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(54) METHOD FOR TRANSFERRING DATA TO A PHARMACEUTICAL COMPOUNDING SYSTEM

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(21) Appl. No.: **11/935,546**

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Related U.S. Application Data

(63) Continuation of application No. 11/003,232, filed on Dec. 3, 2004, now Pat. No. 7,317,967, Continuation-in-part of application No. 10/728,560, filed on Dec. 5, 2003, now Pat. No. 7,343,224, Continuation-in-part of application No. 10/335,552, filed on Dec. 31, 2002, now Pat. No. 7,194,336.

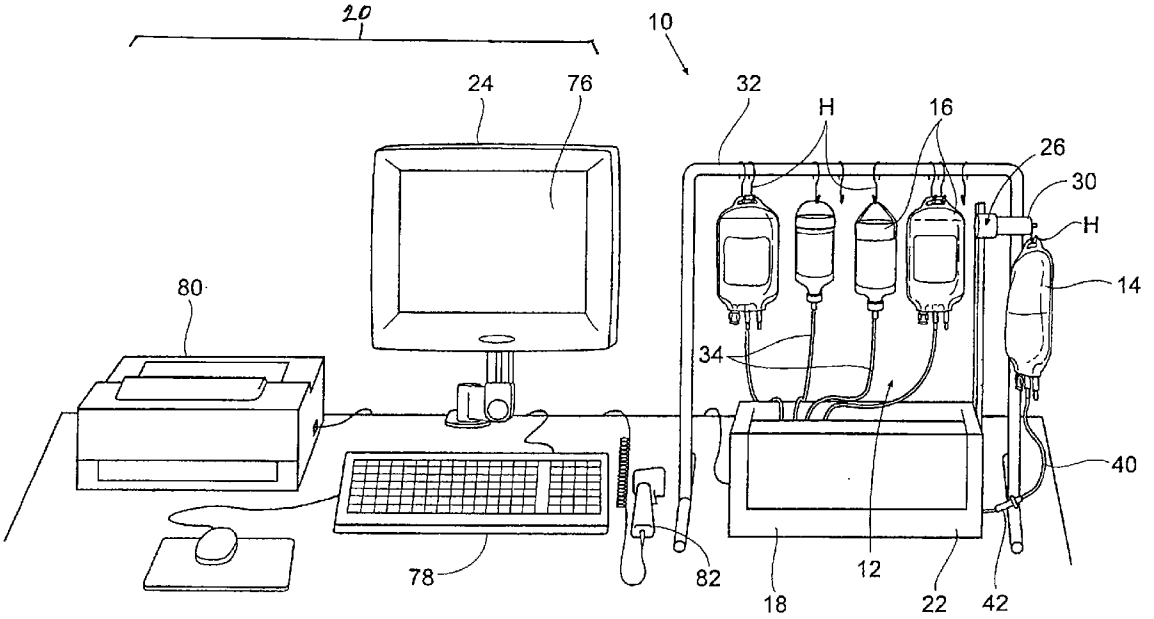
Publication Classification

(51) **Int. Cl.**
G06F 17/00 (2006.01)

(52) **U.S. Cl.** **700/110**; 700/239

(57) **ABSTRACT**

A method for use with a data entry system for providing input data to a pharmaceutical compounding device having an associated plurality of source solutions is provided. A first label comprising first indicia defining a desired pharmaceutical compound is generated. The first indicia is then provided to the pharmaceutical compounding device as an input. The pharmaceutical compounding device then prepares a pharmaceutical compound based on the first indicia and generates a second label comprising second indicia indicative of at least the contents of pharmaceutical compound. The first indicia and second indicia are provided to a comparison device where the contents of the actual pharmaceutical compound as indicated by the second indicia are compared to the desired pharmaceutical compound as indicated by the first indicia.



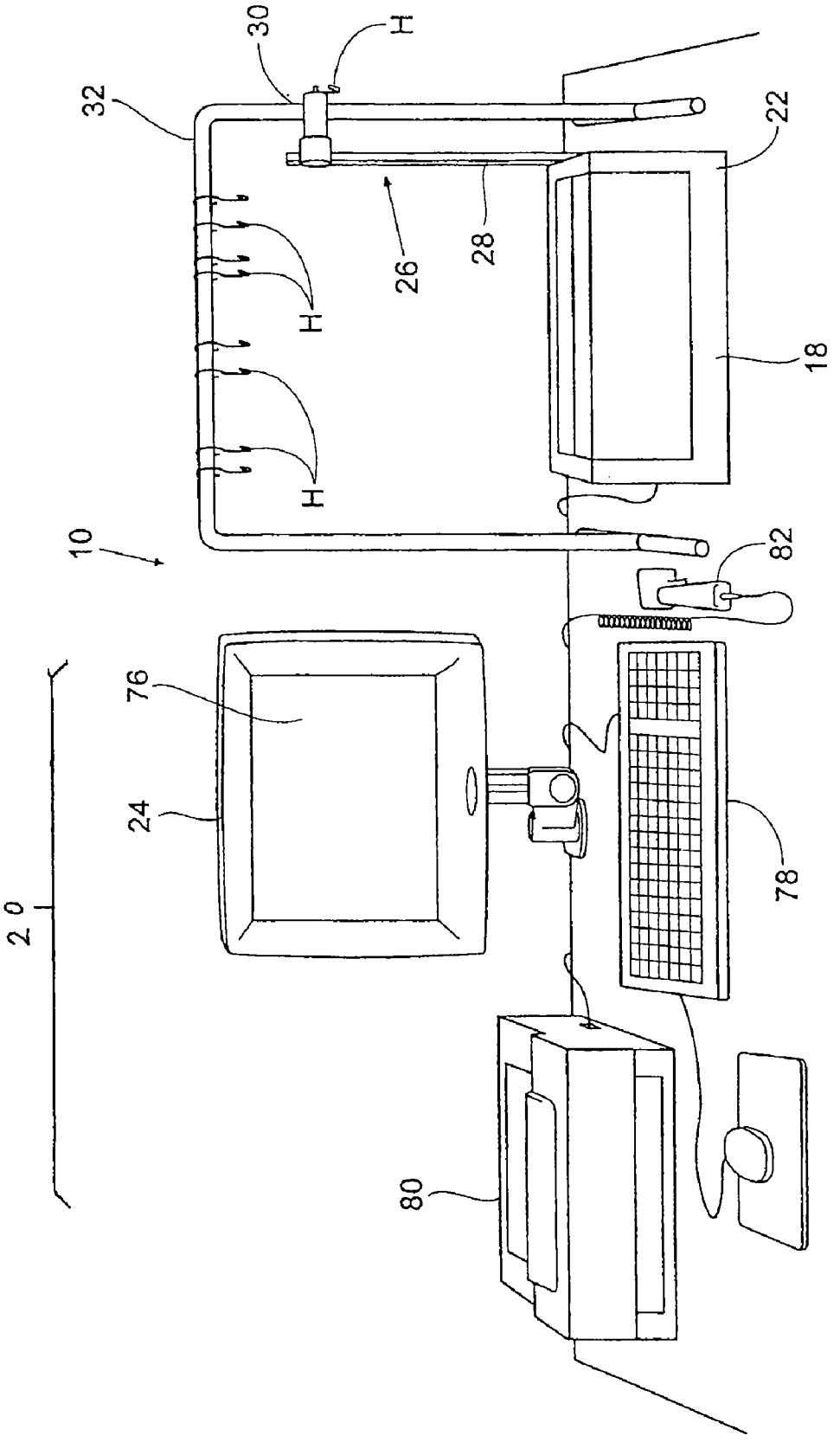
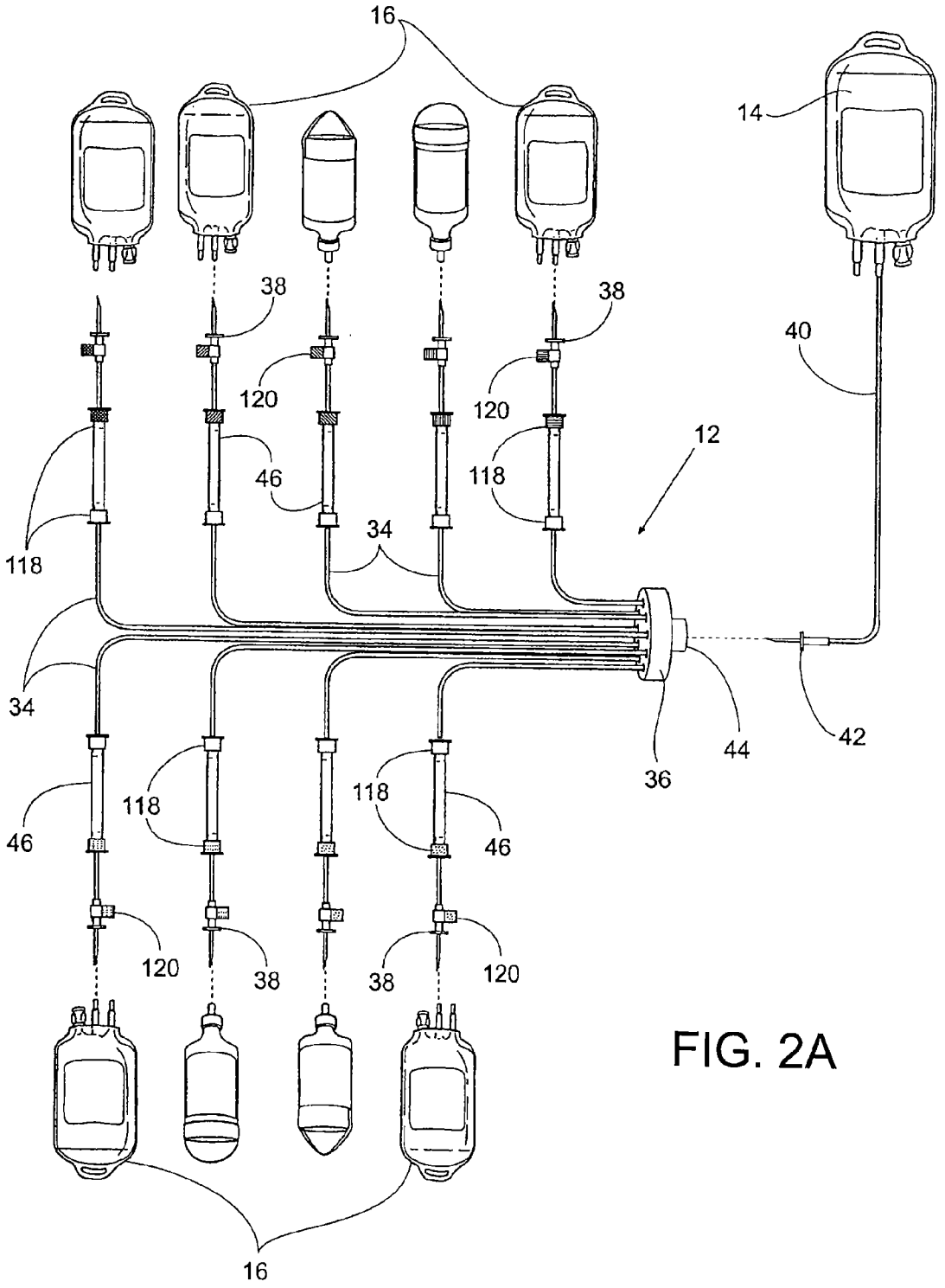


FIG. 1


16
14
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38
120
120
40
12
46
118
118
34
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36
44
42
118
118
46
46
120
38
38
120
16

