-up

The data obtained from the surveys applies to previous models of the InsuJet™, which have been marketed in the past. Feedback about improvement areas of the device provided[13] invaluable input to design & development to improve device performance, functionality and usability. Several items of improvements were identified:

1) Reducing the occurrence of wet injections
2) Reducing the winding torque required to charge the injector
3) Improving the visibility of the dose indication
4) Improving the user interface of the injector
5) Reducing the weight of the Injector

The follow up on each of these items is further explained in the Usability Summary document.

The results of future PMS studies performed for the InsuJet™ V5 will be added to this document.

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References:
(1) Post Market Surveillance Appendix 1 - Question-05
(2) Post Market Surveillance Appendix 1 - Question-08
(3) Post Market Surveillance Appendix 2 - Question-18
(4) Post Market Surveillance Appendix 2 - Question-17
(5) Post Market Surveillance Appendix 1 - Question-11
(6) Post Market Surveillance Appendix 1 - Question-10
(7) Post Market Surveillance Appendix 3 - Question-29
(8) Post Market Surveillance Appendix 3 - Question-33
(9) Post Market Surveillance Appendix 4 - Question-47
(10) Post Market Surveillance Appendix 4 - Question-46
(11) Post Market Surveillance Appendix 4 - Question-45
(12) Post Market Surveillance Appendix 5 - Question-49
(13) Post Market Surveillance Appendix 5 - Question-50

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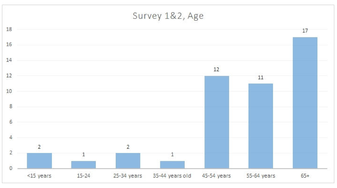
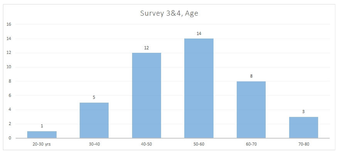
Post Market Surveillance Appendix 1



Question-01



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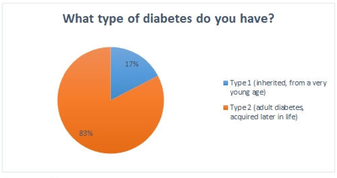

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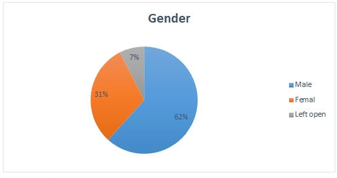
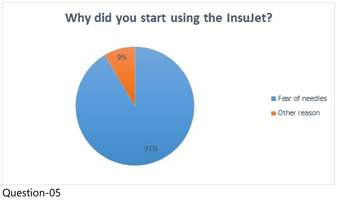
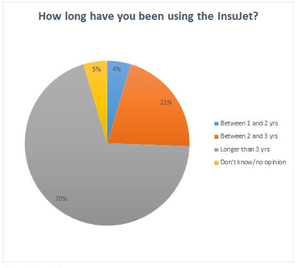


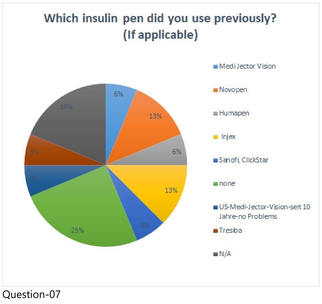
Question-04



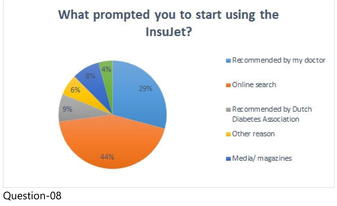
Question-05



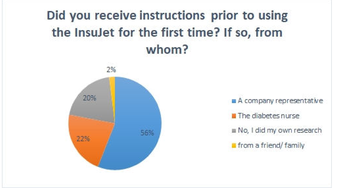
Question-06



Question-07



Question-08



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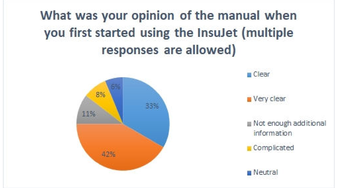

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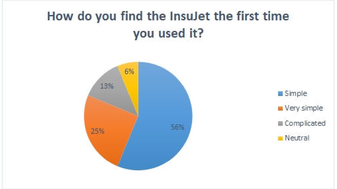
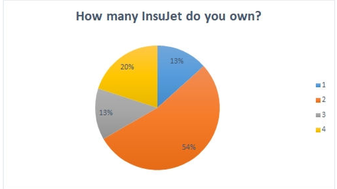
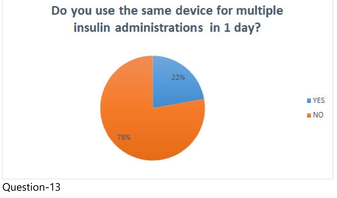


