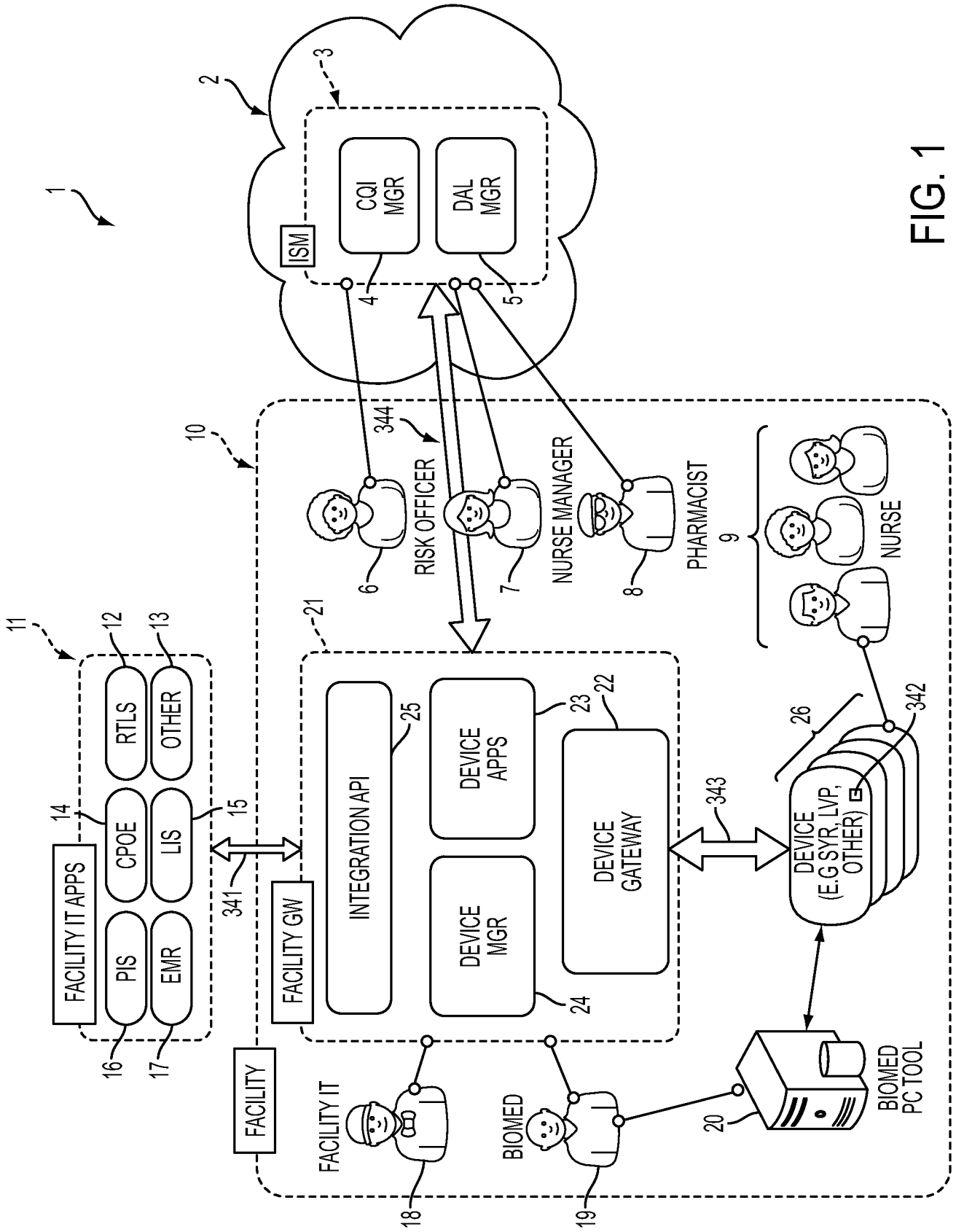
1
2
3
ISM
CQI MGR
DAL MGR
4
5
10
344
RISK OFFICER
NURSE MANAGER
PHARMACIST
NURSE
6
7
8
9
11
12
13
14
15
FACILITY IT APPS
RTLS
OTHER
CPOE
LIS
PIS
EMR
16
17
341
21
FACILITY GW
INTEGRATION API
DEVICE APPS
DEVICE MGR
DEVICE GATEWAY
25
23
22
24
26
342
343
DEVICE (E.G SYR, LVP, OTHER)
FACILITY
FACILITY IT
BIOMED
18
19
20
BIOMED PC TOOL

FIG. 1

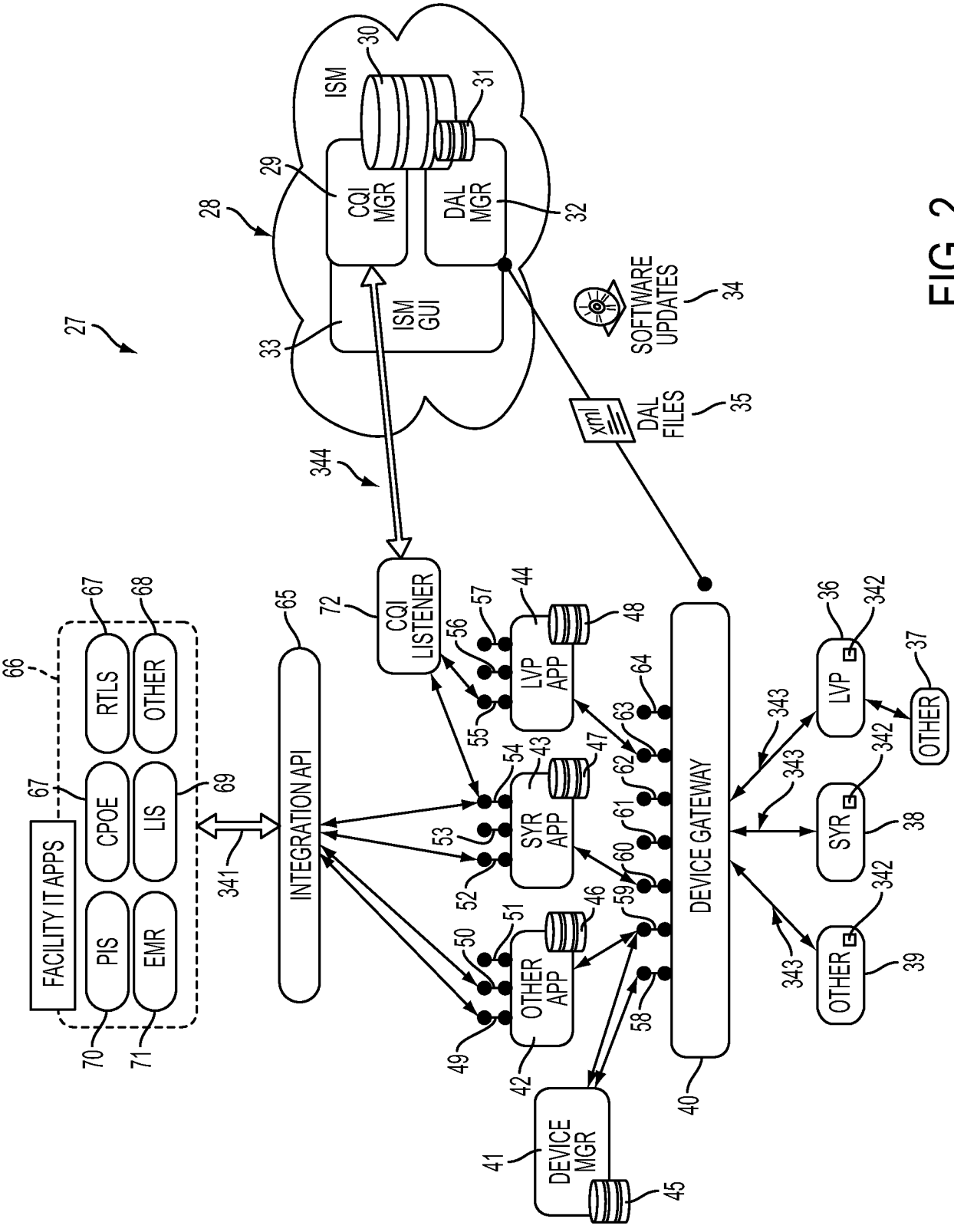
27
28
ISM
30
31
29
CQI MGR
DAL MGR
32
33
ISM GUI
SOFTWARE UPDATES
34
xml
DAL FILES
35
344
CQI LISTENER
72
INTEGRATION API
65
341
66
FACILITY IT APPS
67
PIS
CPOE
RTLS
67
68
EMR
LIS
OTHER
69
70
71
LVP APP
44
48
SYR APP
43
47
OTHER APP
46
51
DEVICE MGR
41
45
42
DEVICE GATEWAY
40
LVP
36
342
SYR
38
OTHER
39
37
343
55
56
57
54
53
52
50
49
58
59
60
61
62
63
64