FIG. 2A

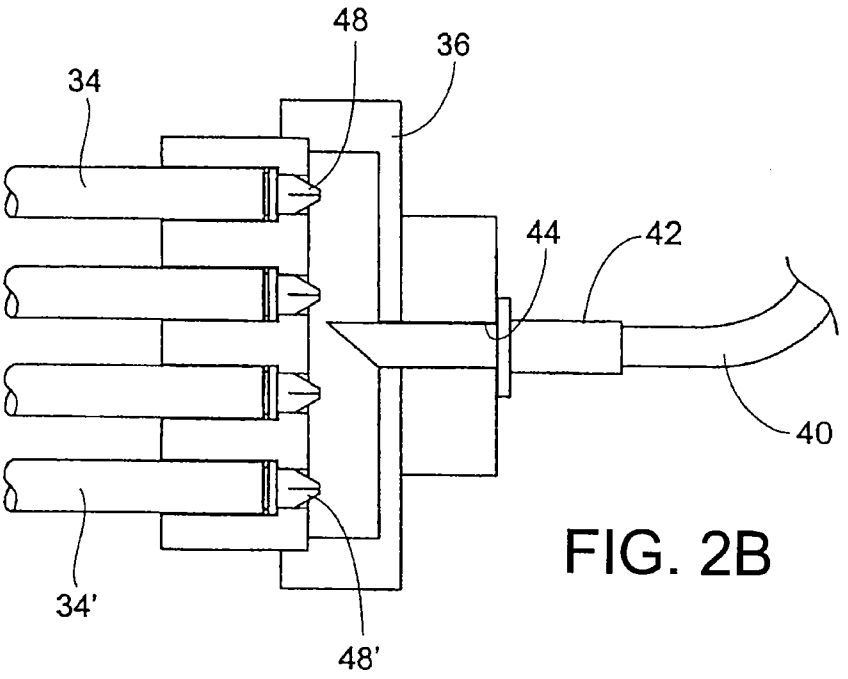


FIG. 2B

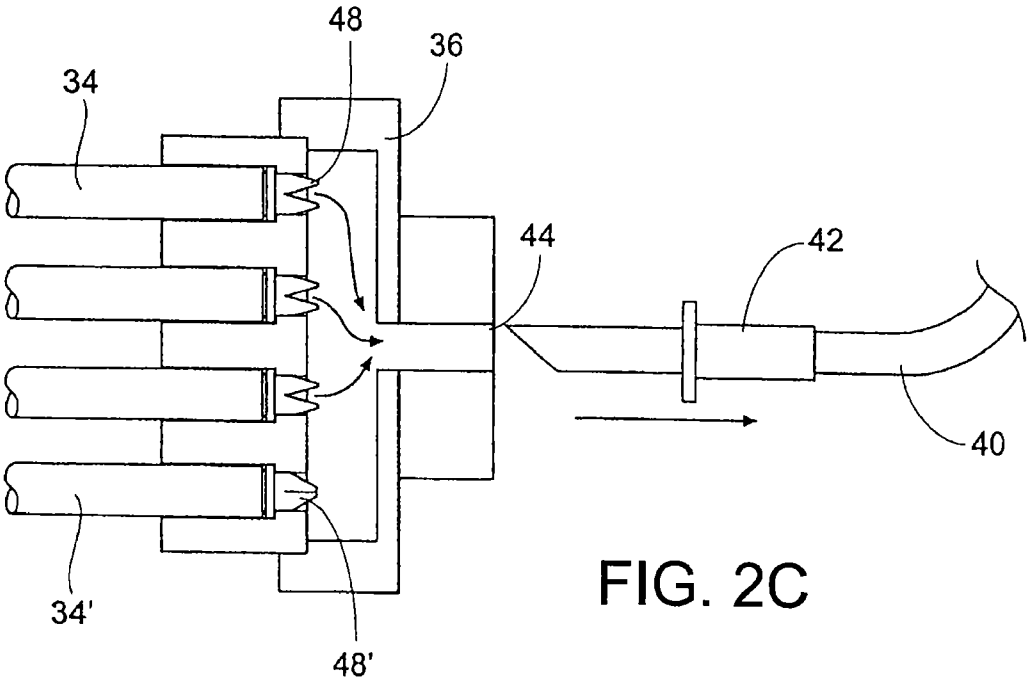


FIG. 2C

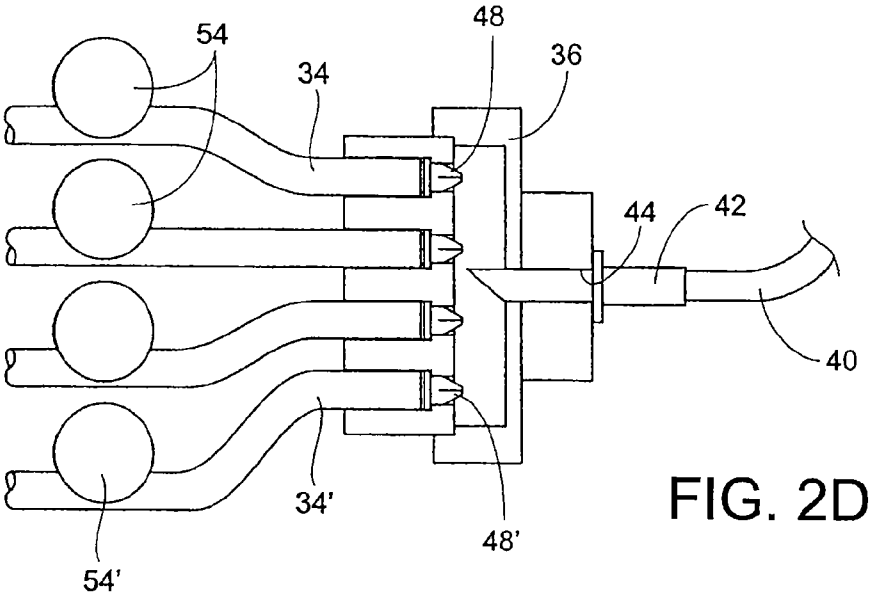


FIG. 2D

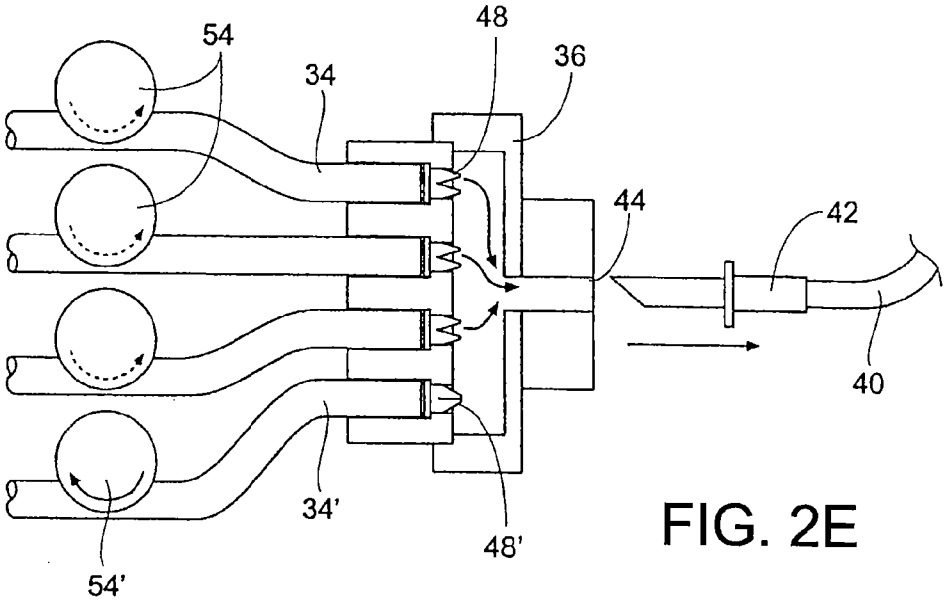


FIG. 2E

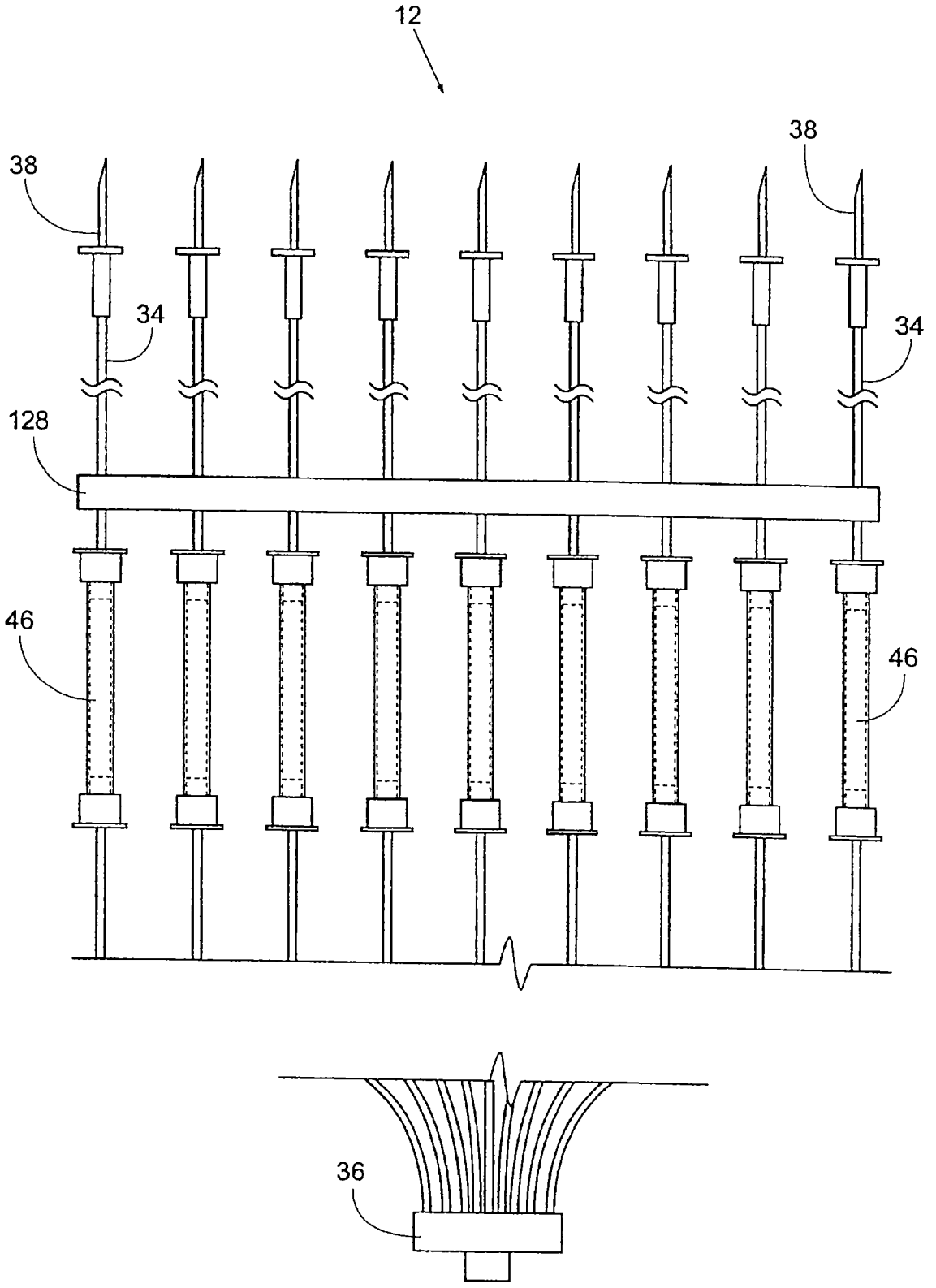