Question-11



Question-12



Question-13

nuGen MEDICAL DEVICES

InsuJet™

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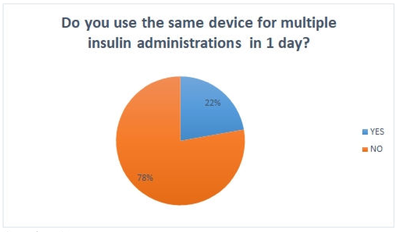
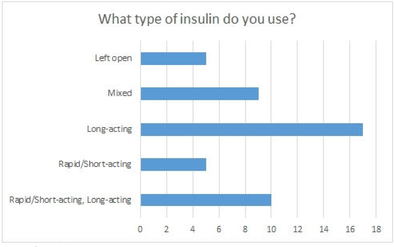
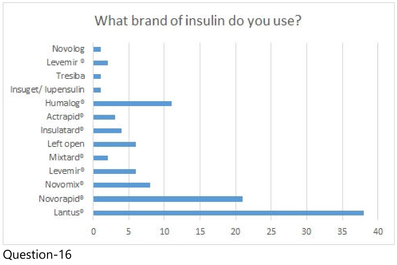
Post Market Surveillance Appendix 2



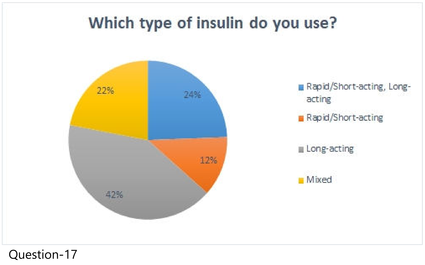
Question-14



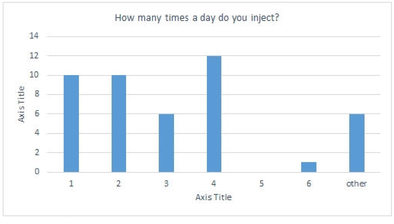
Question-15



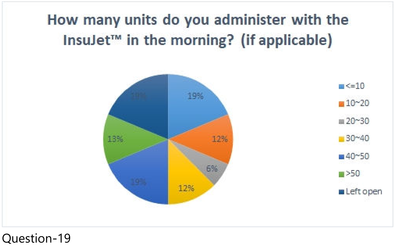
Question-16



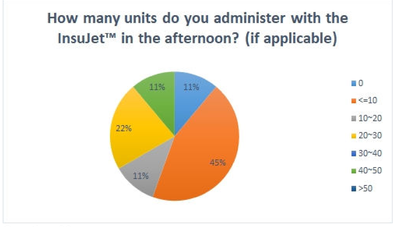
Question-17



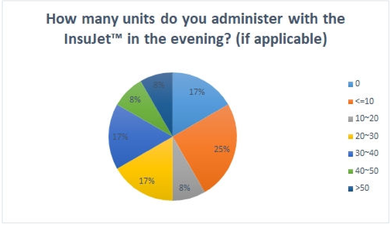
Question-18



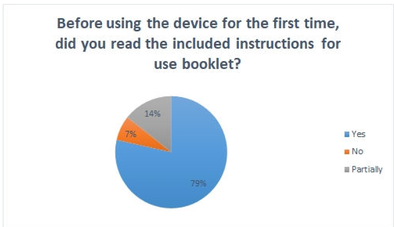
Question-19



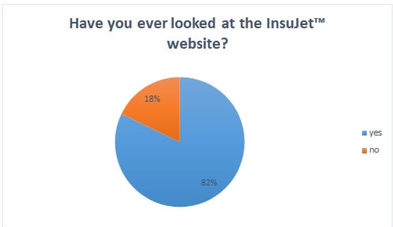
Question-20



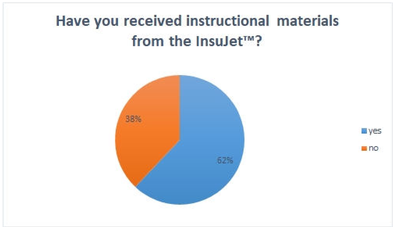
Question-21



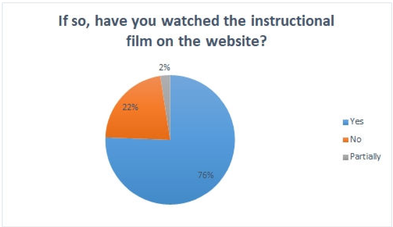
Question-22



Question-23



Question-24



Question-25

nuGen MEDICAL DEVICES

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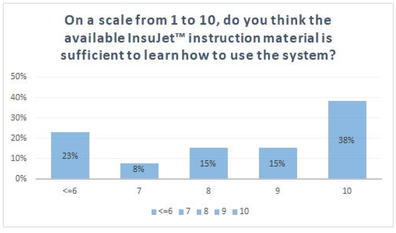
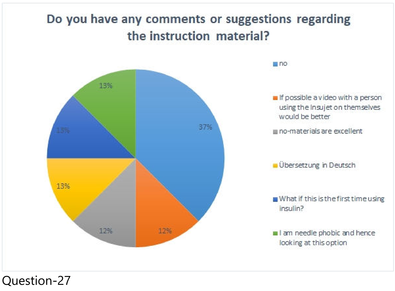
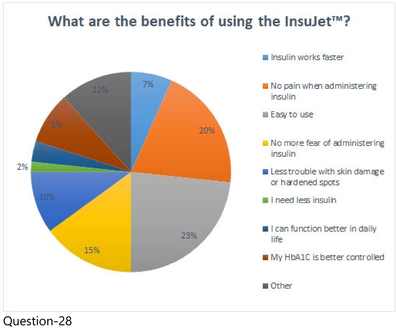
Post Market Surveillance Appendix 3



