



/H&B/'S FOUR-STEP-TECHNOLOGY: STATE-OF-THE-ART IN AUTOMATIC REUSABLE INJECTION SYSTEMS

Ensuring medical devices are easy to use and completely safe are key drivers in developing innovative solutions. In this article, Tobias Morlok, Head of Development – Medical Devices, at /H&B/ Electronic, outlines how the company's Four-Step-Technology approach ensures that devices are totally safe to use by protecting against inappropriate use in several ways and at four key stages: needle insertion, injection of the medication, dwell time and needle withdrawal.

The market for medical supplies faces constant challenges such as coping with new developments in pharmaceuticals but also meeting increasing customer expectations.

To meet these challenges, companies need a thorough understanding of current needs, but also of upcoming requirements and future growth opportunities, as developing new features or entirely new instruments cannot be done in the short-term. Therefore it is paramount to listen to clients, watch market developments carefully and act pre-emptively.

It is also a great advantage when engineering competence, innovative technologies, technical knowledge and, last but not least, extensive manufacturing experience all come together under one roof. That combination – together with short paths and straightforward communication – guarantees close co-operation and turns out reliable product solutions.

The result has been the development of various innovative injection systems over the last 20 years with patented solutions for

“Our primary goal is to provide easy-to-use devices for patients, including those with disabilities or who are under stress, and to make those devices absolutely safe to use.”

single-use, reusable and electromechanical devices. One such system is the Four-Step-Technology.

THE FOUR-STEP-TECHNOLOGY

The driver of innovation and evolution of our devices has always been safety concerns as well as meeting customers' and patients' needs. Our primary goal is to provide easy-to-use devices for patients, including those with disabilities or who are under stress, and to make those devices absolutely safe to use. This is the key to our success as well as our motivation to keep on improving.

To meet these values in a practical setting, any device must be able to be protected against inappropriate use. Our unique Four-Step-Technology aims to ensure



Tobias Morlok
Head of Development
– Medical Devices
T: +49 7056 939351
E: medizintechnik@h-und-b.de

/H&B/ Electronic GmbH & Co KG
Siemensstraße 8
75392 Deckenpfronn
Germany

www.h-und-b.de

this by focusing on safety at four key steps:

- Insertion
- Injection
- Dwell time
- Needle withdrawal.

If one of the preparation steps is executed incompletely or incorrectly the final activation of the device will be prevented.

EXAMPLE OF THE FOUR-STEP-TECHNOLOGY IN PRACTICE

To illustrate how the four-step-technology works, we will use the example of BETACOMFORT®, a device which has been adapted by /H&B/ for Bayer AG to meet the needs of multiple sclerosis patients (Figure 1).

BETACOMFORT® provides application assistance that enables patients to inject medication on their own, subcutaneously at home. Since market entry, almost

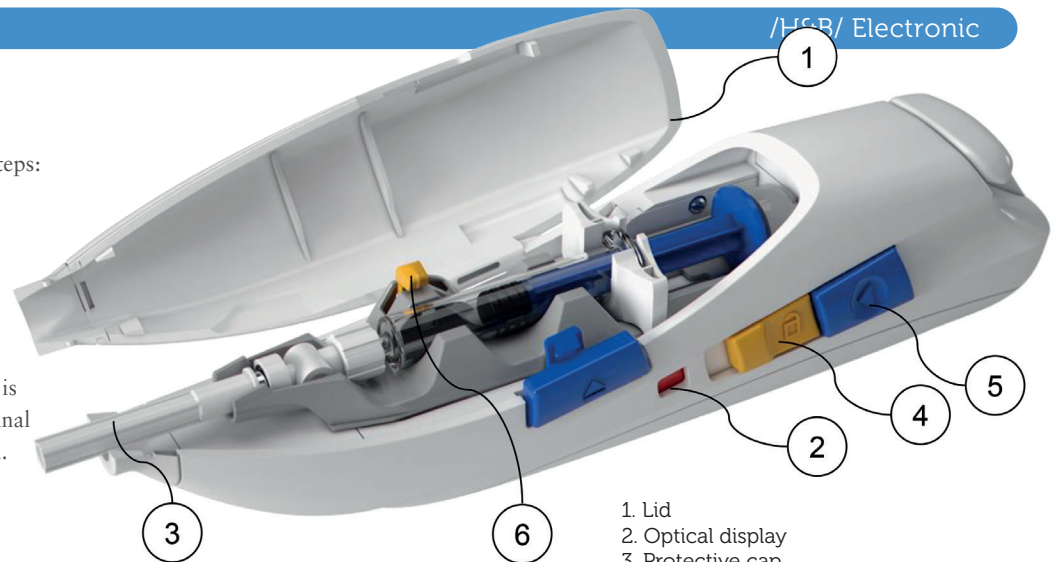


Figure 1: Reusable autoinjector for prefilled syringes.