FIG. 2F

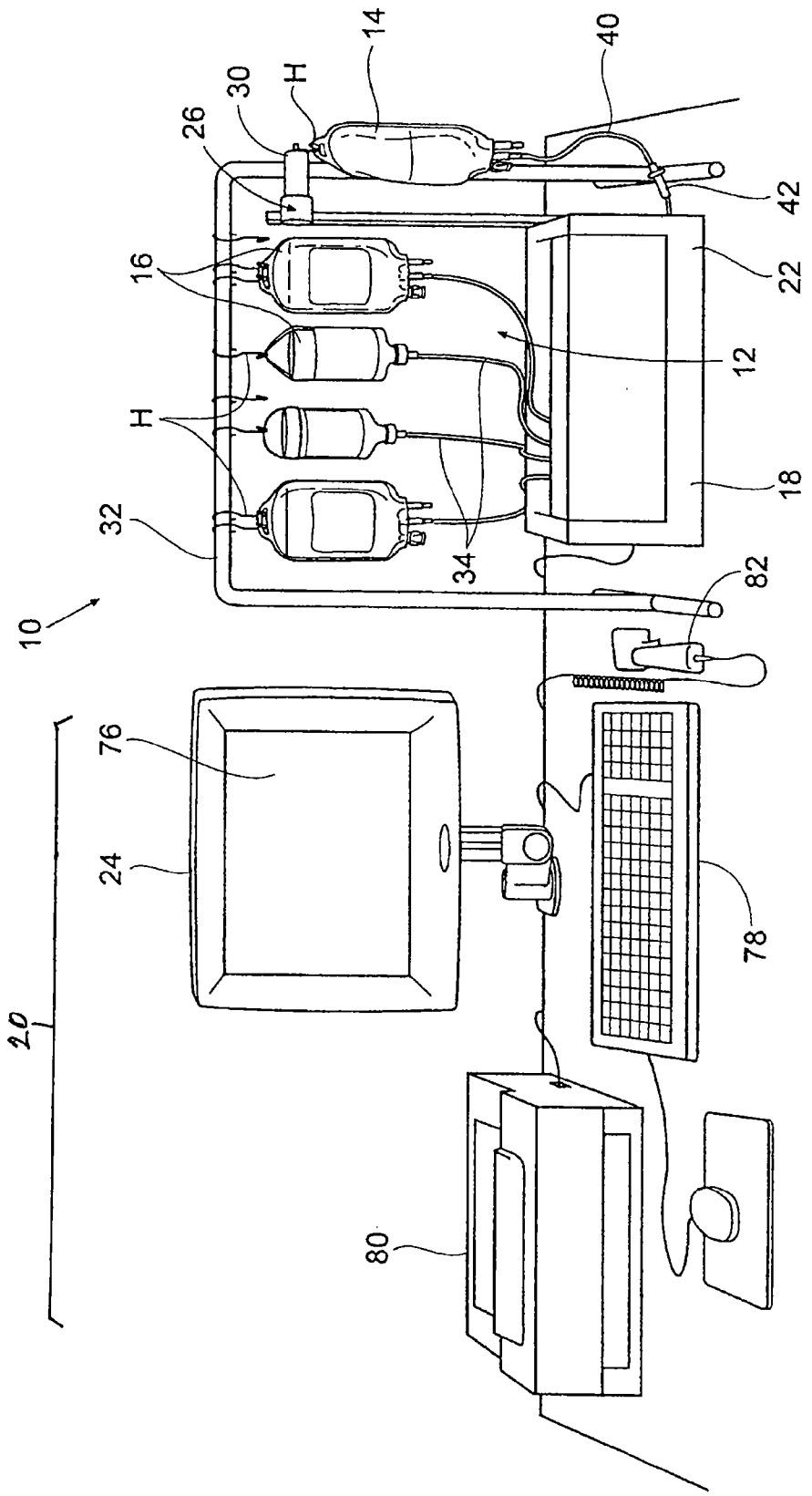


FIG. 3

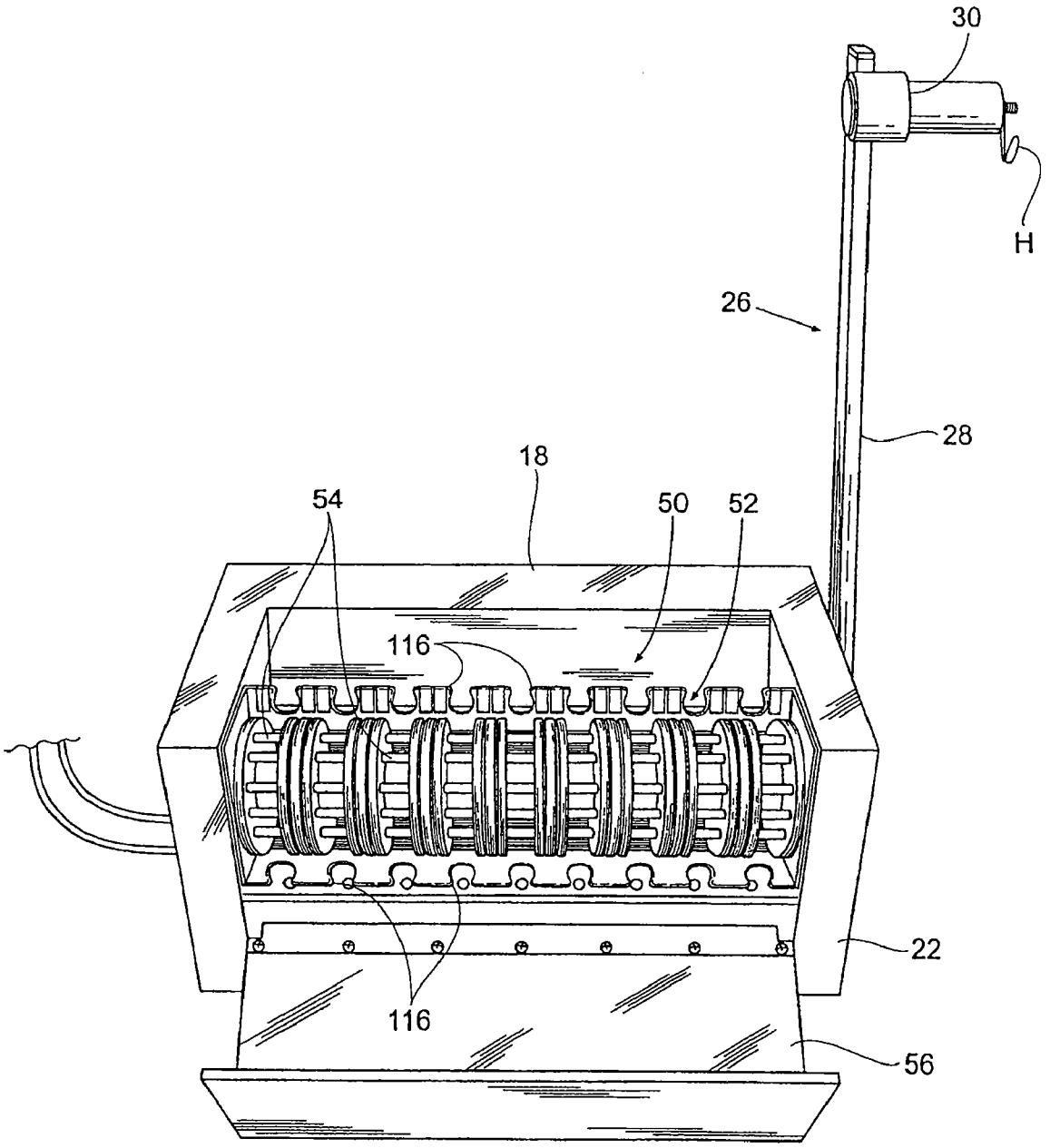


FIG. 4

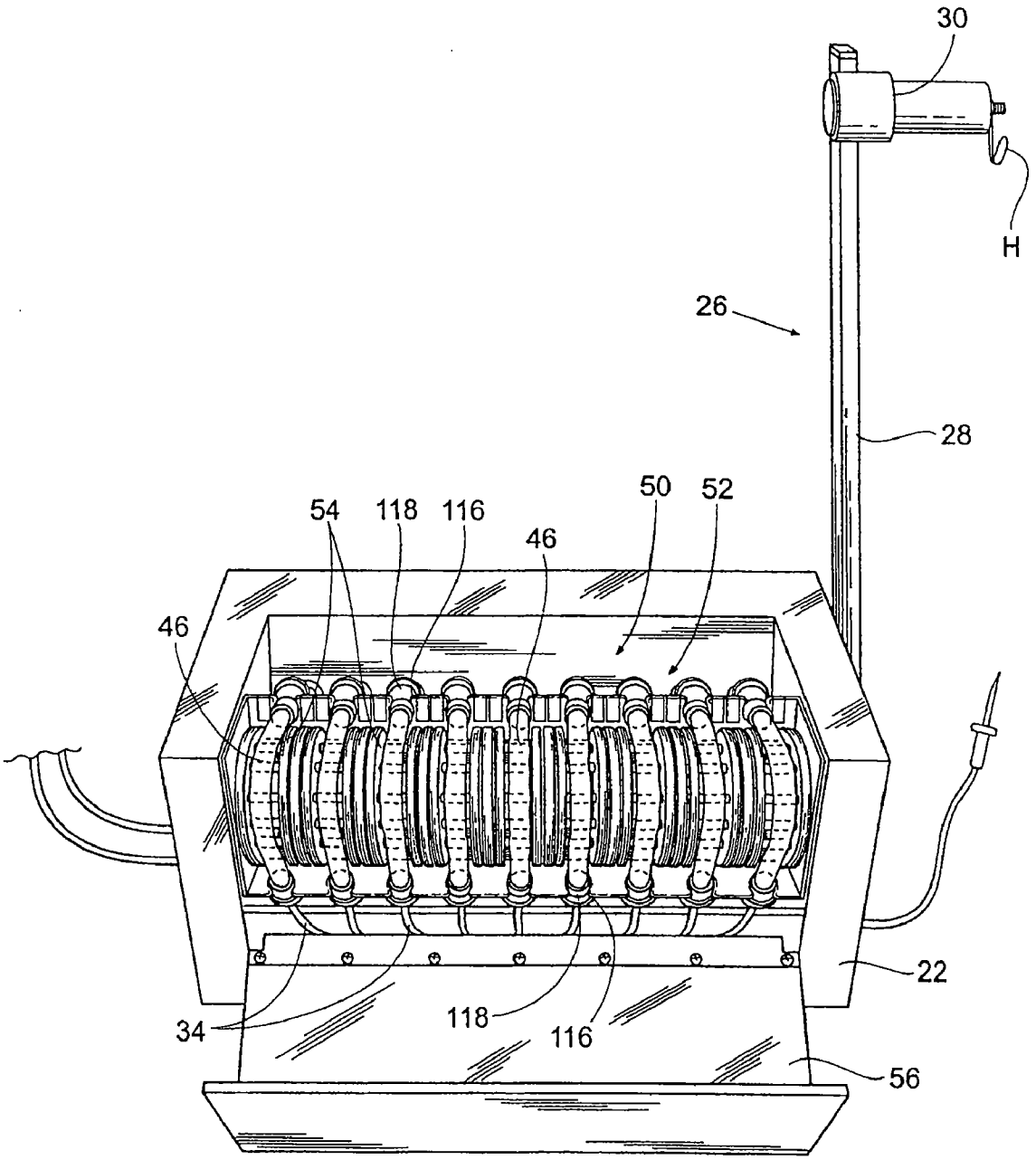


FIG. 5

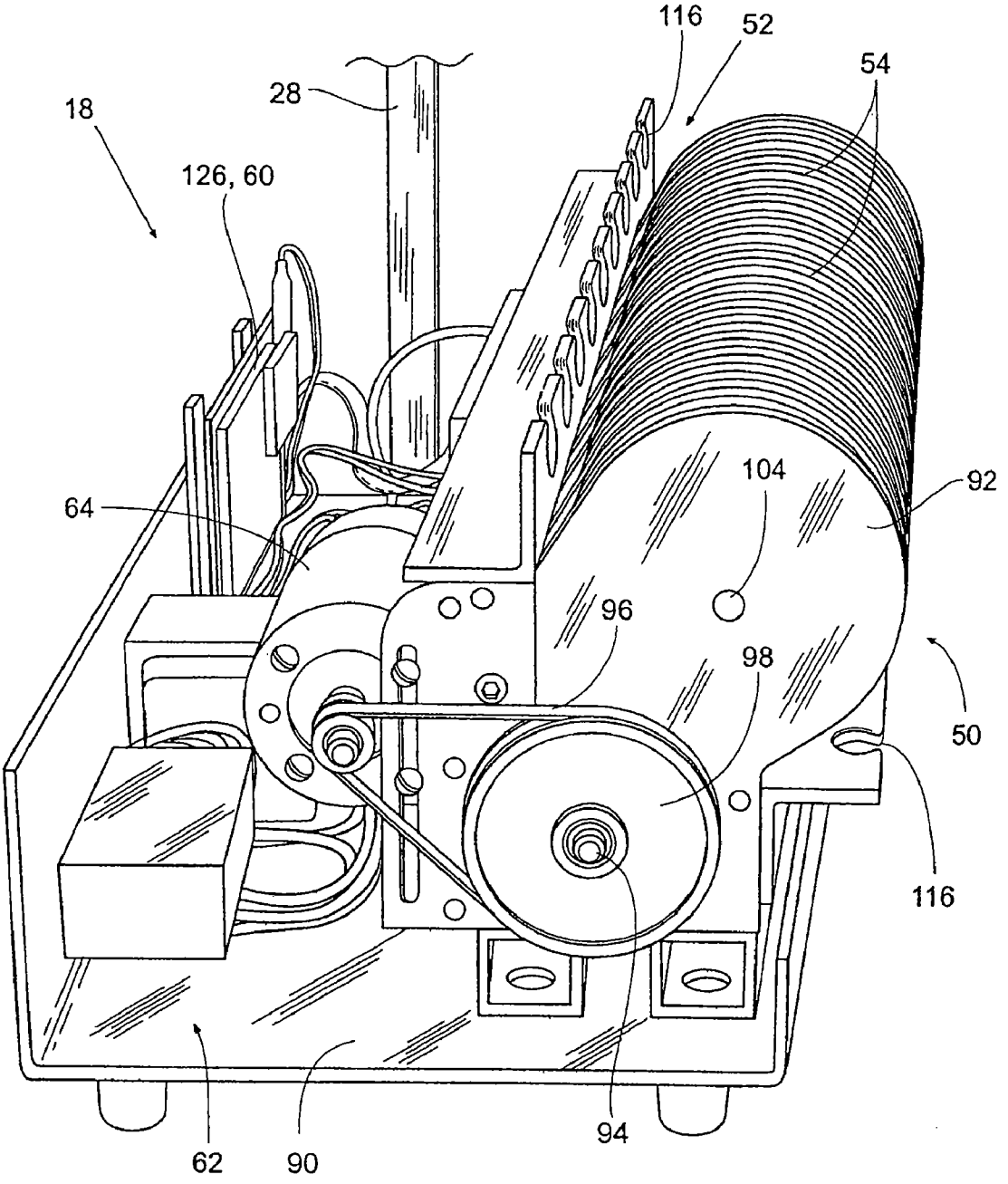


FIG. 6A