FIG. 2

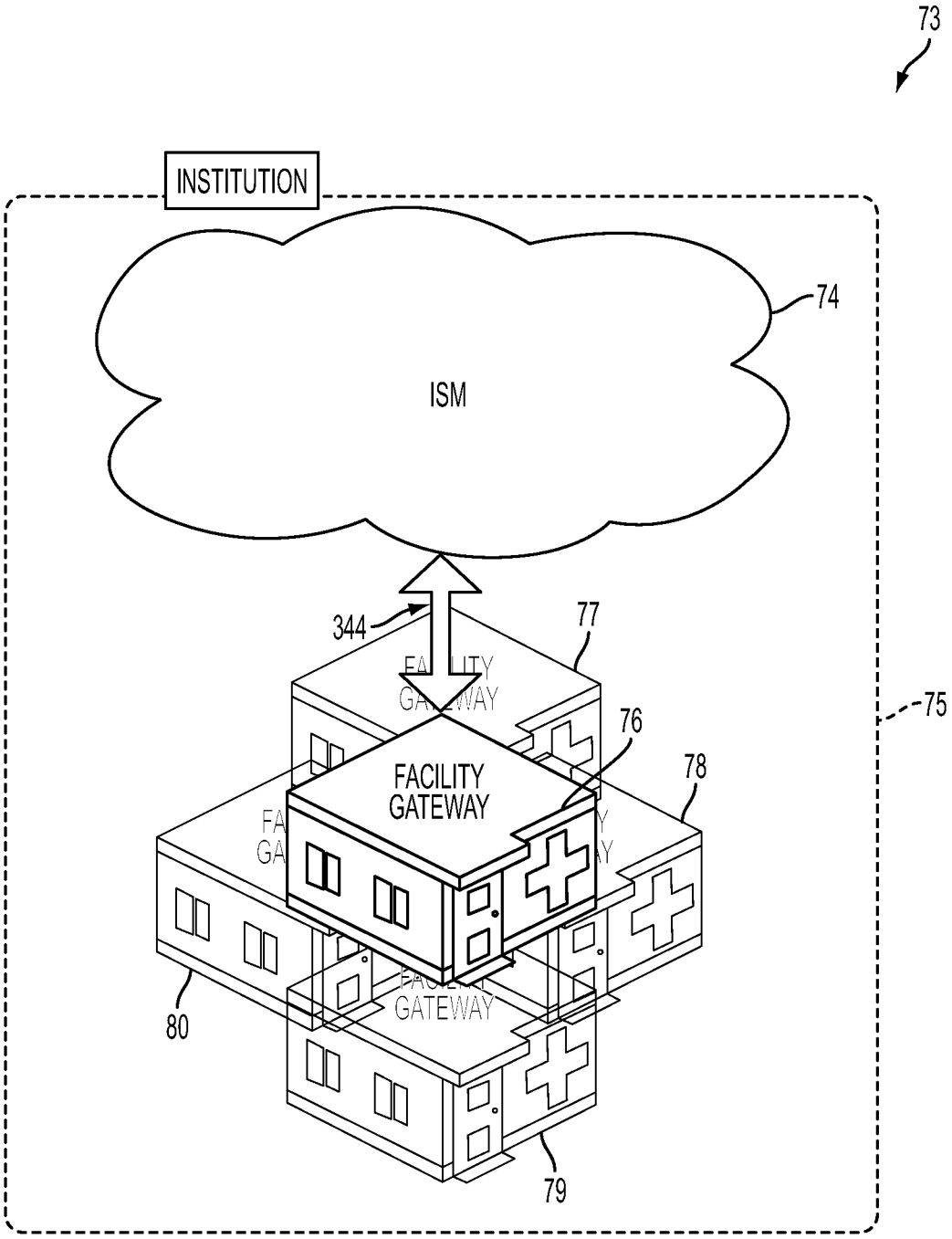

FIG. 3

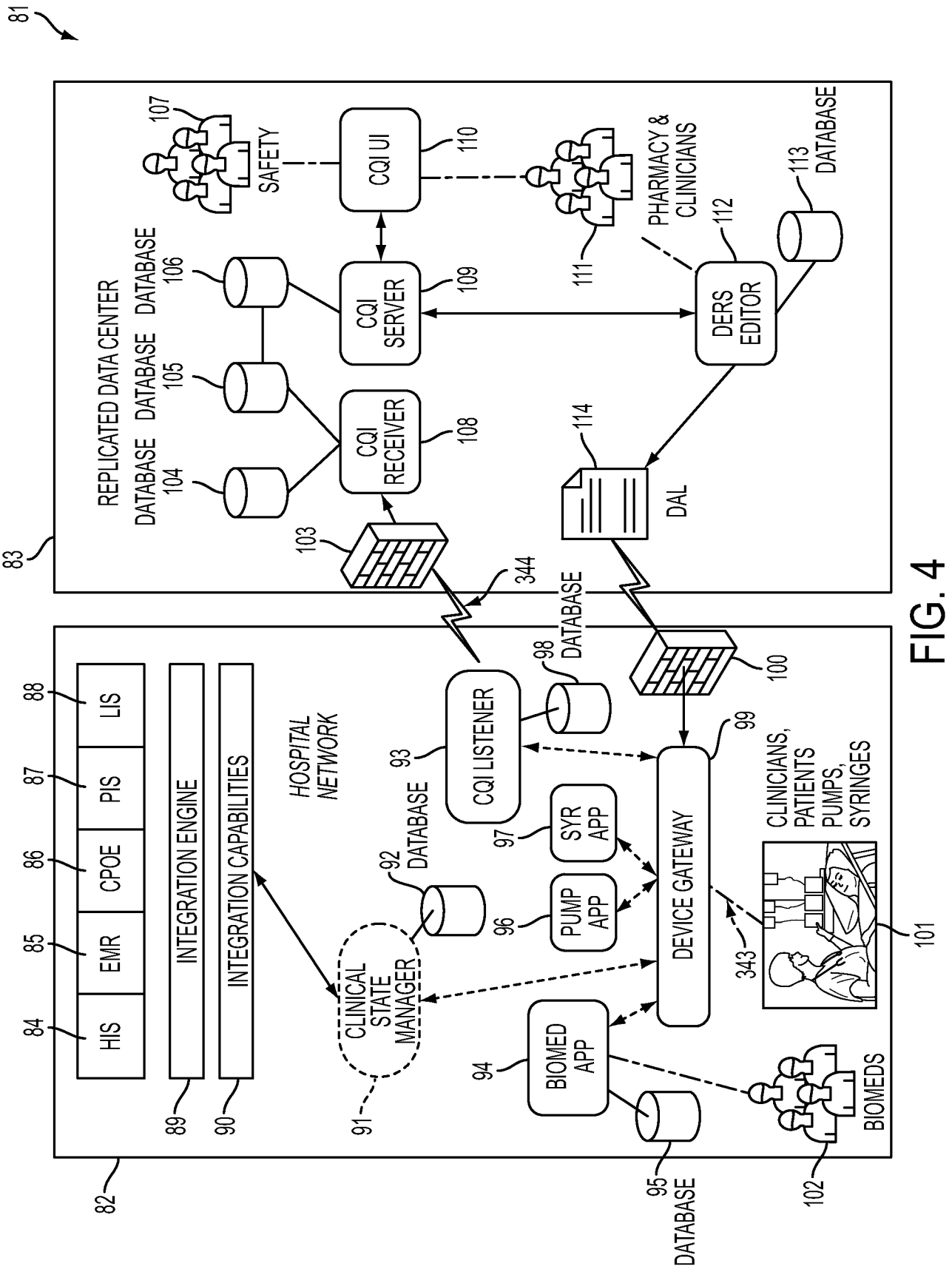
81
83
REPLICATED DATA CENTER
DATABASE 104
DATABASE 105
DATABASE 106
CQI RECEIVER 108
CQI SERVER 109
CQI UI 110
SAFETY 107
PHARMACY & CLINICIANS 111
DERS EDITOR 112
DATABASE 113
DAL 114
103
344
98 DATABASE
100
82
HIS 84
EMR 85
CPOE 86
PIS 87
LIS 88
INTEGRATION ENGINE 89
INTEGRATION CAPABILITIES 90
HOSPITAL NETWORK
CLINICAL STATE MANAGER 91
92 DATABASE
93 CQI LISTENER
97 SYR APP
96 PUMP APP
94 BIOMED APP
95 DATABASE
DEVICE GATEWAY 99
343
CLINICIANS, PATIENTS PUMPS, SYRINGES
101
BIOMEDS
102

FIG. 4

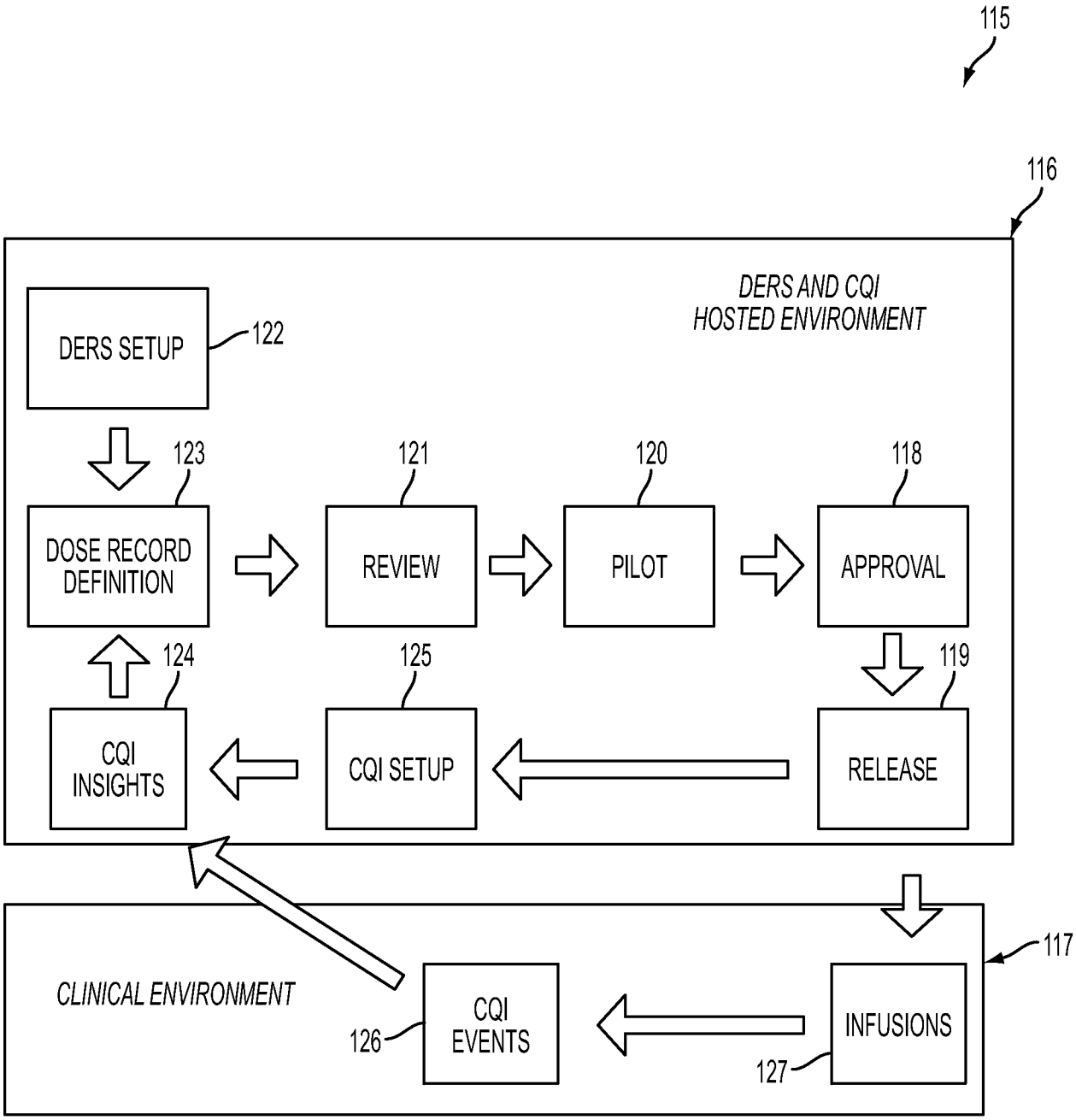
115
116
DERS AND CQI
HOSTED ENVIRONMENT
DERS SETUP
122
123
121
120
118
DOSE RECORD
DEFINITION
REVIEW
PILOT
APPROVAL
124
125
119
CQI
INSIGHTS
CQI SETUP
RELEASE
117
CLINICAL ENVIRONMENT
126
CQI
EVENTS
INFUSIONS
127

FIG. 5

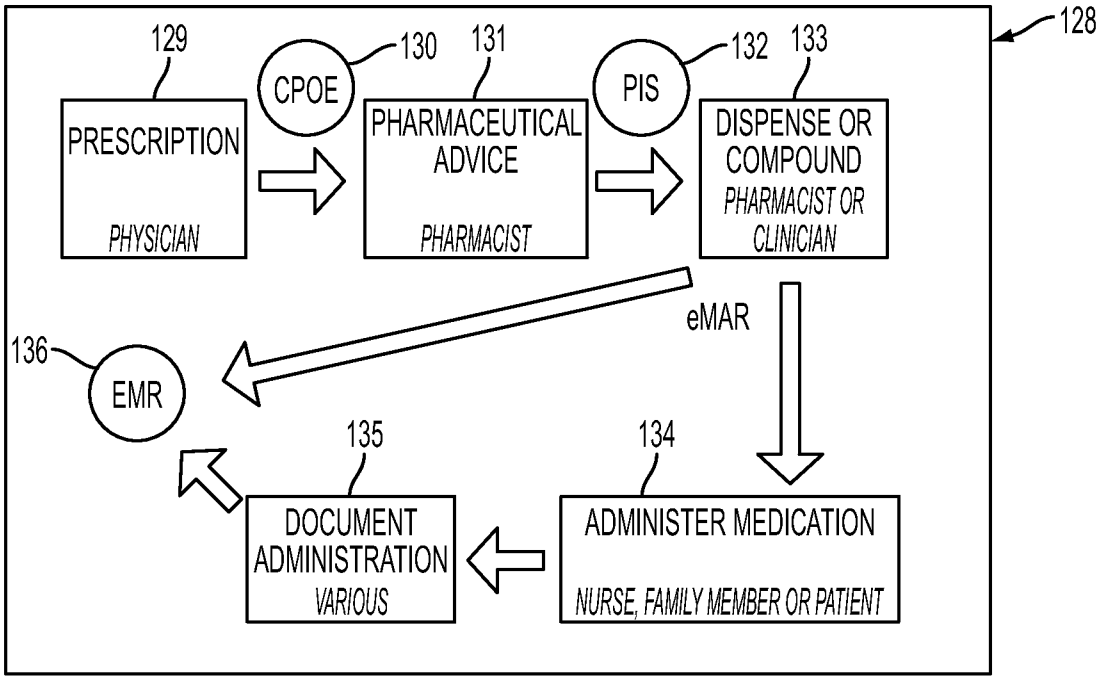
128
129
PRESCRIPTION
PHYSICIAN
CPOE
130
131
PHARMACEUTICAL ADVICE
PHARMACIST
PIS
132
133
DISPENSE OR COMPOUND
PHARMACIST OR CLINICIAN
eMAR
136
EMR
135
DOCUMENT ADMINISTRATION
VARIOUS
134
ADMINISTER MEDICATION
NURSE, FAMILY MEMBER OR PATIENT

FIG. 6

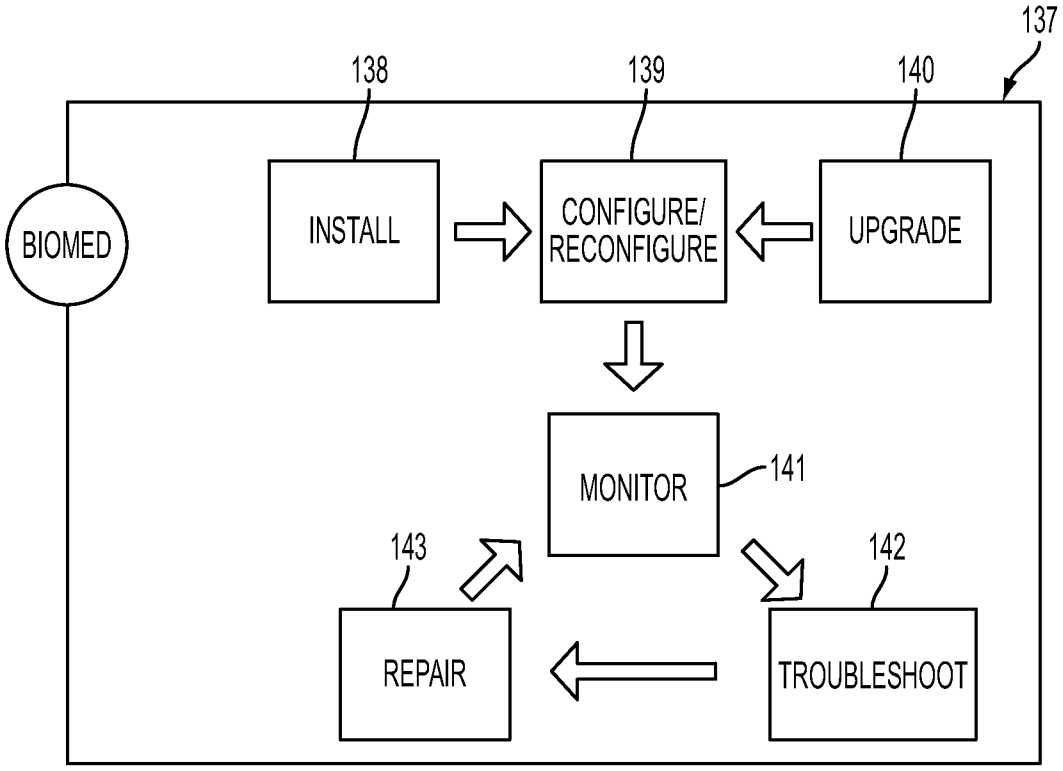
137
138
139
140
BIOMED
INSTALL
CONFIGURE/
RECONFIGURE
UPGRADE
MONITOR
141
143
142
REPAIR
TROUBLESHOOT

