HORIBA MEDISIDE LINKAGE next
~Revolutionizing the Medical Field with Smart Maintenance~

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HORIBA MEDISIDE LINKAGE next is a comprehensive maintenance service support system for medical instrument provided by HORIBA. In addition to monitoring the operation of medical instrument, it can automatically create ledgers based on medical laws and remotely change instrument settings and perform cleaning operations. The system was developed to reduce the workload and support work style reforms by improving operational efficiency in the medical field, and to promote safe and efficient operations. This article describes the overall picture of the system, as well as the form and usefulness of providing an integrated medical solution in combination with the GATELINK electronic medical record integration software.

Keywords
Remote monitoring, Predictive maintenance, Ledgers, Healthcare law reform, MEDISIDE, GATELINK

Introduction

In recent years, Japan has experienced progressing population decline and aging, resulting in chronic shortages of personnel in medical settings. This issue is particularly severe in small- and medium-sized medical institutions in rural areas, where limited staff must carry out numerous testing operations.

Although Point of Care Testing (POCT)[1] devices have been increasingly introduced in recent years and are expected to support medical care through rapid testing, their maintenance and quality control requirements impose burdens similar to those of conventional clinical laboratory instrument.

Furthermore, amendments to the Medical Care Act[2]-[5] in 2018 have made record-keeping a legal obligation for the purposes of maintenance and quality control of clinical laboratory instrument to preserve the quality of test data. This requires the creation of ledgers, including standard operating procedures and work logs, thereby further increasing the workload of laboratory departments. Additionally, with the enforcement of the revised Labor Standards Act[6]-[8] in April 2024, work style reforms for medical professionals have imposed stricter limits on overtime, further exacerbating operational burdens. Therefore, streamlining and improving the efficiency of testing operations, primarily through medical DX, has become an urgent issue.

To address these challenges in medical settings, we have developed a new support system—HORIBA MEDISIDE LINKAGE next (hereafter referred to as HML next)—which integrates clinical laboratory instrument condition monitoring, maintenance support, ledger management, and remote operation functions.

This article provides a detailed description of its main functions, implementation effects, and future prospects.

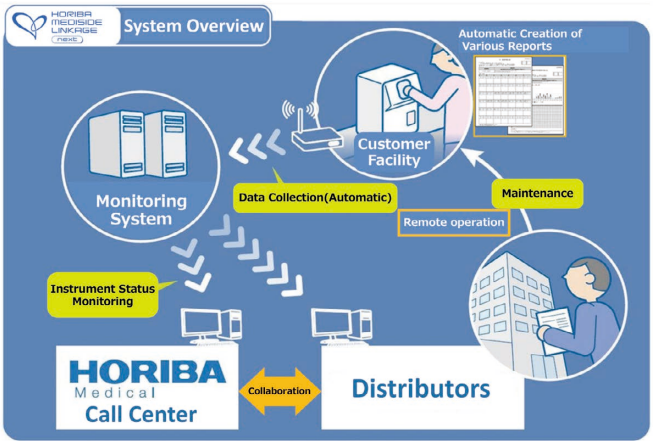

Figure 1 System Overview Diagram.

Overall System Architecture

Figure 1 presents the overall architecture of the HML next system. Clinical laboratory instrument installed at medical facilities transmits measurement results, error logs, and other device-stored data to the monitoring system via a router. The monitoring system analyzes the collected data and sends various ledgers monthly to pre-registered facility email addresses. If necessary, our service department can contact the facility or remotely operate clinical laboratory instrument. Multiple types of clinical laboratory instrument can be connected to a single router for communication.

Main Functions of HML next

This section outlines the main functions of HML next, designed for integrated remote support of multiple clinical laboratory devices and sites, beyond single-device management.

Real-Time Monitoring and Error Detection Technology

By acquiring and analyzing patient test results, logs, error codes, and raw data from various sensors in real time, HML next provides proprietary monitoring functions that support operational surveillance and early detection of error signs in clinical laboratory instrument, enabling prompt corrective actions. Email notifications can be configured to be sent only when errors exceed a certain frequency within a specified period, adjustable for each device.

This function is effective for field engineers, allowing them to confirm operating status and error history before site visits, thereby reducing the number of visits and optimizing initial responses.

Predictive Maintenance Using Raw Data

HML next features a mechanism that notifies service personnel of predictive maintenance alerts based on certain thresholds, even for "latent errors" undetected by the clinical laboratory instrument itself. For example, it can detect slight decreases in suction pressure, abnormal temperature control trends, or signs of deterioration in consumable parts. This enables maintenance visits before instrument failure occurs, minimizing the impact on testing operations in medical settings. The system can propose optimal maintenance timing tailored to the condition of each device rather than relying solely on scheduled maintenance, reducing unnecessary part replacement of parts and minimizing the risk of instrument downtime. This also helps optimize the balance between scheduled maintenance and emergency repairs.