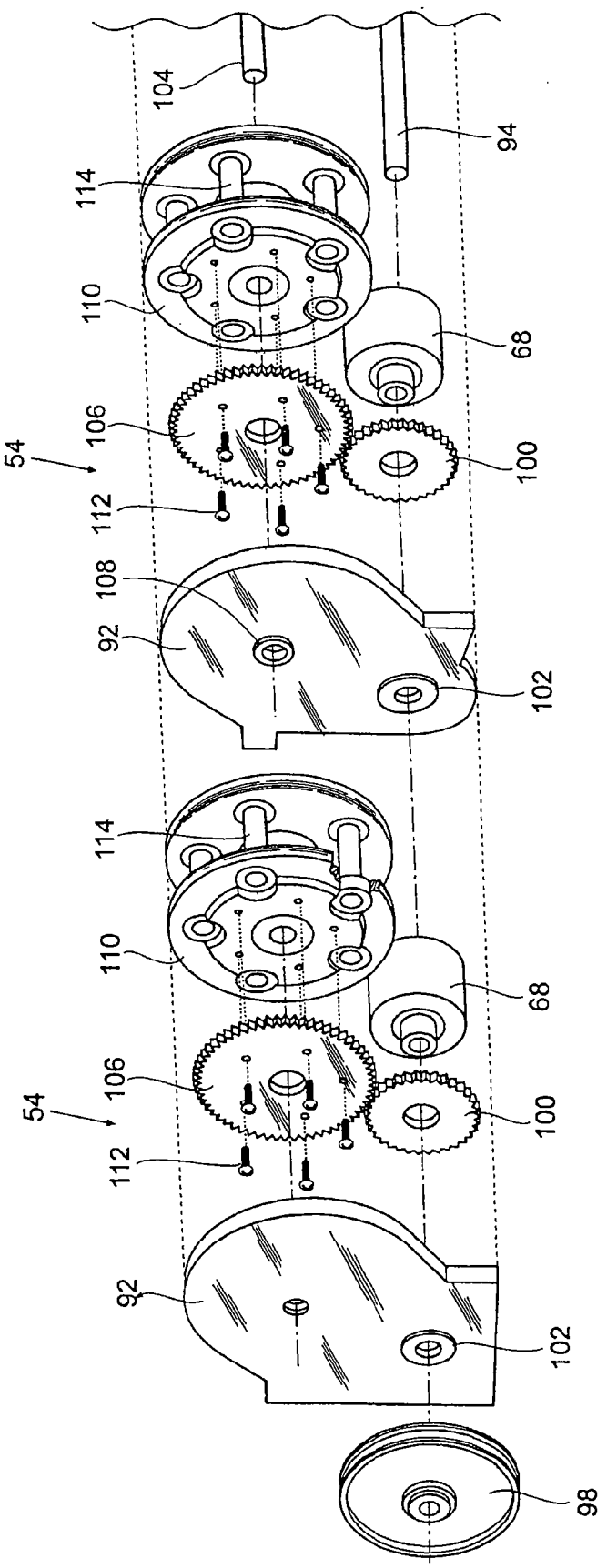

104
94
114
110
68
106
54
100
112
108
92
102
114
110
68
106
54
100
112
92
102
98

FIG. 6B

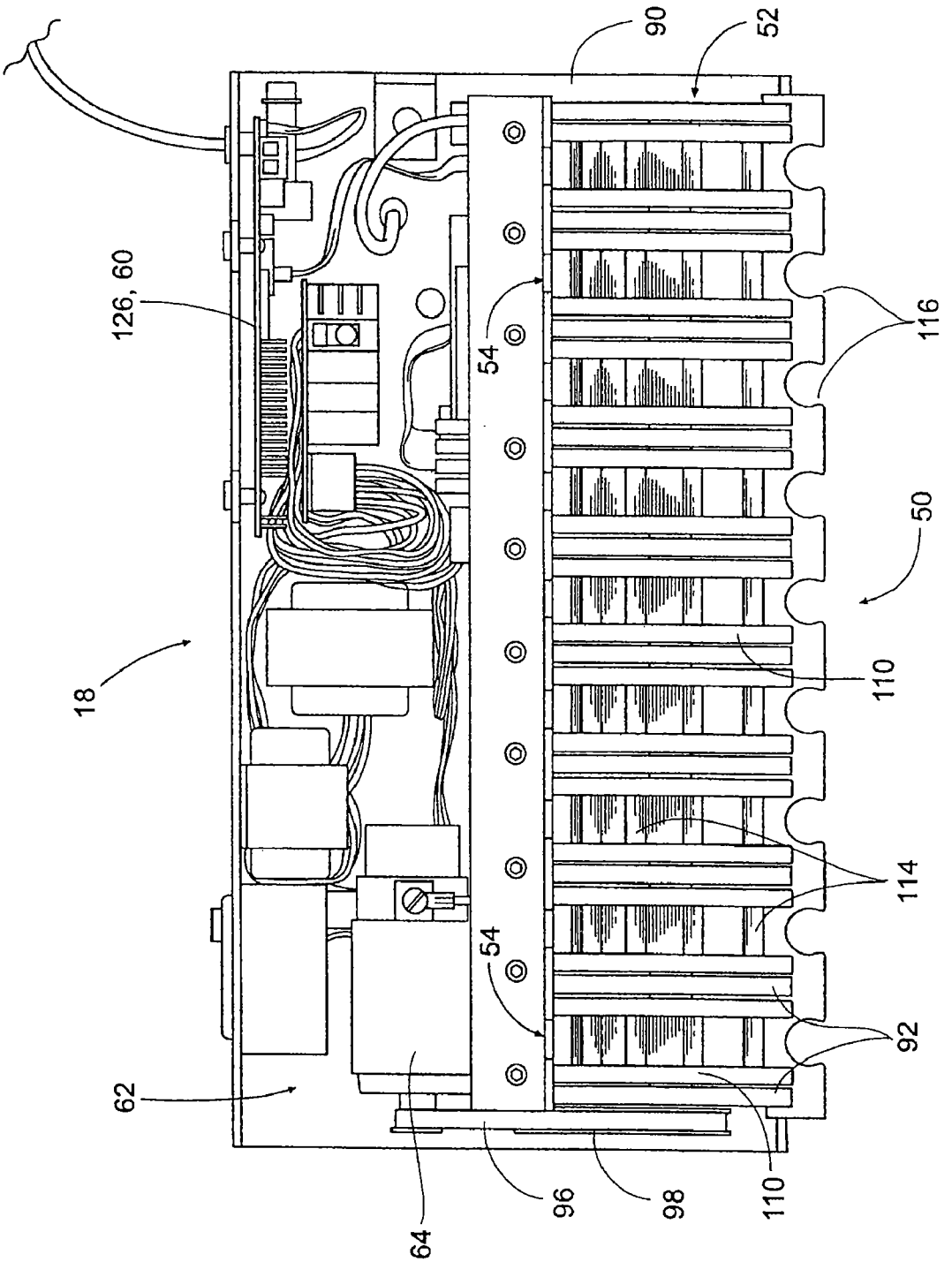


FIG. 7

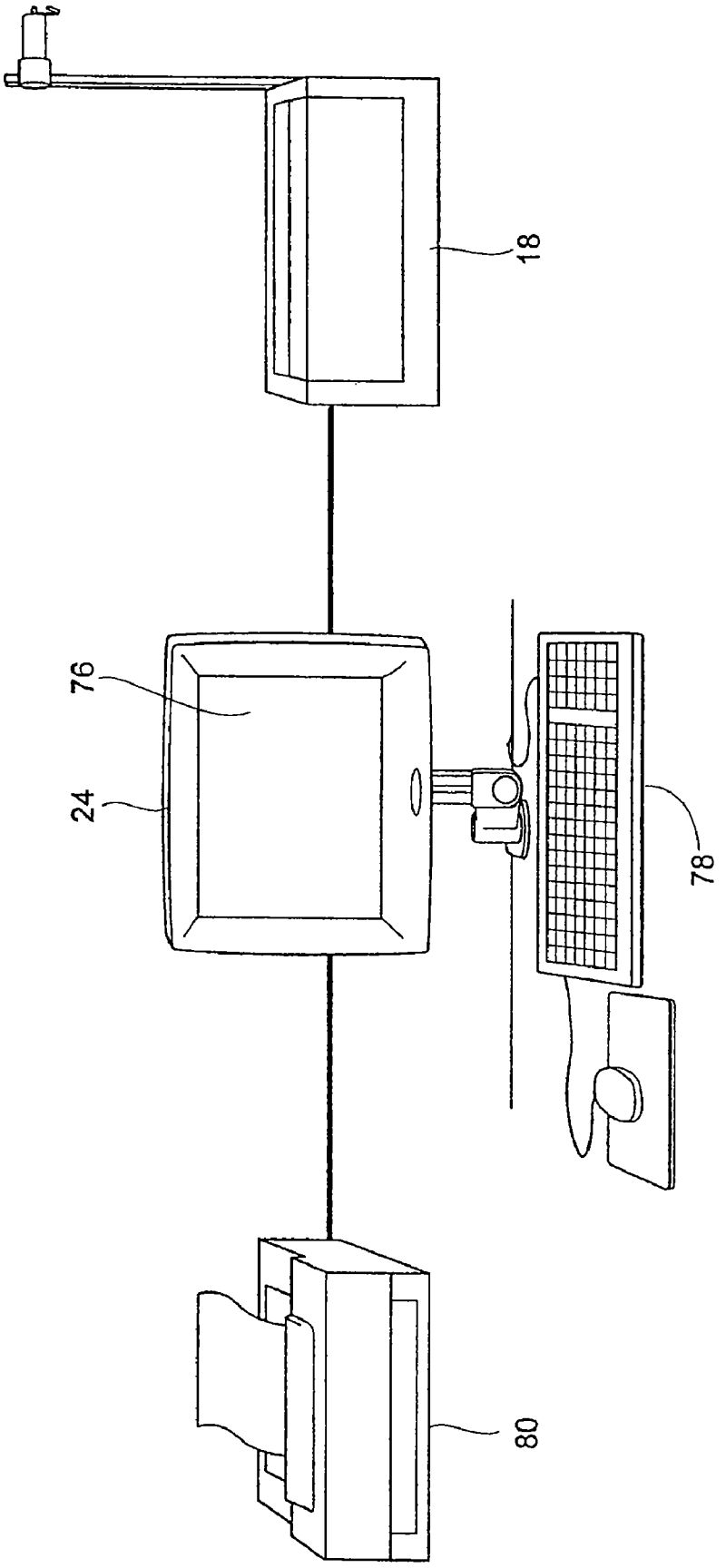


FIG. 8A