FIG. 7

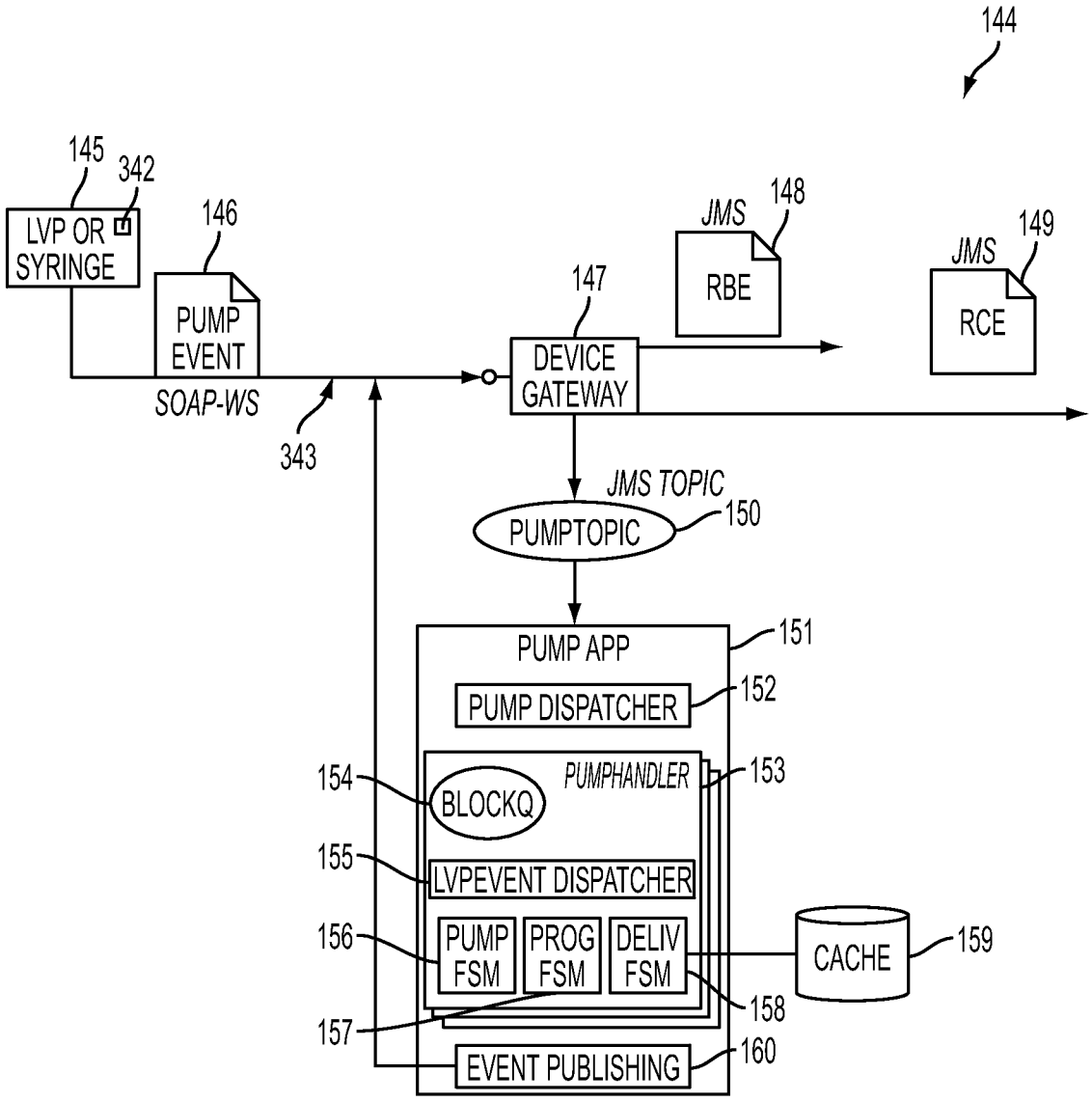
144
145
342
LVP OR SYRINGE
146
PUMP EVENT
SOAP-WS
343
147
DEVICE GATEWAY
JMS
148
RBE
JMS
149
RCE
JMS TOPIC
PUMPTOPIC
150
PUMP APP
151
PUMP DISPATCHER
152
PUMPHANDLER
153
154
BLOCKQ
155
LVPEVENT DISPATCHER
156
PUMP FSM
PROG FSM
DELIV FSM
CACHE
159
158
157
EVENT PUBLISHING
160

FIG. 8

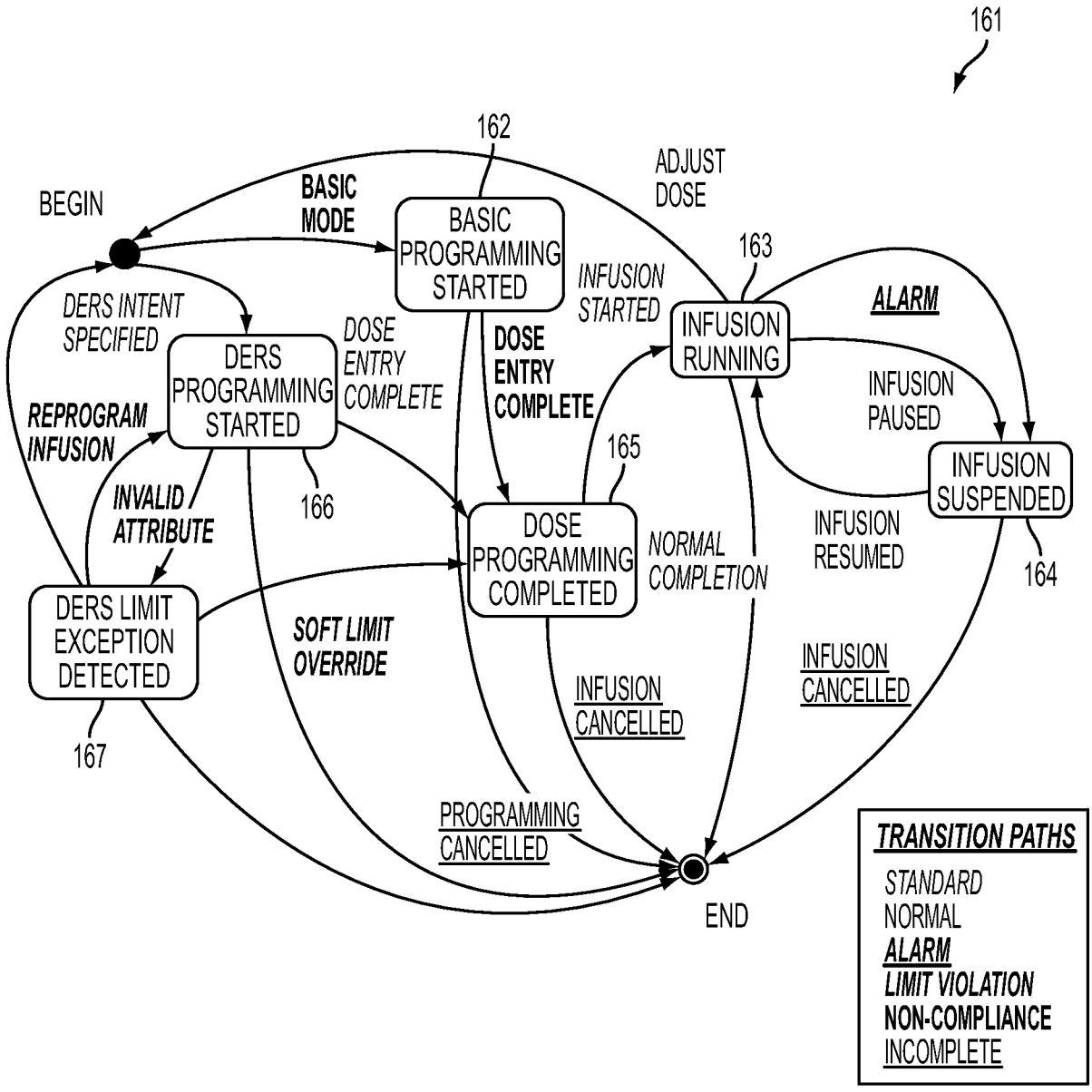
161
162
BEGIN
BASIC MODE
BASIC PROGRAMMING STARTED
ADJUST DOSE
163
INFUSION STARTED
ALARM
INFUSION RUNNING
DERS INTENT SPECIFIED
DERS PROGRAMMING STARTED
DOSE ENTRY COMPLETE
DOSE ENTRY COMPLETE
INFUSION PAUSED
INFUSION SUSPENDED
REPROGRAM INFUSION
INVALID ATTRIBUTE
166
165
DOSE PROGRAMMING COMPLETED
NORMAL COMPLETION
INFUSION RESUMED
164
DERS LIMIT EXCEPTION DETECTED
SOFT LIMIT OVERRIDE
INFUSION CANCELLED
INFUSION CANCELLED
167
PROGRAMMING CANCELLED
END
TRANSITION PATHS
STANDARD
NORMAL
ALARM
LIMIT VIOLATION
NON-COMPLIANCE
INCOMPLETE

FIG. 9

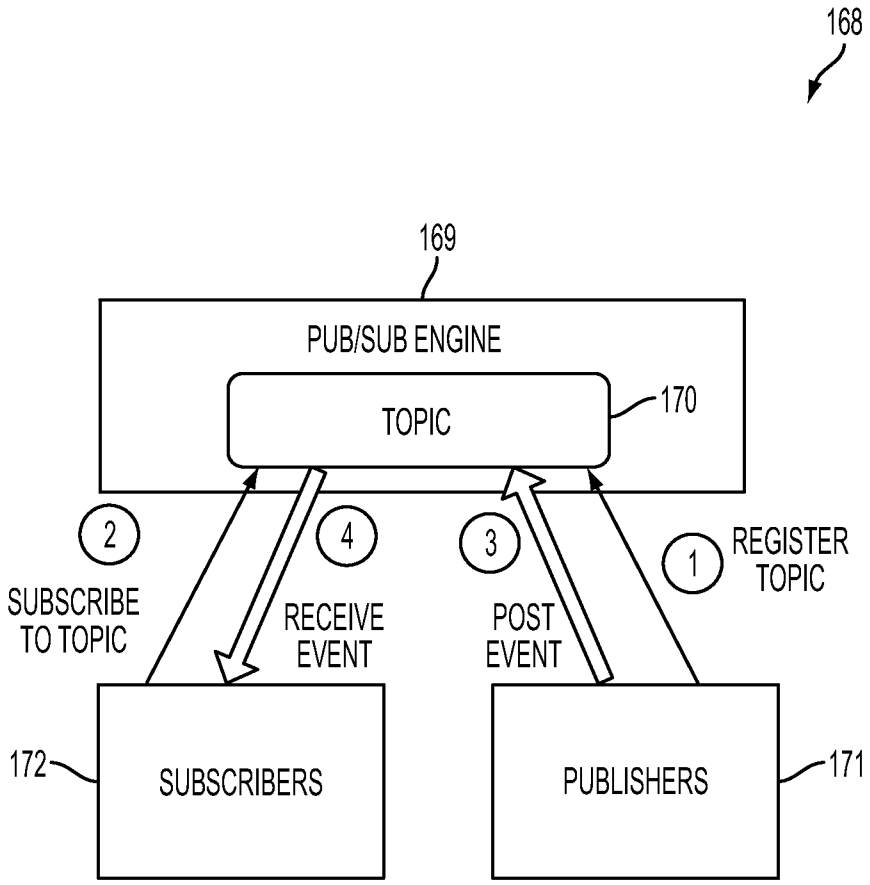
168
169
PUB/SUB ENGINE
TOPIC
170
2
SUBSCRIBE TO TOPIC
4
RECEIVE EVENT
3
POST EVENT
1
REGISTER TOPIC
172
SUBSCRIBERS
PUBLISHERS
171

FIG. 10

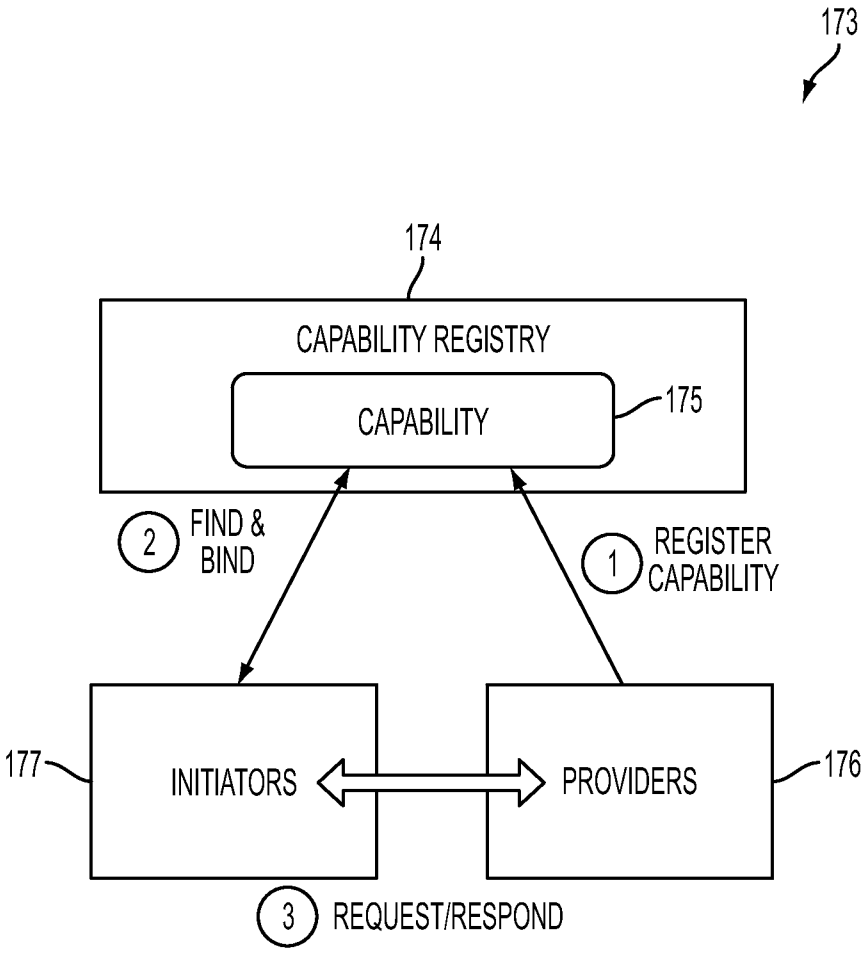
173
174
CAPABILITY REGISTRY
CAPABILITY
175
2
FIND &
BIND
1
REGISTER
CAPABILITY
177
INITIATORS
PROVIDERS
176
3
REQUEST/RESPOND