Such functionality contributes to optimizing instrument operation through prediction of consumable part deterioration and anomaly detection, reducing workload and improving maintenance efficiency for small hospitals and testing centers.

Remote Input of Assay Value Data

For quality control measurements (hereafter QC measurements) performed on clinical laboratory instrument, HML next enables remote input of assay value data predetermined for each lot of control materials. Assay values are reference measurements set by manufacturers for control blood used to verify instrument accuracy. Traditionally, entering assay values required accessing a website, downloading files, saving them to a USB memory, and loading them into the instrument—operations prone to human error. HML next allows for accurate and immediate input of the latest assay values, greatly improving reliability and speed of testing operations.

Additionally, establishing a system for remote provision and input of assay value data serves as an effective means to raise awareness of QC measurement importance and promote proper quality control practices at medical sites.

This function also contributes to stabilizing testing operations at facilities requiring high reliability in quality control or during periods with few personnel.

Automatic Generation of Management Ledgers

To streamline clinical laboratory instrument management and ensure legal compliance, HML next automatically generates and periodically sends various management ledgers based on operational data and maintenance records. This greatly reduces the record-keeping burden for medical professionals and technical staff, allowing them to focus on core duties such as patient care.
The management ledgers include:

- Measurement work logs (**Figure 2**)
- Maintenance management standard work logs
- Reagent management records
- Quality control records

These documents are automatically formatted based on proprietary ledger templates and generated as PDFs monthly (or at user-specified intervals). Facility managers and maintenance personnel only need to print and store them, reducing the workload for legally mandated ledger retention.

Notably, this provides practical solutions to the following on-site challenges:

Immediate and Consistent Evidence for Legal Compliance

Medical instruments used for clinical testing are subject to mandatory periodic maintenance and record retention under the Medical Care Act and related regulations set by the Ministry of Health, Labour and Welfare (2018). Automated record generation and storage in designated folders enable instant presentation of required documents during surprise audits, reducing psychological stress and preparation time for staff.

Elimination of Manual Work and Human Error

Previously, ledger creation required manual transcription, organization, and printing of logs from clinical laboratory instrument, a process susceptible to errors due to busy schedules. HML next automates ledger output via triggers and schedules, eliminating omissions, transcription errors, and formatting mistakes. In case of ledger damage or loss, past data can be instantly reissued, ensuring easy data retrieval and reproducibility.