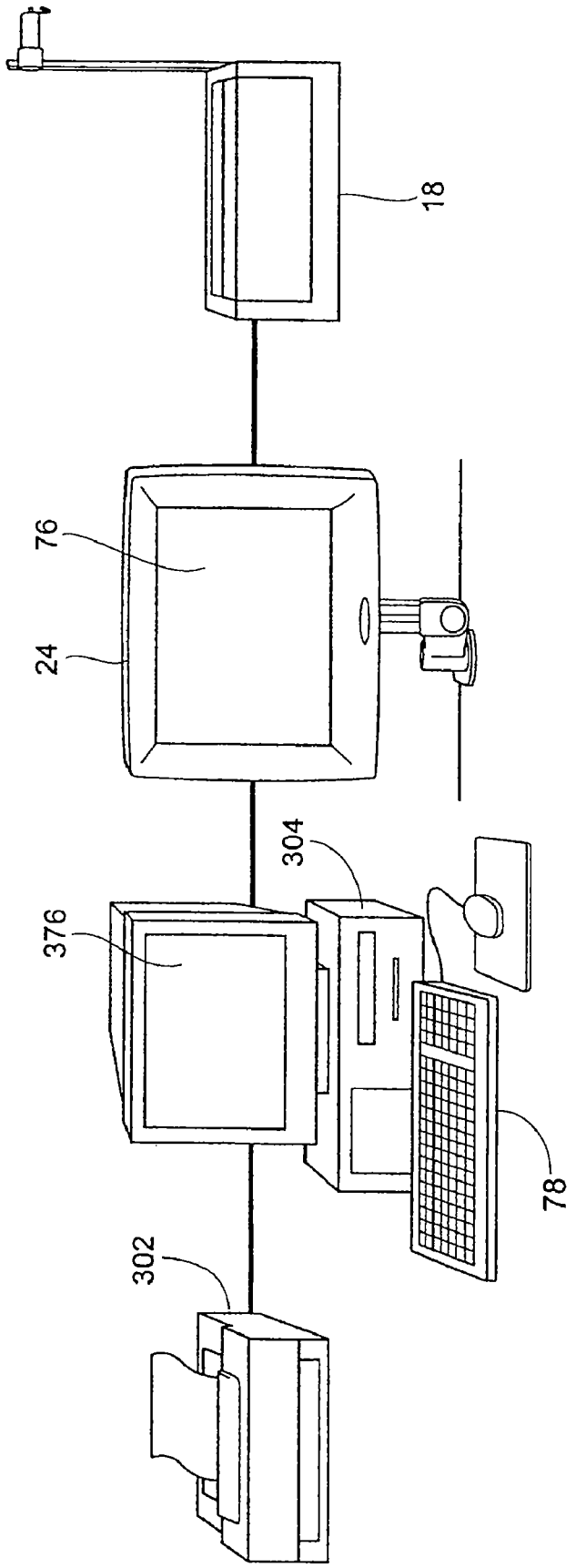


FIG. 8B

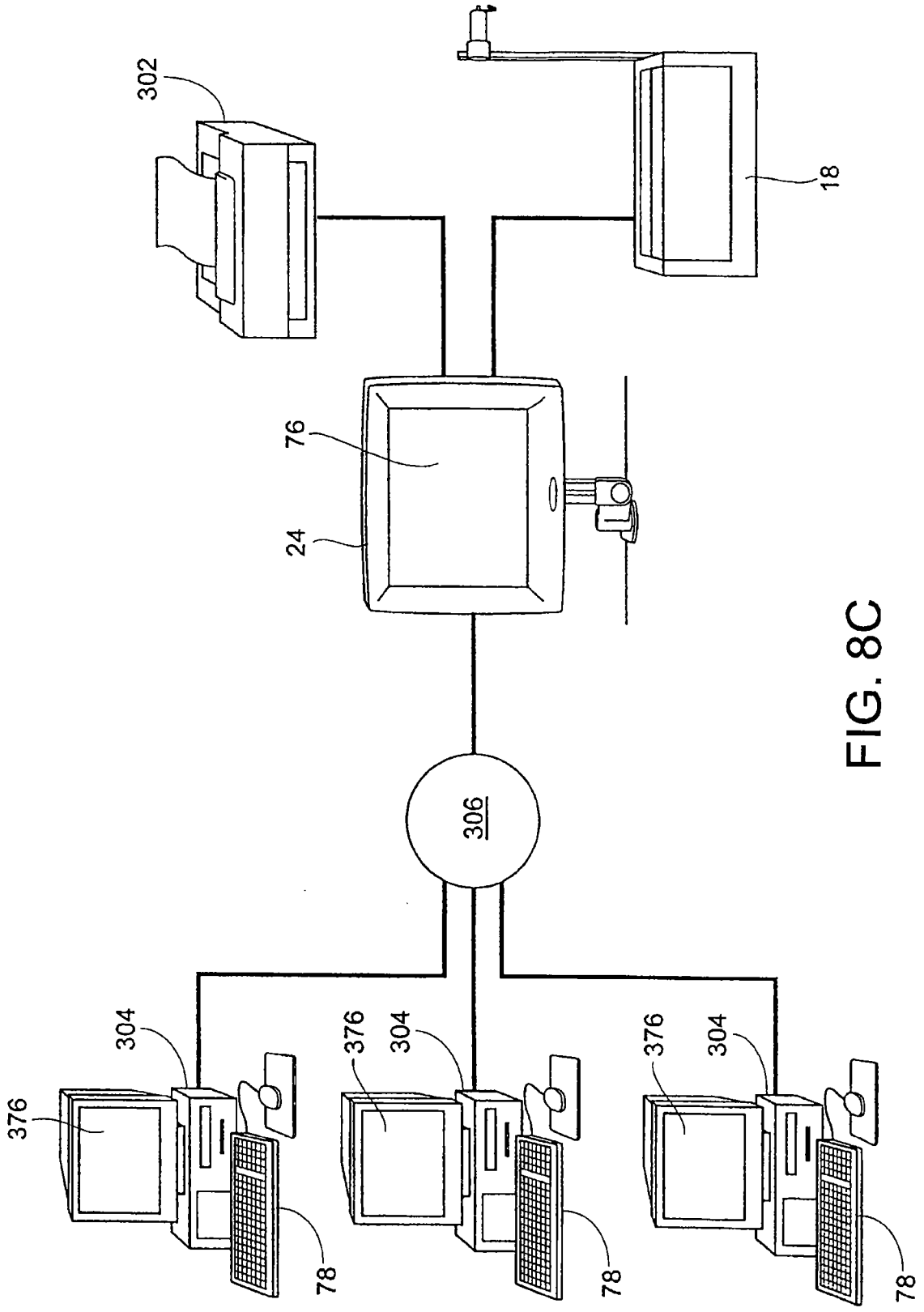


FIG. 8C

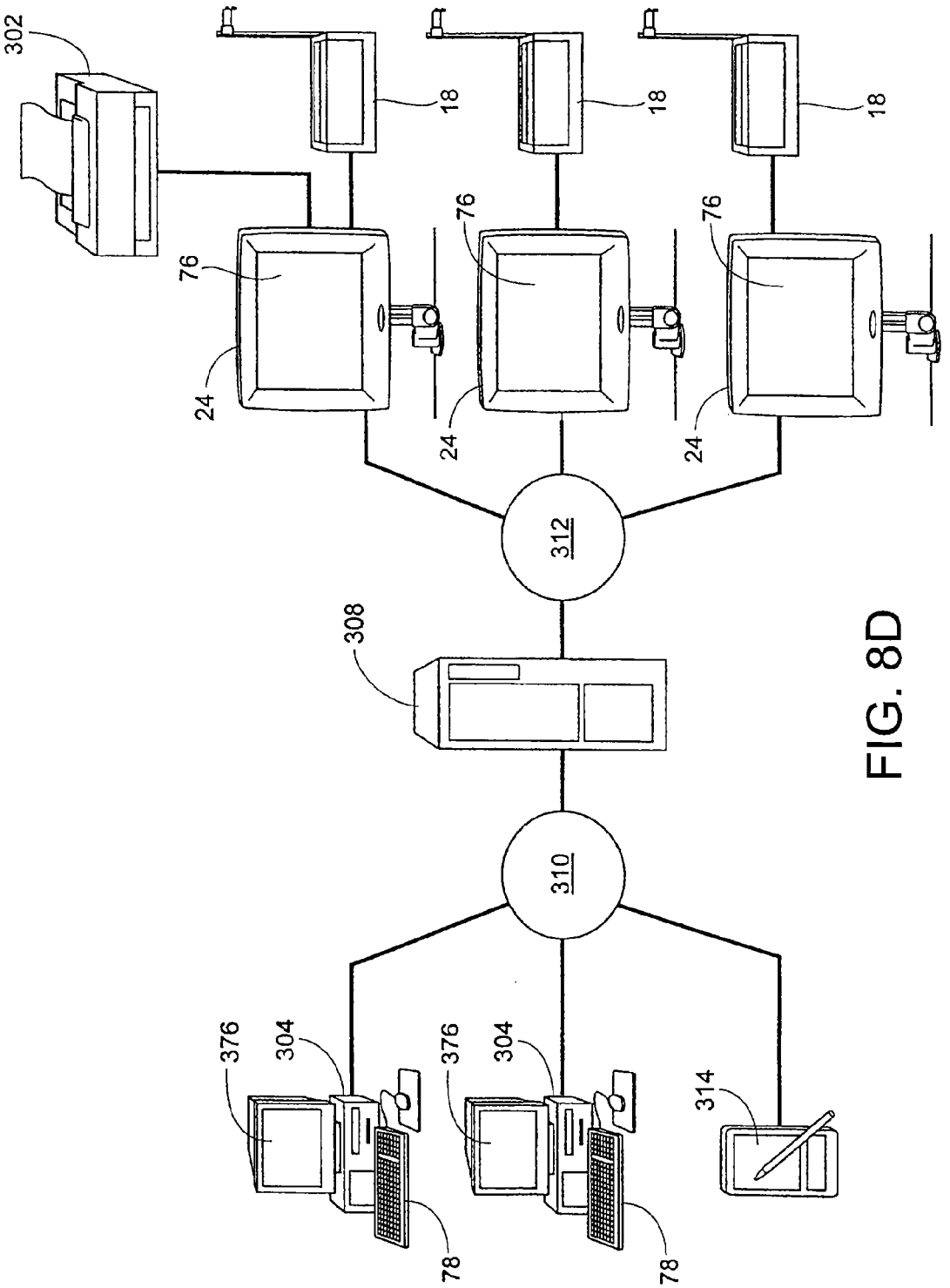


FIG. 8D

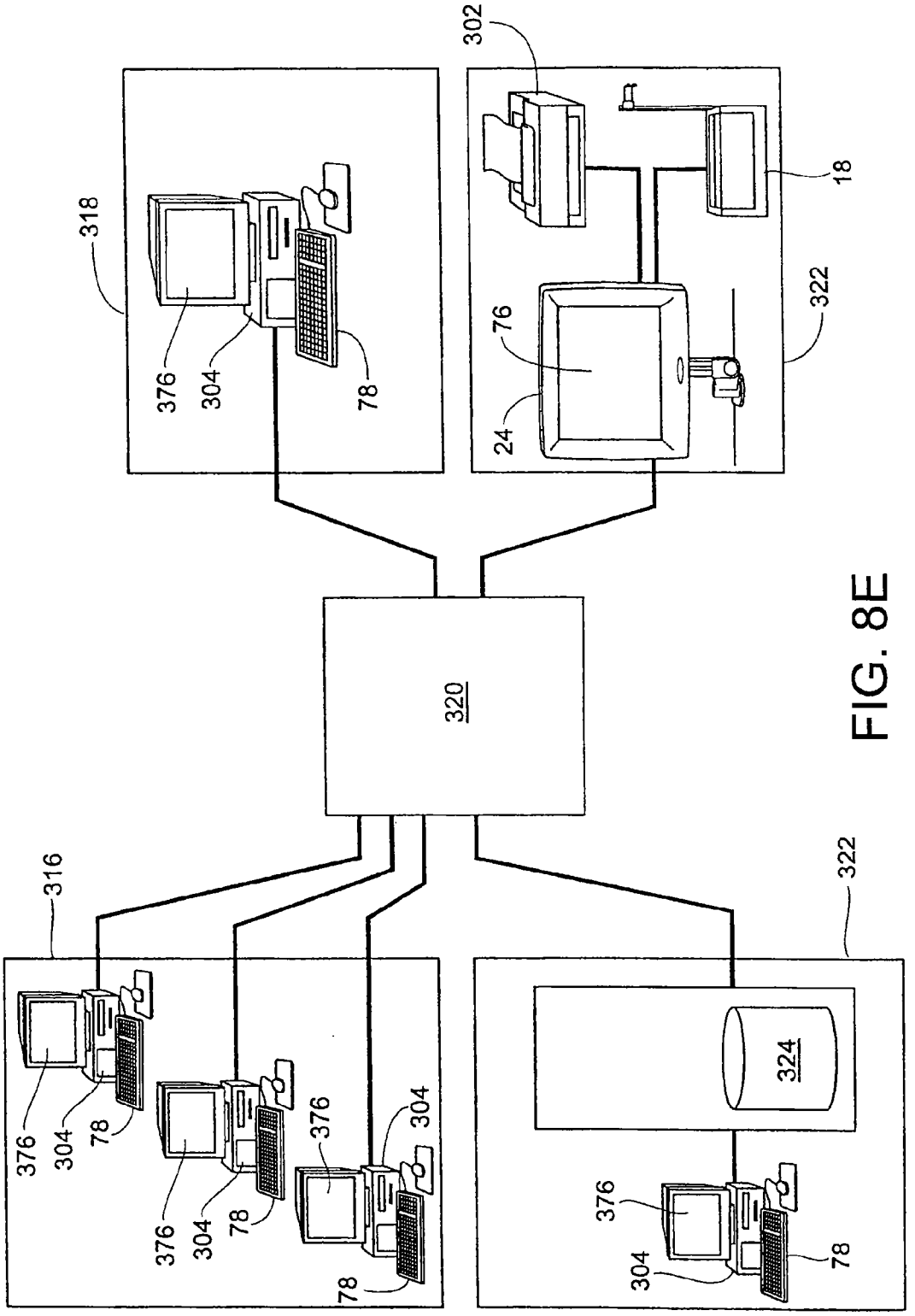


FIG. 8E

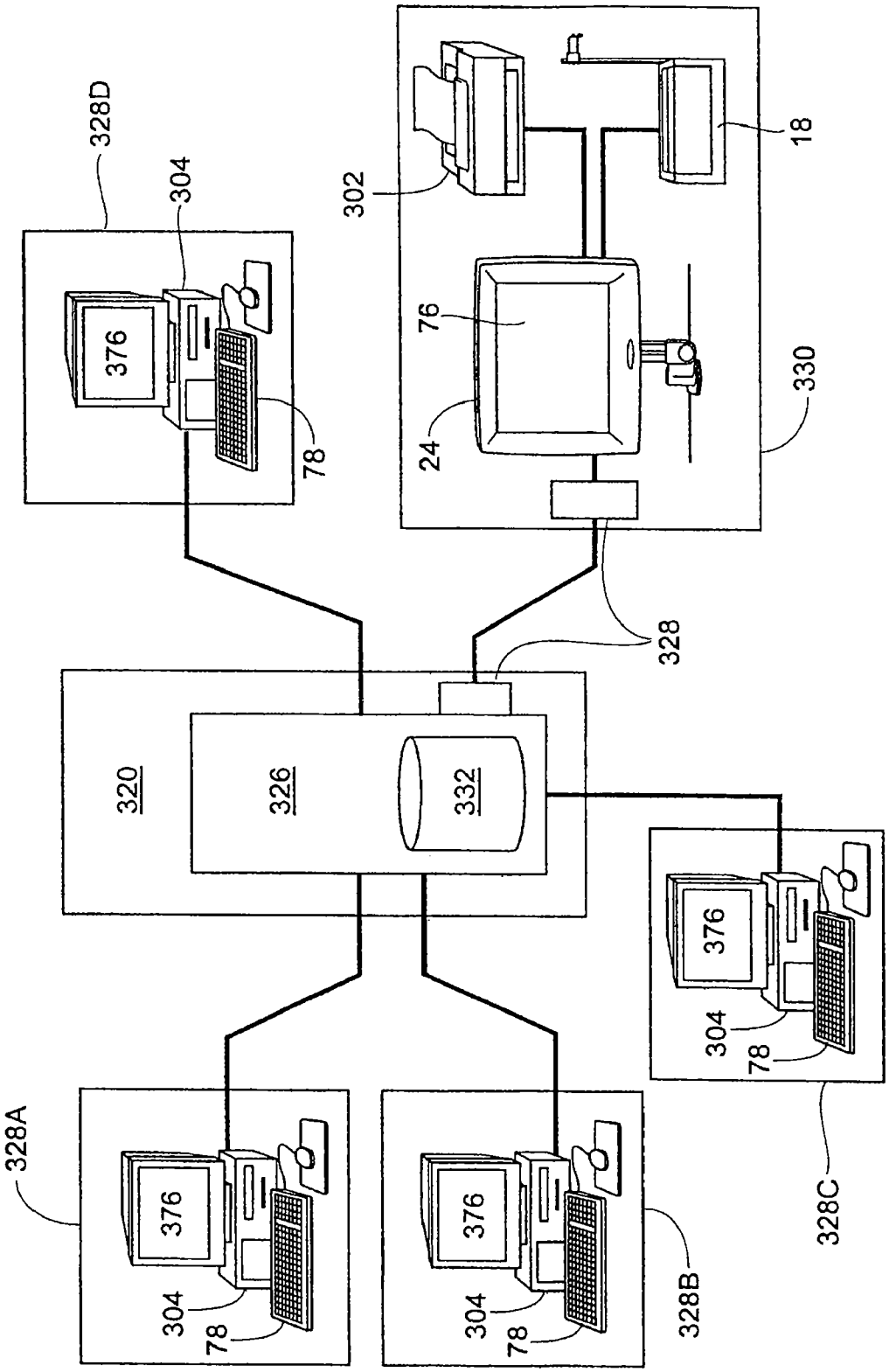