300,000 autoinjectors for the treatment of multiple sclerosis have been sold and they are used in 56 countries worldwide.

Using Four-Step-Technology, the device is protected against inappropriate use in several ways (Figure 2).

1. Lid
2. Optical display
3. Protective cap
4. Safety catch
5. Start button
6. Lever for adjusting the insertion depth

To start with, BETACOMFORT® is equipped with a mechanical locking lid which allows a simple syringe insertion. Just in case the syringe is not inserted correctly the lid can't be closed. Thus an injection with an inaccurately inserted syringe is prevented. After closing the lid completely and manually loading the mechanism, a green indicator in the optical display shows the device is ready to use.

STEP 1: Needle Insertion

After removing the protective cap, pushing the safety catch in the direction of the injection, positioning the device on the desired injection area and pushing the start button, the syringe is pushed forwards so that the needle penetrates the skin. Here another special feature comes into play: the insertion depth is adjustable beforehand depending on the tissue where the medication is being applied.

STEP 2: Injection of Medication

The medication is injected subcutaneously only after the needle has been completely inserted. The speed of injection can be adapted depending on the medication, tissue or patient's needs.

STEP 3: Dwell Time

During this period of waiting, tissue counter pressure is reduced. This reduced pressure prevents a reflux of the medication through the puncture and therefore reduces skin irritations significantly.^{1,2}

STEP 4: Needle Withdrawal

The syringe and the needle are withdrawn automatically. The visual indicator in the optical display has now turned red and an additional acoustic signal indicates the end of the injection process.