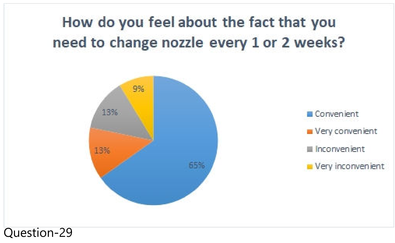
Question-26



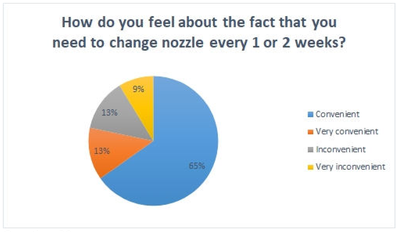
Question-27



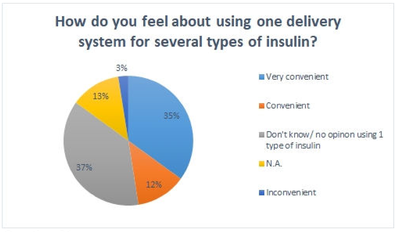
Question-28



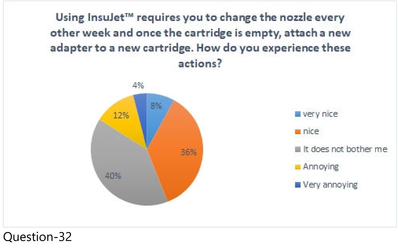
Question-29



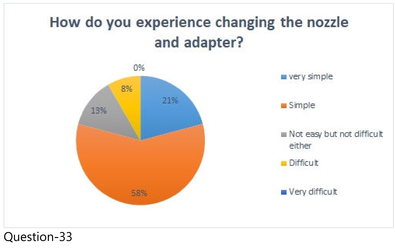
Question-30



Question-31



Question-32



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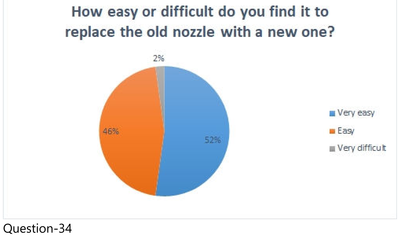
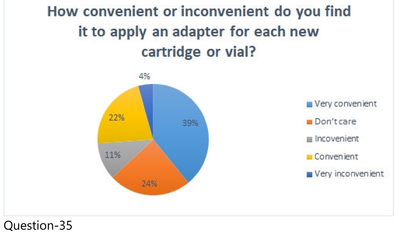
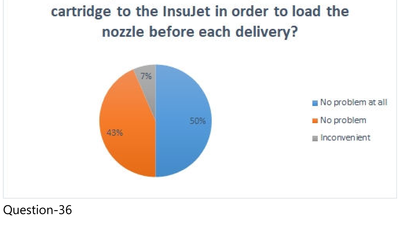


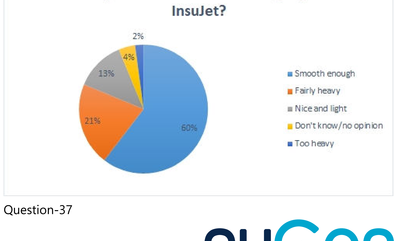
Question-34



Question-35



Question-36



Question-37

nuGen MEDICAL DEVICES

InsuJet™

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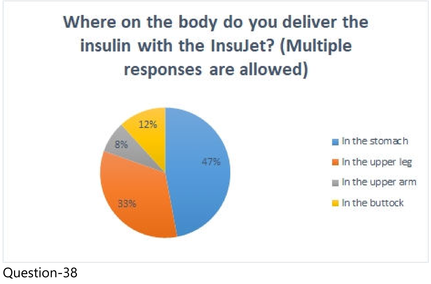
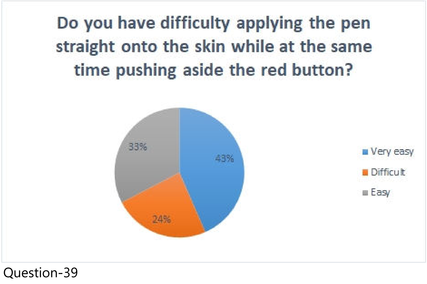
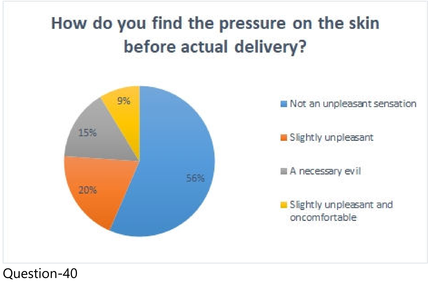


