




CliniPilot®
YpsoMate

Switch on connectivity in your clinical trials.



swissengineering 

Leveraging connectivity to empower, enrich and derisk clinical trials.

- Seamless integration with EDC (Electronic Data Capture) systems and existing workflows enables automated data transfer and enhances operational efficiency in clinical trials
- Automatic data capture eliminates patient diaries, along with associated human errors and manual documentation burden
- Real-time adherence tracking, as well as detection and identification of user errors – minimized through digital guidance – help reduce protocol deviations
- Captures real-world evidence to support regulatory approval and post-market insights
- Developed in line with FDA guidance and applicable for fully decentralized, hybrid and centralized trials

Making selfcare simpler and easier.

YPSOMED
SELF-CARE SOLUTIONS



Seamless data integration into clinical trials

- Seamless integration with existing clinical trial infrastructures without disrupting current workflows
- Automatic Bluetooth® transfer of injection and device data to the participant's smartphone – no user interaction required
- Companion app formats injection data for compatibility with EDC systems, and transmits it via encrypted channels
- Potential embedding into existing ePRO (electronic Patient-Reported Outcomes) app, enabling participants to self-report health outcomes while CliniPilot® data is captured and transmitted automatically in the background
- Possible unification of the clinical workflow by integrating eCOA (electronic Clinical Outcome Assessment) platform – including clinician-reported observations (site-based) and participant self-reports (ePRO) – with real-time CliniPilot® injection data, directly accessible through the EDC system
- Device data is transmitted to Ypsomed's Device Management Cloud, enabling maintenance and cybersecurity

Structured and secure data capture for every injection

- Captures injection data—time, date and injection outcome – automatically and in real time
- Distinguishes between different user errors (such as incomplete injection or holding time violations)
- Check drug-specific metadata (e.g. drug type, expiry date) via optional NFC SmartLabel
- Captures device data (e.g. battery and connectivity status, serial number) for cybersecurity and maintenance reasons
- Injection data owned and controlled by the pharmaceutical trial sponsor, not accessible or viewed by any third parties except clinical trial and CRO staff

Dimensions and specifications Facts and figures

Dimensions	For YpsoMate® 2.25: 5.3 × 1.6 × 1.6 inches or 134.5 × 39.6 × 40.4 mm For YpsoMate® 1.0: 6.1 × 1.4 × 1.4 inches or 153.8 × 36.0 × 35.2 mm
Weight	For YpsoMate® 2.25: 61 g or 0.13 lb For YpsoMate® 1.0: 53 g or 0.12 lb
Type	Handheld, reusable, non-rechargeable
Environmental conditions	41 °F to 95 °F or + 5 °C to + 35 °C @ 15–90 % rH non-condensing within the atmospheric pressure range 700–1060 hPa
Ingress protection classification	IP 20 as defined by IEC 60529
Intended usage lifetime	Reusable without charging for up to 2 years or 120 injections after a storage period of up to 3 years
Data logging	Secured data storage for the captured injection data and device data
Feedback (User Interface)*	Real-time patient guidance using acoustic and visual feedback
Communication	Bluetooth® for the data transmission and the NFC for the pairing
Data security	TLS 1.3 end-to-end secured communication, sensitive data end-to-end ECIES encrypted
Smart NFC-based label*	ISO 15693-compliant NFC reader for the SmartLabel of the YpsoMate®
Sensors and detection capabilities	Automated activation of the device with motion sensing. Detection of autoinjector presence. Inductive coupling detection of the injection status.

* Optional