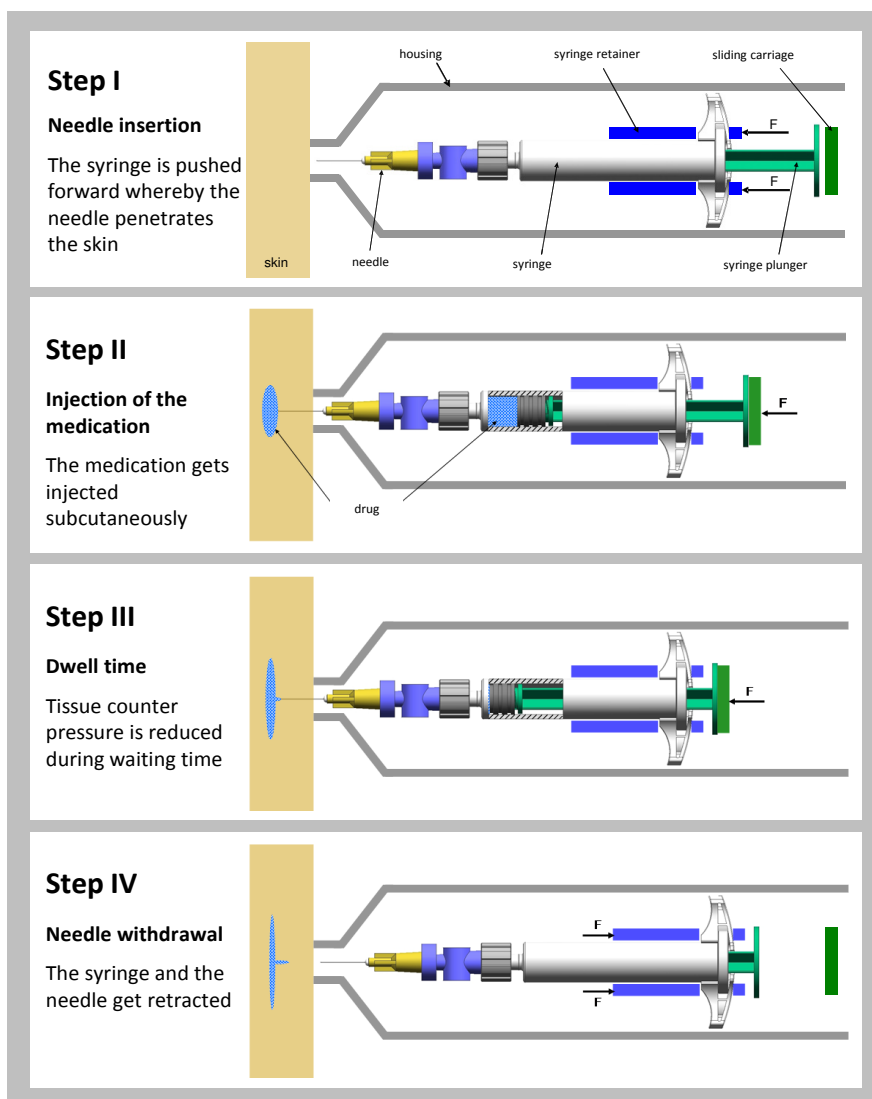


Figure 2: Illustration of the Four-Step-Technology

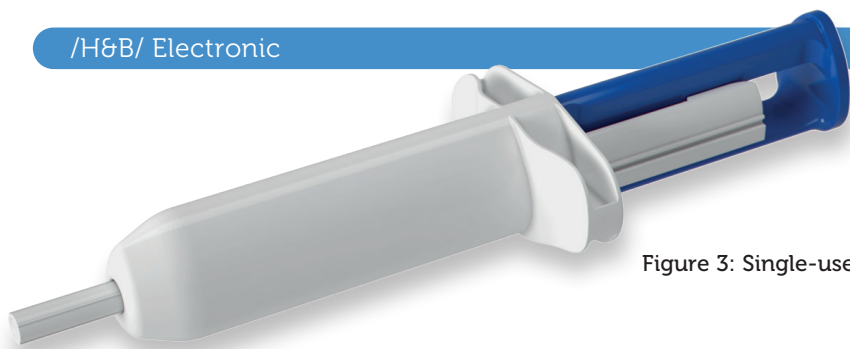


Figure 3: Single-use injector.

Figure 4: Electromechanical autoinjector for prefilled syringes.



EXAMPLE OF THE FOUR-STEP-TECHNOLOGY IN PRACTICE

Various groups of devices have been developed by /H&B/ over the last few years, which make use of the Four-Step-Technology.

It is important to highlight that this technology is available to its full extent in all devices described below – even in the single-use injection systems – giving it a major advantage over other systems in the market.

Group A: Single-Use Injection Systems

- Single-use injector (Figure 3) – injection device with prefilled syringe and single- or dual-chamber cartridge for single-use injection. The injection is performed manually or by pressing a release element (start button) performed by spring tension.
- Application: e.g. as single-use injector for subcutaneous or intramuscular self injection.

Group B: Reusable Injection Systems

- Reusable injector (Figure 1) – injection device with inserted syringe. The injection is performed by pressing a release element by spring tension or manually. Manual resetting of the mechanism.
- Application: e.g. as autoinjector for subcutaneous or intramuscular self injection.

Group C: Electromechanical Injection Systems

- Reusable injector (Figure 4) – electrically driven injection device

with inserted syringe. The injection is performed by pressing a release element. Automatic resetting of the mechanism after the injection. Communication with other devices and datalogging is possible.

- Application: e.g. as autoinjector for subcutaneous or intramuscular self injection with datalogging for therapy monitoring.

Any of the above-mentioned devices can be used with syringes and single-chamber cartridges but can also be adapted to use with dual-chamber cartridges. In addition, the design and features of any device can be adapted to the specific needs of the customer.

ADVANTAGES

The main advantages of the Four-Step-Technology are:

- The injection is completely separated from the penetration of the needle.
- The entire injection needle is capsuled before and after the injection and is at no point visible to the patient (hindering needle phobia and providing total safety).
- It can improve patient confidence during injection and reduce any potential barriers to continuing treatment.
- As the speed of injection and the insertion depth are variable, the injection process can be adapted to safety and effectiveness requirements of the medication.

