# A SMART PLATFORM TECHNOLOGY FOR THE FOUR-STEP INJECTION PROCESS

For a drug delivery device to be successful today, it needs to be able to be adapted to an ever changing and evolving set of market and user needs, whilst remaining financially attractive. Here, Tobias Morlok, Head of Development, Medical Devices, /H&B/ Electronic, explains how /H&B/'s patented device with toothed gearing rises to this challenge.

## INTRODUCTION

Development of new devices, or even just features, is very often a slower process than the flow of constantly changing customer and patient expectations. Hence, sometimes having a thorough understanding of current needs, upcoming requirements and future growth opportunities is still insufficient for keeping products up to date. In addition, companies also need to have options ready and available in order to react quickly, in a customer-friendly way, to the growing and continuously changing pharmaceuticals market.

To meet the challenges presented by this rapidly shifting market, /H&B/ has developed high-quality injection devices with toothed gearing. These devices are the logical next step forward after more than 20 years of developing innovative injection systems with patented solutions for reusable mechanical and electromechanical devices. All of the recent devices utilise /H&B/'s proven "Four-Step-Technology" – insertion, injection, dwell time and needle withdrawal, as discussed in /H&B/'s article in ONdrugDelivery's May 2018 "Injectable Drug Delivery: Devices Focus" issue.

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## INJECTION DEVICES WITH TOOTHED GEARING

Here follows an overview of the features and possible variations of /H&B/'s patented mechanic for injection devices with toothed gearing to illustrate the many possibilities the design offers to customers to suit a variety of needs. There are too many aspects to cover each with sufficient depth, so a selection of the most important has been made.

### Technical Implementation

The injection device was originally developed and optimised for single use, but with only a small number of changes it is equally well suited to a reusable system. One of its major advantages is that it contains only a few components, which not only makes the system financially attractive but also limits the potential sources of error.

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The device's defining element is the gear transmission:

- Needle insertion
- Decoupling of the syringe holder and ram holder
- Injection of medication
- Dwell time
- Recoupling of the syringe holder
- Needle retraction.

These elements all work together to perform the "Four-Step-Technology" injection process. This major feature was achieved with a reversal of the rotation direction of the gearwheel by fixed toothings, arranged on opposite sides. A damping element is integrated in the housing of the device which enables constant operational force.

Rapid needle insertion is initiated after exceeding a required starting force in the manual version. To facilitate this procedure the device can be equipped with a spring to replace the manual operation. The damping adapts to the applied force to ensure the actuation element operates at a constant, consistent speed. The insertion depth is also adjustable depending on the medication or site of injection. The insertion depth can be pre-set or made adjustable by the user.

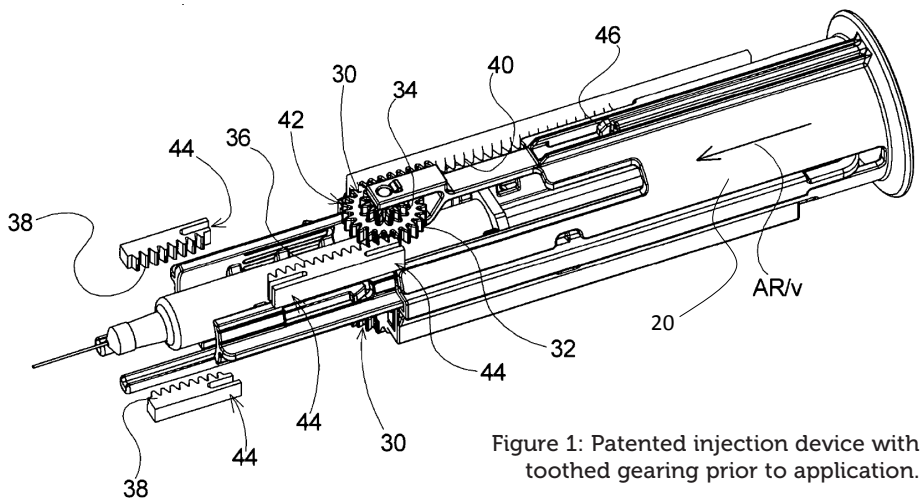


Figure 1: Patented injection device with toothed gearing prior to application.