FIG. 11

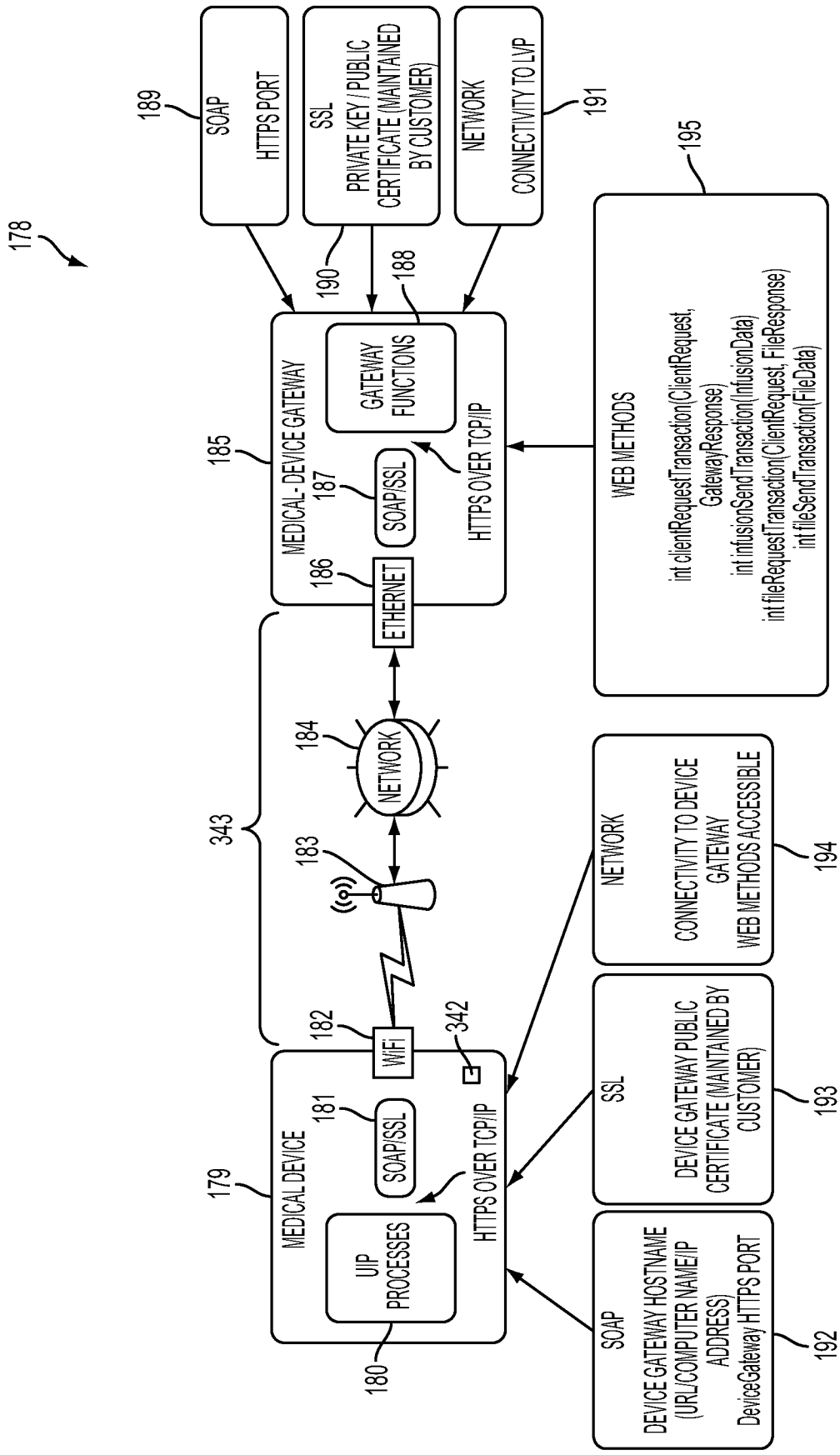
178
189
SOAP
HTTPS PORT
SSL
PRIVATE KEY / PUBLIC CERTIFICATE (MAINTAINED BY CUSTOMER)
190
NETWORK
CONNECTIVITY TO LVP
191
188
185
MEDICAL - DEVICE GATEWAY
GATEWAY FUNCTIONS
187
SOAP/SSL
HTTPS OVER TCP/IP
186
ETHERNET
195
WEB METHODS
int clientRequestTransaction(ClientRequest, GatewayResponse)
int infusionSendTransaction(InfusionData)
int fileRequestTransaction(ClientRequest, FileResponse)
int fileSendTransaction(FileData)
343
184
NETWORK
183
182
WiFi
342
179
MEDICAL DEVICE
181
SOAP/SSL
UIP PROCESSES
HTTPS OVER TCP/IP
180
NETWORK
CONNECTIVITY TO DEVICE GATEWAY WEB METHODS ACCESSIBLE
194
SSL
DEVICE GATEWAY PUBLIC CERTIFICATE (MAINTAINED BY CUSTOMER)
193
SOAP
DEVICE GATEWAY HOSTNAME (URL/COMPUTER NAME/IP ADDRESS)
DeviceGateway HTTPS PORT
192

FIG. 12

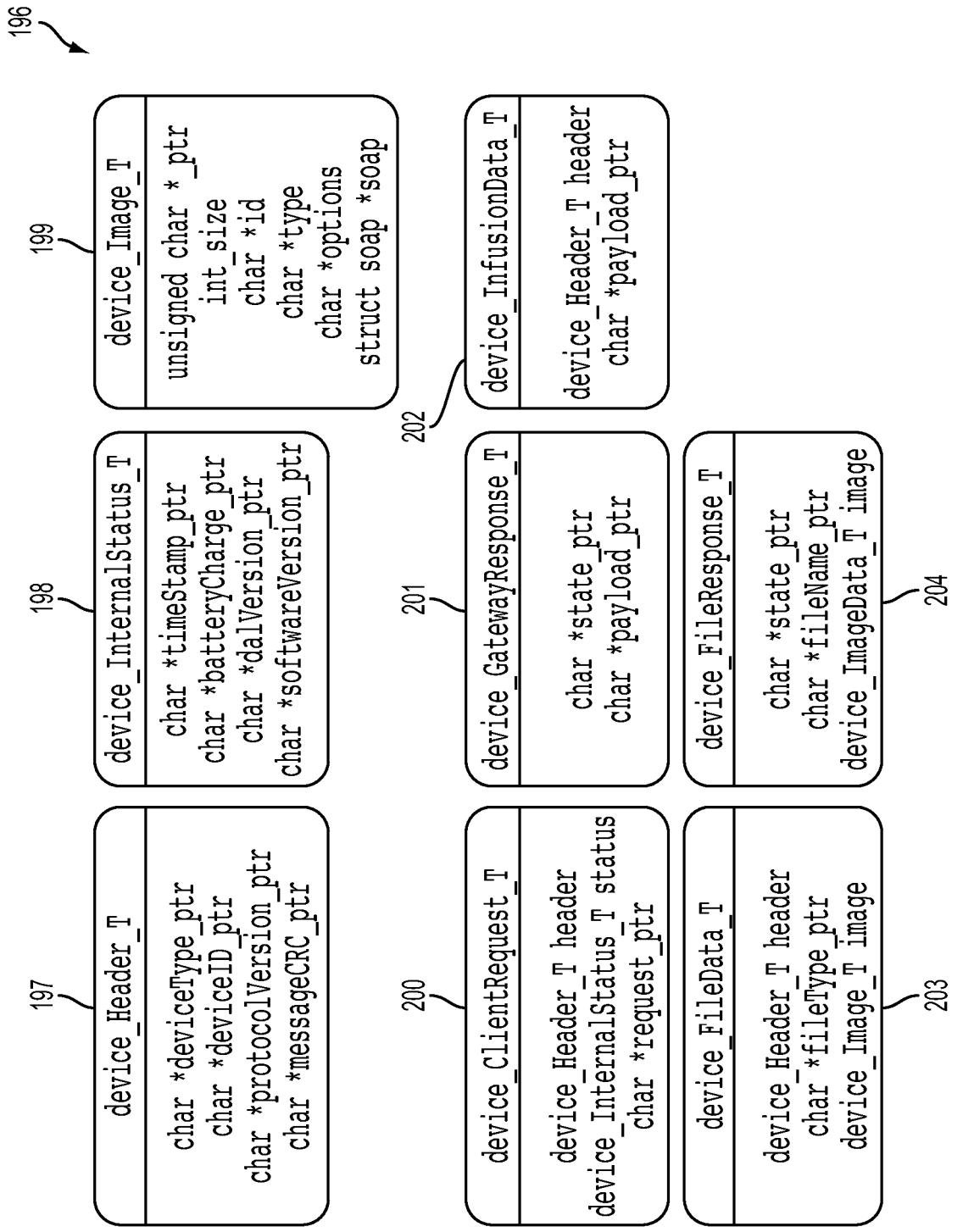
196
197
device_Header_T
char *deviceType_ptr
char *deviceID_ptr
char *protocolVersion_ptr
char *messageCRC_ptr
198
device_InternalStatus_T
char *timeStamp_ptr
char *batteryCharge_ptr
char *dalVersion_ptr
char *softwareVersion_ptr
199
device_Image_T
unsigned char * _ptr
int_size
char *id
char *type
char *options
struct soap *soap
200
device_ClientRequest_T
device_Header_T header
device_InternalStatus_T status
char *request_ptr
201
device_GatewayResponse_T
char *state_ptr
char *payload_ptr
202
device_InfusionData_T
device_Header_T header
char *payload_ptr
203
device_FileData_T
device_Header_T header
char *fileType_ptr
device_Image_T image
204
device_FileResponse_T
char *state_ptr
char *fileName_ptr
device_ImageData_T image

FIG. 13

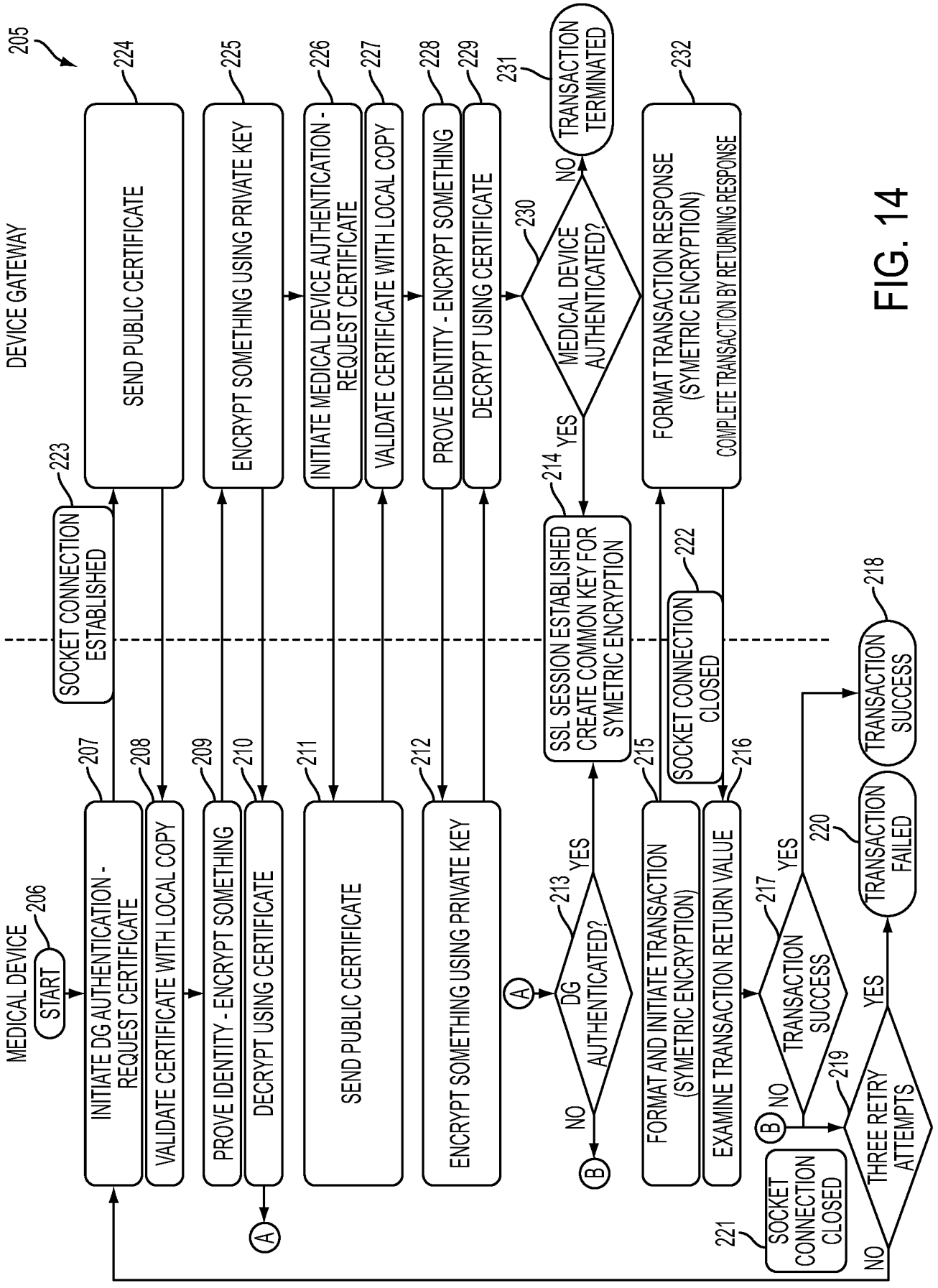
MEDICAL DEVICE
DEVICE GATEWAY
205
START
206
INITIATE DG AUTHENTICATION - REQUEST CERTIFICATE
207
VALIDATE CERTIFICATE WITH LOCAL COPY
208
PROVE IDENTITY - ENCRYPT SOMETHING
209
DECRYPT USING CERTIFICATE
210
SEND PUBLIC CERTIFICATE
211
ENCRYPT SOMETHING USING PRIVATE KEY
212
DG AUTHENTICATED?
213
YES
NO
SSL SESSION ESTABLISHED CREATE COMMON KEY FOR SYMETRIC ENCRYPTION
214
FORMAT AND INITIATE TRANSACTION (SYMETRIC ENCRYPTION)
215
EXAMINE TRANSACTION RETURN VALUE
216
TRANSACTION SUCCESS
217
YES
NO
TRANSACTION SUCCESS
218
TRANSACTION FAILED
220
THREE RETRY ATTEMPTS
219
YES
NO
SOCKET CONNECTION CLOSED
221
SOCKET CONNECTION CLOSED
222
FORMAT TRANSACTION RESPONSE (SYMETRIC ENCRYPTION)
COMPLETE TRANSACTION BY RETURNING RESPONSE
232
MEDICAL DEVICE AUTHENTICATED?
230
YES
NO
TRANSACTION TERMINATED
231
PROVE IDENTITY - ENCRYPT SOMETHING
228
DECRYPT USING CERTIFICATE
229
VALIDATE CERTIFICATE WITH LOCAL COPY
227
INITIATE MEDICAL DEVICE AUTHENTICATION - REQUEST CERTIFICATE
226
ENCRYPT SOMETHING USING PRIVATE KEY
225
SEND PUBLIC CERTIFICATE
224
SOCKET CONNECTION ESTABLISHED
223
A
B

