# Fig. 1

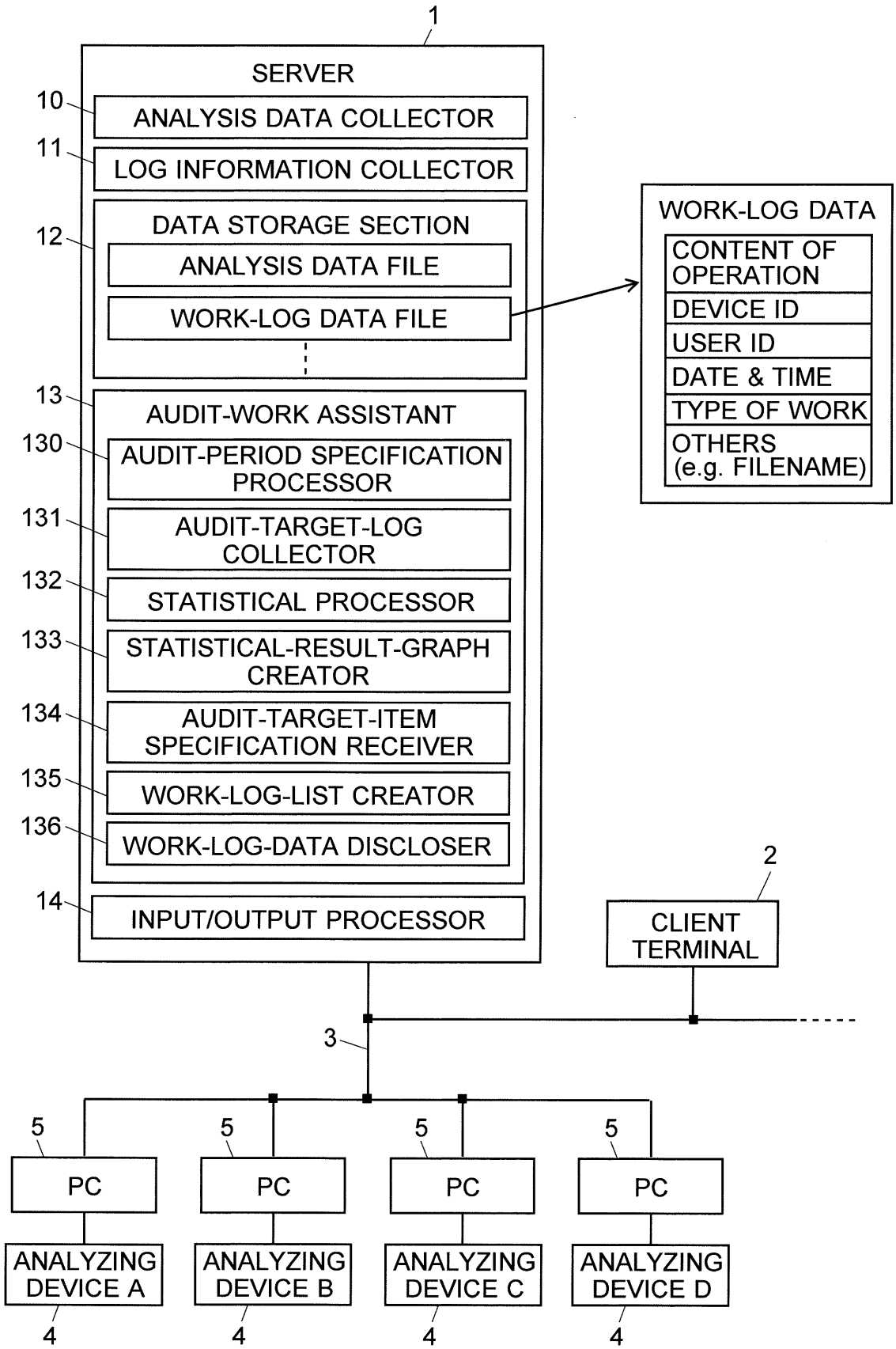

1
SERVER
10
ANALYSIS DATA COLLECTOR
11
LOG INFORMATION COLLECTOR
12
DATA STORAGE SECTION
ANALYSIS DATA FILE
WORK-LOG DATA FILE
13
AUDIT-WORK ASSISTANT
130
AUDIT-PERIOD SPECIFICATION PROCESSOR
131
AUDIT-TARGET-LOG COLLECTOR
132
STATISTICAL PROCESSOR
133
STATISTICAL-RESULT-GRAPH CREATOR
134
AUDIT-TARGET-ITEM SPECIFICATION RECEIVER
135
WORK-LOG-LIST CREATOR
136
WORK-LOG-DATA DISCLOSER
14
INPUT/OUTPUT PROCESSOR
WORK-LOG DATA
CONTENT OF OPERATION
DEVICE ID
USER ID
DATE & TIME
TYPE OF WORK
OTHERS (e.g. FILENAME)
2
CLIENT TERMINAL
3
5
PC
ANALYZING DEVICE A
ANALYZING DEVICE B
ANALYZING DEVICE C
ANALYZING DEVICE D
4