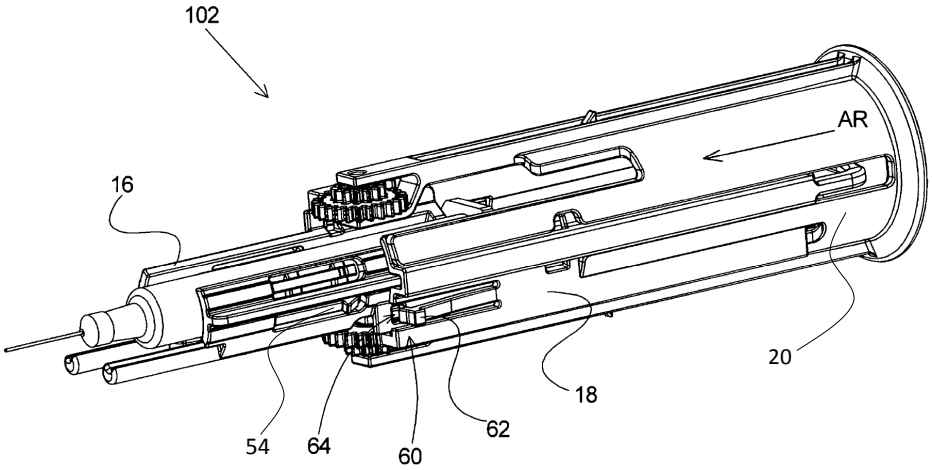


Figure 2: Patented injection device with toothed gearing during application.

## The Injection Process

The needle is never visible to the patient. That not only prevents contamination, but also – even more importantly – hinders needle phobia and prevents patients from hesitating during the injection process. If desired, a protection cap can be attached to the needle to avoid any accidental or incorrect use. The required activation force can be adapted and must be exceeded to activate the device.

The device has an integrated damping element for constant progress of applied force. This is especially important in case of manual use, as even in this case there is almost no noticeable difference from one step to the next. The movement itself can be adapted in its behaviour, depending on the viscosity of the medication, the desired speed of injection and, last but not least, the abilities of the patient.

At the beginning of the injection process the actuation element (20) is being moved with a force in the direction AR (Figure 1). The two-tier gearwheel (30) meshes with the first housing-side toothing (36) and the ram-holder-side toothing (40). The effect is that the ram holder (18) moves with double the speed of the actuation element (20) in the direction AR (Figure 2).

The ram holder (18) is linked through an engagement element (62) with the syringe holder (16). The engagement element (62) is being moved alongside the housing (not shown).

After the insertion stroke is completed (Figure 2), the engagement element (62) evades into a recess in the housing. That interrupts the interconnection between syringe holder (16) and ram holder (18). The ram holder (18) keeps on moving, empties the syringe and remains for a reasonable dwell time. This dwell time is adjustable over a wide range, using the relation between driving force, distance between the housing-side toothings and damping behaviour.

After the syringe is drained, the two-tier gearwheel (30) leaves the first housing-side toothing (36) – start of the dwell time – and then meshes with the second housing-side toothing (38) – end of the dwell time – but still stays in contact with the ram-holder-side toothing (40). This now opposing arrangement of the toothing together with the different sizes of the gearwheels (32) and (34) leads to a reversal of direction of the two-tier gearwheel (30) and thus to a withdrawal of the ram holder (18) against the moving direction AR. This retraction is facilitated by a reduction of the necessary driving force.

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The syringe holder (16), which attaches via a coupling arrangement (54) with the ram holder (18) after the injection, is consequently also pulled back and thus the needle is withdrawn.