FIG. 14

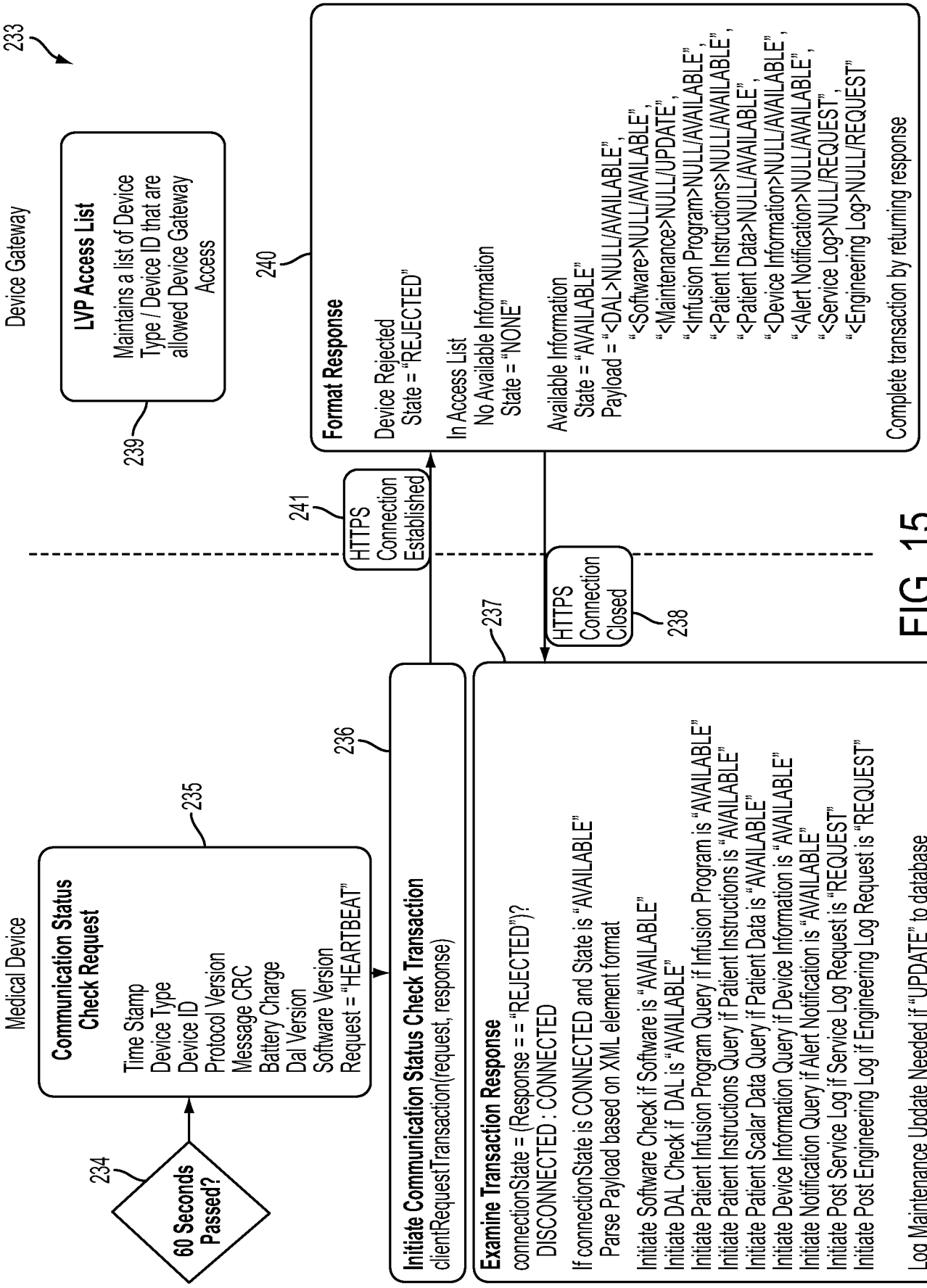
Medical Device
Device Gateway
233
60 Seconds Passed?
234
Communication Status Check Request
Time Stamp
Device Type
Device ID
Protocol Version
Message CRC
Battery Charge
Dal Version
Software Version
Request = "HEARTBEAT"
235
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
239
240
Format Response
Device Rejected
State = "REJECTED"
In Access List
No Available Information
State = "NONE"
Available Information
State = "AVAILABLE"
Payload = "<DAL>NULL/AVAILABLE",
"<Software>NULL/AVAILABLE",
"<Maintenance>NULL/UPDATE",
"<Infusion Program>NULL/AVAILABLE",
"<Patient Instructions>NULL/AVAILABLE",
"<Patient Data>NULL/AVAILABLE",
"<Device Information>NULL/AVAILABLE",
"<Alert Notification>NULL/AVAILABLE",
"<Service Log>NULL/REQUEST",
"<Engineering Log>NULL/REQUEST"
Complete transaction by returning response
241
HTTPS Connection Established
HTTPS Connection Closed
238
236
Initiate Communication Status Check Transaction
clientRequestTransaction(request, response)
237
Examine Transaction Response
connectionState = (Response = = "REJECTED")?
DISCONNECTED : CONNECTED
If connectionState is CONNECTED and State is "AVAILABLE"
Parse Payload based on XML element format
Initiate Software Check if Software is "AVAILABLE"
Initiate DAL Check if DAL is "AVAILABLE"
Initiate Patient Infusion Program Query if Infusion Program is "AVAILABLE"
Initiate Patient Instructions Query if Patient Instructions is "AVAILABLE"
Initiate Patient Scalar Data Query if Patient Data is "AVAILABLE"
Initiate Device Information Query if Device Information is "AVAILABLE"
Initiate Notification Query if Alert Notification is "AVAILABLE"
Initiate Post Service Log if Service Log Request is "REQUEST"
Initiate Post Engineering Log if Engineering Log Request is "REQUEST"
Log Maintenance Update Needed if "UPDATE" to database

FIG. 15

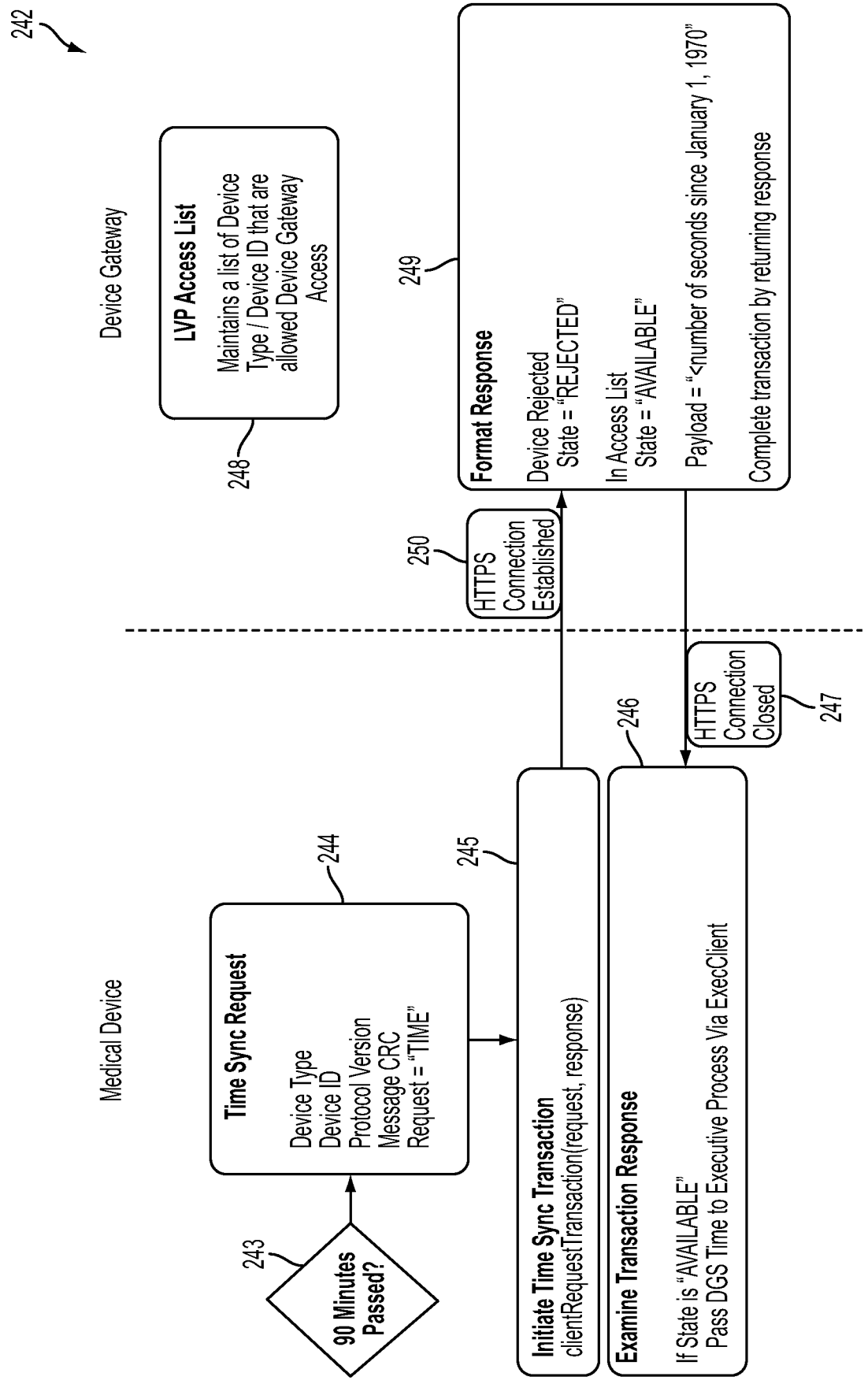
242
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
248
249
Format Response
Device Rejected
State = "REJECTED"
In Access List
State = "AVAILABLE"
Payload = "<number of seconds since January 1, 1970"
Complete transaction by returning response
250
HTTPS Connection Established
Medical Device
Time Sync Request
Device Type
Device ID
Protocol Version
Message CRC
Request = "TIME"
244
245
Initiate Time Sync Transaction
clientRequestTransaction(request, response)
246
Examine Transaction Response
If State is "AVAILABLE"
Pass DGS Time to Executive Process Via ExecClient
HTTPS Connection Closed
247
243
90 Minutes Passed?

FIG. 16

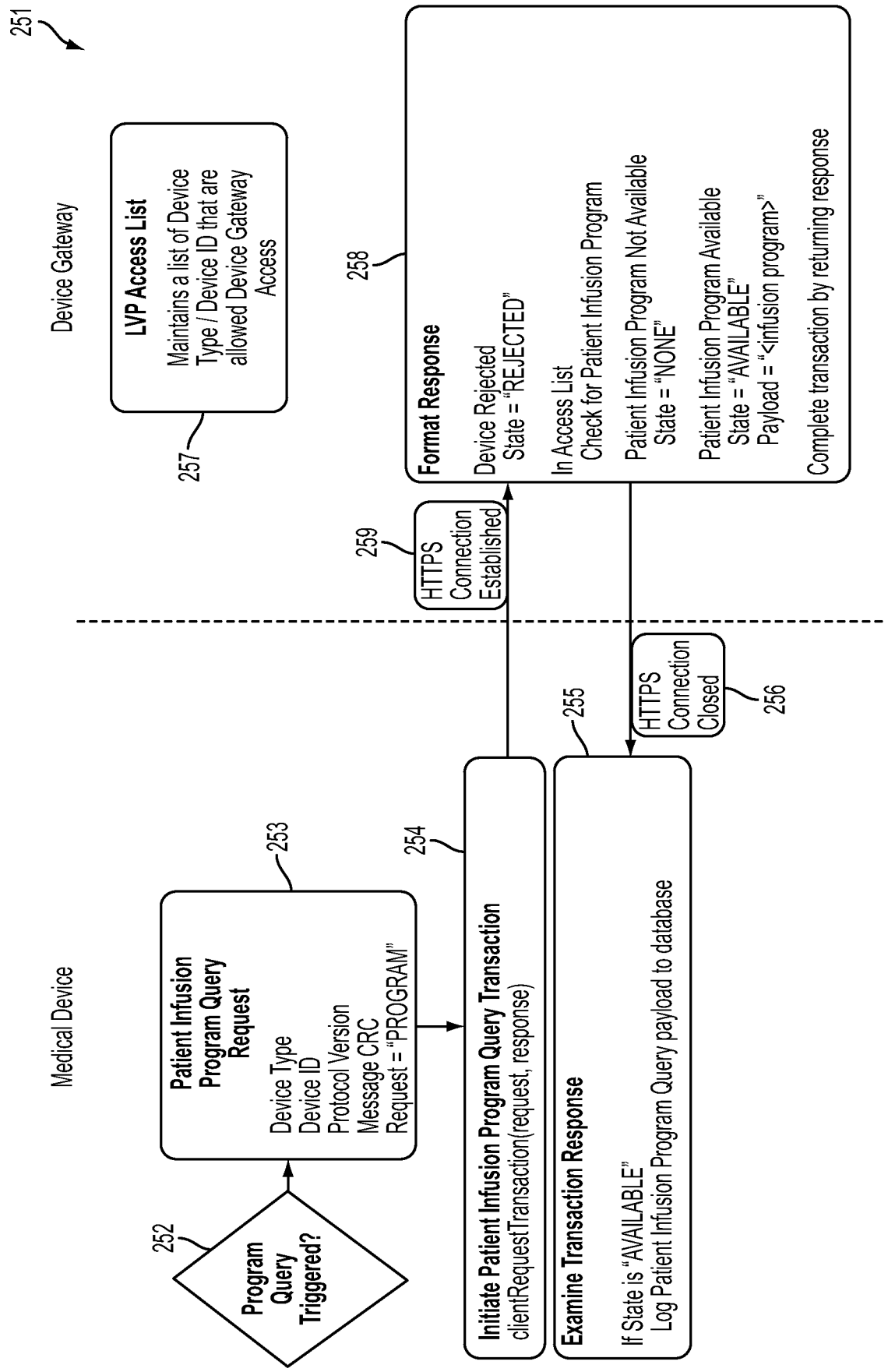
251
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
257
258
Format Response
Device Rejected
State = "REJECTED"
In Access List
Check for Patient Infusion Program
Patient Infusion Program Not Available
State = "NONE"
Patient Infusion Program Available
State = "AVAILABLE"
Payload = "<infusion program>"
Complete transaction by returning response
259
HTTPS Connection Established
HTTPS Connection Closed
256
Medical Device
252
Program Query Triggered?
253
Patient Infusion Program Query Request
Device Type
Device ID
Protocol Version
Message CRC
Request = "PROGRAM"
254
Initiate Patient Infusion Program Query Transaction
clientRequestTransaction(request, response)
255
Examine Transaction Response
If State is "AVAILABLE"
Log Patient Infusion Program Query payload to database

