



WEIBEL CDS AG

safer, easier and faster drug delivery

LARGE-VOLUME WEARABLE DRUG DELIVERY: A VISION BECOMES REALITY

In this article, Hans Peter Manser, Chief Executive Officer; Christoph Egloff, Chief Technology Officer; and Martin C King, Head of Quality & Regulatory; all of Weibel CDS, introduce LV DDS, a flexible-form, low-profile wearable injector platform, for large-volume drug delivery.

Pharmaceutical companies around the globe are focusing on simplified, affordable, large-volume delivery of parenteral drugs. There is a strong trend for subcutaneous delivery and self-administration that is leading to even larger injection volumes and higher viscosity formulations.

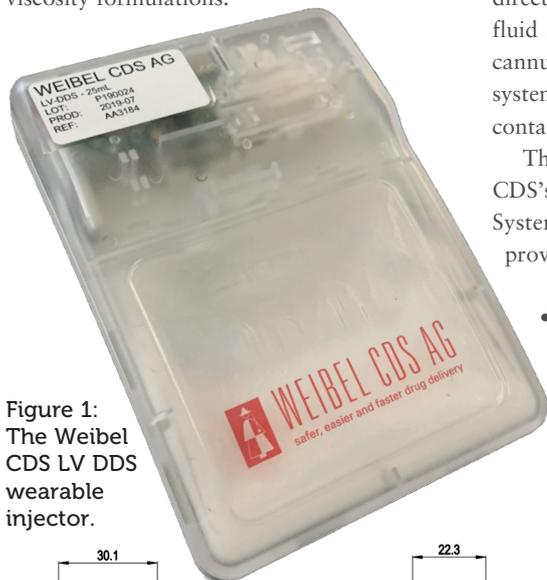


Figure 1:
The Weibel
CDS LV DDS
wearable
injector.

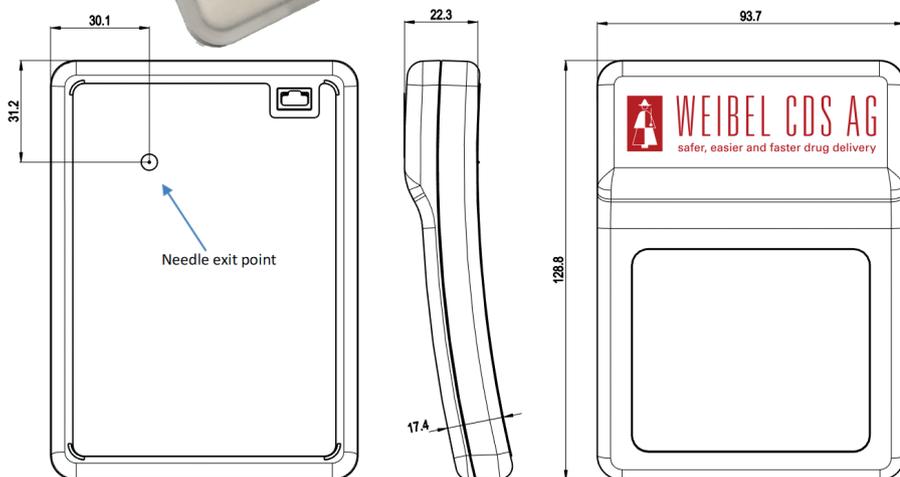


Figure 2: Example based on 25mL and fully disposable LV DDS.

Weibel CDS recently delivered the first prefilled customer units of a new low-profile (22.3 mm) large-volume (25 mL) wearable injector with a flexible form drug reservoir (Figures 1 and 2). It is a single-use disposable device that is worn attached directly to the skin with an integrated fluid path, automatic needle insertion, soft cannula placement and infusion/injection system. The drug reservoir is capable of containing volumes up to 50 mL.

The units were the first from Weibel CDS's new Large-Volume Drug Delivery System (LV DDS) platform, based on proven Weibel CDS innovations:

- The Drug Delivery System, DDS, a valveless volumetric continuous micro-displacement pump
- The MiniBag, a flexible form primary container with similar drug contact properties to glass.



