ProTube™

Product Information

2024, December

Contents

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1. Enhancing Patient Safety

The ProTube™ Suite represents Inpeco's comprehensive solution for improving patient safety throughout the pre-analytical phases. This is achieved by ensuring traceability of activities, such as accurate patient identification, proper alignment between patients and samples as indicated in the test requests, and management of pre-analytical variables via automated labeling containing patient information and necessary tests.

The subsequent sections will provide an in-depth examination of the proposed solution, underscoring:

- **Adaptability:** The technology is designed to seamlessly integrate into hospital environments, allowing for customization of operational workflows to suit the specific organizational and workload demands of healthcare facilities.
- **Scalability and Versatility:** The solution is capable of adapting to various operational scenarios, whether in phlebotomy rooms, hospital wards, or home-care settings.
- **Technological Pervasiveness:** The ProTube™ system can integrate with existing hospital infrastructure to monitor performance KPIs of phlebotomy centers.

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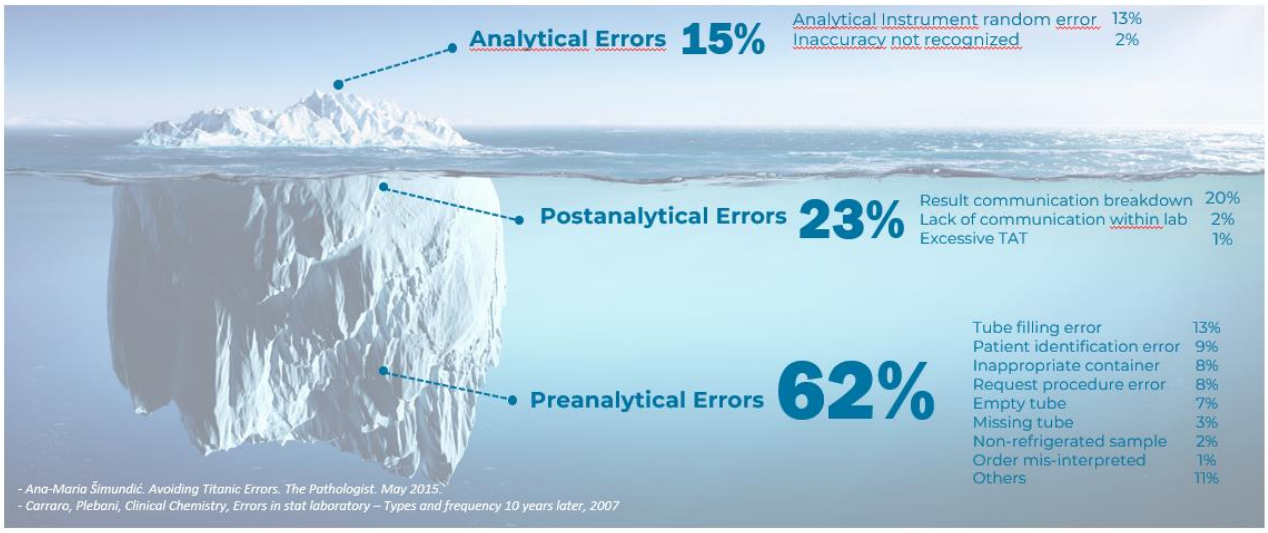
2. Scope

Modern medicine has progressed toward a model where clinical decisions are predominantly guided by information from clinical laboratories. It is estimated that approximately 70% of medical decisions are based on results from blood sample analyses. Consequently, laboratory results critically influence patient diagnosis, treatment, and overall health management.

To ensure the highest reliability of results, high-quality samples are essential; these must be correctly identified, matched to the appropriate patient, accurately labeled, and transported under optimal conditions. Literature indicates that laboratory medicine influences 70% of clinical decisions.



With the growing demand for decentralized patient treatments, the risk of diagnostic errors escalates significantly. Clinical outcomes hinge on the sample collection phase, which currently stands as the most vulnerable segment of the Total Testing Process. Medical literature reveals that 62% of diagnostic errors transpire during the pre-analytical phase, with common issues including tube filling errors, patient mismatches, and the use of incorrectly labeled tubes.

Improper sample handling during initial stages can lead to errors that taint the entire diagnostic workflow, risking misdiagnosis. Complete traceability of samples during the pre-analytical phase is vital for ensuring impeccable sample quality upon laboratory arrival and maintaining an error-free process from blood collection to final laboratory test results.

Although advancements in analyzers and automation have notably reduced errors within laboratory environments over the past decades, the external phases leading to

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the laboratory often remain poorly monitored. As such, there is a pressing need for technologies that facilitate comprehensive monitoring of activities surrounding laboratory operations. Leveraging Inpeco's technology, the proposed initiative involves the development of a traceability system for the Pre-Pre-Analytical phase, aimed at minimizing errors and simultaneously monitoring the entire sample journey—from laboratory LIS order reception through to tube delivery for analysis, encompassing the collection phase.

[1] - Beastall GH. Adding value to clinical biochemistry. *Ann Clin Biochem* (2010) ;47(Suppl 1);
Hallworth MJ. The '70% claim': what is the evidence base? *Ann Clin Biochem* (2011);48
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[1] Šimundić A-M, Avoiding Titanic Errors, The Pathologist, (2015)
Plebani M, Mistakes in a stat laboratory types and frequency HL; Chimical Chem (1997);43
Carraro P, Plebani M, "Errors in a stat laboratory: types and frequencies 10 years later," Clin Chem (2007), 53

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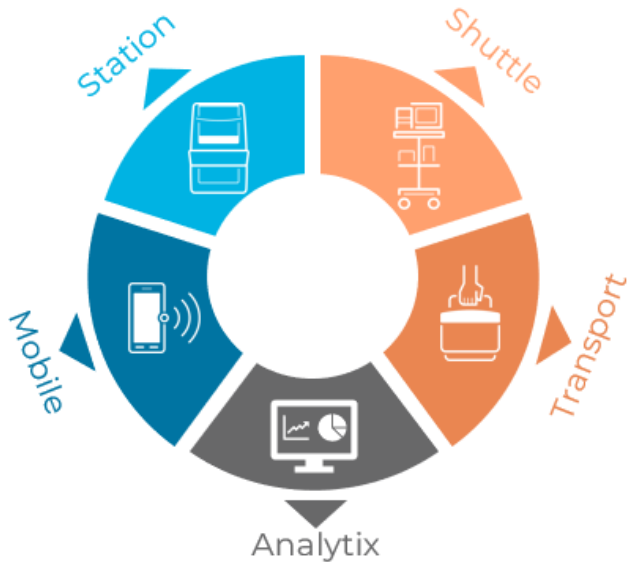
3. ProTube™ Suite

The solution devised by Inpeco for pre-analytical phase traceability consists of various options tailored for adaptability to diverse requirements, as well as scalability and versatility. The technological support offered by the ProTube™ Suite is comprised of:



1. ProTube™ Station
2. ProTube™ Mobile
3. ProTube™ Transport
4. ProTube™ Analytix
5. ProTube™ Shuttle

ProTube™ is offered in both Standard and Mobile configurations:

- **Standard Configuration**: Includes both software and hardware components.
- **Mobile Configuration**: Comprises software components developed in Inpeco and third parties' devices.