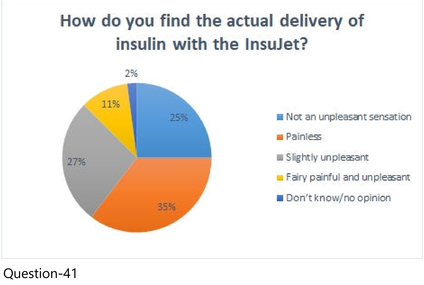
Question-38



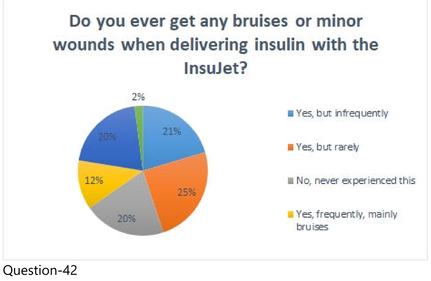
Question-39



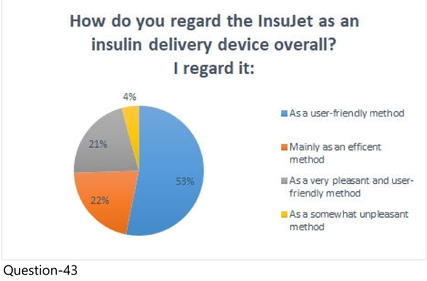
Question-40



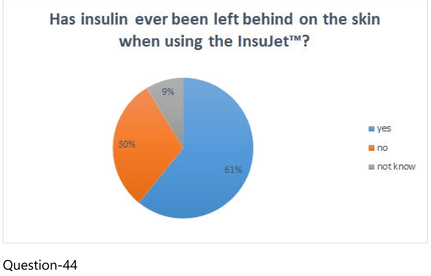
Question-41



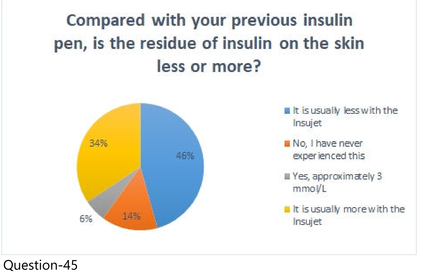
Question-42



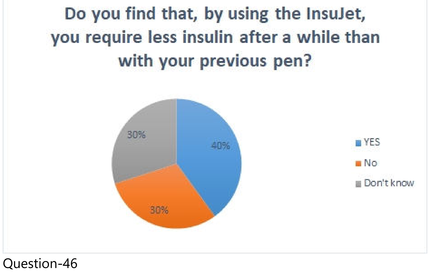
Question-43



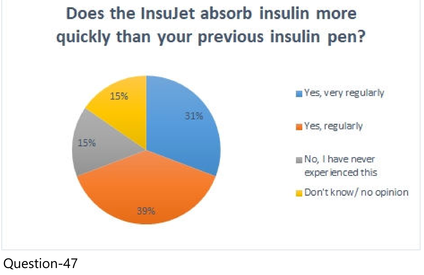
Question-44



Question-45



Question-46



Question-47

nuGen MEDICAL DEVICES

InsuJet™

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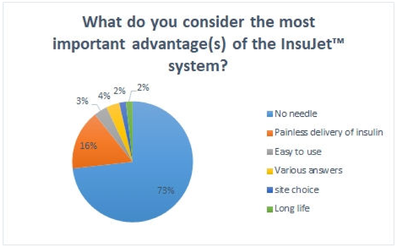
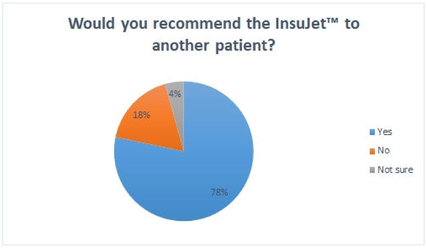
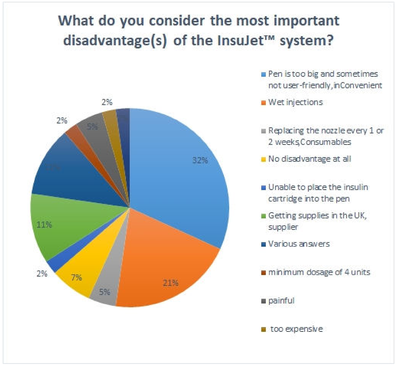


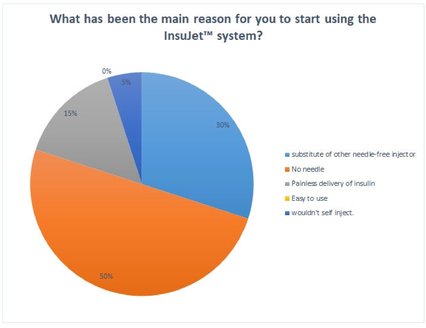
Question-48



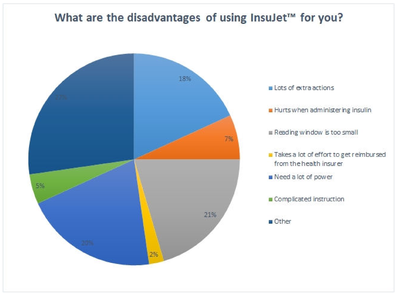
Question-49



Question-50



Question-51



Question-52

nuGen MEDICAL DEVICES

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.