Hans Peter Manser
Chief Executive Officer
T: +41 71 351 73 22
E: sales@weibelcds.com



Christoph Egloff
Chief Technology Officer
T: +41 71 351 73 23



Martin C King
Head of Quality & Regulatory
T: +41 71 351 73 23

Weibel CDS AG
Umächerstrasse 51
CH-9104 Waldstatt
Switzerland

www.weibelcds.com

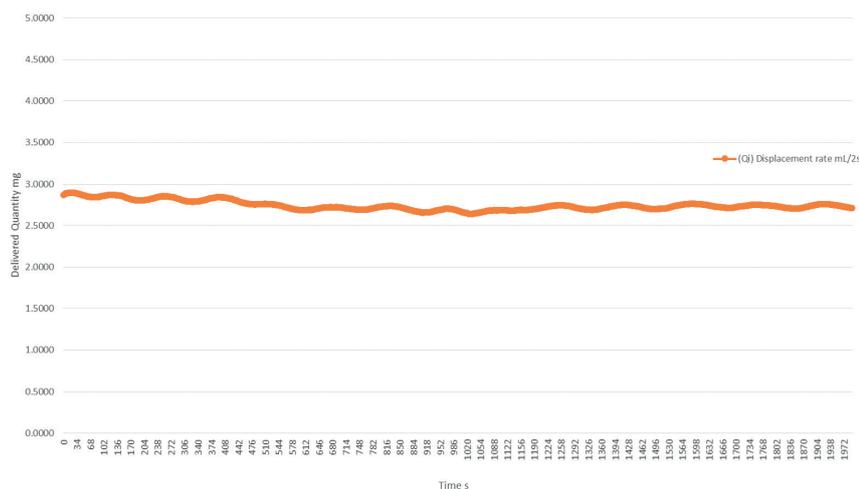


Figure 3: The pump has a constant displacement rate in compliance with IEC 60601-2-24.

LARGE-VOLUME DRUG DELIVERY: SIMPLIFIED

User-filled or prefilled, the single-use Weibel CDS LV DDS simplifies drug administration at home, or in the clinical environment by healthcare professionals, to three steps:

1. Peel-off backing
2. Attach device to body
3. Start injection.

Ready for Customisation

The LV DDS platform is ready for customisation to specific “intended-use” user- or drug product-specific requirements. With unsurpassed dose accuracy (Figure 3), its continuous volumetric displacement pump (Figure 4) supports a range of high viscosity large molecule drug products.

The Weibel CDS LV DDS supports the following features:

- Safe, user-friendly simple to use system with minimised steps.
- Automatic needle insertion system (ANIS), with all needle safety steps performed automatically. The needle remains hidden at all times and is made safe after injection and device removal.
- Automatic soft cannula placement as an option for long duration injections and patient comfort.
- Automatic injection commences when attached to the skin and the drug is ready for injection.
- Suitable for combination therapies from a single device.
- Suitable for continuous flow slow injection, bolus and long duration injections
- Unique high dose accuracy, continuous volumetric pump supporting a range of high viscosity drug products.

- Programmable electronics provide:
 - Personalised patient feedback and connectivity
 - “patient-personalised” programmable injection time and rate profile for the healthcare professional.

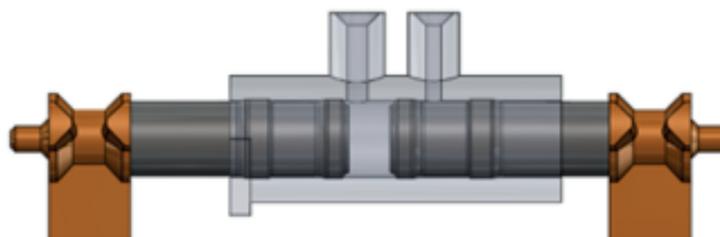


Figure 4: Valveless volumetric displacement pump.