FIG. 8F

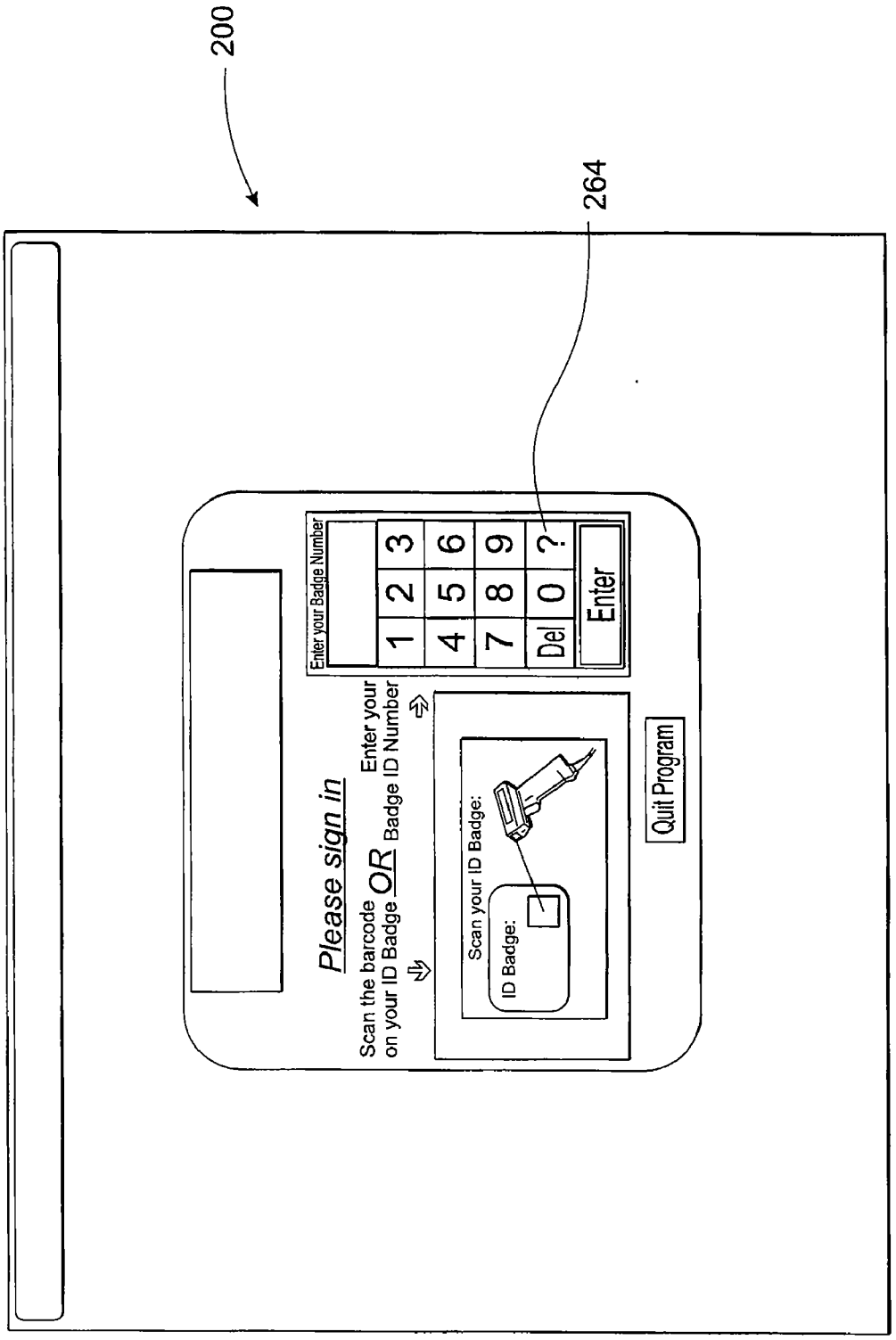

200
264
Please sign in
Scan the barcode on your ID Badge OR Enter your Badge ID Number
Enter your Badge Number
1 2 3
4 5 6
7 8 9
Del 0 ?
Enter
Scan your ID Badge:
ID Badge:
Quit Program