To avoid any danger of injury by the needle, the syringe is locked in the end position. In single-use systems that final step prevents any further use. Reusable injection systems can be brought back into the starting position again after removal of the empty syringe or cartridge.

## EXAMPLE DEVICE VARIATIONS

### Manual Single-Use Device

Of course, even these simple devices (Figure 3) are equipped with /H&B/'s "Four-Step-Technology". The logical and simple working principle allows for the same intuitive handling as with a standard syringe.

The device is ready-to-use, with a prefilled syringe is already installed, so that the patient only has to remove the protection cap (optional), position the device on the desired spot and then – as with an ordinary syringe – press the plunger. The distance covered when pressing the plunger provides direct feedback about the progress of the injection and a safe fixation at the end position guarantees that there is no danger of injury.

For patients, healthcare providers and pharma companies who like to track injection parameters, such as date and hour or duration of injection, possibly on a smartphone health app, the device provides a characteristic and easy to perceive click sound for communication with the app.

With this model, there is an extensive variety of options the customer can choose from:

- The dwell time is adjustable according to a wide variety of requirements by adapting the distance between the housing-side toothings and the damping behaviour.
- The design and size of the device are adaptable to customers' and patients' wishes and needs.
- A viewing window to control the medication before application is mandatory, and a second viewing window to display the progress of the injection is optional.
- In cases where the medication has to be cooled constantly prior to use the devices could be constructed differently so they can be sent to the customer without the container. Container and syringe would be inserted in the devices on-site. That would save valuable space during shipping and storage.
- The devices are typically equipped with syringes; however, cartridges and dual-chamber cartridges can be used instead.

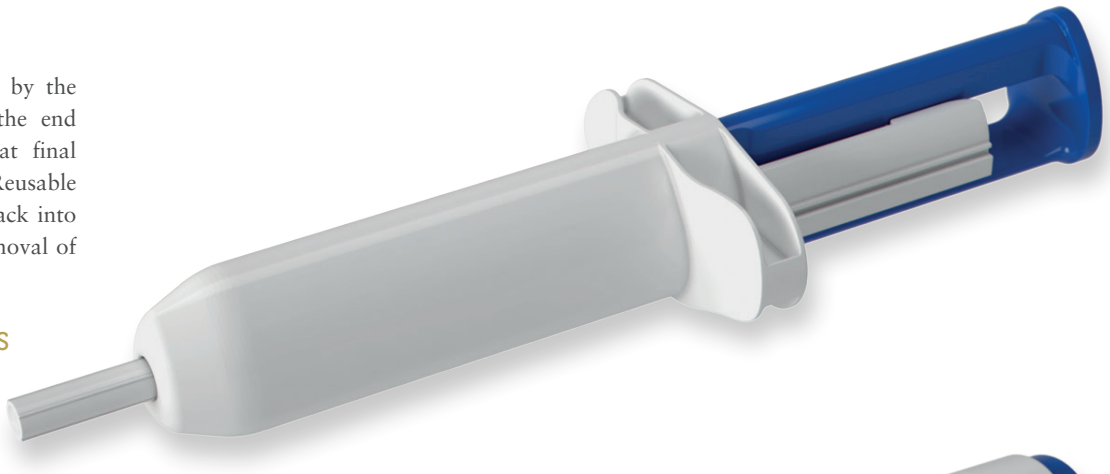

Figure 3: Manual single-use device.

