



FPPV **TRACK&TRACE DEVICES -** **SERIALIZATION**

Serialization in the pharmaceutical industry ensures full supply chain traceability, helping to prevent counterfeiting and protect patient safety. At Opticum, we provide a wide range of serialization devices compliant with global regulations, suitable for packaging elements like blisters, leaflets, bottles, and wallets. Our solutions are built for strict GxP environments and meet FDA 21 CFR Part 11 and GMP Annex 11/15 requirements.

FPPV – FLAT PACK PRINT AND VERIFY SYSTEM

The FPPV is a system designed for the most demanding pharmaceutical environments. It enables printing with print inspection on unformed packaging elements. The device's feeding mechanism supplies packaging elements from the infeed magazine to the transport system, where the material code inspection, printing, and product material code control are carried out. Incompliant products are rejected into the rejection bin.

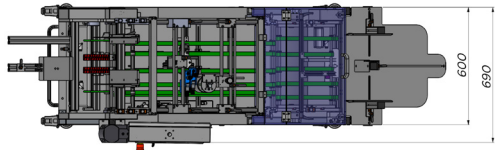
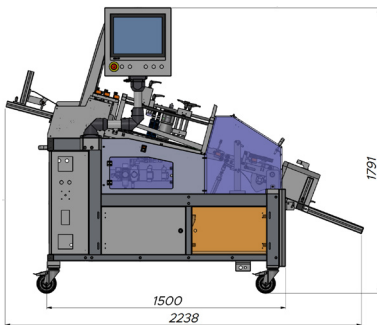
HIGHLIGHTS:

- **Output up to 100 products/min:** With consistent precision and quality.
- **Versatile Product Handling:** Supports printing on both standard and non-standard carton formats, including wallets and large folding cartons.
- **Compact Footprint:** Extremely compact structure fits perfectly even in space-constrained environments.
- **Unified Human-Machine Interface (HMI):** All device functions are intuitively managed through a single, user-friendly touchscreen interface, simplifying operation and reducing training time.
- **Printed Text Verification** – Utilizes OCR/OCV and pattern matching to ensure all printed data is accurate, legible, and compliant.
- **Automated Rejection System:** Features a smart rejection mechanism with integrated sensors to confirm successful removal of non-compliant products.
- **Material code control:** Code reader for material code control.
- **High autonomy:** Infeed magazine adjustable up to a height of 600 mm.
- **Modular Software Architecture:** Ensures robust operation in accordance with GxP and also reduces production line downtime required for validation.
- **Flexible Communication Interface:** Seamlessly connects with Track & Trace servers, recipe systems, MES, SAP, and other higher-level IT infrastructures.

TRACK & TRACE

The device's core software can be extended with a **Track & Trace module**, designed to meet the evolving demands of global pharmaceutical serialization and aggregation regulations. This module ensures compliance with all currently known regulatory requirements across key markets, including **Europe, USA, Russia, Japan, China, Saudi Arabia**, and more.

- **GS1-Compliant Code Grading:** Supports a wide range of serialization formats including 2D DataMatrix, 1D Code 128, GS1 DataBar, with real-time grading for quality assurance.
- **Seamless Integration with Aggregation Sub-Devices:** Integrates with various aggregation sub-devices such as casepacker, manual aggregation station and supports on-the-fly switching between device types during batch changeovers.



TECHNICAL SPECIFICATIONS

Device dimensions (length x width x height) [mm]	1755 x 760 x 2150
Device weight [kg]	300
Minimum product dimensions (length x height x depth) [mm]	40 x 0.2 x 50*
Maximum product dimensions (length x height x depth) [mm]	408 x 15 x 400*
Printer type	Continuous inkjet
Line Integration	Standalone device

**Specifications reflect the standard configuration and can be fully customized to meet specific customer requirements.*