Fig. 2

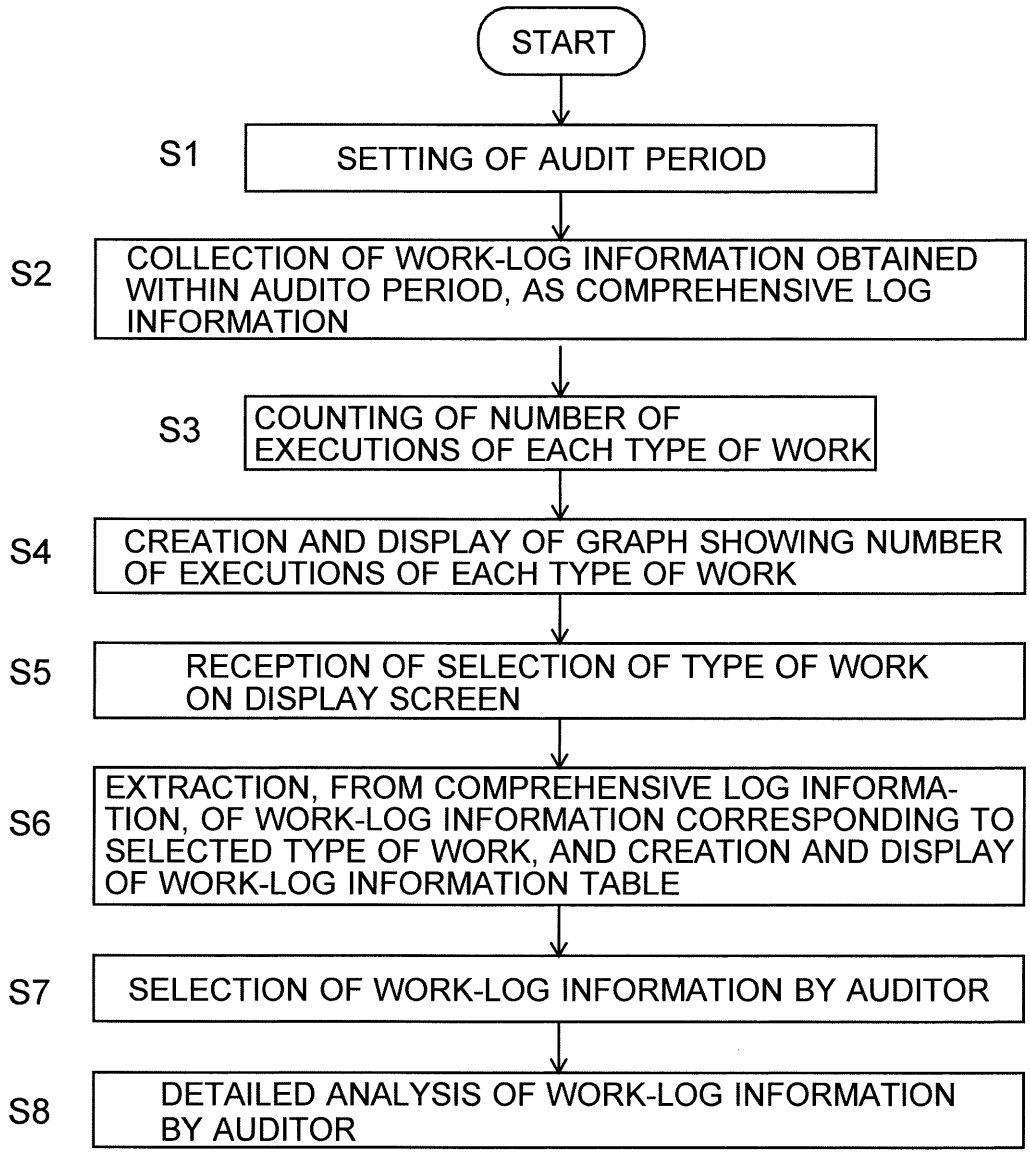
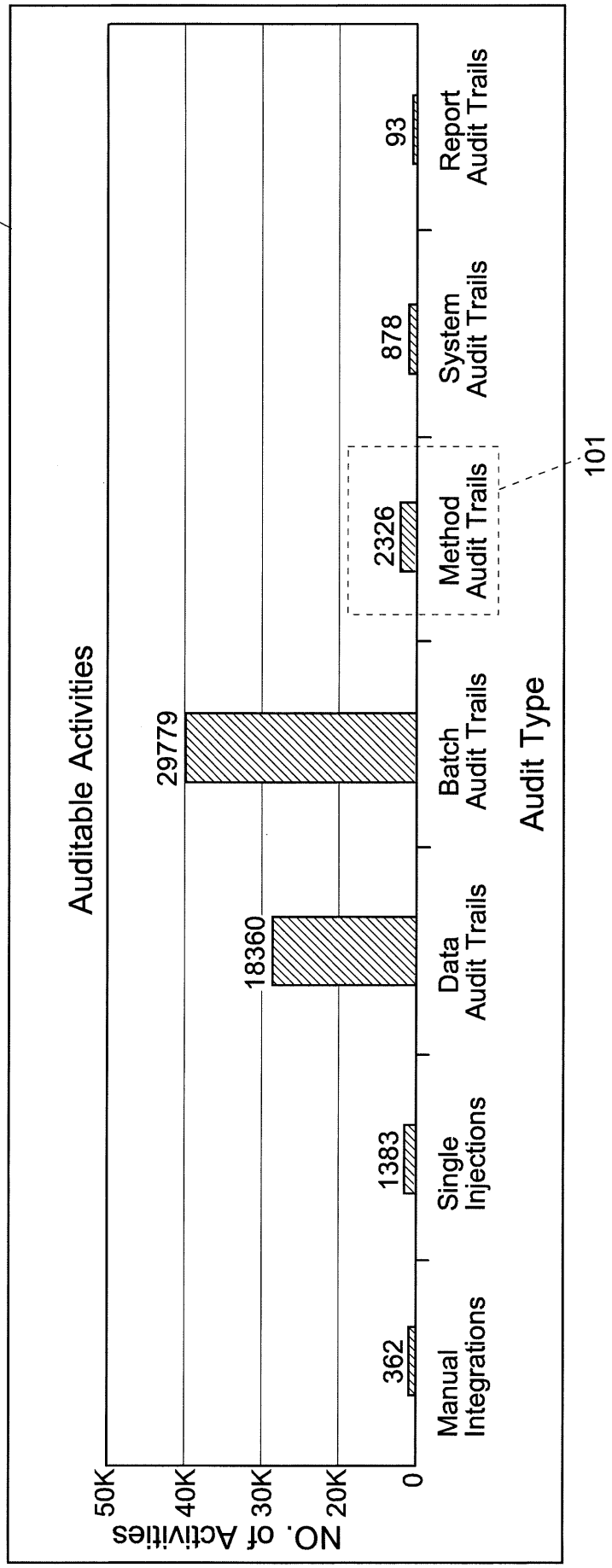