Customers enjoy the flexibility to begin with either configuration and seamlessly add components from the other, without any technical or business limitations.

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3.1.ProTube™ Station

ProTube™ Station serves as a compact desktop automation and traceability solution, ideal for phlebotomy centers and environments where biological sample (blood and/or other) collection is necessary.

Key Hardware Components of ProTube™ Station:

- ProTube™ Master (primary automatic labeling device for samples)
- Auxiliary printer (for printing additional labels, swabs, special containers, etc., as well as reprinting patient labels)
- Tablet (for user interface management)

Main Software Components:

- Traceability Hub (T-Hub): Middleware responsible for system management
- ProTube™ Phlebotomy Assistant SW: Software installed on the tablet
- Data Analytics System (platform for process data collection and analysis)

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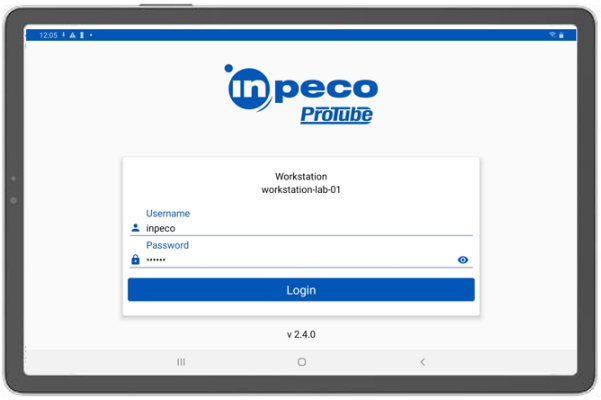
Operational Steps for Phlebotomists using ProTube™ Station:

1. **Operator Traceability at Login:** Each operator is uniquely identified with personal credentials, ensuring complete traceability.



2. **Patient Identification:** The operator receives guidance for patient identification through reading health cards, acceptance forms, identification bracelets, and more.

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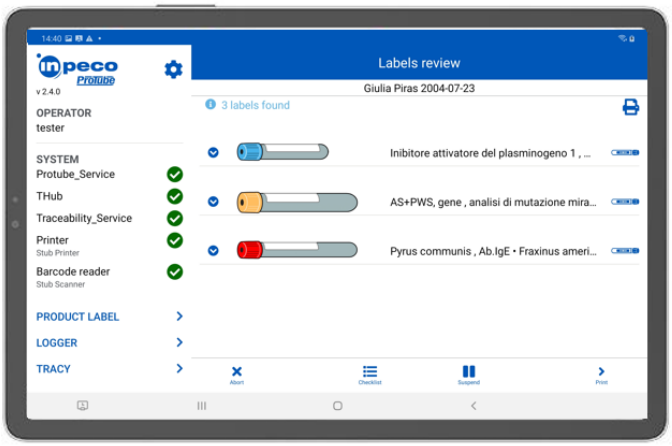
3. **Order Review:** The system displays all relevant details related to prescribed tests for the patient, including tubes/containers requiring labeling, facilitating a cross-check against the original prescription.



4. **Labeling:** The ProTube™ identifies the tube selected by the phlebotomist; if correct, it automatically applies the label while ensuring the inspection window and filling notch remain clear. Incorrect tubes are automatically discarded in an easily accessible compartment.

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5. **Sample Collection Execution:** The graphical interface provides vital information to the operator regarding sample collection order and required tube inversions.

6. **Sample Checkout:** At the conclusion of the collection process, phlebotomist must scan tube barcodes to confirm execution and time record. Any errors or suggestions regarding sample preservation are automatically presented, and it verifies that all required tubes have been collected. The checkout for each tube and any clinical notes entered may be reported to the laboratory's LIS (Laboratory Information System).

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Benefits of the ProTube™:

- Reliable traceability for blood samples and biological materials.
- Record of collection with accurate ties between collector, patient, and samples.
- Comprehensive collection reports with insightful annotations for operators.
- Reduction of human error-related issues.
- Sample traceability compliant with ISO UNI EN ISO15189 regulations.
- User-friendly system that ensures operational reliability.
- Collection data for statistical analysis (Data Analytics System).

Key Features of ProTube™:

- **Secure Patient Identification:** Utilizing an integrated barcode reader, the system scans a unique barcode linked to the patient (e.g., health card, report retrieval form) and retrieves demographic data, which is confirmed by the collector before proceeding with orders and further steps.
- **Automatic Management of Label/Tube Association:** The application presents the operator with the necessary tubes (type and quantity) and executes the labeling process automatically, producing specific labels for each tube/test while also generating auxiliary labels for special requirements or reprints. The high level of automation optimizes traceability in the collection and retrieval process for biological samples. Each operational step is monitored by dedicated sensors that confirm:
    - Tube presence in the insertion compartment
    - Tube placement in the labeling chamber
    - Tube dimensions
    - Color of tube cap
    - Position of pre-existing label on the tube

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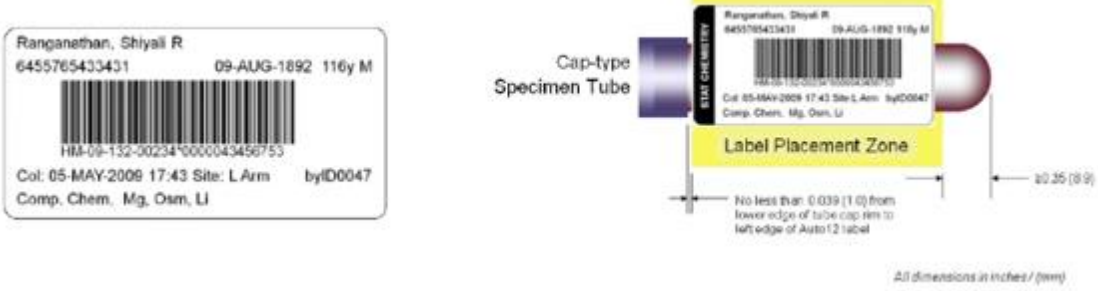
- **Label Format Configuration (Standard CLSI Auto 12-A):** The ProTube™ allows for configuration and printing of sample identification labels according to international CLSI AUTO 12-A standards or the laboratory's current protocols. It accommodates various types of barcode identifiers:
    - CODE39
    - CODE39 with check digit
    - CODE128
    - CODABAR
    - INTERLEAVED 2 of 5
    - INTERLEAVED 2 of 5 with check digit

Templates for different tube/container types can also be configured.