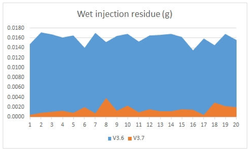
The results

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.

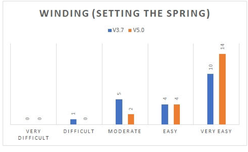
90%
Reduction of residue

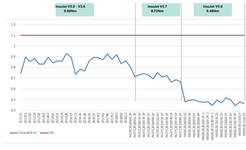


2) High winding torque

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.

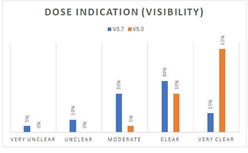
Before
70%
Easy to very easy to wind

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

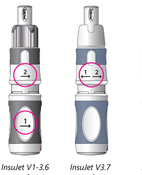
Before
55%
Clear to very clear

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.



InsuJet V1-3.6 Interface *InsuJet V3.7 Interface* *InsuJet V5 Interface*

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

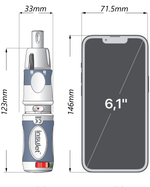
5) Heavy injector

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

InsuJet™

Inject Needle-Free

FAQs on insulin compatibility

InsuJet™ compatibility

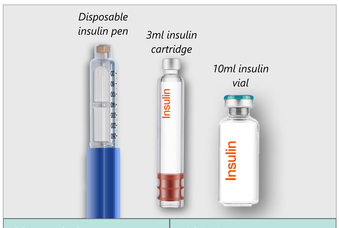
The InsuJet™ device is calibrated for U100 insulins, and compatible with all types available on the market. As there are many different insulins; regular, rapid acting, short acting, intermediates, long acting and premixed, we are often asked whether a specific insulin can be used with the device.

We support the compatibility of the device with all U100 insulins based on 3 different types of data (i) Efficacy data from clinical investigations, (ii) Integrity testing of various types of insulin propelled by the InsuJet™, and (iii) Literature from comparable devices.

Not only are there different types of insulin, there are also different types of insulin primary packaging, such as insulin cartridges (3ml), insulin vials (10ml) and disposable insulin pens. The InsuJet™ comes with Adaptors that ensures compatibly with all these packaging variations.

Suitable for all U100 insulins and its primary packagings.

InsuJet™ Adaptors



Primary packaging	Adaptor type
3ml insulin cartridge	InsuJet™ 3ml Adaptor
Disposable insulin pen	InsuJet™ 3ml Adaptor
10ml insulin vial	InsuJet™ 10ml Adaptor

An InsuJet™ adaptor for every primary packaging

The InsuJet does not come with insulin. Any patient's prescribed insulin can be used in combination with the InsuJet™ device.
To allow the device's compatibility with different insulin primary packagings on the market, different adaptors can be purchased. The adaptor allows insulin to be transferred from an insulin reservoir to the InsuJet™ Nozzle, prior to injection.

Key to the InsuJet™ adaptor range is its suitability for all U100 insulin cartridges, or vials standard available on the current market worldwide.

With the possibility to future-proof itself by only having to add possible additions in the InsuJet™ Adaptor range, the flexibility of the system has the potential to become a worldwide needle-free solution for insulin therapy.

Overview of Insulin and Non-Insulin Delivery Devices in the Treatment of Diabetes

Table 1 Pharmacokinetics of Available Insulin Preparations[a]

Insulin, Generic Name (Brand, Manufacturer)	Onset	Peak	Effective Duration
Rapid-acting			
Insulin aspart injection (Novolog, Novo Nordisk)	5–15 minutes	30–90 minutes	< 5 hours
Insulin lispro injection (Humalog, Lilly)	5–15 minutes	30–90 minutes	< 5 hours
Insulin glulisine injection (Apidra, Sanofi-Aventis)	5–15 minutes	30–90 minutes	< 5 hours
Short-acting			
Regular	30–60 minutes	2–3 hours	5–8 hours
Intermediate, basal			
Neutral protamine Hagedorn insulin	2–4 hours	4–10 hours	10–16 hours
Long-acting, basal			
Insulin glargine injection (Lantus, Sanofi-Aventis)	2–4 hours	No peak	20–24 hours
Insulin detemir injection (Levemir, Novo Nordisk)	3–8 hours	No peak	6–23 hours
Premixed			
75% insulin lispro protamine suspension/25% insulin lispro injection (Humalog Mix 75/25)	5–15 minutes	Dual	10–16 hours
50% insulin lispro protamine suspension/50% insulin lispro injection (Humalog Mix 50/50)	5–15 minutes	Dual	10–16 hours
70% insulin aspart protamine suspension/30% insulin aspart injection (Novolog Mix 70/30)	5–15 minutes	Dual	10–16 hours
70% neutral protamine Hagedorn insulin/30% regular	30–60 minutes	Dual	10–16 hours

Insulin compatibility data

(i) Efficacy data from clinical investigations

Multiple clinical investigations have been conducted with the InsuJet™ as is documented in the Clinical investigations chapter. In the clinical investigations, the InsuJet™ was used with:

- Insulin Aspart (NovoRapid, Novo Nordisk)
- regular human Insulin (Humalin R, Eli Lilly)

and was shown to be both safe and effective.
Refer to the clinical investigation deck for detailed information.

