

Application bulletin | Medical devices

innomatec collaborates with leader in diabetes management devices, Inreda, designing a multi-step leak test process for a complex medical assembly

Drug delivery pumps have transformed the management of chronic medical conditions, offering a convenient and precise way to administer medications. **Inreda Diabetic B.V.** is a manufacturer of these pumps, based in the Netherlands, transforming the way people with diabetes live their lives.

The company's flagship product, the **Inreda AP® (artificial pancreas) device** is a fully automated, bi-hormonal fully closed loop system, designed to continuously monitor glucose levels and automatically regulate insulin and glucagon delivery for people with diabetes type 1. By mimicking the body's natural processes, the Inreda AP® reduces the burden and simplifies diabetes management, providing users with more freedom, stability, and peace of mind.

The device is revolutionizing diabetes management. The Inreda AP® is currently participating in a large multicenter clinical trial in the Netherlands, with the goal of the device being deemed entitled for reimbursement by basic health insurance packages (decision expected in 2026).

Inreda®

When developing their latest medical device, **Inreda put their trust in innomatec.** Not only did they require an accurate, reliable leak test, but the solution had to be able to scale with projected market growth.



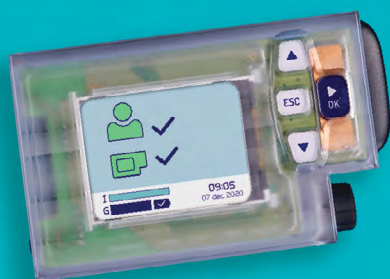
Inreda AP® device



LTC-802

Harnessing the flexibility and performance of the LTC-802 leak tester, innomatec designed a solution that set their team up for success.

CE 0344
MDR certified



AP[®]5
Used in
projects and studies



AP[®]6
In development

Previously a study with the Inreda AP[®]5 was published in [The Lancet Digital Health](#) in March 2024, in which 79 people with diabetes type 1 were followed during their first year of treatment with the bi-hormonal system. The study reported a significantly improved quality of life, the diabetes burden decreased from 30.0 to 10.0 (assessed with the PAID “Problem Areas in Diabetes” questionnaire). The primary metric used to assess diabetes control was the time in range (TIR; glucose concentration 3.9–10.0 mmol/L). This also presented an impressive result after the first year; the mean TIR increased from 55.5% to 80.3%.

As Inreda began the development of their latest model, the AP[®]6, they turned to innomatec to develop a new leak test system to ensure the highest product quality and a process that would meet IPX8 specifications, allowing users to safely wear their devices in environments with water, etc.

This process began with designing a leak test for a one-drug delivery pump, in preparation for the development of a leak test process for the upcoming AP[®]6, which will need to accommodate substantially higher production volumes. Given the nature of the application, achieving an accurate, reliable leak test was of the utmost importance, but the design also needed to be operator-friendly, and can meet scaled production goals in years following the launch.

Designing a multi-step leak test process for a complex medical assembly using innomatec's LTC-802 leak tester

To ensure reliable product quality in the field, each step of drug delivery pump assembly needed to be leak tested, requiring a complex, multi-step leak test process. Built for manual assembly, the leak test station was designed to ensure an efficient and repeatable manufacturing process. First, the components of the assembly would be leak tested to ensure quality, followed by each step of the manual assembly process. After each phase of the assembly process that had the potential to create a new leak path, the operator would place the unit into a test chamber for leak testing run by two LTC-802 leak tester models.

Special adjustments were made to make the leak test procedures as operator-friendly as possible, selecting fixturing options that would reduce the operation force with manual tooling. The whole solution, detailed below, was designed to keep the test process as fast and efficient as possible while maintaining the utmost leak measurement accuracy.

Two types of leak testing methods are being used:

1. Pressure decay test

Testing for leak tightness by measuring the rate at which pressure drops within a sealed object over time. With this method, the leak tightness is tested for:

- **Drive unit** – to ensure proper sealing of the drive unit, which is responsible for the proper output of medication in controlled increments, making a highly accurate measurement extremely important.
- **Battery tube** – to ensure the battery chamber is leaktight and that no moisture can enter the inside of the housing toward the electronics and impede the function of the device.
- **Medication tube** – to ensure proper placement and leak-tightness of the medication tube.

- **Welded housing parts** – plastic laser welding is used to precisely and efficiently join the housing parts of the device. After welding, the housing is leak tested using the dosing/closed component method to ensure there are no leaks or weaknesses in the welded seam.
- **Completed device** – the finished assembly is leak tested using the dosing/closed component method to ensure the leak tightness of the final completed device.

2. Flow test

This method is used when the test item is not closed, and its continuity must be tested for volume. The flow test method is used for testing:

- **Venting membranes** – these membranes operate as part of a two-way venting system to accommodate the slight overpressure that can naturally occur inside the housing and/or medication tube of the device. This flow leak test confirms that the membrane is present and measures that it has the correct flow value.



The manual assembly bench was designed to ensure an efficient and repeatable manufacturing process. Two LTC-802 models were used for ease-of-process in the design and function of the station. Operators scan the barcoded test part, then place the part onto a quick connector. They then flip a lever and select the appropriate program number for their test. This approach allows for a flexible, compact design, using only one test chamber.

The benefits of a hands-on, collaborative approach to leak test development

As part of this prototyping process, innomatec not only delivered a proven system for an accurate and repeatable leak test, but collaborated with the Inreda team to develop a new process and standard for the development of Inreda's medical pump devices moving forward.

"It wasn't just a matter of testing to see if the product was leak tight or not. Of course, that's important, but innomatec also helped us learn more about how the design of the product could help improve leak tightness," said

Mr. Olaf van Straaten, COO, Inreda.

innomatec's expert knowledge, attention to detail, and persistent pursuit of excellence led to a very fruitful collaboration between the two companies, which ultimately led to developing the best solution for Inreda's needs, ensuring an effective, efficient, and operator-friendly test procedure.

"A real difference with innomatec was their hands-on approach," said Mr. Van Straaten.

"Any time we came across an issue, it was always solved. The innomatec team was dedicated to really understanding our product and helping us make the best product possible. They made themselves available to us locally in the Netherlands, which fostered great collaboration as we worked together on the design and development of the testing."

The Inreda AP®6 is projected to be available to the public in Q3 2026. With their new scalable leak test solution, Inreda will be able to easily scale their manufactured volume as they expand to serve diabetes patients worldwide.

The power of robust, flexible leak test instrumentation

The robustness and flexibility of innomatec's LTC leak test platform made it possible to achieve this complex and precise test solution using standard instrumentation.

“innomatec is accustomed to designing leak test solutions for complex needs. The best thing is that most applications can be served with our standard instrumentation, requiring only simple configuration. Ultimately, it comes down to taking the time to understand the part being test and designing the test in the most efficient and effective manner to reach the manufacturers' goals

— Mr. Robin Harms, Head of Sales, innomatec

innomatec has over 40 years' experience working with leading manufacturers across the globe, helping them design accurate, repeatable leak tests and solve leak test challenges on their manufacturing lines to ensure production efficiency and the highest product quality.

Need help designing or improving a leak test process on your line?

Contact the experts at innomatec!