Label Placement: ProTube™ supports label printing for patient and sample information as per the CLSI AUTO12-A standard, detailing format and field positioning for patient labels, mandatory fields, and optional fields such as collection date, demographic data, request ID, and barcode sample ID. The new identification label is affixed automatically over the manufacturer's original label, while ensuring visibility of the inspection window and fill level mark to facilitate optimal collection.

Additional Operational Features:

- **Reprint:** Immediate reprinting of labels can be performed via an input available on the IUI of the ProTube™ App. In the case of the ProTube™ Station, the label can be printed using either the ProTube™ Master or the Auxiliary printer. In the case of the ProTube™ Mobile, the label can be reprinted via the Bluetooth printer.
- **Order Suspension:** The ProTube™ allows for temporary suspension of the workflow in case of issues, with the ability to resume later while tracking collected and pending samples.

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- **Timed Collection Management:**

  The ProTube™ is designed to prepare only the necessary tube in real-time and in front of the patient at the specific time, avoiding the need to produce all the samples required for all curve tests at the same time. This prevents the need to deliver or keep tubes at the collection point that could be lost track of.

- **Management of Biological Samples Beyond Blood:**

  The ProTube™ accommodates a variety of sample types, including urine, ensuring comprehensive traceability across different collection methods.

- **Differentiated Sample Management:**

  Each collection site can be tailored to manage specific collection of biological samples, optimizing patient flow within the center.

- **Special Sample Management:**

  ProTube™ provides instructions for handling each individual tube for specific tests, such as signing the "blood type" tube or indicating to immediately place the tube on ice (Homocysteine test), or at 37°C. These and other "Alerts" are configured during device programming. The nurse will have all the data related to the tube treatment (e.g., place on ice) or patient (e.g., verify fasting for 12 hours and rest for 15 minutes) available on-screen; in some cases, the system will not allow the collection until the collector explicitly confirms viewing the instructions, and all operations will be tracked..

- **Clinical Data Entry During Collection:**

  The ProTube™ allows for Clinical Data entry of essential data impacting test results, which can be printed on labels and sent electronically to the LIS.

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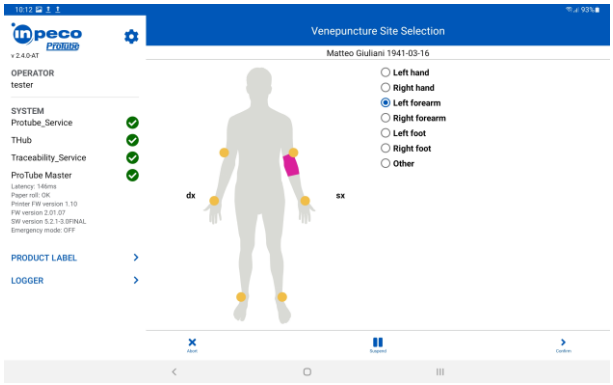
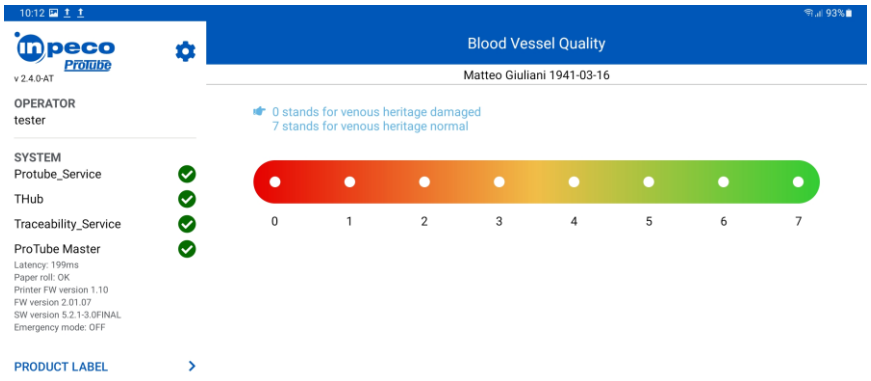
The application on the tablet accompanying the ProTube™ device facilitates access to additional screens for enhanced traceability, allowing for site identification from which the sample was collected.



Additionally, the system will prompt operators to assess collection complexity on a scale from 1 to 7, providing insights into potential increases in collection time and guiding operators in future collections. This information aligns the ProTube™ with the requirements outlined in the current open procedure.



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3.2. ProTube™ Mobile

ProTube™ Mobile is the portable solution designed to manage biological sample collections with utmost security and traceability for Point of Care (POC) applications.

With the healthcare system increasingly embracing patient-centric models, Point of Care applications have garnered heightened importance. ProTube™ Mobile has thus been developed as a flexible, user-friendly solution capable of extending traceability beyond hospital borders, facilitating safe process execution in external environments, including home collection.

The ProTube™ Phlebotomy Assistant software installed on the handheld device provides an intuitive graphical interface that guides healthcare operators through the entire sample preparation and collection process, while the Bluetooth printer enables label printing in the patient's presence.

Additionally, ProTube™ Mobile facilitates the transportation of tubes from collection points to laboratories or, in specific cases, supports the movement of tubes across different laboratories.