Needle-Free Jet Injection Technology improves Pharmacokinetic and Pharmacodynamic Profile of Rapid-Acting Insulin*

**Improved Pharmacokinetic and Pharmacodynamic Profile of Rapid-Acting Insulin Using Needle-Free Jet Injection Technology Diabetes Care, August 2011*

Jet injection advances the pharmacodynamics of regular insulin to that of an analogue**

***A comparison of the pharmacodynamic profiles of jet-injected regular human insulin versus conventionally administered insulin aspart in healthy volunteers. Diabetes Research and Clinical Practice, September 2016*

(ii) Integrity testing of various types of insulin propelled by the InsuJet™

The research by BasicPharma laboratory shows that different types of insulin remain molecular structurally intact after being propelled (injected) by the InsuJet™.

The molecular structure of insulin injected with InsuJet™ remains intact and functional.

The research included the following insulin brands:

- Insulin Lantus, Sanofi Aventis
- Insulin Levimir, Novo Nordisk
- Insulin Mumuline NHP, Eli Lilly
- Insulin Aspart, EDQM

The tests replicated extreme conditions and proved the stability and capability of the InsuJet™ medical device and its suitability for its purpose.

No degradants were measured. The limit of detection was set at approximately 0.0001% relative to the respective insulin used with testing.
The full report is available upon request.

(iii) Literature from comparable devices

The use of needle-free injection for administration of various types of insulins is well supported by clinical investigations with similar devices. Below is a literature overview of various investigations.

Many clinical investigations support liquid jet injection of insulins as a effective and safe method

Future developments will include further research into adding all U100 and other insulin therapy options to the compatibility library or InsuJet™.

Overview of insulin administration using Needle-free administration devices as reported in clinical literature.

#	Reference	Device	Insulin	Remarks
1	Comparison of jet injector and insulin pen in controlling plasma glucose and insulin concentrations in type 2 diabetic patients Guo, Lixin MD; Xiao, Xinhua MD; Sun, Xue MD; Qi, Cuijuan MD Comparison of jet injector and insulin pen in controlling plasma glucose and insulin concentrations in type 2 diabetic patients., Medicine: January 2017 - Volume 96 - Issue 1 - p e5482 doi: 10.1097/MD.0000000000005482	QS-M, QS Medical Technology; Beijing, China) and an insulin pen (NovoPen 5, Novo Nordisk, Copenhagen, Denmark	insulin, regular and insulin analog	Sixty patients with type 2 diabetes were treated with rapid-acting insulin (regular insulin) and insulin analog (insulin aspart) using the jet injector. Regular insulin and insulin aspart administration by the jet injector showed significant decreases in plasma glucose levels as compared to the pen injection ($P < 0.05$). Postprandial plasma insulin levels were markedly higher in the jet-treated patients than the pen-treated ones ($P < 0.05$).
2	Xing Y, Xie X, Xu J, et al. Efficacy and safety of a needle-free injector in Chinese patients with type 2 diabetes mellitus treated with basal insulin: a multicentre, prospective, randomised, crossover study. Expert Opin Drug Deliv. 2019;16(9):995-1002. doi:10.1080/17425247.2019.1649251 PMID: 31359813	QS-M, QS Medical Technology; Beijing, China) and an insulin pen (NovoPen 5, Novo Nordisk, Copenhagen, Denmark	Glargine insulin	The use of a needle-free injector can lower the dosage of insulin required to achieve good glycaemic control in patients with type 2 diabetes. The results of this study indicate that the benefits of a needle-free injector in the treatment of the type 2 diabetes may be superior to those of glargine pen injections, not only by reducing the adverse effects associated with high insulin dosages, but also by reducing typical adverse reactions and the fear of injections, which should help to improve patient compliance with insulin treatment
3	Comparison of Blood Sugar and Insulin Kinetics following Needle-free and Pen Injection of Insulin; M. Ehren, D. Lieber, S. Engelbert, H. Schatz, M. Pfohl, (abstracts) Diabetes and Metabolism 10.suppl. May 2001, 19-09.	Injex™	NPH insulin regular insulin	[...] compares well to the insulin pen and provides an attractive alternative to the conventional pen injection for most patients.
4	Delivery of insulin by jet injection: recent observations; D.L. Bremseth, Diabetes TechnolTher., (2001 Summer) 3(2): 225-32	Medi-Jector Vision	rapid-, regular-, intermediate and long-acting	Well accepted by people with diabetes and offers a reliable alternative to the use of needles.
5	Jet-injected Insulin Is Associated With Decreased Antibody Production and Postprandial Glucose Variability When Compared With Needle-Injected Insulin in Gestational Diabetic Women; Diabetes Care, vol 16, 11 (November 1993)	Tender Touch	Human NPH and human regular	Jet injected insulin is acceptable to GDM Women and produces less hypo- and hyperglycemia after meals. In addition, less of an immune response to insulin injected with the jet injector than with a syringe and needle has been observed.
6	Risks of jet injection of insulin in children; G.E. Theintz, P.C. Sizonenko, abstract Eur J Pediatr (1991) 150:554-556	Preci-jet-20 Preci-jet-50	rapid/intermediate-acting and long-acting	May be an alternative to syringe and needle for older children and adolescents, provided repeated detailed information and tight medical supervision is available.
7	Efficacy of a new needleless insulin delivery system monitoring of blood glucose fluctuations and free insulin levels; E.C. Katsoulis, E.K. Drosinos, G.K. Dimitriadis, D.J. Hadjidakis, P.G. Mavrokefalos, S.A. Raptis, Int J Artif Organs (1989 12) 333-8	Vitajet™	intermediate acting: Humulin NPH & Regular 70/30, Eli Lilly	Blood glucose control attained is better than with conventional injection
8	A New Insulin Jet Injector: Short and Long Term Effects on Blood Glucose, Dosage Accuracy and Patient Acceptance; F.A. Arduino, D.B. Benchimol, ArquivosBrasileiros de Medica, vol 58.1 (JanuFeb 1984)	Vitajet	Actrapid	There appears to be a strong patient preference to the jet injector. Diabetic patients achieved significantly improved blood glucose levels with the jet injector compared to conventional syringe.
9	Comparison of Plasma Insulin Profiles After Subcutaneous Administration of Insulin by Jet Spray and Conventional Needle Injection in patients With Insulin-Dependent Diabetes Mellitus; G.B. Pehling, J.E. Gerich, Mayo Clin. Proc, November 1984, Vol 59	Medi-Jector	Actrapid	Administration of insulin with a jet injector may be considered as a useful alternative to subcutaneous needle injection of insulin or pump administration of insulin in patients who prefer not to use these modes of insulin delivery or in whom these methods do not produce satisfactory glycemic control.
10	Painfulness of needle and jet injection in children with diabetes mellitus; U. Schneider, R. Brimbacher, E. Schober, Eur.J.Pediatr (1994) 153:409-410	Vitajet II U 40	N.A.	There seems to be no advantage in using this device in the treatment of diabetic children.
11	Plasma Free Insulin Profiles After Administration of Insulin by Jet and Conventional Syringe Injection; R. Taylor, P.H. Home, K.G.M.M. Alberti, Diabetes Care 4: 377-379, (May-June, 1981)	Med-E-Jet	Actrapid	Jet administration results in more rapid absorption of insulin and could be useful in providing a more physiological postprandial insulin profile.
12	Jet injection of insulin: comparison with conventional injection by syringe and needle; R. Worth, J. Anderson, R. Taylor, K.G.M.M. Alberti, Br.Med.J. 1980 v281 713-714	Med-E-Jet	short-acting and intermediate-acting	
13	Evaluation of the insulin jet injector as a potential source of infection."; Price JP, Kruger DF, Sarwinski LD, Whitehouse FW, Department of Internal Medicine, Henry Ford Hospital, Detroit, MI 48202, Oct 17, 1989	Medi-Jector-II jet injector	Insulin	This study demonstrates that in 14 days repeated administration of insulin by needle-free application, no study patient showed any clinical evidence of infection attributable to needle-free injections.