FIG. 9A

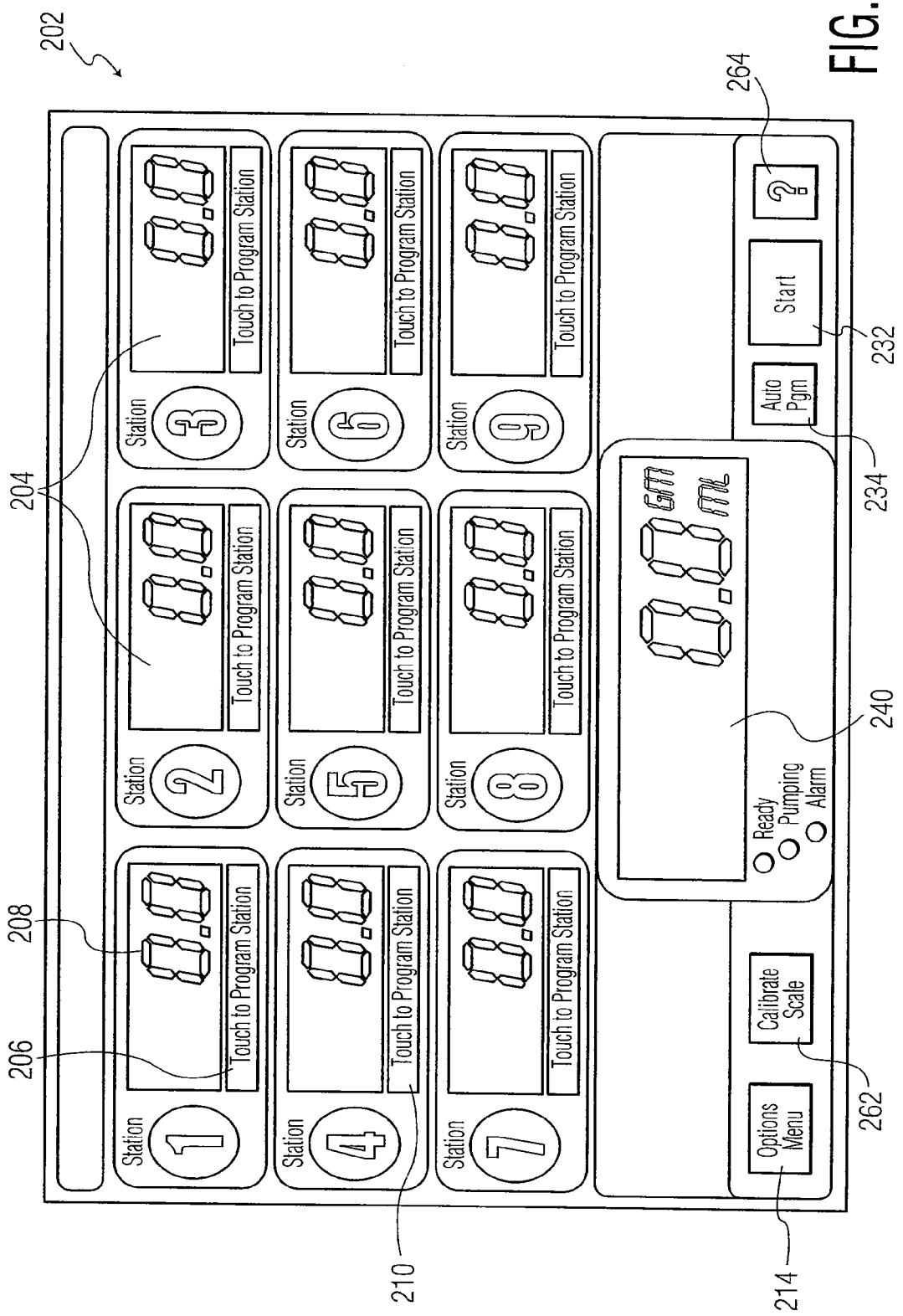

202
204
206
208
210
214
262
264
232
234
240
Station 1
Station 2
Station 3
Station 4
Station 5
Station 6
Station 7
Station 8
Station 9
Touch to Program Station
Ready
Pumping
Alarm
Options Menu
Calibrate Scale
Auto Pgm
Start

FIG. 9B

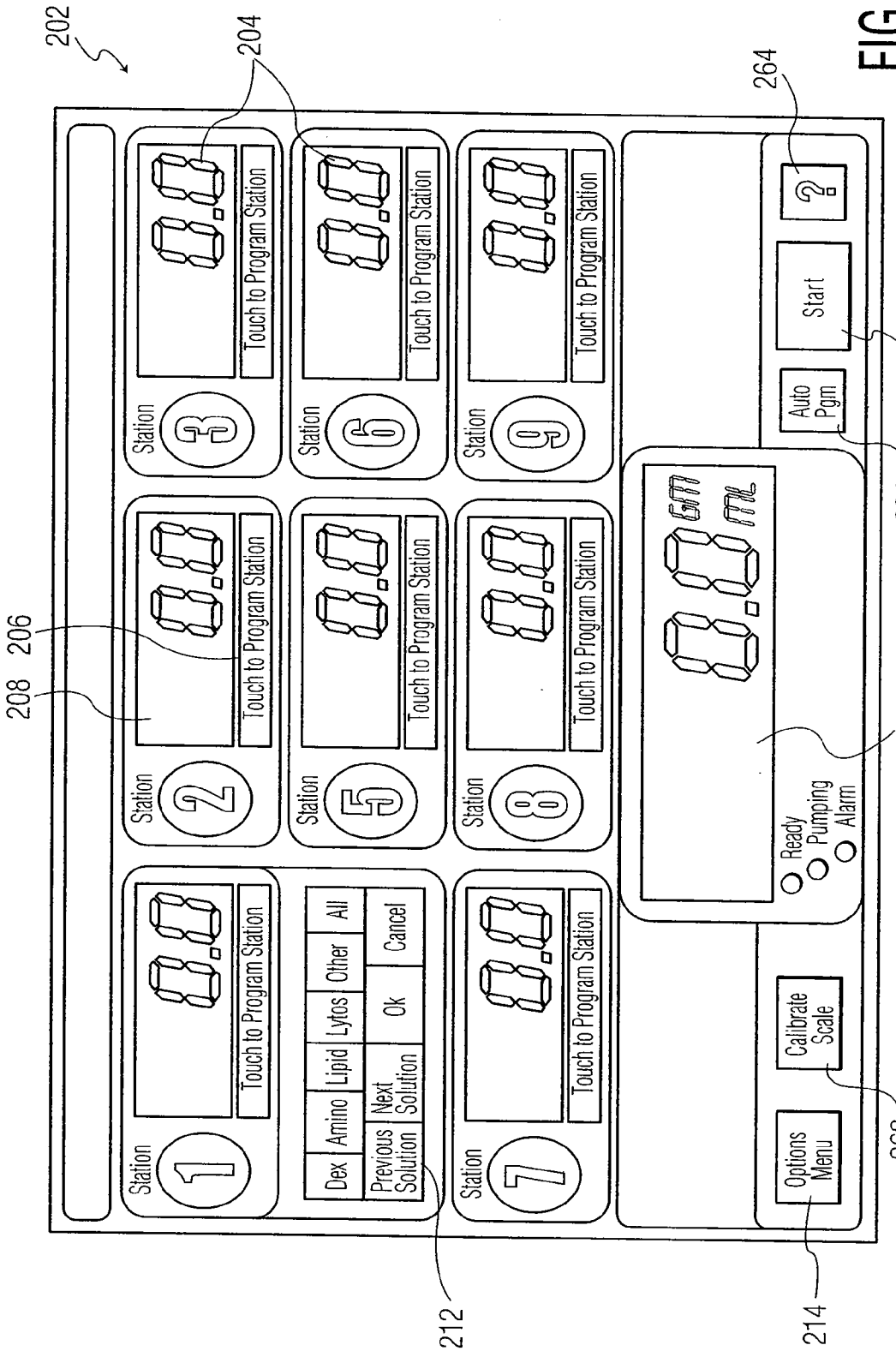

202
204
206
208
212
214
262
264
232
234
240
Station 1
Station 2
Station 3
Station 5
Station 6
Station 7
Station 8
Station 9
Touch to Program Station
Dex
Amino
Lipid
Lytos
Other
All
Previous Solution
Next Solution
Ok
Cancel
Options Menu
Calibrate Scale
Ready
Pumping
Alarm
Auto Pgm
Start
2

FIG. 9C

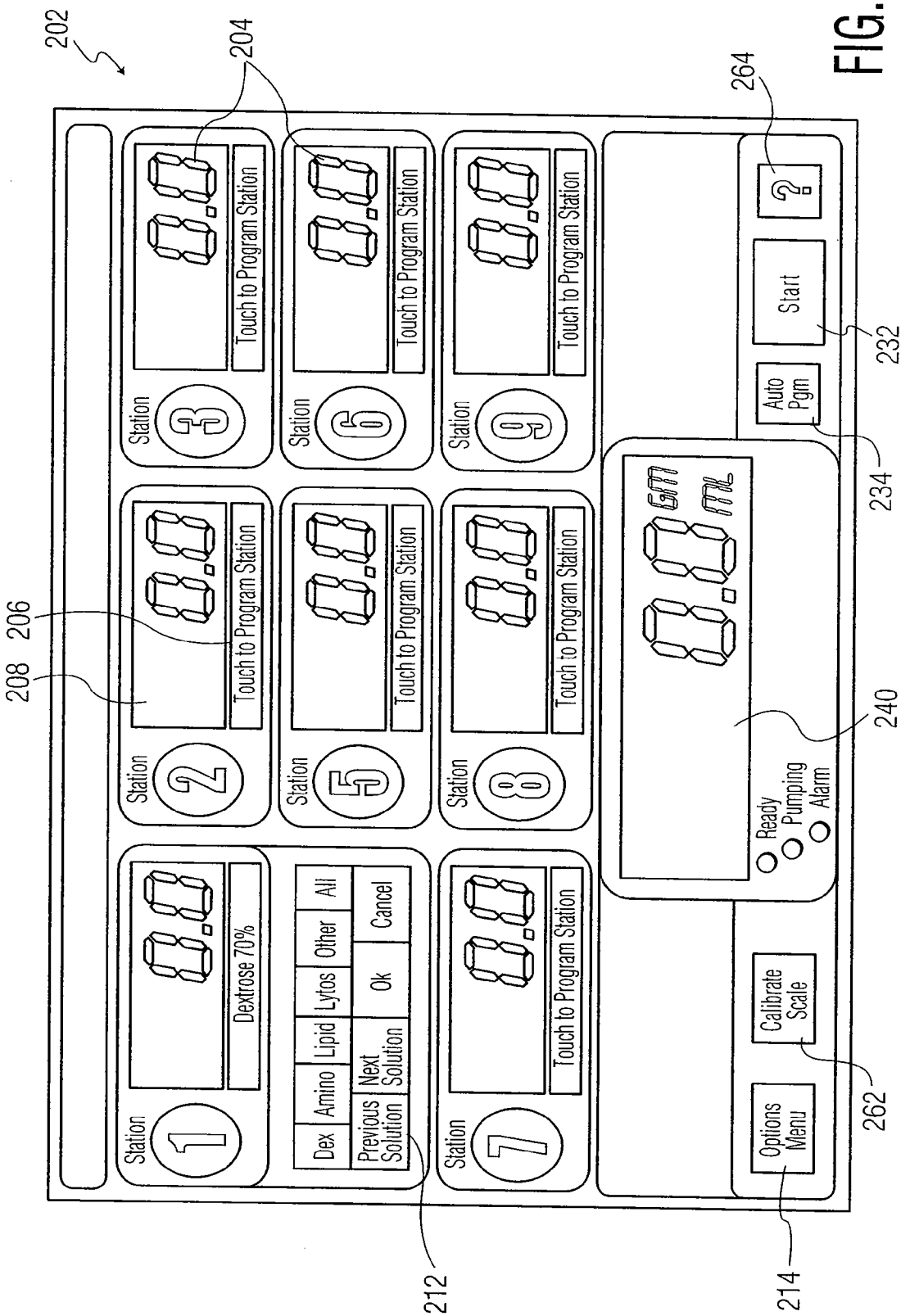

202
204
206
208
212
214
262
264
232
234
240
Station 1
Dextrose 70%
Station 2
Touch to Program Station
Station 3
Touch to Program Station
Station 5
Touch to Program Station
Station 6
Touch to Program Station
Station 7
Touch to Program Station
Station 8
Touch to Program Station
Station 9
Touch to Program Station
Dex
Amino
Lipid
Lytos
Other
All
Previous Solution
Next Solution
Ok
Cancel
Ready
Pumping
Alarm
Auto Pgm
Start
Options Menu
Calibrate Scale