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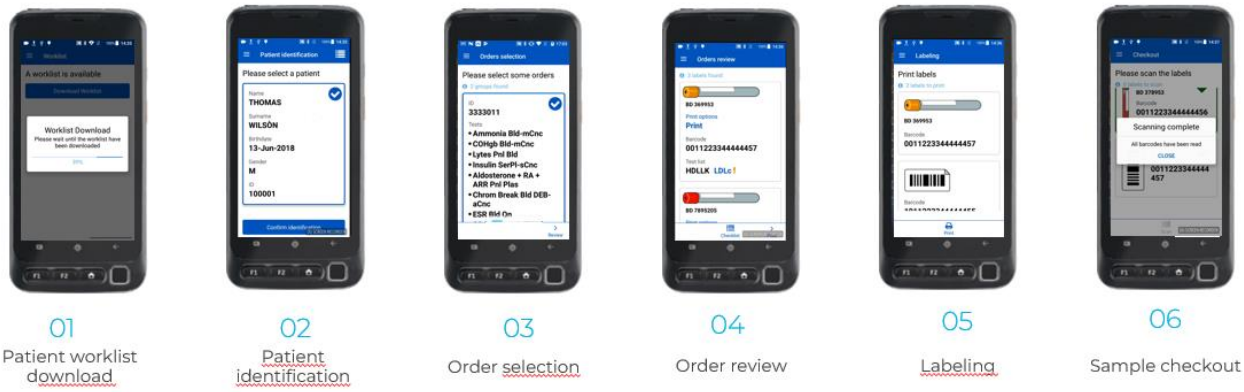
Hereafter the operational steps that guide the Phebotomist during the sampling process while using ProTube™ Mobile.



1. **Operator Login:** Access the system using unique credentials, tying all traceability and process events to the operator.
2. **Download Patient Worklist:** Through secure hospital network connectivity, a patient list can be downloaded, optimizing daily routines and managing tasks both online and offline.
3. **Patient Identification:** A built-in barcode reader scans the unique patient ID (e.g., health card, identification bracelet).
4. **Order Selection and Label Printing:** Operators select the order to process for the patient, revealing necessary tubes and other sample information.
5. **Labeling:** The graphical interface assists operators in accurate sample labeling.
6. **Checkout:** Confirmation of collection is achieved by scanning the individual sample barcodes.

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3.3. ProTube™ Transport

ProTube™ Transport is the intelligent solution developed for ensuring traceability of biological samples during their journey from the collection center to the clinical laboratory. This system comprises data loggers and traceability tags compatible with conventional racks and transport containers, supplemented by a Fast Check-in station positioned within the laboratory acceptance area for efficient sample intake. If Inpeco racks are utilized, the barcode on the rack can be scanned for immediate recognition.

Benefits

- Full sample transportation traceability
- Fully integrated transport system (sample collection data)
- Open solution → integrable with commercial rack and transportation box
- Guaranteed chain of custody
- Faster lab-turnaround time → sample accessioning optimization
- Expected laboratory workload (incoming samples in transit/ arrived)

Applications

- Internal sample transportation
- External sample transportation

The software developed for ProTube™, when the Transport software module is enabled, can guide transport operators at the phlebotomy center to efficiently prepare samples by loading them into the recognized rack at the beginning of the daily operations, while providing condition tracking to uphold chain of custody.

Main Features

- Tracking of individual samples transported
- Time and temperature monitoring
- Automatic sample arrival registration
- Monitoring system → alerts if transportation conditions do not comply with set parameters

Other Features

- Transportation mission start/end time
- Single tube - rack matching
- Single rack - box matching
- Mid-Range RFID technology
- Transportation mission history list
- Threshold settings for samples acceptance criterizza

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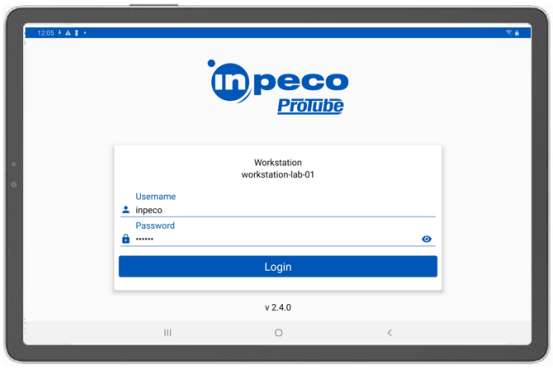
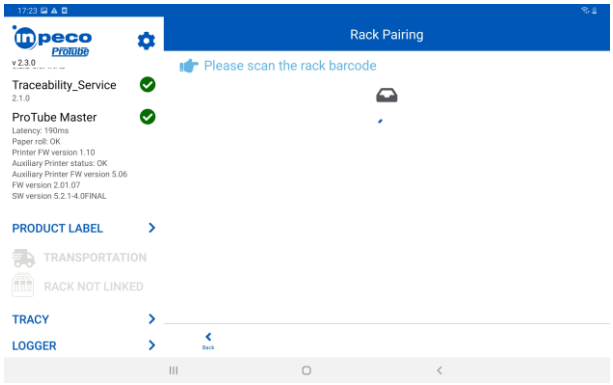
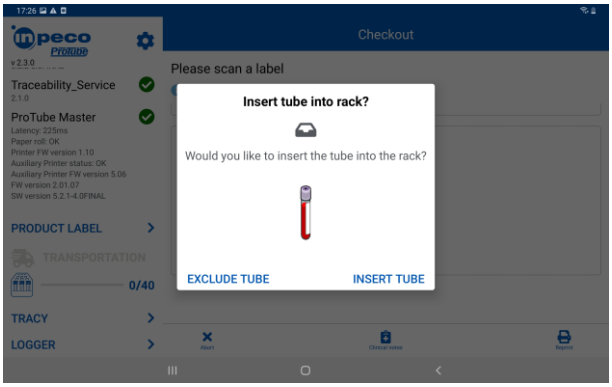
1. **Operator Traceability at Login:** Each operator is uniquely identified with a personal password, ensuring comprehensive traceability.



When the Transport Module is activated on the ProTube™ Station workstation, the operator identifies the rack being used for tube collection by scanning its QR Code.



2. **Checkout of Collected Samples:** After sample collection, operators must scan the tubes' barcodes to confirm and certify correct, complete execution and time registration. The checkout process also ensures verification of all expected tubes, while any preservation errors or notifications automatically appear on screen.