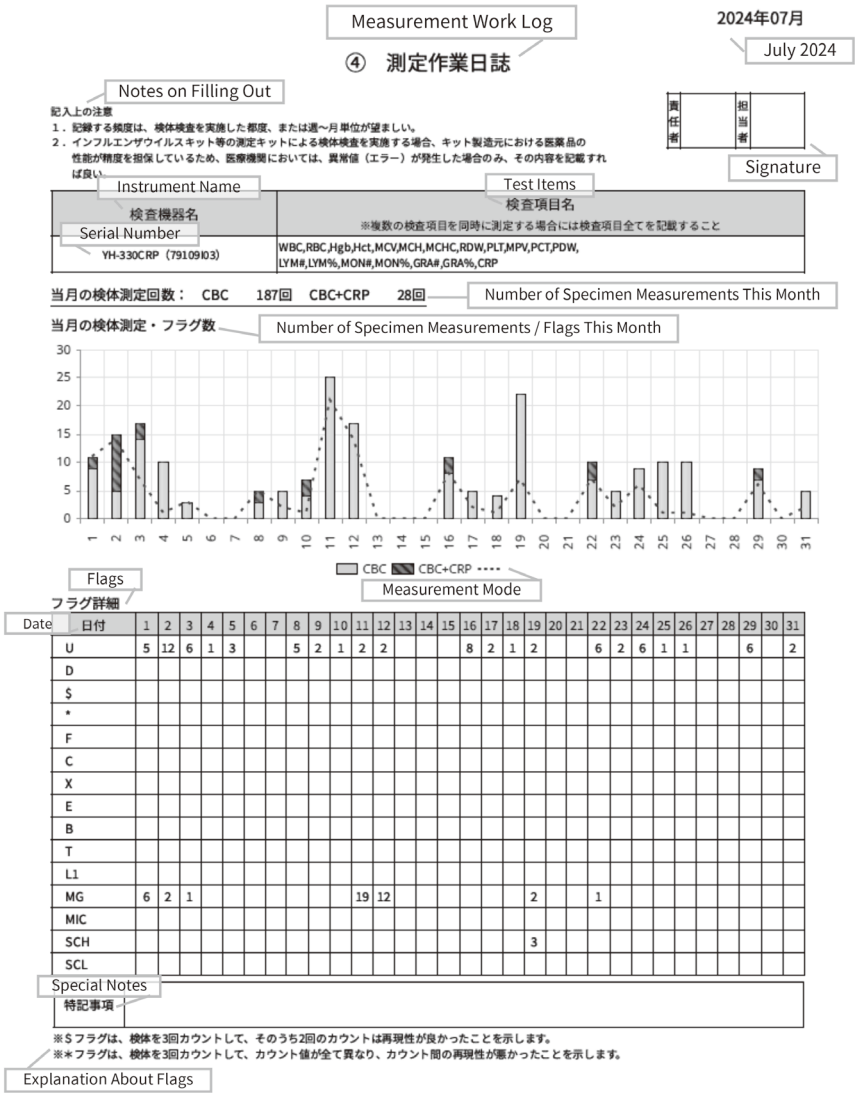

Figure 2 Measurement Record Log.
(Note: The original form is in Japanese. English words are added by the authors for reference only and do not constitute a full translation.)

Environment for Focusing on Core Duties (Patient Care)

Automating ledger creation enables medical staff—including doctors, laboratory technologists, and nurses—to devote more time to high-value medical activities and patient interaction. This is especially significant for small facilities or during night shifts, where optimal allocation of human resources is achieved through labor-saving measures.

This function greatly contributes to improved work efficiency and prevention of human error at medical institutions requiring legal compliance and unified ledger management. Corporations operating multiple sites can achieve standardized ledger management without inter-site discrepancies, enhancing internal and external audit responsiveness. It also alleviates the workload of busy laboratory technologists and administrative staff, promoting concentration on specialized tasks.

Remote Access to Clinical Laboratory Instrument

HML next provides remote access functionality for service engineers, aiming to streamline maintenance operations and enable rapid response to malfunctions.
Key features and effects include:

Practical Operation Style Based on Telephone Coordination

In practice, service engineers contact facility staff (e.g., laboratory technologists) by phone, confirm on-screen warnings on the clinical laboratory instrument, and then execute remote operations via HML next.

For example, if an alarm is displayed, the staff reads the alarm code and status, and the engineer executes appropriate remote commands (e.g., nozzle cleaning, reboot, parameter changes). Thus, HML next serves not only as a remote control system but also as an infrastructure for smooth communication between on-site and maintenance staff.

This hybrid operation prevents erroneous actions and provides reassurance to on-site staff.

Automation of Major Work Support via Remote Operations

Maintenance personnel can perform the following operations remotely without visiting the facility:

- Sending various commands (e.g., nozzle cleaning) for routine or immediate troubleshooting
- Changing reagent settings and confirming replenishment information
- Acquiring operation logs and checking device status
- Remote monitoring of alarm history and early prediction of troubles

Leveraging high compatibility with HORIBA products and command specifications tailored to each device, the system enables reliable control while minimizing operational risks.
This remote access environment allows safe, real-time execution of maintenance tasks from remote locations, significantly reducing the number and duration of required site visits.

Strict Management of Safety and Operational Permissions

As clinical laboratory instrument handles patient samples, erroneous or unauthorized operations could lead to serious medical incidents. HML next implements multi-layered security measures:

- User authentication and hierarchical permission management
- Automatic saving of operation logs and tamper-prevention mechanisms
- One-time remote connection approval (facility-side authorization required)

These measures ensure device operation is complemented remotely while maintaining safety and compliance in medical settings.

Transformation of Maintenance Services and Impact on On-Site Operations

This function enables rapid initial response in emergencies. For example, in minor issues such as reagent clogs, service engineers can immediately perform nozzle cleaning remotely via HML next, restoring instrument operation within minutes and minimizing disruption to testing operations and patient impact.

Remote preparation for scheduled maintenance also shortens on-site work time. Reduced site visit frequency lowers maintenance costs and supports sustainable maintenance frameworks for medical devices.

This function reduces field engineer travel and accelerates troubleshooting, minimizing downtime especially for

remote or small facilities with limited after-hours support. It also enables standardized support regardless of technician experience, contributing to uniform service quality.

Advantages of Integration with GATELINK

Main Functions of GATELINK

GATELINK is an interface software that facilitates data linkage between upper-level systems (electronic medical records and LIS) and clinical laboratory instrument (**Figure 3**). Patient IDs and test order information entered into upper-level systems are transmitted in real time to clinical laboratory instrument via GATELINK, automating the process from test request to result acquisition and greatly improving operational efficiency.

Manual entry of test orders into laboratory instrument can result in input or transcription errors, potentially leading to misattribution of test results. Duplicate data entry and manual transcription errors decrease efficiency and cause delays, especially during busy clinical hours, negatively affecting patient service and reliability.