nuGen MEDICAL DEVICES

insuJet™

Inject Needle-Free

Cost analysis - North America

The cost of insulin therapy

The cost of insulin therapy varies greatly per country.
We devised a model to calculate the costs of insulin therapy with clear assumptions for different global markets.

The resulting model allows for a comparison between the costs of the InsuJet™ vs conventional treatment methods and utilizes norms for specific geographical markets.

Regional Diabetic Metrics:
Insulin Use: 50 IU/day [1,2] Exploited (body weight x IU/kg)
Adult: TDD of insulin usually ranges from 0.3 IU/kg to 0.6 IU/kg[2]
Adult body weight: ~ 81kg body weight
Injections: 4/day[3]

Syringe Pricing (USD)
Hospital Safety Syringe Pricing (considering pricing from 3 representative sources)
McKesson, Monoject, & Magellan: $0.35/safety syringe
Note: Price in USD, not reflecting volume discounts

NuGen MD Retail List Price Effective Dec 2021 (USD)
InsuJet™ V5 Injector: $260
InsuJet™ Nozzle: $6.00
InsuJet™ 10 mL Adaptor: $4.70

The above pricing, results in the below monthly costs of therapy as compared to safety syringes:

	Safety syringe	InsuJet™
Starting costs	-	$ 260.00
Monthly costs	$ 42.00*	$ 19.05

The results

Figure 1.0: Based on the above prices and diabetic norms the following extrapolations demonstrates the potential market value proposition for end-users or buying groups over the lifetime of a needle-free device (5000 uses) compared to 3 years of safety syringe use.

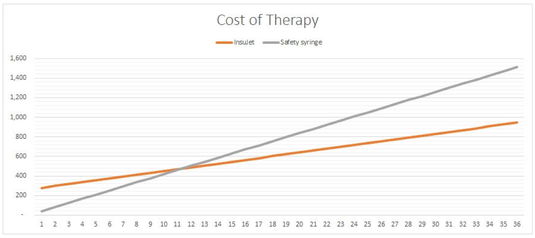


***Figure 1.0**. InsuJet™ Breakthrough Cost Savings for an Individual Diabetic patient/Lifetime of Device, Canada, not including insulin cost*

The higher onset costs of the InsuJet™ are offset by a much lower slope which is the result of lower monthly cost of therapy ($42/ month for the safety syringe vs $19/month for the needle free device).