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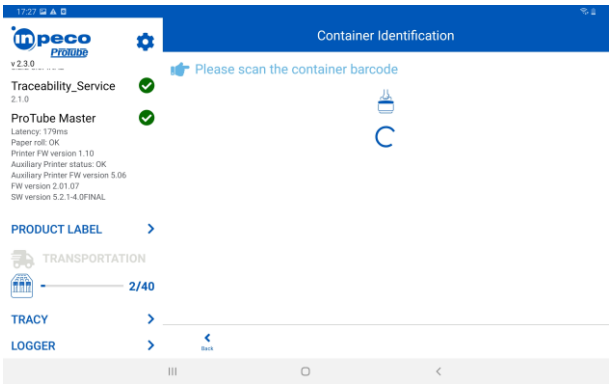
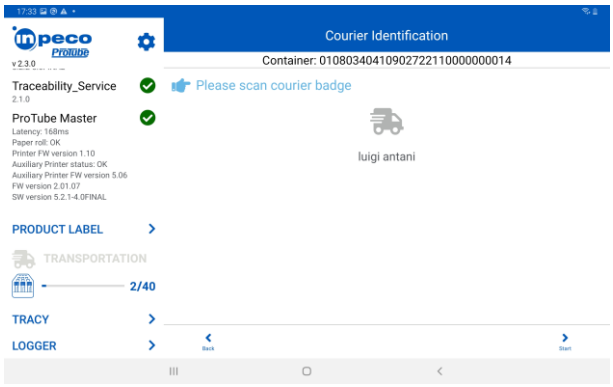
3. **Transport:** Once the rack is prepared for shipment to the laboratory, the transport phase initiates via the dedicated graphical interface. The system will request identification of the transport container (not supplied by Inpeco; user-defined containers may be used) by scanning the QR code of the data logger within the transport container. Each rack being shipped requires association with this container, achieved by reading the QR code on the transport rack.



4. **Courier Identification:** As part of maintaining chain of custody, operators will identify the courier responsible for transporting the samples, using a [system-specific] recognition card.



Upon completion of these steps, the system will display a message indicating that the tubes are ready for transport to the laboratory.

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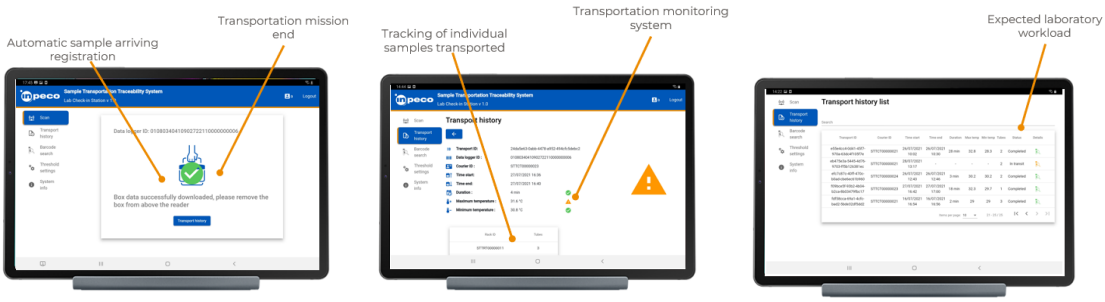
Fast Lab Check-in Station with Traceability Software

The Fast Lab Check-in Station facilitates quick and automatic sample registration in the laboratory without manual intervention. The mid-range RFID reader detects the container's arrival and automatically retrieves transport mission data.

Transport traceability software enables immediate inspection of transport conditions, validating time and temperature compliance with acceptance criteria established by laboratory personnel. The easy-to-use graphical interface alerts operators if sample acceptability criteria are not met, permitting tracking of each transport mission and forewarning the laboratory of incoming containers to enable efficient workload planning.



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RFID Data Logger

The RFID data logger, installable in any transport container, records time and temperature metrics during transport, ensuring these details are captured from the onset until laboratory identification by the Fast Lab Check-in Station. The logger has a unique identification code to associate each transport rack with its corresponding container.

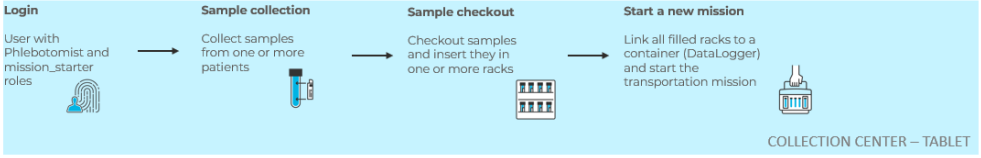
3.3.1. Centralized Mission Coordination for ProTube™ Transport

This innovative module provides an alternative to previously outlined Transport features, empowering users to efficiently coordinate shipment racks from one or multiple workstations (drawing stations) within the same collection center. By leveraging synergy between two key devices in the ProTube™ portfolio, this feature marks a significant advancement in our operational capabilities.

The transportation process may now be seamlessly initiated via the handheld ProTube™ Mobile device, enhancing user convenience and flexibility.

Two operational scenarios that arise:

1. An operator assumes the roles of "Phlebotomist" and "Mission Starter." Using the app installed on the tablet paired with the ProTube™ Station, the operator retains full control over the sample collection process and can smoothly commence transport missions.



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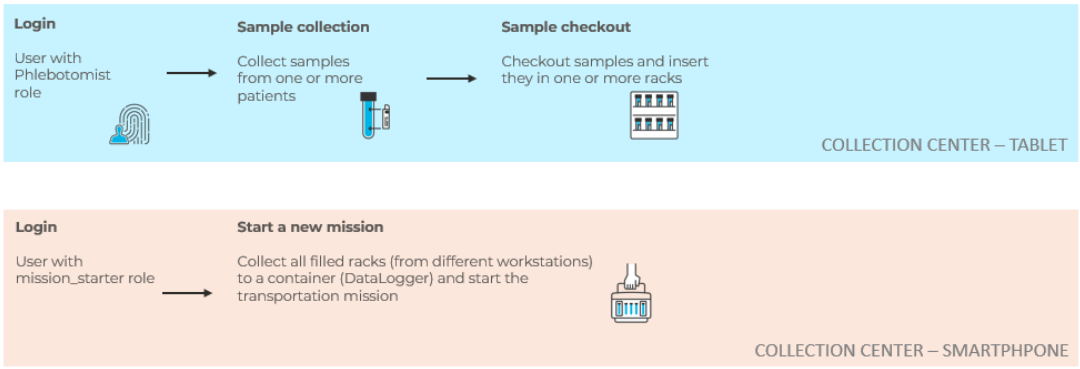
2. An operator, acting as the "Phlebotomist," manages the sample collection using the ProTube™ Tablet. After samples are linked to one or multiple racks and prepared for shipment, the Phlebotomist notifies the designated "Mission Starter" operator responsible for sample transport. This user utilizes the app on the handheld device to facilitate rack pairing with the DataLogger in the transportation box, subsequently initiating the transport mission to ensure smooth sample transit.