Introduction of GATELINK enables automatic linkage of test requests and results with upper-level systems, reducing the workload and risk of human error for laboratory technologists and nurses. GATELINK can connect up to 10 laboratory devices (including those from other manufacturers), flexibly integrating diverse in-hospital test data. Real-time access to test results during patient consultations via upper-level systems accelerates preparation and clinical decision-making, shortening response times and improving the quality of explanations.

Integration of GATELINK and HML next

Future integration of GATELINK and HML next will enable unified management and remote monitoring of test data and patient information, including data from devices made by other manufacturers. This is especially advantageous for small- and medium-sized facilities, allowing advanced collaboration environments to be built with limited resources.

Specifically, test data from clinical laboratory instrument for blood, biochemistry, urine, coagulation, genetics, etc. can be managed and analyzed in real time on HML next. Real-time understanding of patient conditions based on data collected from all connected devices will facilitate timely and appropriate treatment, potentially preventing disease progression. Integrated utilization of multi-disciplinary test data is expected to improve medical quality and realize higher standards of patient care.

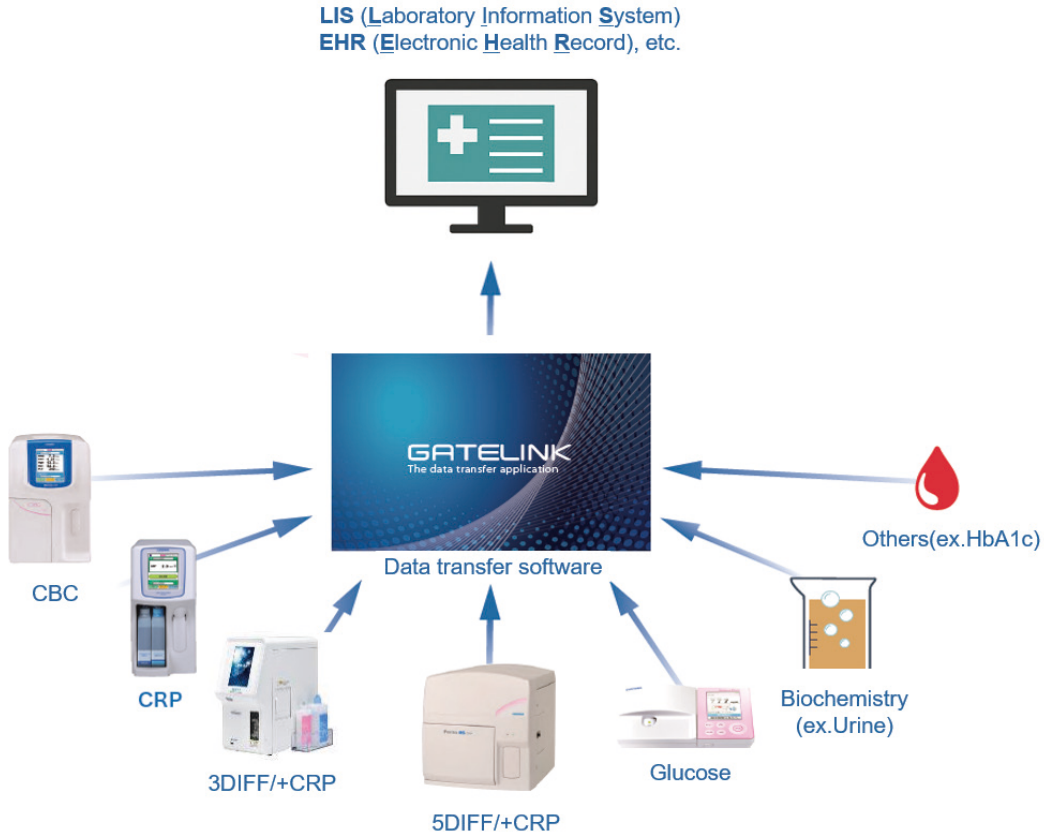

Figure 3 GATELINK connection configuration diagram.

Conclusion

This article has introduced HML next, which was designed and developed as an integrated IT-based solution rather than as a standalone clinical laboratory device.. Through diverse functions such as device operation monitoring, predictive maintenance, ledger output, and remote operation, HML next supports both operational efficiency and legal compliance in medical settings. Moving forward, we aim to accelerate the shift from product sales to solution sales by advancing technology development for clinical laboratory instrument and medical information systems, expanding our business with solutions such as automation and data management, and providing comprehensive solutions to operational challenges in medical institutions, thereby contributing to the creation of environments where medical professionals can devote themselves to their core medical duties.

* Editorial note: This content is based on HORIBA's investigation at the year of publication unless otherwise stated.

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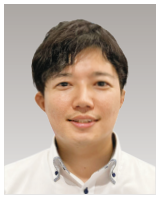

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