FIG. 17

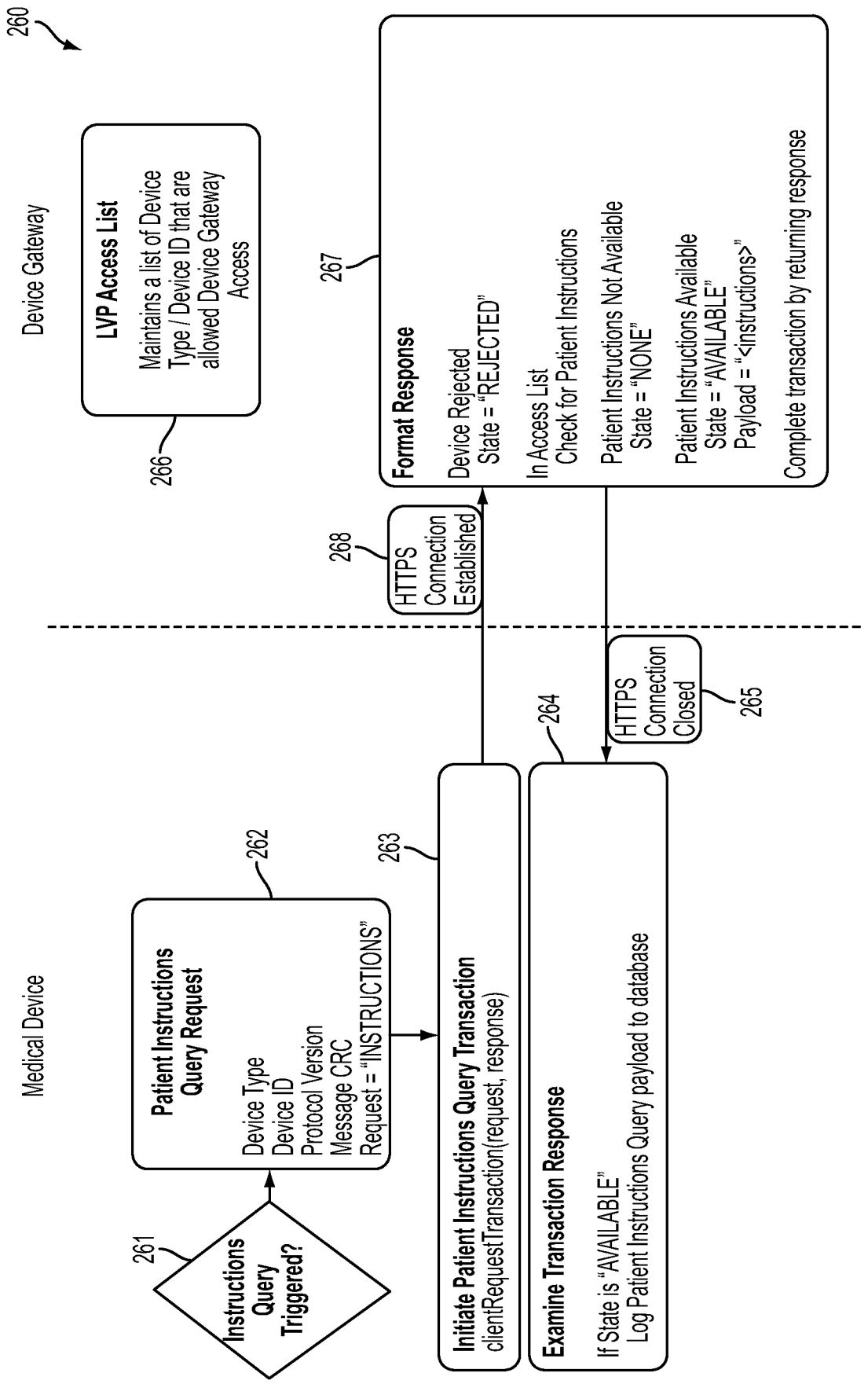
260
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
266
267
Format Response
Device Rejected
State = "REJECTED"
In Access List
Check for Patient Instructions
Patient Instructions Not Available
State = "NONE"
Patient Instructions Available
State = "AVAILABLE"
Payload = "<instructions>"
Complete transaction by returning response
268
HTTPS Connection Established
HTTPS Connection Closed
265
Medical Device
Instructions Query Triggered?
261
Patient Instructions Query Request
Device Type
Device ID
Protocol Version
Message CRC
Request = "INSTRUCTIONS"
262
Initiate Patient Instructions Query Transaction
clientRequestTransaction(request, response)
263
Examine Transaction Response
If State is "AVAILABLE"
Log Patient Instructions Query payload to database
264

FIG. 18

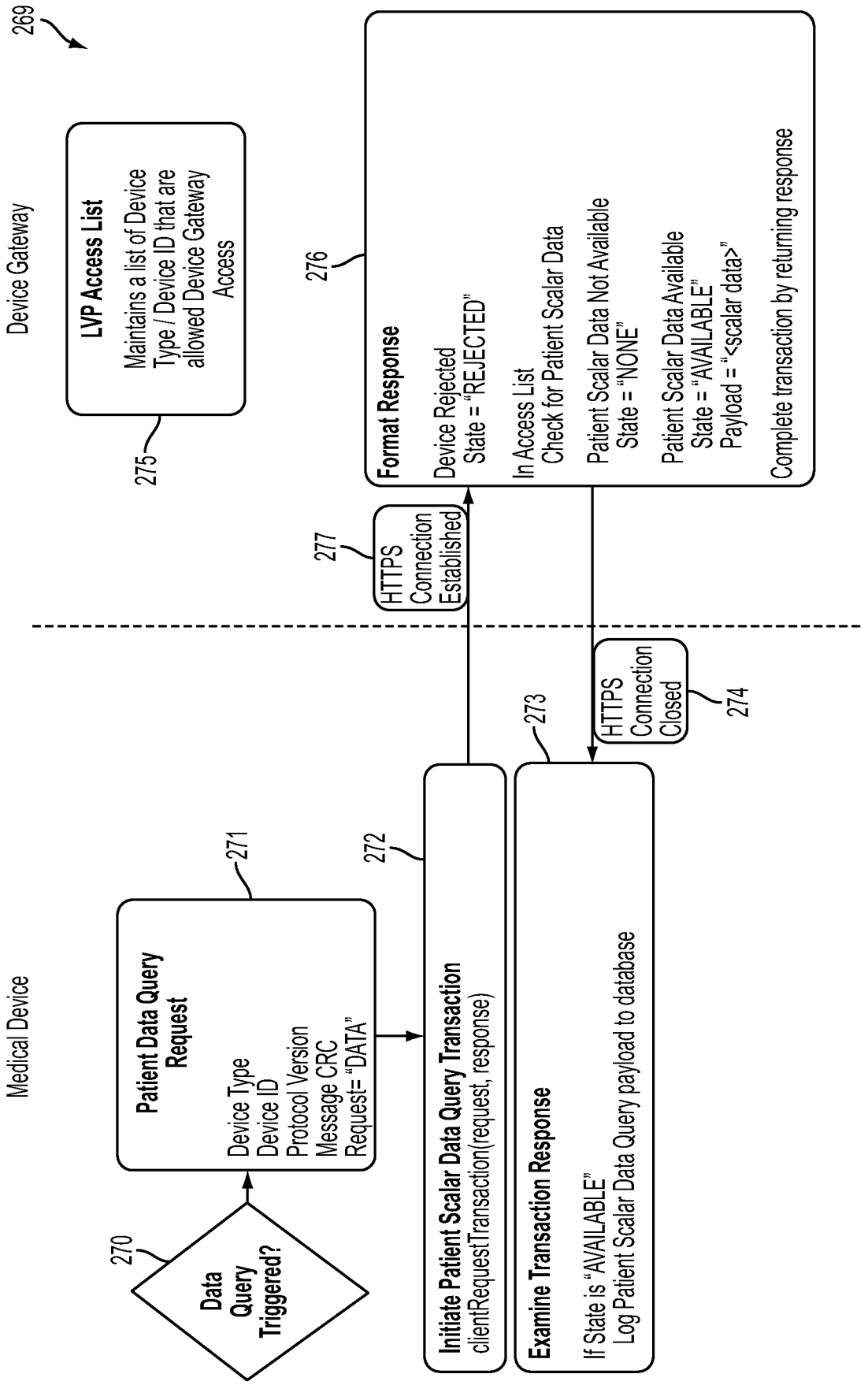
269
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
275
276
Format Response
Device Rejected
State = "REJECTED"
In Access List
Check for Patient Scalar Data
Patient Scalar Data Not Available
State = "NONE"
Patient Scalar Data Available
State = "AVAILABLE"
Payload = "<scalar data>"
Complete transaction by returning response
277
HTTPS Connection Established
HTTPS Connection Closed
274
Medical Device
270
Data Query Triggered?
271
Patient Data Query Request
Device Type
Device ID
Protocol Version
Message CRC
Request= "DATA"
272
Initiate Patient Scalar Data Query Transaction
clientRequestTransaction(request, response)
273
Examine Transaction Response
If State is "AVAILABLE"
Log Patient Scalar Data Query payload to database

FIG. 19

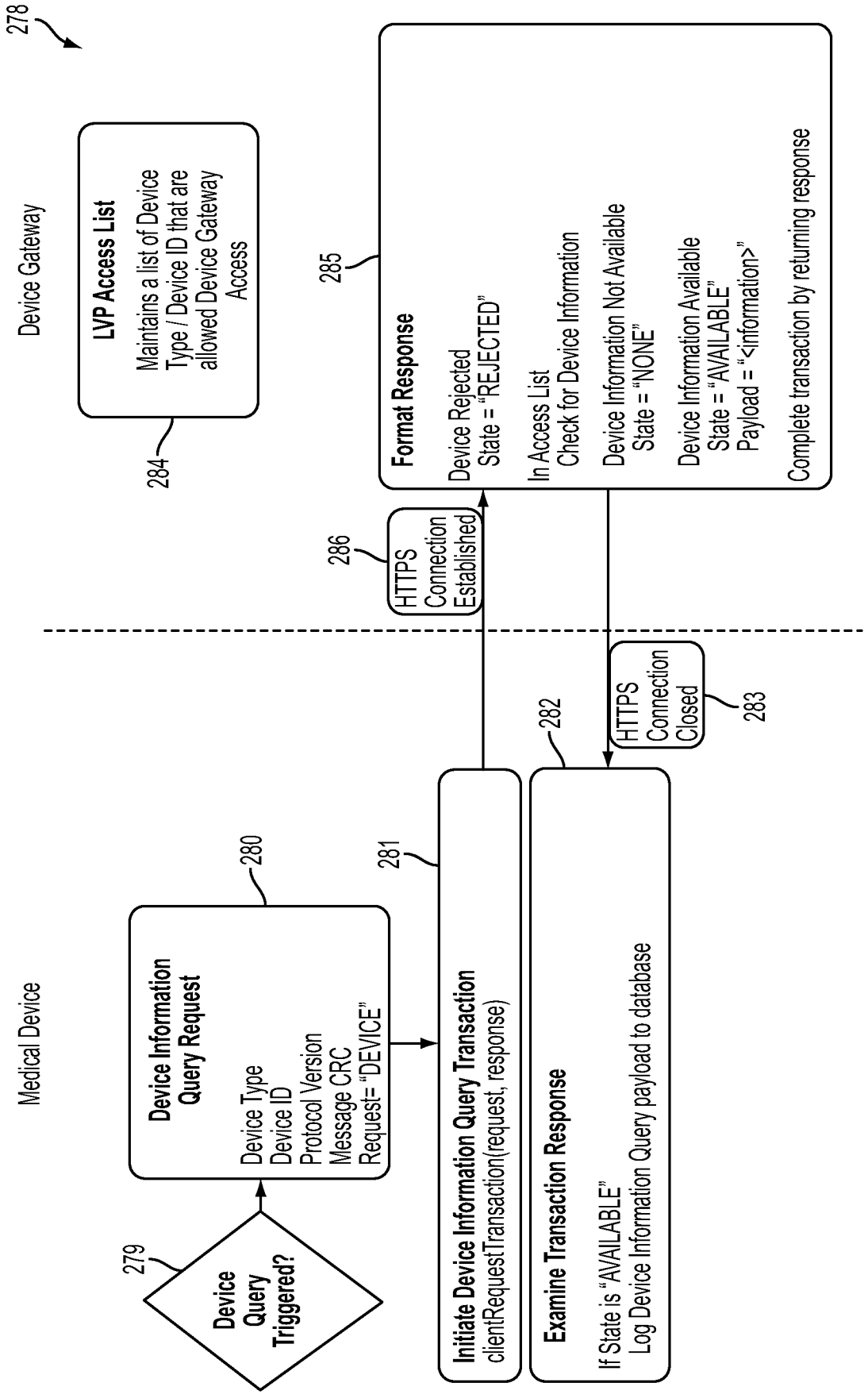
278
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
284
285
Format Response
Device Rejected
State = "REJECTED"
In Access List
Check for Device Information
Device Information Not Available
State = "NONE"
Device Information Available
State = "AVAILABLE"
Payload = "<information>"
Complete transaction by returning response
286
HTTPS Connection Established
HTTPS Connection Closed
283
Medical Device
279
Device Query Triggered?
280
Device Information Query Request
Device Type
Device ID
Protocol Version
Message CRC
Request= "DEVICE"
281
Initiate Device Information Query Transaction
clientRequestTransaction(request, response)
282
Examine Transaction Response
If State is "AVAILABLE"
Log Device Information Query payload to database