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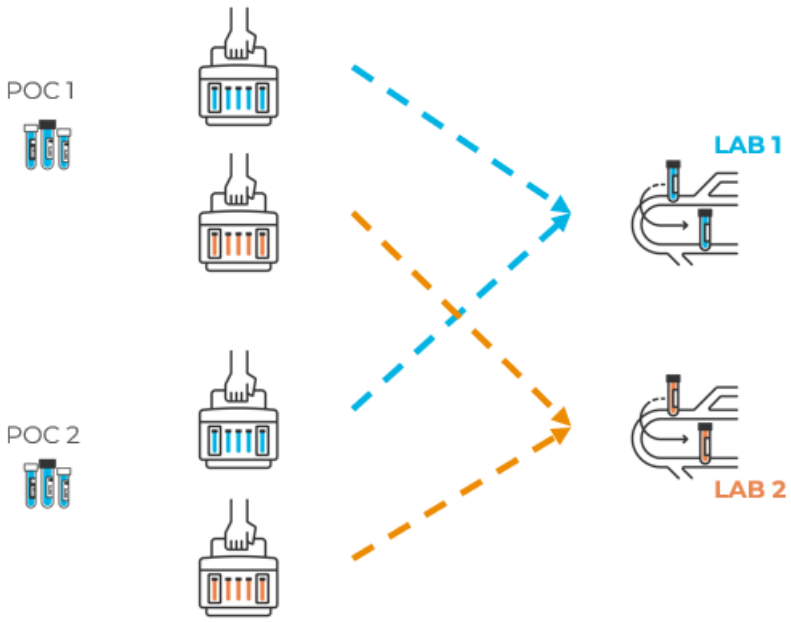
3.3.2. System for Optimizing Workflow with Multiple Destination Management

The new feature for managing multiple destinations is designed to simplify and optimize the transport of samples, ensuring greater accuracy and speed at all stages of the process.

The system guides the operator in sorting the samples right from the collection point, associating each sample tube with a rack defined for a specific final destination. This approach eliminates the need for additional sorting and allows for a smoother management of transports.

Once the rack is prepared, it is associated with a DataLogger (placed inside the transport box) to monitor transport data. Upon arrival, the immediate check-in system automatically recognizes both the rack and its destination, ensuring fast and accurate processing.



Phase 1: Sorting of Tubes at Check-Out

The process begins at the check-out of the sample tube.

The user interface guides the operator by showing in real time which rack each sample tube should be placed in.

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Thanks to this feature, sorting happens directly at the collection box, optimizing time and reducing the risk of errors.

Phase 2: Rack Preparation and Mission Initiation

Once the rack is complete, it is associated with a DataLogger, which is placed inside the transport container.

At this point, the system defines the transport mission based on the destination associated with the rack, allowing for a targeted and organized shipping process. The transport mission will then be initiated by the designated operator.

Phase 3: Immediate Check-In at Final Destinations

Upon arrival at the laboratory, the system further simplifies the process. With immediate check-in antennas, the DataLogger and associated racks are automatically recognized.

This allows for instantaneous verification of destination accuracy and speeds up sample processing.
Additionally, multiple check-in antennas can be configured at each destination to handle the flow of containers in parallel, further reducing waiting times.

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3.4. Data Analytics System (DAS)

All traceability and process data generated through the ProTube™ devices (Station, Mobile) are consolidated on the Data Analytics System software platform. ProTube™, meticulously tracks every event throughout the process, ensuring sample history accessibility. The DAS software platform provides customizable reporting screens (graphs, key indicators) for valuable insights aimed at optimizing the clinical, operational, and financial performance of healthcare facilities.

Data aggregation facilitates the generation and visualization of critical reports aimed at monitoring and enhancing the pre-pre-analytical phase, helping to optimize both the process and resources employed in phlebotomy centers and field operations.

Key Indicators Include:

- Operator activities concerning managed patients
- Real-time load across each phlebotomy point
- Hourly influx for optimized resource management
- Average processing times per operator
- Patient timeline tracking
- Consumables traceability (Needles, samples tubes, other containers)
- Monitoring of sample status (completed, suspended, or interrupted)

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3.5. ProTube™ Shuttle

The ProTube™ Shuttle is a component distributed with the ProTube™ Suite, representing the pinnacle of automation and traceability for bedside blood collection. This cart comes equipped with a high-performance battery, empowering nurses to conduct all routine blood collection activities without the dependency on physical outlets.

With this innovative device, nursing staff can transport the ProTube™ Station positioned on the cart's top shelf around various hospital wards to efficiently complete sample collections from each in-patient.

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4. Increasing Process Efficiency

The ProTube™, through the T-Hub middleware, adeptly connects with hospital information systems, ensuring comprehensive sample traceability. By monitoring, digitizing, and tracking all pre-analytical variables, the ProTube™ assists operators with requisite activities, facilitating a reduction in non-conformities and enhancing overall process efficiency.

The business intelligence features embedded within the ProTube™ solution allows for comprehensive monitoring of system performance, delivering immediate insights into the operational efficiency of phlebotomy centers, with particular focus on resource utilization. This insight promotes optimized planning and activity execution within phlebotomy centers while managing consumable procurement.

4.1. Architecture of the ProTube™ System

The architectural schema of the ProTube™ solution illustrates the integration and connection among various components of the ProTube™ Suite, along with the Laboratory Information System (LIS) via standard HL7 interfacing.

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4.2. LIS Connection

Inpeco's traceability project is designed to establish intra-hospital connections between multiple phlebotomy centers and central laboratories. This connection is fundamentally supported by the installation of middleware (T-HUB), which efficiently manages all devices within the ProTube™ Suite to oversee the sample journey from patient arrival at the phlebotomy center until sample delivery to laboratories.

The T-HUB will interface with hospital LIS or multiple LIS systems, as required through communication systems, notably Lab 61 and Lab 63 employed for order reception from the LIS to the ProTube™ Suite and vice versa for communication regarding sample progress.

Within phlebotomy centers, patient management will employ existing methodologies common in these facilities, utilizing technologies from various queue management systems for optimal ProTube™ connectivity.

The ProTube™ consists of two main components:

- **Traceability Hub (T-Hub):** A singular T-Hub per laboratory acts as a connector between laboratory systems and ProTube™ Workstations, residing within the laboratory's network (either in the same physical LAN or through designated VPN).
- **ProTube™ Workstation (PWs):** With workstation is identified every single ProTube™ Station and ProTube™ Mobile. These workstations ensure safe and traceable biological sample collection, supporting positive patient identification, order review, automatic tube recognition, automatic tube labeling, and tracing of biological samples.