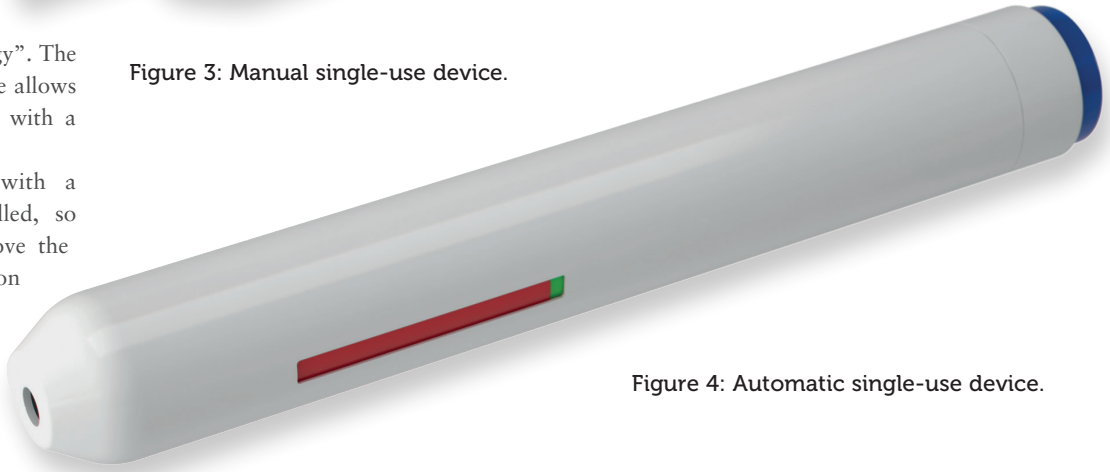

Figure 4: Automatic single-use device.

### Automatic Single-Use Device

All of the automatic, single-use device features and possibilities are identical to the manual. The only difference is that the actuation element is activated by a start-button and driven by a spring, rather than manually by the user (Figure 4).

### Reusable Injection Systems

Reusable injection systems use the same technology as the single-use systems. Both systems will be locked in the final position to prevent any misuse or injuries. However, the reusable device can be brought back into the starting position after removal of the syringe or cartridge. Only a few extra components have to be installed in the reusable devices. According to the material used for these components, more than 1000 injections are possible, if required.

## CONCLUSION

With its variety of devices and the Four-Step-Technology /H&B/ already offers a wide range of products. However, further advances in design and manufacturing technology are necessary. The requirement to be able to achieve a market-ready device in an efficient and timely manner has encouraged medical device manufacturers to evolve quickly. In an increasingly competitive landscape, output attained must not only meet the desired device specifications and market regulations, but also the requirements of the end-user.

One way to achieve that goal is to develop systems which provide maximum flexibility. With /H&B/'s patented technology of toothed gearing, its devices offer exactly that. Adaption to customers' needs can not only be achieved quickly, but can also be financially attractive.

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Needless to say, with this system the safety and protection of end-users and healthcare professionals is guaranteed and meets the highest possible standards. /H&B/ has brought together product design and manufacturing engineering to create an injection system that will improve lives, reduce healthcare costs and deliver treatments more efficiently.

## ABOUT THE COMPANY

Established in 1984, /H&B/ Electronic soon became a reliable and important supplier for key players in the automotive and industrial electronics sector, developing and manufacturing high-precision mechanical components, connectors, sensors, housings and electromechanical systems. In 1998, /H&B/ made the step into medical engineering. Providing solutions and developments in medical devices using metal and polymer hybrid components made /H&B/ a trusted partner in more than 50 countries worldwide, especially in the field of injection systems for multiple sclerosis.

Today, /H&B/ has built a reputation for ultraprecise products, providing product development from the initial concept to maturity, planning of all project phases, simulations, part design and tools as well as customer-specific, cost-optimised and certified manufacturing. For many years, the company has implemented – besides the standard certifications – EN ISO 13485 and EU Directive 93/42 EEC Annex II.

/H&B/ is situated at the north rim of the Black Forest region in southern Germany. Its 13500 m² production and development site houses more than 350 employees.

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## ABOUT THE AUTHOR

**Tobias Morlok** is Head of Development for Medical Devices and has worked for /H&B/ since 2009. He started working for the company during his dual course of study specialising in construction and development. He also studied innovation and technology management and holds a Masters degree in Mechanical Engineering. Today his focus is on developing new products in medical engineering and he is responsible for IP management as well as the expansion of the the company's medical sector.

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