SYSTECH® PCE

SOLUTION BRIEF

# Overcome the challenges of label printing for clinical trials

The PCE T11 Manual Mark & Verify offers a flexible, cost-effective solution that ensures label accuracy.

## The complexity of clinical trial labels

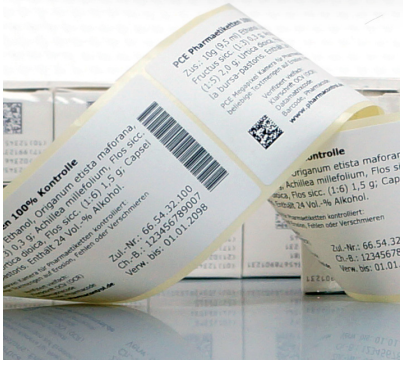
Printing and verifying labels for investigational medicinal products (IMPs) used in clinical trials is challenging. Stringent regulatory compliance, country-specific language requirements, and the implementation of European Union Clinical Trial Regulation 536/2014 (EU CTR) add to the complexity.

Label content varies based on the design, phase, and location of the clinical trial. Updated labelling is required any time changes in dosage, expiry dates, and other label components arise between or during clinical trials.

Just-in-time printing may be required for site-specific or additional labelling requirements to prevent delays and help with supply chain management. Other situations may call for short-run printing and verification of labels for later use. Both scenarios can make outsourcing or the investment in separate printing and verification systems costly and inefficient.

Despite these and other issues, subject safety and the integrity of clinical trial data are critical. There is no room for labelling errors.

The PCE T11 Manual Mark & Verify overcomes the challenges with a single solution designed for flexibility, ease of use and accuracy.



## Space-saving all-in-one solution

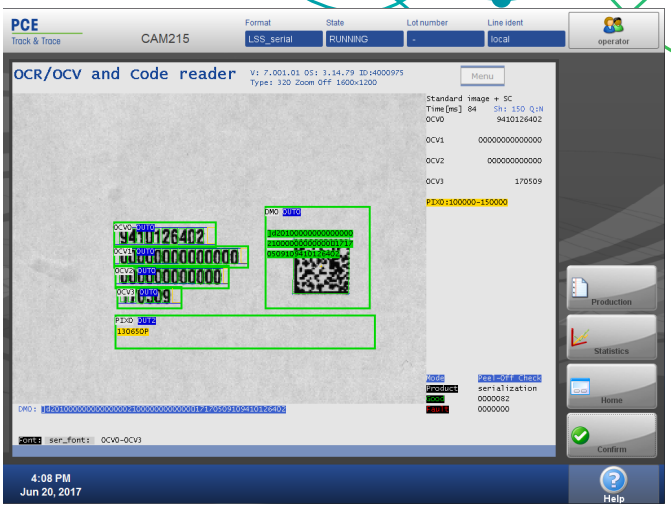
The T11 provides agile label printing and precise verification capabilities in a compact, integrated solution. Featuring an ergonomic, space-saving design, it can be comfortably used in small, confined environments or moved to other spaces or sites when needed.

## Designed for flexibility

The T11 supports variable data and formats. That includes the labelling requirements specified in the EU CTR, which went into effect 31 January 2022 and replaces the European Union Clinical Trial Directive (EU CTD) 2001/20/EC. The system can handle content associated with whichever regulatory framework applies or changes that arise during the transition period between EU CTD and EU CTR.

Country-specific language requirements can be accommodated as well. The T11's flexibility also enables it to be used for serialization, expanding its potential usage and return on investment. In addition, other capabilities can be enabled as needs change.

**The T11 supports label content associated with both EU CTR and EU CTD, as well as country-specific language requirements.**




## Quick setup and production

**Setting up a new label takes only minutes, helping prevent potential delays in clinical trials.**

1. IMP label design and content approved
2. Information input manually or via software
3. Data dynamically assigned to PDF template
4. Labels printed in peel-off or reel-to-reel mode
5. Camera inspection with PDF comparison
6. Error/omission alert; production stops
7. Manual removal of faulty label
8. Production proceeds
9. PLM software displays defect origination

## Now or later usage options

For additional efficiency and flexibility, the T11 offers two production modes:

- Peel-off mode supports just-in-time printing and enhanced supply chain management.
- Rewind mode enables labels to be printed and verified in batches and rewound reel-to-reel for later use.

Learn how the T11 Manual Mark & Verify can meet your needs for cost-effective, accurate and efficient printing and verification of labels for IMPs used in clinical trials.

Ensure accuracy and efficiency in your clinical trials label production! **REQUEST A DEMO →**

SYSTECH® | PCE

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Traceability and serialization solutions to drive efficiency, achieve compliance and protect your brand.



+1 800 847 7123 (toll free)
+1 609 395 8400 (local)

Info@SystechOne.com
SystechOne.com