General Specifications

GS 33J05H40-01EN

VP6H4200
Historical Message Integration Package
(meeting FDA Regulations)

CENTUM VP

[Release 6]

■ GENERAL

The Model VP6H4200 Historical Message Integration Package embodies centralized management of historical messages collected at each Human Interface Station (HIS) in a CENTUM VP system, using a computer. It enables the following:

- Reference and permanent retention of multiple HISs' historical messages at a single computer. The Historical Message Integration Package integrates the historical messages distributed at multiple HISs into a single computer 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

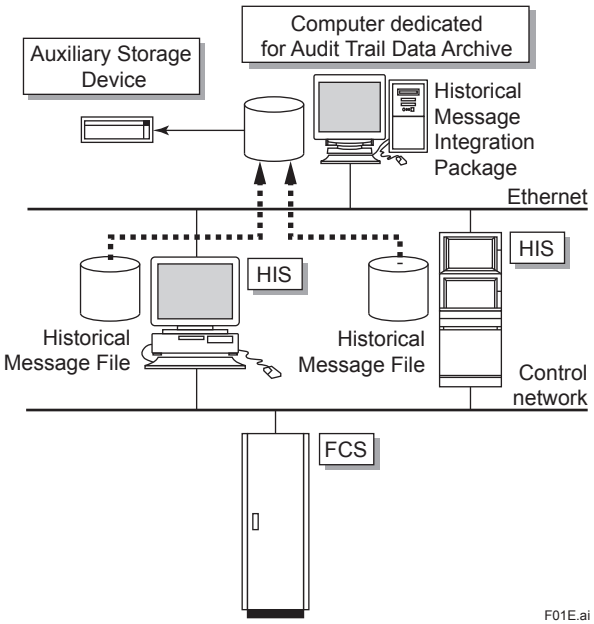

Figure: Example of System Configuration for Historical Message Integration Package

■ 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 computer in which Historical Message Integration Package is installed. The size of the message retention area in the computer is not limited by the package, but depends on the storage (*1) capacity of the computer. Saving the historical messages retained in the computer to a different medium at appropriate intervals will retain historical messages permanently.

*1: For SSD, it is supported by R6.12.00 or later, and Windows 10 LTSC 2021 or later, or Windows Server 2022 or later.

Messages 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

Viewer functions are provided as a multi-window application and enable the retained historical messages to be viewed on the computer 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.

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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.

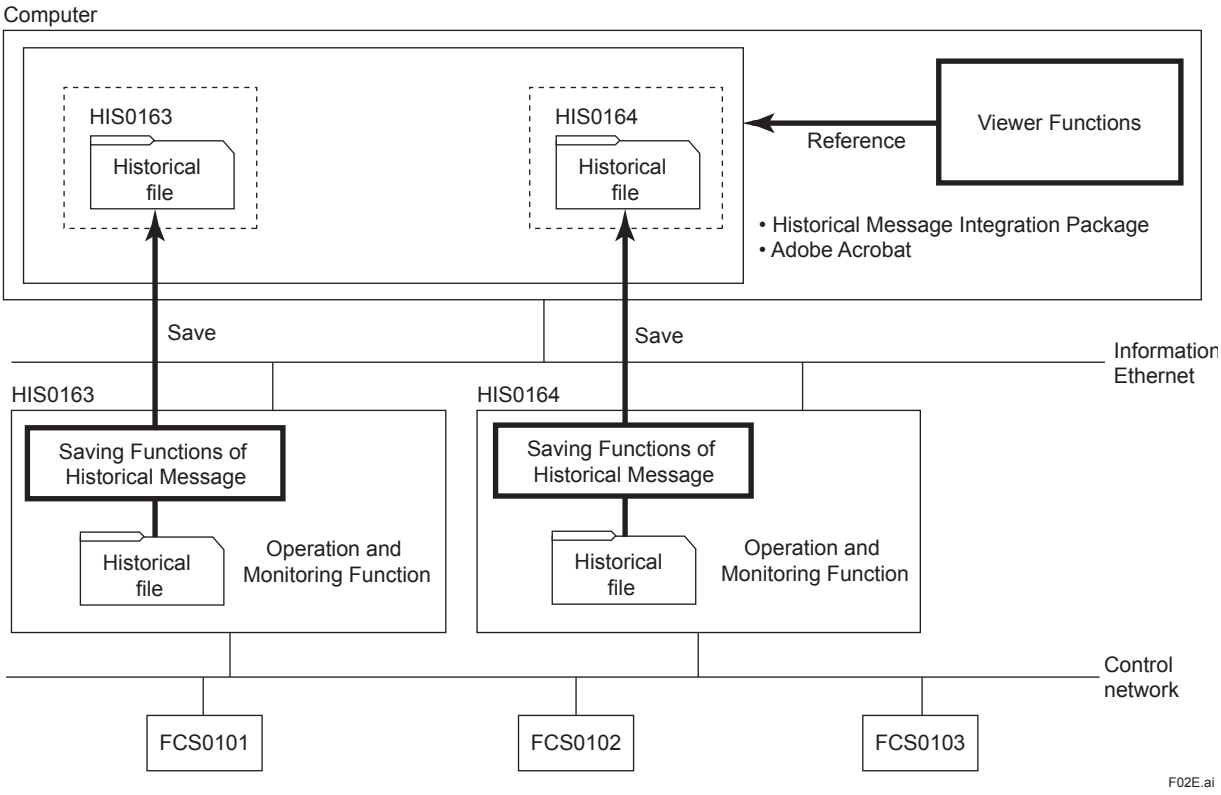

Figure: Example of System Configuration for Historical Message Integration Package

■ OPERATING ENVIRONMENTS

● Hardware Requirements

Conforms to operating environment of VP6E5100 Standard Engineering 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 VP6E5100 Standard Engineering Function with the following exceptions:

- This package is required only for the computer implementing integrated message management, and is not required of each HIS.
- This package can not be installed on the same computer with the following functions.
  VP6H1100 Standard Operation and Monitoring Function
  VP6E5100 Standard Engineering Function

Adobe Acrobat is used when converting Historical report file into PDF compatible database and using Electronic Signature. Refer to VP6E5100 Standard Engineering Function package (GS 33J10D10-01EN) software requirements for the supported versions of Adobe Acrobat.

■ MODEL AND SUFFIX CODES

		Description
Model	VP6H4200	Historical Message Integration Package (meeting FDA Regulations)
Suffix Codes	-V	Software license
	1	Always 1
	1	English version

■ ORDERING INFORMATION

Specify model and suffix codes.

■ TRADEMARK ACKNOWLEDGMENT

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