




**Delivery**systems

# Go for insights in clinical trials

Now for  
clinical trials



swissengineering 

## CliniPilot, our SmartPilot™ for Ypsomed® 1.0 and 2.25, tailored to meet your clinical trial needs

- Seamless integration into clinical trial flow without altering existing setups.
- Adherence tracking removes uncertainties from clinical trials through automated data capture.
- Higher cost-effectiveness and operational efficiency by reducing patient visits and medical staff burden.
- Real-time identification of user errors.
- Enabling decentralised trials with the objective and reliable real-time data as in conventional clinical trials.



More confidence. More success. With Ypsomed Delivery Systems.

**YPSOMED**  
SELF CARE SOLUTIONS



## CliniPilot

A powerful digital tool for connected clinical trials

CliniPilot integrates with YpsoMate® 1.0 and 2.25 autoinjectors, transforming them into powerful digital tools for clinical trials. It fits seamlessly into existing trial workflows, allowing adherence tracking and replacing manual diaries with real-time, objective and reliable data to remove human errors and documentation burden. No regulatory approval is required, allowing for immediate application in clinical trials, and its compatibility with standard EDC systems ensures easy integration into existing trial setups. CliniPilot also enhances cost-effectiveness and operational efficiency, reducing patient visits and easing the strain on medical staff in both conventional and decentralised trials. It detects and identifies user errors, such as partial injection or insufficient holding time, and optionally provides visual and acoustic feedback for real-time patient guidance, helping to minimize these errors. Supporting decentralised trials with the same reliability and objectiveness of conventional ones, CliniPilot enables remote monitoring and timely interventions through real time analytics, ensuring adherence and improving outcomes.



Insert



Remove cap



Inject



Press button



Remove



## Dimensions and specifications

Facts and figures

<b>Dimension</b>	<b>For YpsoMate® 2.25:</b> 5.3x1.6x1.6inches or 134.5x39.6x40.4mm <b>For YpsoMate® 1.0:</b> 6.1x1.4x1.4inches or 153.8x36.0x35.2mm
<b>Weight</b>	<b>For YpsoMate® 2.25:</b> 61 g or 0.13 lb <b>For YpsoMate® 1.0:</b> 53 g or 0.12 lb
<b>Type</b>	Handheld, reusable, non-rechargeable
<b>Battery</b>	Main battery (non-rechargeable): CR 2032 Li-manganese dioxide. Secondary battery (charged by the main battery): Lithium-ion polymer
<b>Environmental conditions</b>	41 °F to 95 °F or + 5 °C to + 35 °C @ 15–90 % rH non-condensing within the atmospheric pressure range 700–1060 hPa
<b>Ingress protection classification</b>	IP 20 as defined by IEC 60529
<b>Intended usage lifetime</b>	Re-usable without charging for up to 2 years or 120 injections after a storage period of up to 3 years
<b>Activation time</b>	Less than 1s on insertion of an autoinjector
<b>Data logging</b>	Secured data storage for the captured Injection Data and Device Data. ECIES*-based encryption of the data in the local memory
<b>Feedback (User Interface)**</b>	Real-time patient guidance using acoustic and visual feedback
<b>Communication</b>	Bluetooth® Low Energy 5.1 for the data transmission and the NFC tag interface for the initial pairing procedure
<b>Data security</b>	TLS 1.3 end-to-end secured communication via BLE, sensitive data end-to-end ECIES* encrypted
<b>Smart NFC-based label**</b>	ISO 15693 compliant NFC reader for reading the SmartLabel of the YpsoMate®
<b>Sensors and detection capabilities</b>	Detection of autoinjector presence. Detection when the NFC tag is read. Inductive coupling-based detection of the injection status of the inserted autoinjector. Motion sensing used to wake-up from standby mode

\* ECIES - Elliptic Curve Integrated Encryption Scheme

\*\* Optional