



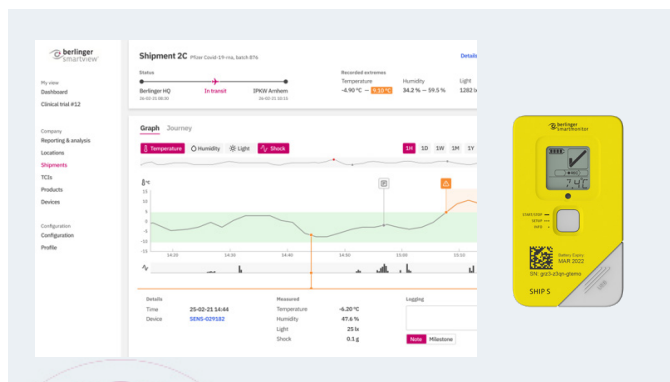
Supply Chain Visibility made easy, End-to-End

The Berlinger SmartMonitor® by Sensitech enables global, real-time end-to-end location tracking with validated, GxP-compliant temperature monitoring. Tailored for life sciences, the SmartMonitor solution proactively notifies logistics and partners, providing in-transit and stationary visibility and instant alerts, while speeding product release by automating data sent to the cloud. The SmartMonitor solution adds intelligent visibility to your shipments and sites. It enables validated, GxP-compliant shipment accept/reject decisions. Built-in, rechargeable battery management simplifies device management. The solution provides crucial insights into what occurred during shipment and storing to support root cause analysis.

In-transit Monitoring with SmartMonitor SHIP S

Key Features and Benefits

- Modular, real-time in-transit monitoring with validated temperature and light sensors.
- Product-level monitoring via parent-child intercommunication (BLE) with gateway devices (SmartMonitor SHIP L).
- Standalone monitoring device for shipments with easy data retrieval through USB readout functionality.
- Lithium coin cell (no IATA Dangerous Goods label required).
- Streams secure cGxP-compliant data to SmartView when connected via BLE intercommunication for seamless quality and product release workflows.
- Fully compliant with FDA 21 CFR Part 11, GAMP5, and more.



SmartMonitor for In-transit



SmartMonitor SHIP L

Modular Real-time
Monitoring Device for Shipments



SmartMonitor SHIP S

Modular Real-time as Child or Standalone
Monitoring Device for Shipments



SmartMonitor SHIP S Specifications	
Recording Option	Single-Use, Real-time with BLE Intercommunication
Certified Modes of Transport	Air, Ocean, Road, Rail (Airline approvals upon request)
Sensor Types	Temperature, Light
Temperature Measurement Range	-30°C to +75°C (Other ranges, SmartSensor can be used)
Temperature Accuracy Range	±0.5°C in range -10°C to +45°C / ±1.0°C in ranges -40°C to -10°C and +45°C to +75°C
Alarms	Up to 24 individually programmable alarm/warning rules, for temperature
Remote Device Configuration	Automatic when connected via BLE intercommunication
Temperature Accuracy Certification	A sampling lot acceptance test (Berlinger Standard Calibration) is performed and documented with a Certificate of Conformance per batch; Individual device calibration, including Certificate of Calibration, is available upon request
Temperature Sensor Sample Interval	5 to 240 minutes (5 minute increments)
Temperature Measurement Responsiveness	Complies with EN12830
Start Up Delay	0 minutes to 4 hours
Light Sensor Range	Light intensity threshold detection 0.1 to 1000 lux
Communication	Bluetooth Low Energy (BLE)
Memory	120 days @ 10 minutes measurement interval (all sensors active)
Battery Type	Non-rechargeable, Lithium coin cell
Shelf Life	12 months, Single-use
Operating Life	Typical battery run time 120 days with BLE (at 1 hour cloud synchronization interval)
Dimensions and Weight	100 x 75.5 x 12 mm, 50 g
Environmental Rating	IP65
Regulatory	CE (RED), FCC, IC 21 CFR Part 11, GAMP5, IEC 62368-1, RTCA DO-160, RoHS
Display Indicators	LCD screen icons: Ready to Start, Running, Stopped, Alarm status (OK (✓) and Alarm (✗), Warning, Start-up Delay, Uploading to Cloud, Upload to Cloud Complete, Bluetooth En-/Disabled, Battery Status; Static or Scrolling Text to Support User
Secondary Download	USB type A read-out
Software Interfaces	SmartView Platform
Cold Chain PDF Report	PDF generated by cloud software, Manual read-out option via USB

Sensitech has performed all necessary testing and can provide documentation supporting our compliance at your request.