START
S1
SETTING OF AUDIT PERIOD
S2
COLLECTION OF WORK-LOG INFORMATION OBTAINED WITHIN AUDITO PERIOD, AS COMPREHENSIVE LOG INFORMATION
S3
COUNTING OF NUMBER OF EXECUTIONS OF EACH TYPE OF WORK
S4
CREATION AND DISPLAY OF GRAPH SHOWING NUMBER OF EXECUTIONS OF EACH TYPE OF WORK
S5
RECEPTION OF SELECTION OF TYPE OF WORK ON DISPLAY SCREEN
S6
EXTRACTION, FROM COMPREHENSIVE LOG INFORMATION, OF WORK-LOG INFORMATION CORRESPONDING TO SELECTED TYPE OF WORK, AND CREATION AND DISPLAY OF WORK-LOG INFORMATION TABLE
S7
SELECTION OF WORK-LOG INFORMATION BY AUDITOR
S8
DETAILED ANALYSIS OF WORK-LOG INFORMATION BY AUDITOR

Fig. 3


100
Auditable Activities
50K
40K
30K
20K
0
No. of Activities
362
1383
18360
29779
2326
878
93
Manual Integrations
Single Injections
Data Audit Trails
Batch Audit Trails
Method Audit Trails
System Audit Trails
Report Audit Trails
Audit Type
101

# Fig. 4

110

Showing Log data for **Method Audit Trails** in the data range
[25-05-2019 to 25-11-2019]

| PC Name | Project Name | Instrument Name | User Name | Application Name | Audit Type | File Name | Review Status | Audit Trail Versions | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| PC-01 | FILM COATED TABLETS DISSO BY HPLC | Ins01 | User01 | Analysis Service | Method Audit Trails | WASH-D(PE015).lcm | *Not Reviewed* | 4 | Show Details |
| PC-02 | METHOD DEVELOPMENT | Ins02 | User02 | Analysis Service | Method Audit Trails | SHUT_MTH.lcm | *Not Reviewed* | 6 | Show Details |
| PC-03 | METHOD DEVELOPMENT | Ins03 | User03 | Analysis Service | Method Audit Trails | SHUT(PE075)_ INST_MTH.lcm | *Not Reviewed* | 27 | Show Details |
| PC-04 | METHOD TRANFER FOR TZ DISSOLUTION BY HPLC | Ins04 | User04 | Analysis Service | Method Audit Trails | WASH.lcm | *Not Reviewed* | 4 | Show Details |