FIG. 20

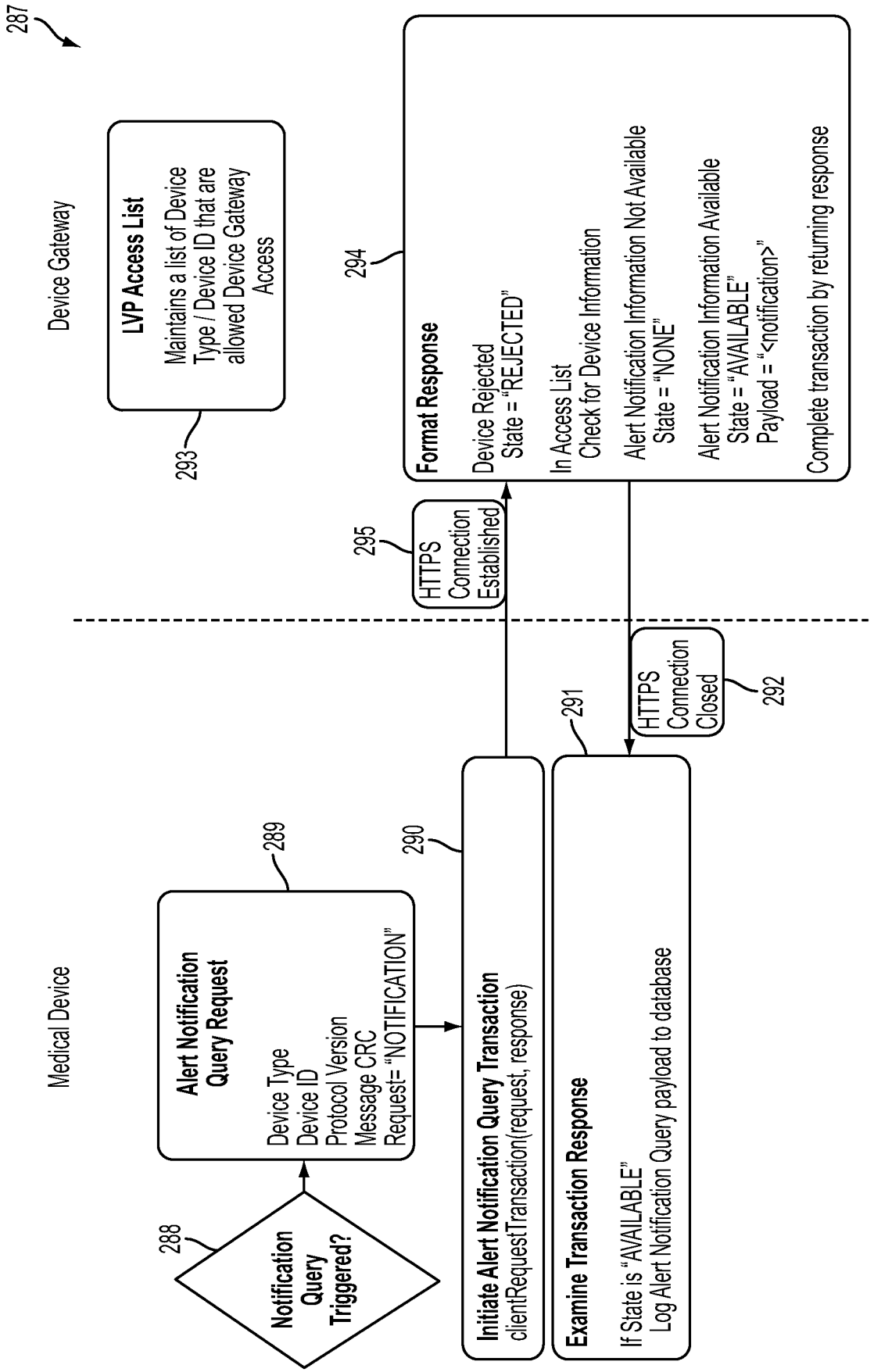
287
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
293
294
Format Response
Device Rejected
State = "REJECTED"
In Access List
Check for Device Information
Alert Notification Information Not Available
State = "NONE"
Alert Notification Information Available
State = "AVAILABLE"
Payload = "<notification>"
Complete transaction by returning response
295
HTTPS Connection Established
HTTPS Connection Closed
292
Medical Device
288
Notification Query Triggered?
289
Alert Notification Query Request
Device Type
Device ID
Protocol Version
Message CRC
Request= "NOTIFICATION"
290
Initiate Alert Notification Query Transaction
clientRequestTransaction(request, response)
291
Examine Transaction Response
If State is "AVAILABLE"
Log Alert Notification Query payload to database

FIG. 21

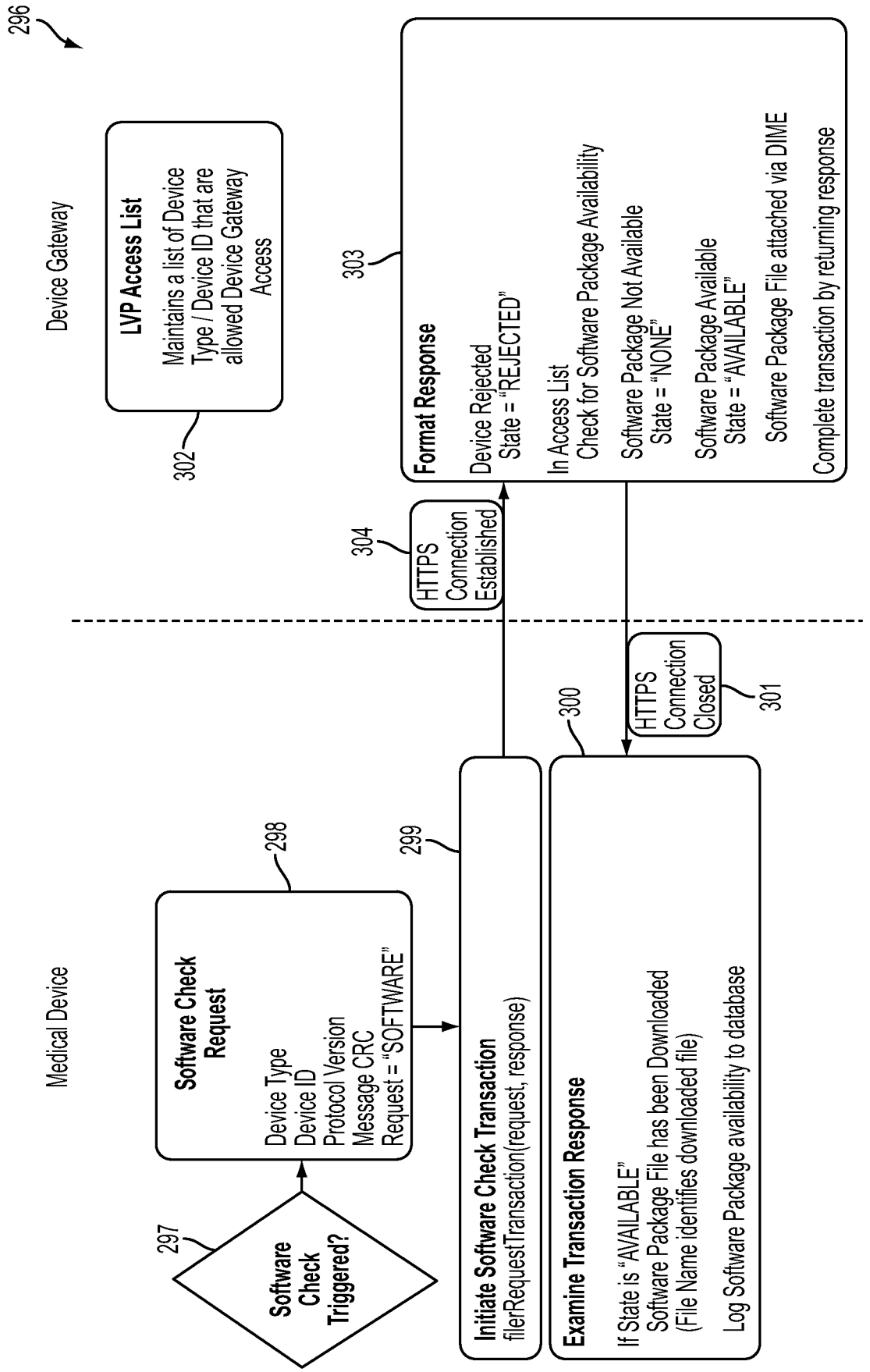
296
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
302
303
Format Response
Device Rejected
State = "REJECTED"
In Access List
Check for Software Package Availability
Software Package Not Available
State = "NONE"
Software Package Available
State = "AVAILABLE"
Software Package File attached via DIME
Complete transaction by returning response
304
HTTPS Connection Established
HTTPS Connection Closed
301
Medical Device
Software Check Request
Device Type
Device ID
Protocol Version
Message CRC
Request = "SOFTWARE"
298
299
300
Initiate Software Check Transaction
filerRequestTransaction(request, response)
Examine Transaction Response
If State is "AVAILABLE"
Software Package File has been Downloaded
(File Name identifies downloaded file)
Log Software Package availability to database
Software Check Triggered?
297

FIG. 22

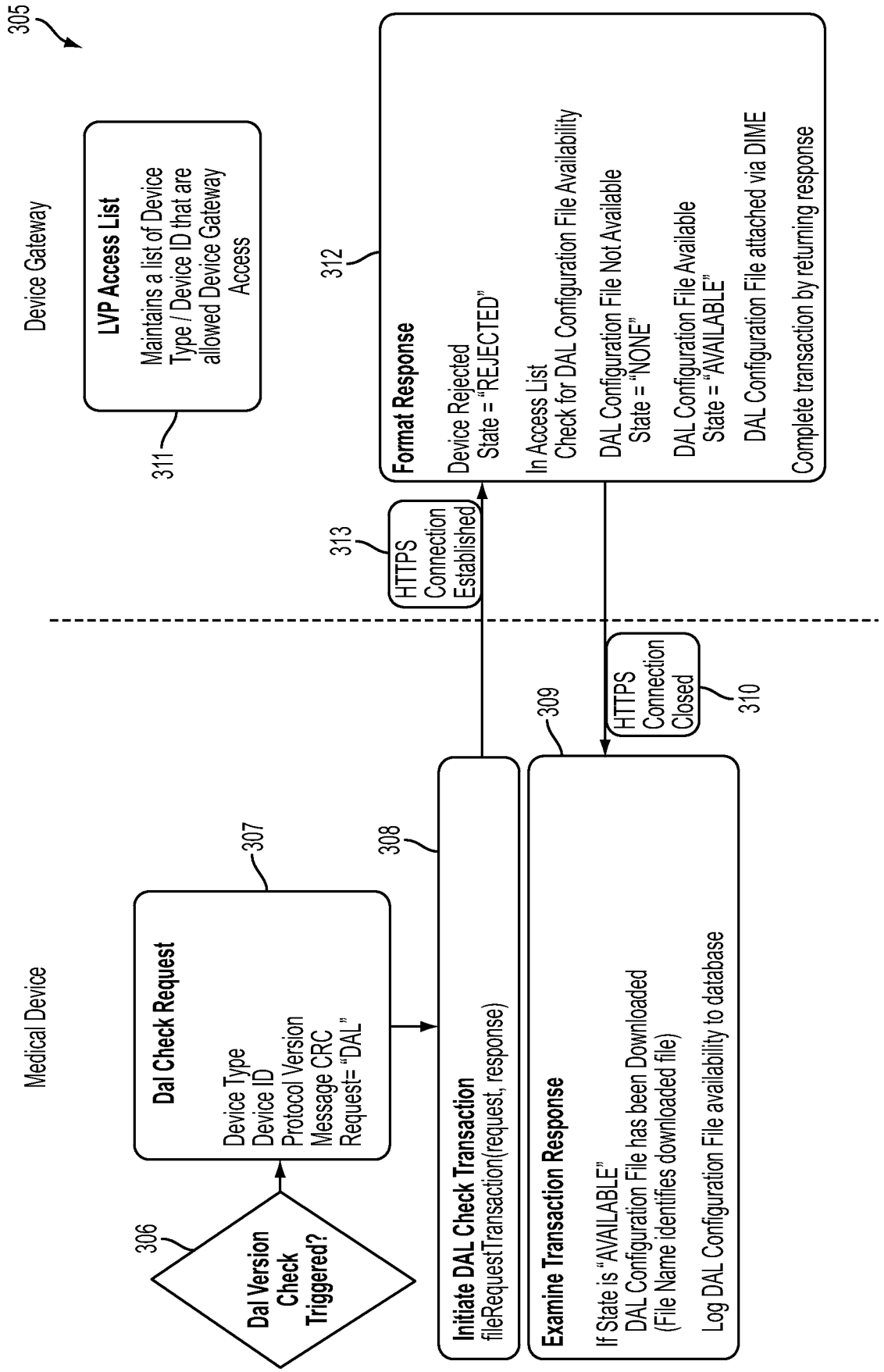
305
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
311
312
Format Response
Device Rejected
State = "REJECTED"
In Access List
Check for DAL Configuration File Availability
DAL Configuration File Not Available
State = "NONE"
DAL Configuration File Available
State = "AVAILABLE"
DAL Configuration File attached via DIME
Complete transaction by returning response
313
HTTPS Connection Established
HTTPS Connection Closed
310
Medical Device
306
Dal Version Check Triggered?
307
Dal Check Request
Device Type
Device ID
Protocol Version
Message CRC
Request= "DAL"
308
Initiate DAL Check Transaction
fileRequestTransaction(request, response)
309
Examine Transaction Response
If State is "AVAILABLE"
DAL Configuration File has been Downloaded
(File Name identifies downloaded file)
Log DAL Configuration File availability to database