KEY PARAMETERS

Primary Packaging: 2-50mL MiniBagSystem (Larger Volumes on Request)

Needle System: 27G cannula with a 25G soft cannula, automatic insertion

Dimension: 128.8mm x 93.7mm x 22.3mm

	Min.	Typ.	Max.	Units
Water Proofing		IP 33		
Device Weight (Empty Reservoir)		100		g
Operating Temperature	+4	+23	+37	°C
Operating relative humidity range	20		90	%
Non-condensing Operating atmospheric pressure	600		1065	hPA
Viscosity of forwarded Medium			100+	cP
Reservoir		40		mL
Dosage Range with liquid viscosity of 10cP	tbd		360,000	µL/h
Single Stroke Pump Volume	10		200	µL

*Depending on the drug delivery rate required, higher viscosities may be possible.

Table 1: Key parameters and technical specs of the Weibel CDS LV-DDS.

- Customisable device shell supporting customer-specific branding schemes.
- Preloaded or loaded at time of use without the need of a cleanroom environment.

The key parameters and technical specs of the LV DDS are summarised in Table 1.

Low-Shear-Force Volumetric Displacement Pump

The Weibel CDS valveless volumetric displacement pump (Figure 3) performs well with highly viscous products and offers good compatibility with shear force-sensitive drugs resulting in no measurable change to the protein structure. Weibel CDS provides Test Platforms for Pharmaceutical Companies to evaluate the delivery characteristics of drug products in the security of their own laboratories.

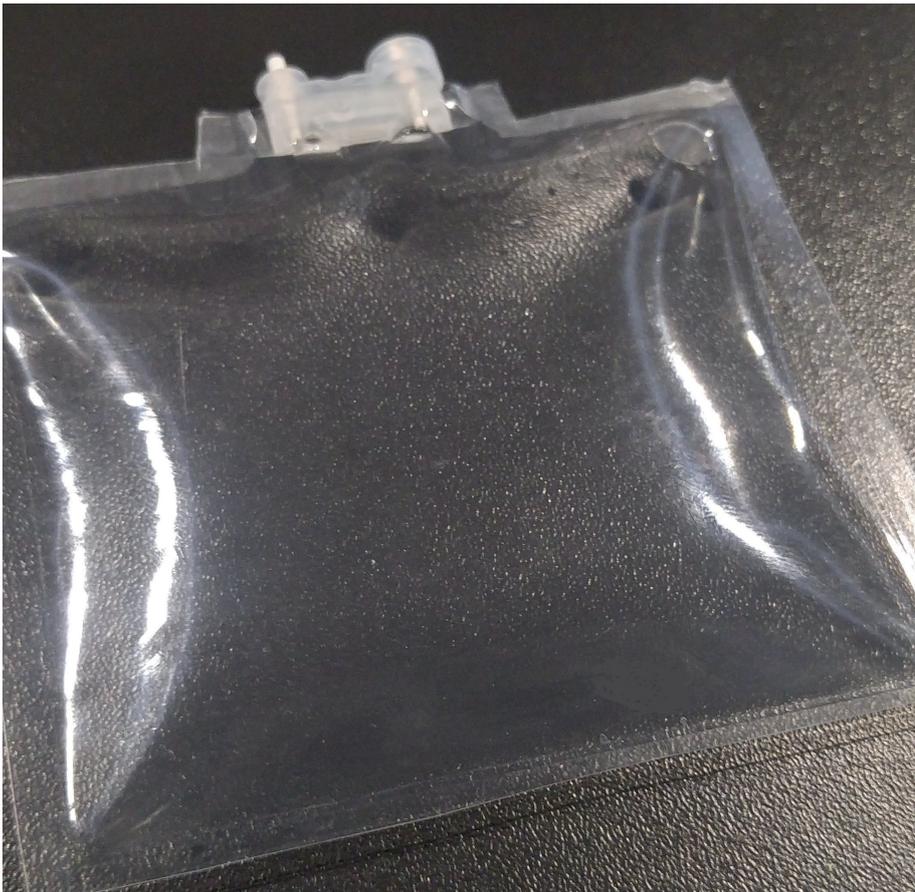


Figure 5: MiniBagSystem is a primary packaging solution with similar drug contact properties to glass.