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Fig. 5

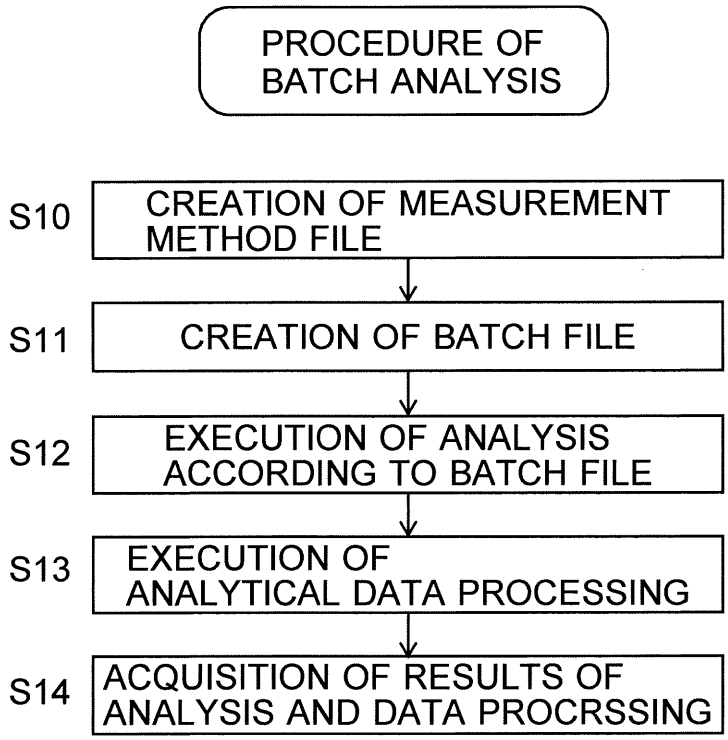
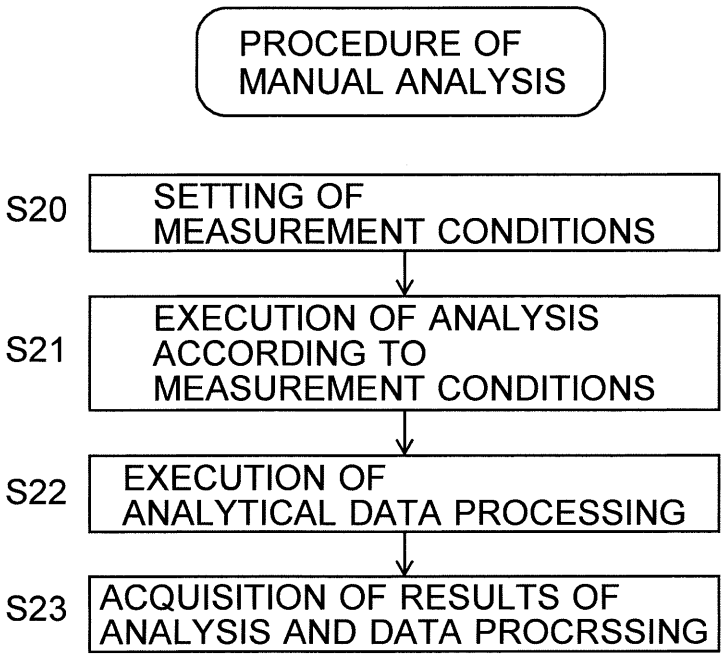

PROCEDURE OF BATCH ANALYSIS
S10
CREATION OF MEASUREMENT METHOD FILE
S11
CREATION OF BATCH FILE
S12
EXECUTION OF ANALYSIS ACCORDING TO BATCH FILE
S13
EXECUTION OF ANALYTICAL DATA PROCESSING
S14
ACQUISITION OF RESULTS OF ANALYSIS AND DATA PROCRSSING

Fig. 6


PROCEDURE OF MANUAL ANALYSIS
S20
SETTING OF MEASUREMENT CONDITIONS
S21
EXECUTION OF ANALYSIS ACCORDING TO MEASUREMENT CONDITIONS
S22
EXECUTION OF ANALYTICAL DATA PROCESSING
S23
ACQUISITION OF RESULTS OF ANALYSIS AND DATA PROCRSSING