FIG. 23

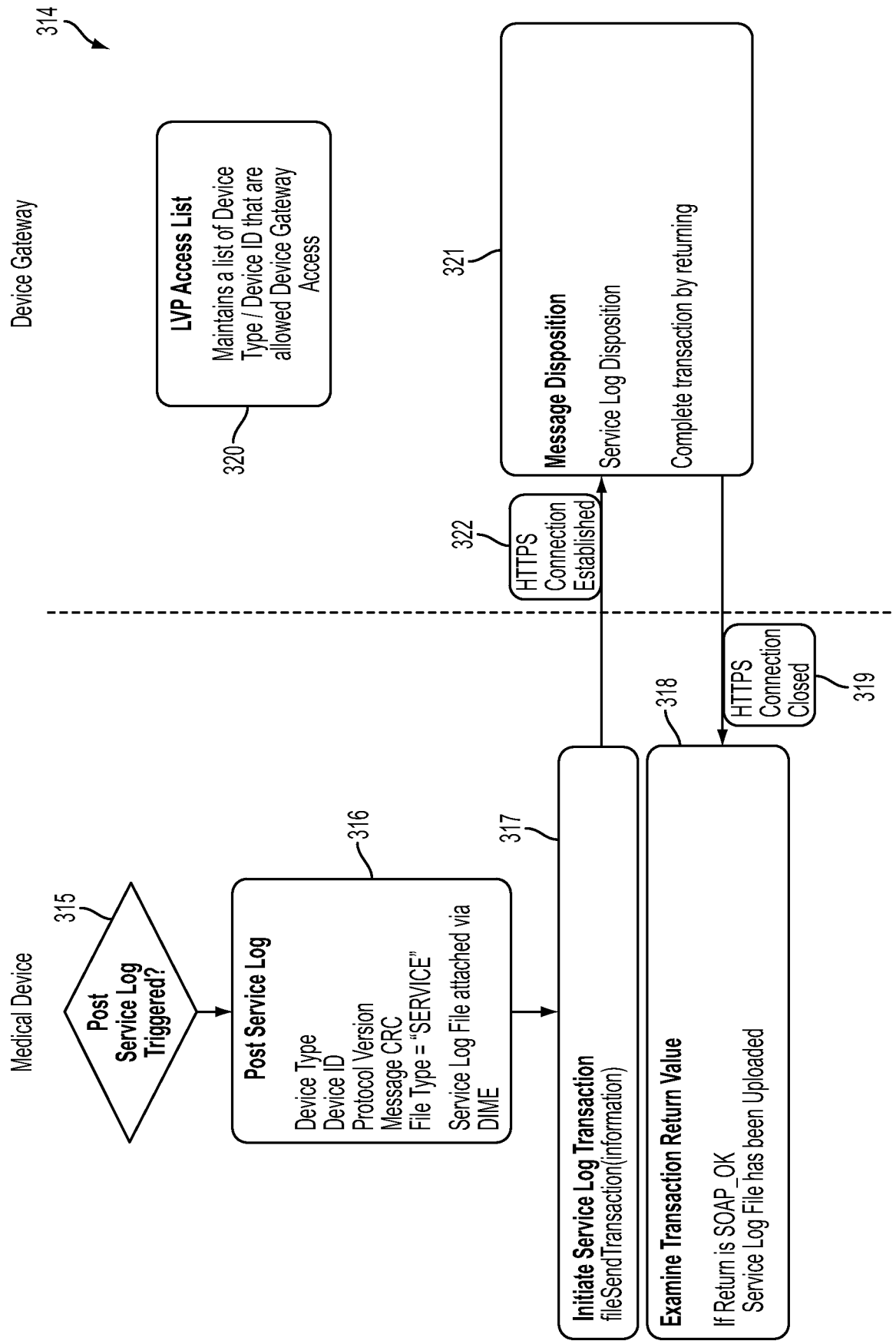
Medical Device
Device Gateway
314
315
Post Service Log Triggered?
316
Post Service Log
Device Type
Device ID
Protocol Version
Message CRC
File Type = "SERVICE"
Service Log File attached via DIME
317
Initiate Service Log Transaction
fileSendTransaction(information)
318
Examine Transaction Return Value
If Return is SOAP_OK
Service Log File has been Uploaded
319
HTTPS Connection Closed
320
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
321
Message Disposition
Service Log Disposition
Complete transaction by returning
322
HTTPS Connection Established

FIG. 24

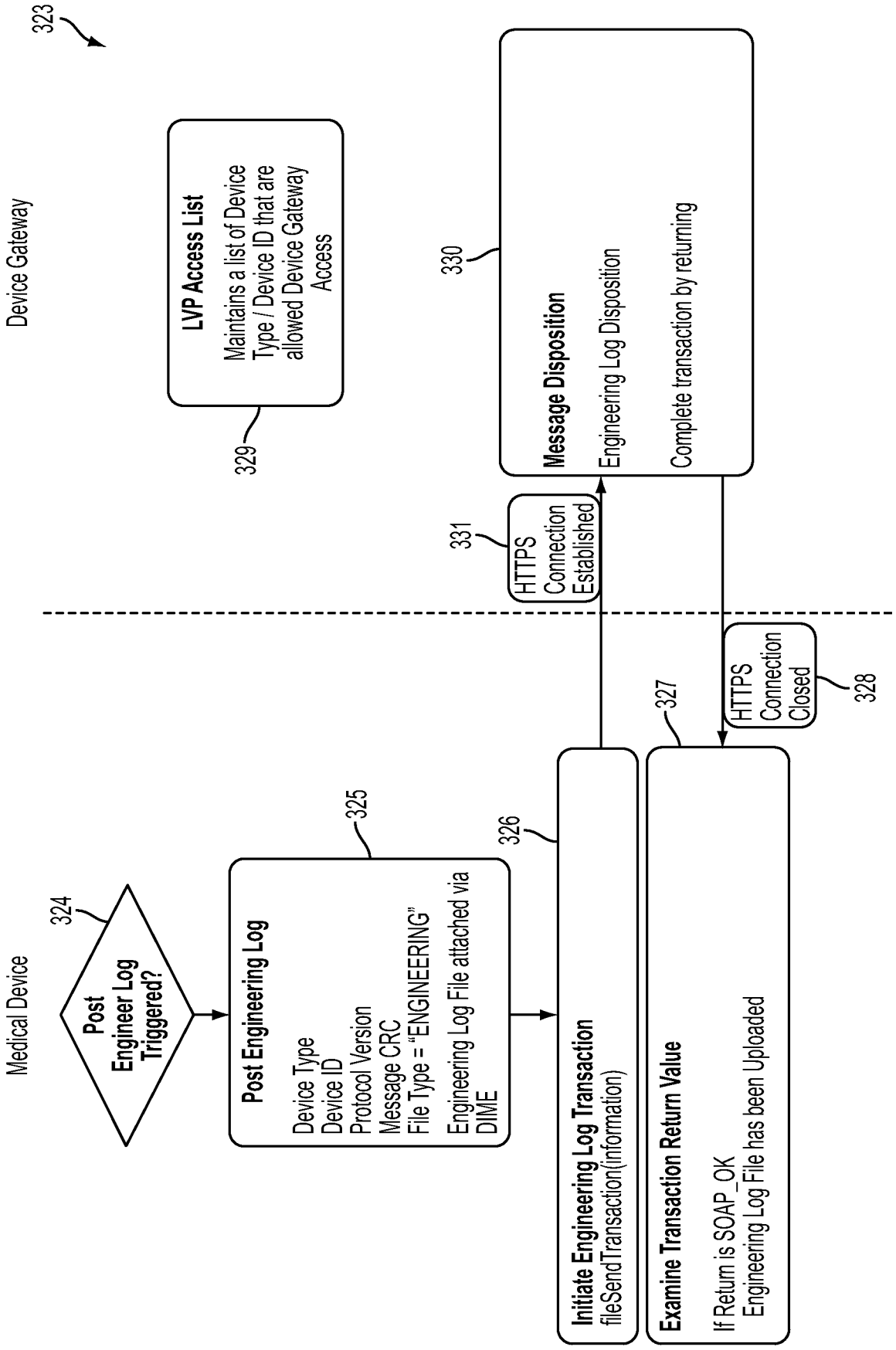
Medical Device
Device Gateway
323
Post Engineer Log Triggered?
324
Post Engineering Log
Device Type
Device ID
Protocol Version
Message CRC
File Type = "ENGINEERING"
Engineering Log File attached via DIME
325
326
Initiate Engineering Log Transaction
fileSendTransaction(information)
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
329
HTTPS Connection Established
331
Message Disposition
Engineering Log Disposition
Complete transaction by returning
330
HTTPS Connection Closed
328
327
Examine Transaction Return Value
If Return is SOAP_OK
Engineering Log File has been Uploaded

FIG. 25

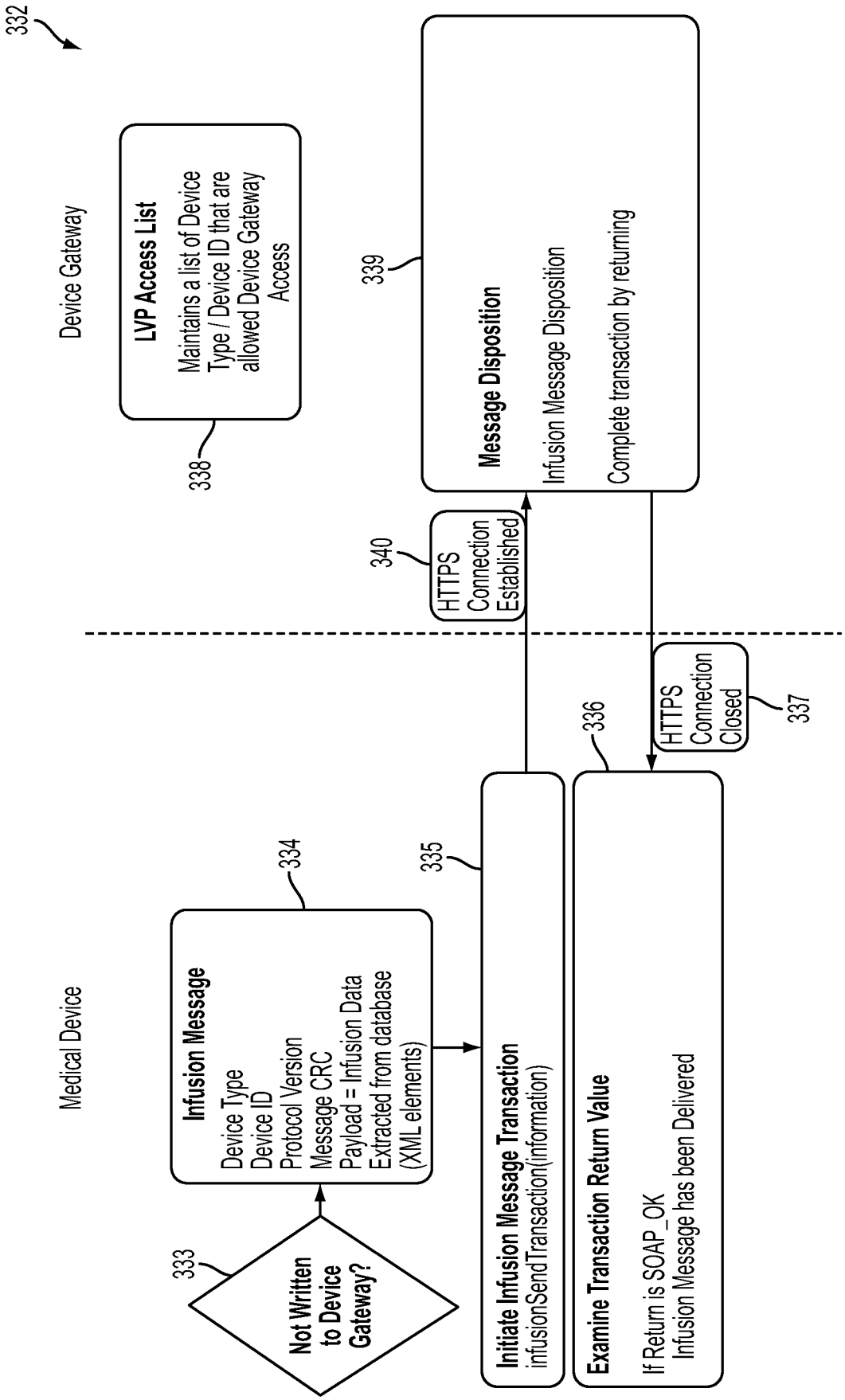
332
Device Gateway
LVP Access List
Maintains a list of Device Type / Device ID that are allowed Device Gateway Access
338
339
Message Disposition
Infusion Message Disposition
Complete transaction by returning
340
HTTPS Connection Established
HTTPS Connection Closed
337
336
Medical Device
334
Infusion Message
Device Type
Device ID
Protocol Version
Message CRC
Payload = Infusion Data Extracted from database (XML elements)
335
Initiate Infusion Message Transaction
infusionSendTransaction(information)
Examine Transaction Return Value
If Return is SOAP_OK
Infusion Message has been Delivered
333
Not Written to Device Gateway?

FIG. 26