Monthly costs:

$42/month
Safety Syringe

$19/month
InsuJet™

Breakeven point cost savings ~ 11.3 months*

**These prices are reflective only of our current price list and do not necessarily reflect the price point of distributors in this given area in the future. $260.00/($42.00 - $19.05) = 11.3*

These significant cost savings are the result of a reduction in the use of disposables. The InsuJet™ Nozzle lasts for 14 days or 56 uses, while the InsuJet™ Adaptor lasts for the lifetime of the insulin vial. This greatly reduces sharps waste and reduces costs.

120 Needle Sharps /month
Safety Syringe

2 Nozzles & **1.5** Adaptors /month
InsuJet™

In 3 years (device lifetime) each individual will save $556 using the assumptions given. For every 1000 devices sold, it is estimated to be approximately $556,000 every 3 years, as related to total costs using a safety syringe to the individual, stake holders, NGOs, and governmental agencies.

Saving per individual per lifetime of device (3 yrs):

$556

When considering the total insulin dependent diabetic population for various countries, potential cost savings given a certain market penetration can be estimated. Working with a conservative market penetration rate of only 1%, the following numbers can be achieved for the USA and Canada (Table 1.0 and 2.0) .

Country information	
Country	Canada
Population [4]	37,742,154
Diabetics prevelance [5]	8
Diabetic patients	2,868,404
Insulin users [6]	553,602
1% of Insulin Users	5,536

Country information	
Country	United States
Population [4]	331,002,651
Diabetics prevelance [5]	11
Diabetic patients	35,748,286
Insulin users [6]	6,899,419
1% of Insulin Users	68,994

***Table 2.0** Country estimated insulin dependent population*

	1) Number of needle sharps eliminated based on 1% of the market	2) Total reduction in cost of therapy based on 1% of the market
USA	100,731,521	$ 39,064,512
Canada	8,082,588	$ 3,134,494

***Table 3.0** Saving Value Proposition based on model assumptions*
1) Total projected environmental sharps waste stream reduction of needle sharps/year (assuming 4 injections per day)
2) InsuJet™ positive economic impact by total savings per lifetime of device

Sharps waste management

When estimating cost of therapy, the cost of needle sharp waste management should be considered. The precise cost of needle sharp management per individual syringe is difficult to obtain, as multiple actors may be involved, but a reference in tied to handling and waste management across the US, defines an estimate range of $1.0 to $3.0 per syringe. For this model we selected $1.0 per syringe. This important overlooked metric will significantly increase the overall cost of use of syringes and increase the total environmental impact of conventional therapy.

Including the cost of sharps waste management into the cost of therapy.

	Safety syringe	InsuJet™
Starting costs	-	$ 260.00
Monthly costs	$ 162.00*	$ 19.05**

***Table 4.0** Price assumptions, use of 10ml insulin vial.*
** 4 x daily injection 30 days x ($0.35 + $1.0 sharps waste management costs)*
*** 2 x InsuJet™ Nozzle ($6.00) + 1.5 x InsuJet™ 10ml Adaptor ($4.70)*

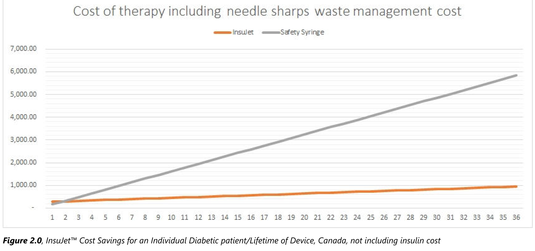


***Figure 2.0**. InsuJet™ Cost Savings for an Individual Diabetic patient/Lifetime of Device, Canada, not including insulin cost*

Monthly costs:

$162/month
Safety Syringe

$19/month
InsuJet™

Breakeven point cost savings ~ 1.8 months*

Saving per individual per lifetime of device (3 yrs):

$ 4,886

*These prices are reflective only of our current suggest price list and do not necessary reflect the price point of distributors in this given area in the future. $260.00/($162.00 - $19.05) = 1.8

	1) Number of needle sharps eliminated based on 1% of the market	2) Total reduction in cost of therapy based on 1% of the market
USA	100,731,521	$ 337,119,424
Canada	8,082,588	$ 27,050,097

***Table 5.0** Saving Value Proposition based on model assumptions including needle sharps waste management cost*
1) Total projected environmental sharps waste reduction of needle sharps/year (assuming 4 injections per day)
2) InsuJet™ positive economic impact by total savings per lifetime of device

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References:
1. Clin Interv Aging. 2006 Jun; 1(2): 107–113.
2. https://en.wikipedia.org/wiki/Human_body_weight
3. InsuJet Post Market Surveillance Survey data
4. https://www.worldometers.info/world-population/population-by-country/
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6. https://haiweb.org/wp-content/uploads/2019/07/Estimate-of-Insulin-Use-in-Type-2-Diabetes.pdf