MiniBagSystem

MiniBagSystem (Figure 5) has undergone rigorous mechanical characterisation and stability testing with large-molecule drug products confirming it as a primary packaging solution with similar drug contact properties to glass, and resilience to pharmaceutical industry standard sterilisation processes.

Exclusive to Weibel CDS, this cyclic olefin copolymer/polychlorotrifluoroethylene (COC/PCTFE) flexible film, CETA160, has been specially developed to store drug product. Manufactured to cGMP standards, the film is high-barrier, transparent, radiation sterilisation stable, non-yellowing and US FDA-compliant.

The PCTFE element is Aclar® from Honeywell International, which gives the film its high barrier to moisture and to aromatic and aliphatic hydrocarbon species and excipients (Table 2).

Water vapour transmission rate (@38°C, 90% RH)	0.06 g / m ² / 24 h	0.004 g / 100 in ² / 24 h
Oxygen transmission rate (@23°C, 50% RH)	19 cm ³ / m ² / 24 h	1.23 cm ³ / 100 in ² / 24 h

Table 2: Barrier properties of Aclar® film used for the MiniBagSystem.

ABOUT THE COMPANY

Weibel CDS is a privately owned, ISO-certified medical technology company developing, manufacturing and supplying affordable, innovative, user-friendly injection systems and devices to ensure safer, easier and faster delivery of parenteral drugs for home, point-of-care and clinical users around the world. The company is situated at the heart of a medtech cluster based in Schaffhausen, Switzerland.

Weibel CDS holds numerous international patents covering its product portfolio of parenteral drug delivery platform technologies. LyCaJect is a patch injector with in-device automatic reconstitution. The Large-Volume Drug Delivery System (LVDDS) is a low-profile, on-body injector or infusion system capable of delivering up to 50 mL. SuperCapSyringe® is an advanced safety syringe platform based on a modular design with sharps protection, reuse prevention, and an integrated drug transfer

vial-to-syringe fluid path. Reconstyringe® is the first to offer fully automated in-device reconstitution of lyophilised drug. Contained in its original vial, the solvent is automatically transferred into the vial. Like a Swiss watch, it runs through the full reconstitution cycle. After this, the drug is drawn through the integrated fluid path into the SuperCapSyringe® ready for injection.

SuperCapSyringe® and Reconstyringe® are registered trademarks of Weibel CDS AG, Switzerland.

ABOUT THE AUTHORS

Hans Peter Manser, Chief Executive Officer at Weibel CDS, holds a diploma in Business Administration and Applied Technical Management. After perennial stays in the UK, Australia, the US, France and Germany, he assumed sales management and executive functions in the communications industry with global responsibilities. Mr Manser transitioned to the pharmaceutical packaging industry in 2001 and subsequently joined Weibel CDS in May 2011 as Business Director, responsible for setting up and management of all administrative and commercial aspects of the company, taking over the overall responsibility of the company in October 2016.

Christoph Egloff is the Chief Technology Officer at Weibel CDS. His role covers innovation, technical design, management of the engineering department and project management. Mr Egloff worked on the design, manufacture, installation and qualification of the company's precision drug delivery, injection, micro-infusion and automatic reconstitution devices.

Martin C King is Head of Quality and Regulatory at Weibel CDS. He has extensive experience in the fields of international medical device development and pharmaceutical management, encompassing all aspects of quality management and regulatory affairs. Mr King has served as a Deputy Swissmedic Responsible Person and Certified Lead Auditor under ISO 13485:2016, with specific expertise in ISO 62304, ISO 14971, 21 CFR 820 and MDSAP.

**The vision of Large Volume
Wearable Drug Delivery
becomes reality**



Large Volume Wearable Drug Delivery System

safer, easier and faster
drug delivery

International patents pending



WEIBEL CDS AG

safer, easier and faster drug delivery

Urnäscherstrasse 51 | CH-9104 Waldstatt

+41 71 351 73 22 | www.weibelcds.ch