General Specifications

GS 33K05H40-50E

Model LHS4200 Historical Message Integration Package (meeting FDA Regulations)

[Release 5]

GENERAL

The Model LHS4200 Historical Message Integration Package embodies centralized management of historical messages collected at each Human Interface Station (HIS) in a CENTUM VP system, using a PC. It enables the following:

- Reference and permanent retention of multiple HISs' historical messages at a single PC. The Historical Message Integration Package integrates the historical messages distributed at multiple HISs into a single PC having a sufficiently large disk capacity, and allows the multiple historical message files to be referenced and retained permanently.
- Audit trails (historical messages) to be easily maintained as required by FDA's 21 CFR Part 11
- Operation condition analyses by searching through the retained historical messages using an HIS name and date
- Retention of historical messages as electronic records (PDF files), including application of electronic signatures to those electronic records, with joint use of Adobe Acrobat



FUNCTIONAL SPECIFICATIONS

Historical Message Integration Package consists of two blocks of functions: saving functions for retaining the historical messages collected by multiple HISs, and viewer functions for displaying and searching through the retained historical messages to generate paper or electronic reports.

• Function Details

Saving Functions of Historical Message

Historical messages in the individual HISs are collectively retained on a PC in which Historical Message Integration Package is installed. The size of the message retention area in the PC is not limited by the package, but depends on the capacity of the hard disk of the PC. Saving the historical messages retained in the PC to a different medium at appropriate intervals will retain historical messages permanently.

| essages to be retained: Process alarms, status |
|--|
| change messages, operator guide |
| messages, sequence messages, |
| maintenance messages, operation record |
| messages, system alarms, and fieldbus |
| messages |

Viewer Functions

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Viewer functions are provided as a multi-window application and enable the retained historical messages to be viewed on the PC that retains those messages. The users can search through the retained historical messages to find those meeting specified conditions. The search results and conditions can be printed or saved to a file as a report. If Adobe Acrobat is installed, such reports can be saved to PDF files. In PDF format, electronic signatures and the file contents can be protected against tampering and revision records can be saved.



HIS Uptime Record Display

Through analyses of historical messages, the uptime records of a given HIS can be displayed as a Gantt chart (created from "HIS name" and "time period" information).

Batch Operation Result Display

Through analyses of historical messages, the batch operation results of a given HIS can be displayed as a Gantt chart (created from "HIS name" and "time period" information).

Backup of Retained Data

Use the backup functions of the Windows operating system or commercial-off-the-shelf software.



Figure: Example of System Configuration for Historical Message Integration Package

OPERATING ENVIRONMENTS

• Hardware Requirements

Conforms to operating environment of LHS5100/LHM5100 Standard Builder Function with the following exceptions:

- An external storage unit is required to back up the retained historical messages.
- Guidelines for the required size of the local disk Each HIS creates an historical message file of an average size of 0.5 MB. Retaining historical files of five HISs therefore requires 2.5 MB (0.5 MB x 5) per day. Hence, a disk having a space of 20-GB for message retention will become full in 20 GB/2.5 MB = 8000 days (approx. 22 years).

• Software Requirements

Conforms to operating environment of LHS5100/LHM5100 Standard Builder Function with the following exceptions:

- This package is required only for the PC implementing integrated message management, and is not required of each HIS.
- This package can not be installed on the same PC with the following functions.
 - LHS1100, LHM1101 Standard Operation and Monitoring Function
 - LHS5100, LHM5100 Standard Builder Function

Adobe Acrobat is used when converting Historical report file into PDF compatible database and using Electronic Signature. Refer to LHS5100, LHM5100 Standard Builder Function package (GS 33K10D10-50E) software requirements for the supported versions of Adobe Acrobat.

■ MODEL AND SUFFIX CODES

| | | Description |
|--------------|---------|---|
| Model | LHS4200 | Historical Message Integration Package [Media model: LHSKM50-V11] |
| | -V | Software License |
| Suffix Codes | 1 | Always 1 |
| | 1 | English version |

ORDERING INFORMATION

Specify model and suffix codes.

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