- The withdrawal of the needle occurs automatically. This is convenient for the user as injuries and pain are excluded³ – especially when the device is withdrawn at an angle.
- Both previous points make all kinds of tissues – especially abdominal regions – easily accessible for an injection.
- A reflux of the injection through the puncture is prevented as the dwell time leads to a reduced counter pressure in the tissue. That leads to significantly less skin irritation.^{1,2} And – on top of that – the dwell time is variable and adaptable to customers' needs.
- It can easily be adapted to different cartridges and volumes.
- The user does not need to take any extra steps to shield the needle after use. This reduces the risks associated with needle re-use and the risk of needlestick injuries, and provides additional protection for patients and healthcare professionals.

All these devices (like the BETACOMFORT® device) are ideal for self-injection by any patient at home.

FUTURE PROSPECTS

The medical devices market provides constant challenges. /H&B/ is well prepared and eager to tackle these new prospects, further developing existing devices and also creating new products. Our efforts are focused on expanding new services and generating sustainable, lasting results to improve the experience of patients. In addition it will be a major improvement to provide connectivity for single-use injection systems as well as mechanical injection systems.

CONCLUSION

With safety becoming ever more important in healthcare, medical device manufacturers are exploring new ways to protect end-users and healthcare professionals. The requirement 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, the output achieved must not only meet the desired device specifications and market regulations, but also the end-user requirements.

With our portfolio of devices and the Four-Step-Technology, /H&B/ already

offers an ideal range of products, bringing together product design and manufacturing engineering to create an injection system that will help 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 hybrid components made of metal and polymers 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 – the EN ISO 13485 and the EU Directive 93/42 EEC Annex II.

/H&B/ is situated at the north rim of the Black Forest region in southern Germany. Its 13,500 m² production and development site houses more than 350 employees.

REFERENCES

1. Arnason BG, "Long-term experience with interferon beta-1b (Betaferon) in multiple sclerosis". *J Neurol*, 2005, Vol 252 (Suppl 3), iii28-iii33.
2. Brochet B, Lemaire G, Beddiaf A et l'Epicure Study Group, "Reduction of injection site reactions in multiple sclerosis (MS) patients newly started on interferon beta 1b therapy with two different devices". *Rev Neurol (Paris)*, 2006, Vol 162(6-7), pp 735-740.

3. Baum K, "Improving patient satisfaction with injection devices in multiple sclerosis improves adherence".

European Neurological Review, 2009, Vol 4, pp 64-68.

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 innovations 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.

PFS & Injectables returns to San Diego – September 5-7, 2018



8TH EDITION

PFS & INJECTABLES

SUMMIT 2018

Confirmed Partner



2017 Attendees Included:

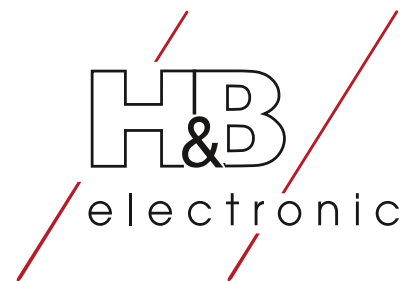
Allergan • Amgen • Antares Pharma Inc. • Bayer • BD • BMS • Cheisi • Dr. Reddy's Laboratories • Eli Lilly & Co. • Fresenius Kabi • Ionis Pharma • La Jolla Pharma • Leo Pharma • MedImmune • Momenta Pharmaceuticals • Novo Nordisk • Owen Mumford • Pfizer • Takeda • Teva Pharmaceuticals • UCB • West Pharma • ZebraSci

To register your interest for the 2018 meeting, please visit www.pfs-injectables.com

@info@hansonwade.com ☎ +1 617 455 4188

PARTNERING

FOR OUR SAFE, GENTLE,
4-STEP TECHNOLOGY



INJECTION SYSTEMS
BY SPECIALISTS



1

FIRST

INSERTION

2

SECOND

INJECTION

3

THIRD
OPTIONAL

DWELL TIME

4

FOURTH

WITHDRAWAL

Injection process

You are looking for an existing, time-tested injection technology or a partner to develop and manufacture your product idea?

We are looking for new partnerships to which we can contribute our long years of experience and our extraordinary vertical integration.

See more at

www.4-step.de

or contact

Tobias Morlok at phone +49 7056 9393 51