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4.3. Configuration Scenarios

For the ProTube™ labeling system to function effectively, the following configuration data must be established:

- Label templates tailored to site needs, managed via T-Hub.
- Tube/test associations defined through rules selecting from the ProTube™ internal database of primary vendor tubes.

Two different scenarios exist based on LIS management of configuration data:

- **Transcoding on LIS:** In this configuration, the LIS manages tube/test associations and fills the necessary OML^O33 fields with Inpeco IDs for tubes and label templates. Transcoding rules must be created and managed in T-Hub to determine which tubes and label templates to employ at any given time.
- **Transcoding on ProTube™:** In this case, the LIS employs its internal tube codes, which are then transcoded by the ProTube™ system.

4.4. ProTube™ LIS HL7 Interface

This section delineates the technical and functional specifications necessary for HL7 message integration between a Laboratory Information System (LIS) or a Hospital Information System (HIS) capable of sending HL7 messages and the ProTube™ system. The T-Hub communicates with the LIS through a specific set of HL7 messages, namely OML^O33 and ORL^O34, facilitating order transmission from the LIS/HIS to ProTube™.

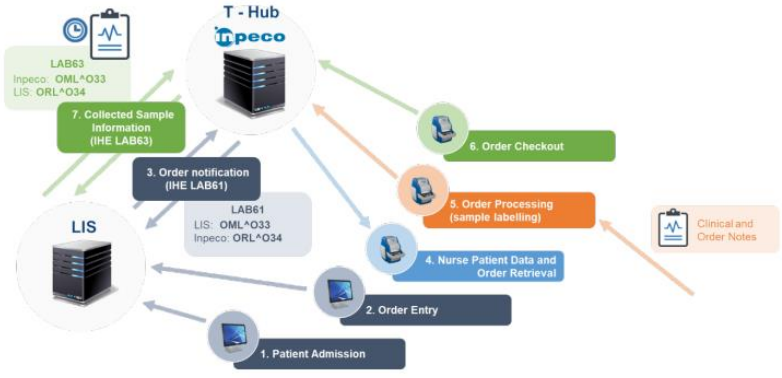

Figure 1 - HL7 Push LIS integration

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4.5. Queue Management Systems

The ProTube™ is designed to integrate with available queue management systems through appropriate interfaces to reduce patient waiting times and optimize routine operations for healthcare personnel.

Operational Functions Include:

- **Call Next Patient:** A service retrieves the next patient based on priority rules established in the Waiting List Management system, triggering all updates and alerts on display boards.
- **Recall Already Called Patient:** A service setup allows for re-calling previously called patients, with corresponding display board updates.
- **Mark Patient as Absent:** This service marks previously called patients as absent within the Waiting List Management system, automatically updating the list and notifications.

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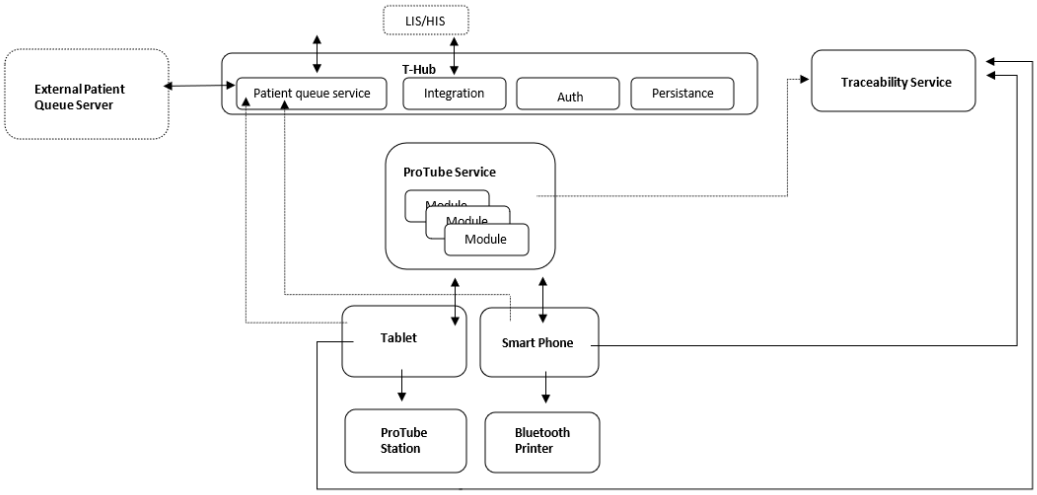
4.6. System Technical Requirements

This section summarizes ProTube™ Technical Requirements that are essential during the site assessment phase.

The ProTube™ encompasses three primary software components and Smart devices:

- **T-Hub:** A middleware providing product-agnostic functions, including authentication, persistence, traceability, and interoperability.
- **ProTube™ Service:** Responsible for gateway access to T-Hub services, clinical configurations, and worklist management.
- **Traceability Service:** Retrieves traceability events from smart devices and relays them to analytical systems when present.
- **Smart Device** (Tablet, Smartphone for ProTube™ Mobile, Bluetooth printer for ProTube™ Mobile, ProTube™ Station): Implements the ProTube™ workflow's business logic, enabling both online and offline processing modes and facilitating patient operations.



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4.7. Server Requirements

The ProTube™ System offers the following user authentication methods:

- **Local Database:** Stored locally within the Authentication Service.
- **Active Directory:** Connecting to one or more LDAP servers for user group configuration.

All inter-component communications utilize secure channels, ensuring robust data integrity.

4.8. T-Hub

T-Hub installation can be executed via:

- **Physical Server:** Requisite minimum hardware specifications include:
  - **CPU:** 1 x Intel Xeon E3-1120 v5 @3.00GHz
  - **Memory:** 32 GB RDIMM
  - **Internal Storage:** 3 x 500GB SATA 7,200 rpm 3.5" hot-swappable hard drives
  - **Storage Controller:** HW RAID controller
  - **Power Supply:** Dual redundant hot-swappable
- **Virtual Server:** Minimum requirements include:
  - Lanscape: Hospital virtualization platform must be WMWARE EXSI version 6.0 or higher, with specs including:
    - **CPU:** 4 vCPUs
    - **RAM Memory:** 16 GB
    - **Disks:** 300 GB
    - **Network:** X GbE network connections

Supported Systems:

- **OS Versions:** T-Hub, ProTube™ Service, and Traceability Service should be installed on Red Hat Enterprise Linux 8.4 Minimal (no GUI).
- **Database:** MySQL 8.0.21 Commercial is supported.

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Integrations: ProTube™ System seamlessly integrates with LIS/HIS for retrieving orders and patient data via HL7 Push, confirming biological sample collection through HL7 messaging.

4.8.1. Consumables

- **Compatible Tubes:** ProTube™ natively supports Inpeco Qualified Tubes; other tubes may be qualified with R&D involvement by following accurate qualification test.
- **Labels:** ProTube™ System supports standard CLSI AUTO12-A label layouts and various barcode formats, accommodating further development possibilities.

4.8.2. Clinical Configurations:

ProTubeTM supports various patient identification and order/container association modes, ensuring optimized healthcare delivery.

The ProTube™ supports the following patient identification modes: Patient ID

- Account Number (es. Tax Code, SSN, Account Number)
- Patient Visit Number
- Specimen ID
- Placer Group Number

The ProTube™ System supports the following ways to associate orders to containers/labels: The LIS provides the Inpeco ID of the container to be used for each order (the association is therefore performed on the LIS-side).

- The association between orders and containers is configured in the T-Hub.

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5. International Regulatory Bodies

ProTube™ allows the point of care to be compliant with leading international standards and guidelines as stipulated by various regulatory bodies:

- **UNI EN ISO 15189:** This standard outlines the essential requirements for medical and clinical laboratories seeking certification in accordance with this specific international quality management standard. The latest revision, published in 2012, incorporates several new recommendations across all operational phases of the laboratory. Thus emphasizes the importance of accurately identifying and recording the details of the phlebotomist, allowing for effective management in real-time to address any discrepancies with non-compliant samples.
- **Joint Commission:** In the "National Patient Safety Goals 2014," it is mandated that:
    1. Sample labeling must occur only in the presence of the patient.
    2. At least two patient identification parameters are necessary to ensure accurate identification.
- **Clinical and Laboratory Standards Institute (CLSI):** The ProTube™ system adheres to the CLSI AUTO12-A standard, which delineates the content, size, and arrangement of information on labels that must be affixed to biological samples.
- **Integrating the Healthcare Enterprise (IHE):** Integration of the ProTube™ system with hospital information systems follows IHE guidelines concerning the labeling of biological samples. Furthermore, ProTube™ facilitates data exchange with information systems in HL7 standard format, in alignment with IHE guidelines.
- **World Health Organization (WHO):** The WHO advocates for the utilization of automated instruments to diminish patient identification errors and emphasizes the proper order of sample collection, with this information being implemented in the ProTube™ phlebotomy process.
- **Center for Phlebotomy Education (CPE):** In compliance with CPE guidelines, the ProTubeTM system assists operators in verifying correct patient identification and mandates that labeling occurs solely in the patient's presence, with the checkout functionality being a pivotal aspect of operational recommendations.

In alignment with these guidelines, the ProTube™ system is engineered to record and store each action performed by operators at every phlebotomy station within the Traceability HUB. This capability not only enables phlebotomy center managers to demonstrate organizational efficacy for certification or accreditation but also affords real-time insights into center operations for enhanced human resource management

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(e.g., peak influx times, operational challenges at specific stations).

Key events recorded by the ProTube™ system include:

- Login (with device-operator association) and logout
- Patient identification and parameters used for search
- Retrieval of orders for the identified patient, along with the list of all found tests
- Commencement and completion of labeling, detailing labels produced, tubes utilized, related tests, and barcodes
- Any reprints conducted, along with a list of reprinted labels
- Process interruptions with associated mandatory reasons
- Full or partial checkout for each sample, confirming labels and motivations in cases of partial checkout
- Activation/deactivation of emergency mode along with related justifications

CE Mark

The ProTube™ product adheres to the essential requirements set forth by the following Directives/Regulations:

- Regulation (EU) 2017/746 – In Vitro Diagnostic (IVD) Regulation

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6. ProTube™ Suite – Items numbers

Item Number	Description	Funzionalità
PTB-100-10	**ProTube™ Station kit (PTB Master + Auxiliary Printer + Tablet + stand + SWs)**	**ProTube™ Station**
PTB-001-02	ProTube™ Master	Device for automatic labeling
PTB-003-00	Auxiliary Printer	Auxiliary Printer
PTB-015-00	Tablet Android	Tablet with user interface
PTB-016-00	Tablet stand	Tablet stand
PTB-200-00	**Kit ProTube™ Mobile KIT (Handled Device + BT Printer + SWs)**	**ProTube™ Mobile**
PTB-013-00	ProTubeTM Mobile - Handheld Device	Mobile device with user interface
PTB-014-00	ProTubeTM Mobile - Bluetooth Printer	Labels' Bluetooth printer
PTB-300-00	**Fast Lab Check-in Station**	**ProTube™ Transport**
PTB-020-00	Mid-Range RFID reader	Antenna check-in
PTB-015-00	Tablet Android	Tablet with user interface
PTB-016-00	Tablet stand	Tablet stand
PTB-021-00	USB-C Ethernet Hub	Ethernet cable
PTB-017-00	Traceability tag for rack kit (20x pcs)	Tag for rack identification
PTB-018-00	Courier ID Card kit (10x pcs)	Card for courier identification
PTB-019-00	RFID data logger kit (10x pcs)	Datalogger for transport condition traceability
0A00026366	Inpeco Rack	Rack Inpeco

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PTB-030-00	Cart with power supply	ProTube™ Shuttle
Accessories and consumables		
0A00039866.00	Labels Pack 10 Rolls With 1500 Labels Each	ProTube™ Master and auxiliary printer's labels
2A00000125.00	Q.ty10 Label roll for ProTubeTM mobile printer	Bluetooth printer's labels (ProTube™ Mobile)
PTB-050-00	External Barcode Reader	External Barcode Reader
Softwares		
PTB-CLN	ProTube™ Phlebotomy Assistant SW	User interface software ProTube™ Station/Mobile
PTB-ANX	ProTube™ Analytix Server	Traceability software ProTube™ Station/Mobile
PTB-TRA	ProTube™ Transport SW Module	Transport management software ProTube™ Station/Mobile
PTB-MED	ProTube™ Medical Device SW module	Medical devices selection software ProTube™ Station/Mobile
PTB-QMS	ProTube™ Queue Management SW Module	Queue management system software ProTube™ Station/Mobile
PTB-LCS	ProTube™ Fast Lab Check-in Station Traceability SW	User interface software and user interface ProTube™ Transport SW

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