FIG. 9D

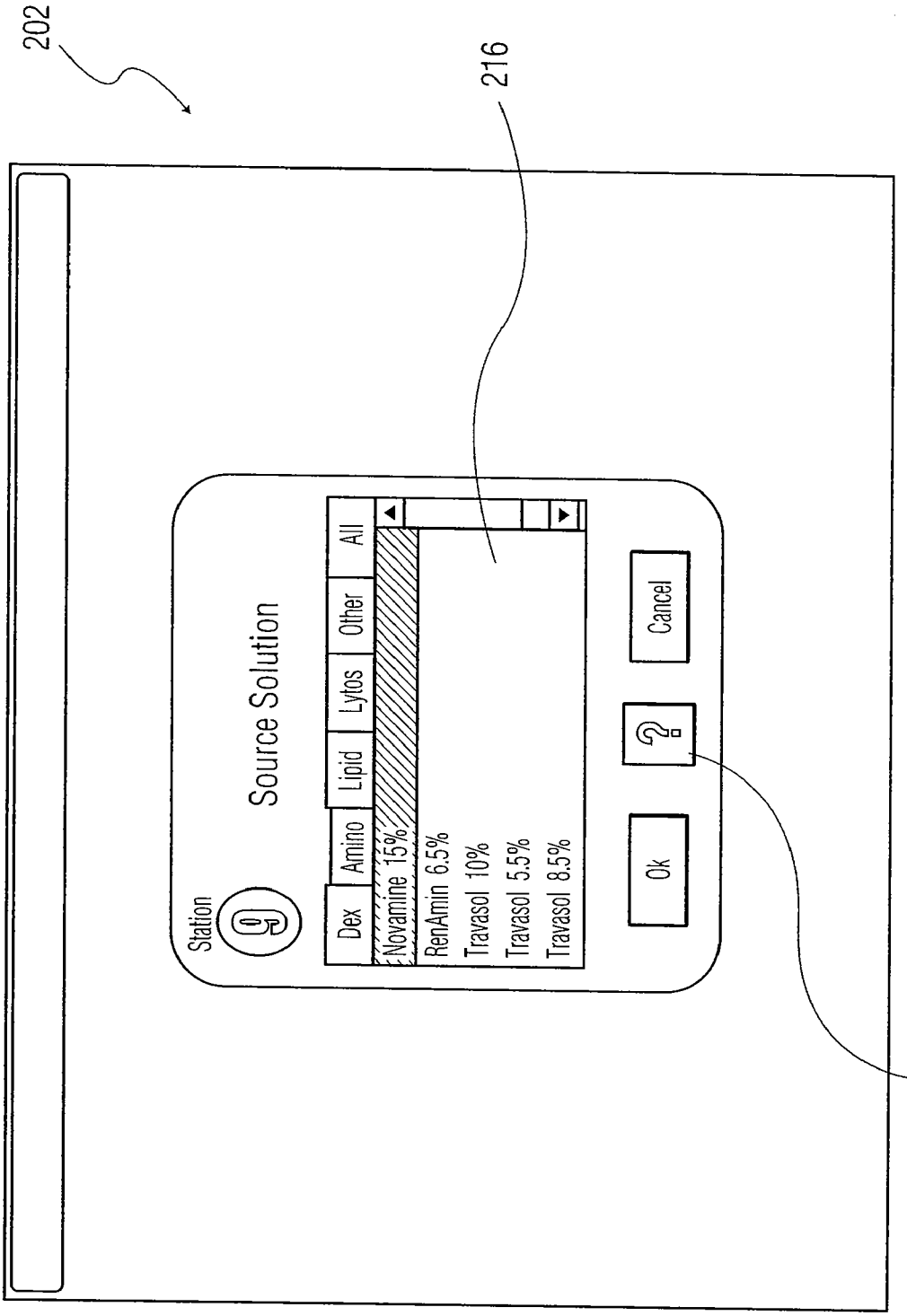

202
216
Source Solution
Station
Dex
Amino
Lipid
Lytos
Other
All
Novamine 15%
RenAmin 6.5%
Travasol 10%
Travasol 5.5%
Travasol 8.5%
Ok
Cancel
264

FIG. 9E

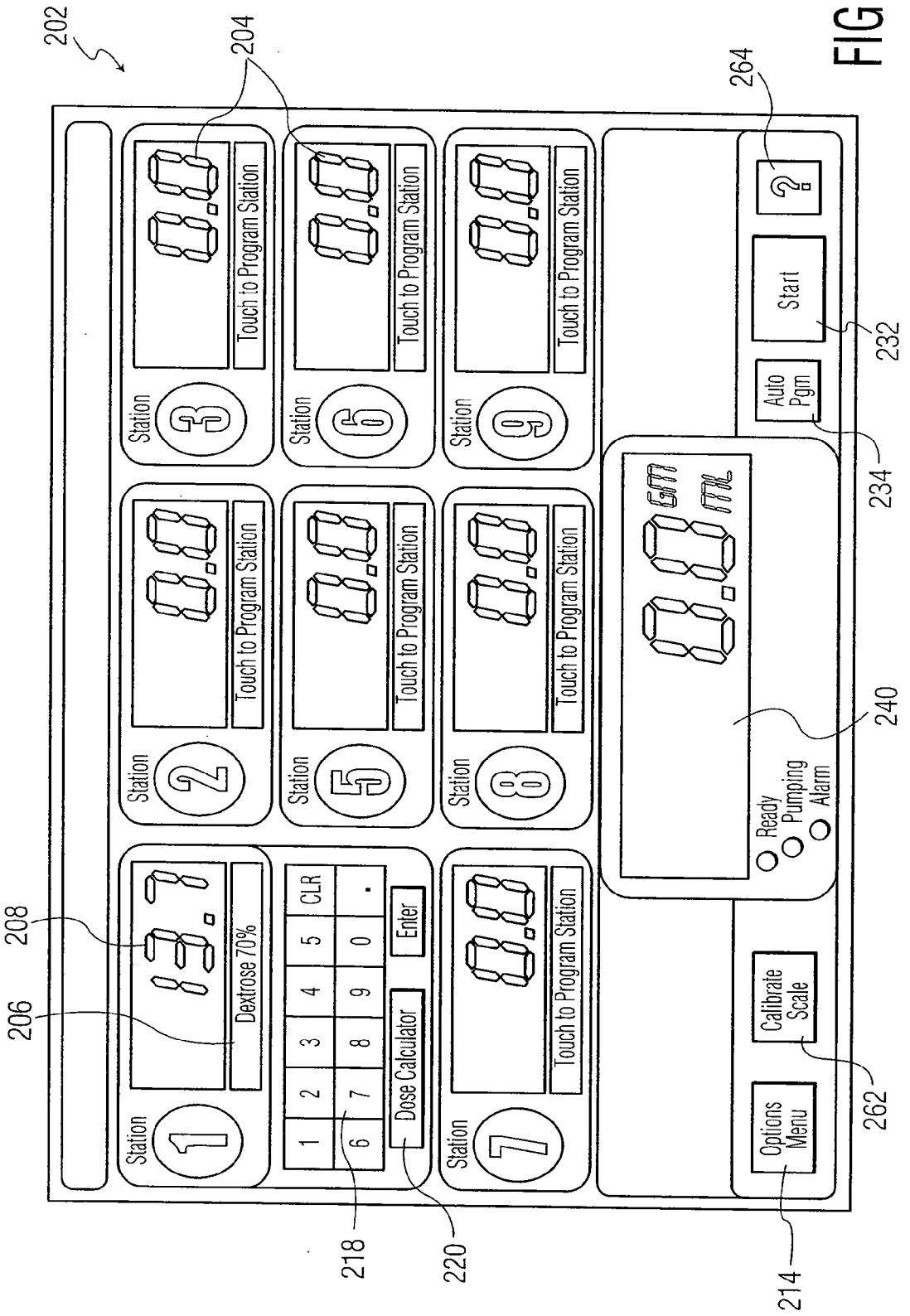

202
204
264
208
206
218
220
214
232
234
240
262
Station 1
Dextrose 70%
Station 2
Station 3
Station 5
Station 6
Station 7
Station 8
Station 9
Touch to Program Station
1 2 3 4 5 CLR
6 7 8 9 0 .
Dose Calculator
Enter
Ready
Pumping
Alarm
Auto Pgm
Start
Options Menu
Calibrate Scale

FIG. 9F

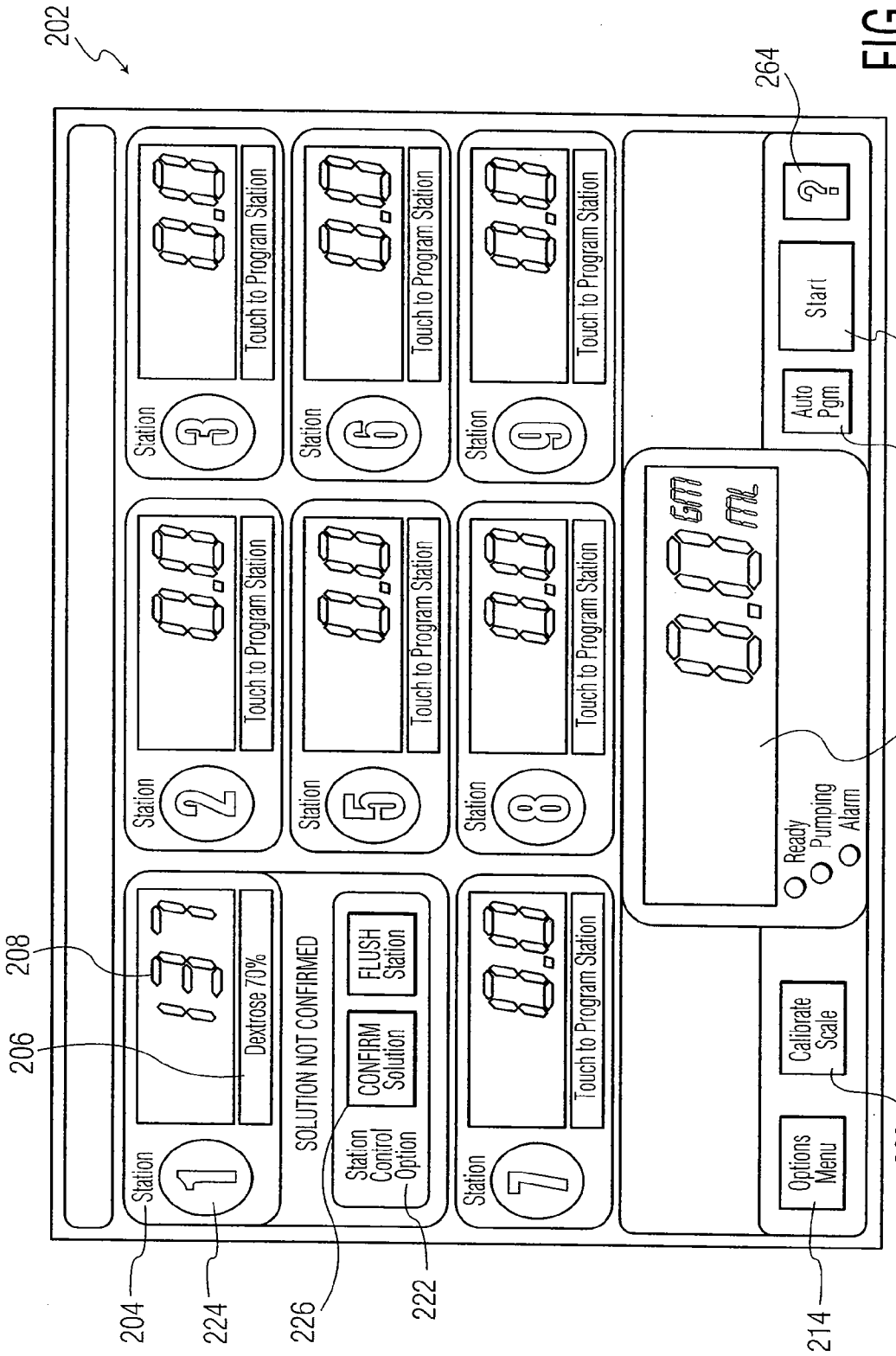

202
208
206
204
224
226
222
214
262
240
232
234
264
Station 1
137
Dextrose 70%
SOLUTION NOT CONFIRMED
Station Control Option
CONFIRM Solution
FLUSH Station
Station 2
Touch to Program Station
Station 3
Touch to Program Station
Station 5
Touch to Program Station
Station 6
Touch to Program Station
Station 7
Touch to Program Station
Station 8
Touch to Program Station
Station 9
Touch to Program Station
0.0 GTT
0.0 mL
Ready
Pumping
Alarm
Auto Pgm
Start
Options Menu
Calibrate Scale

FIG. 9G

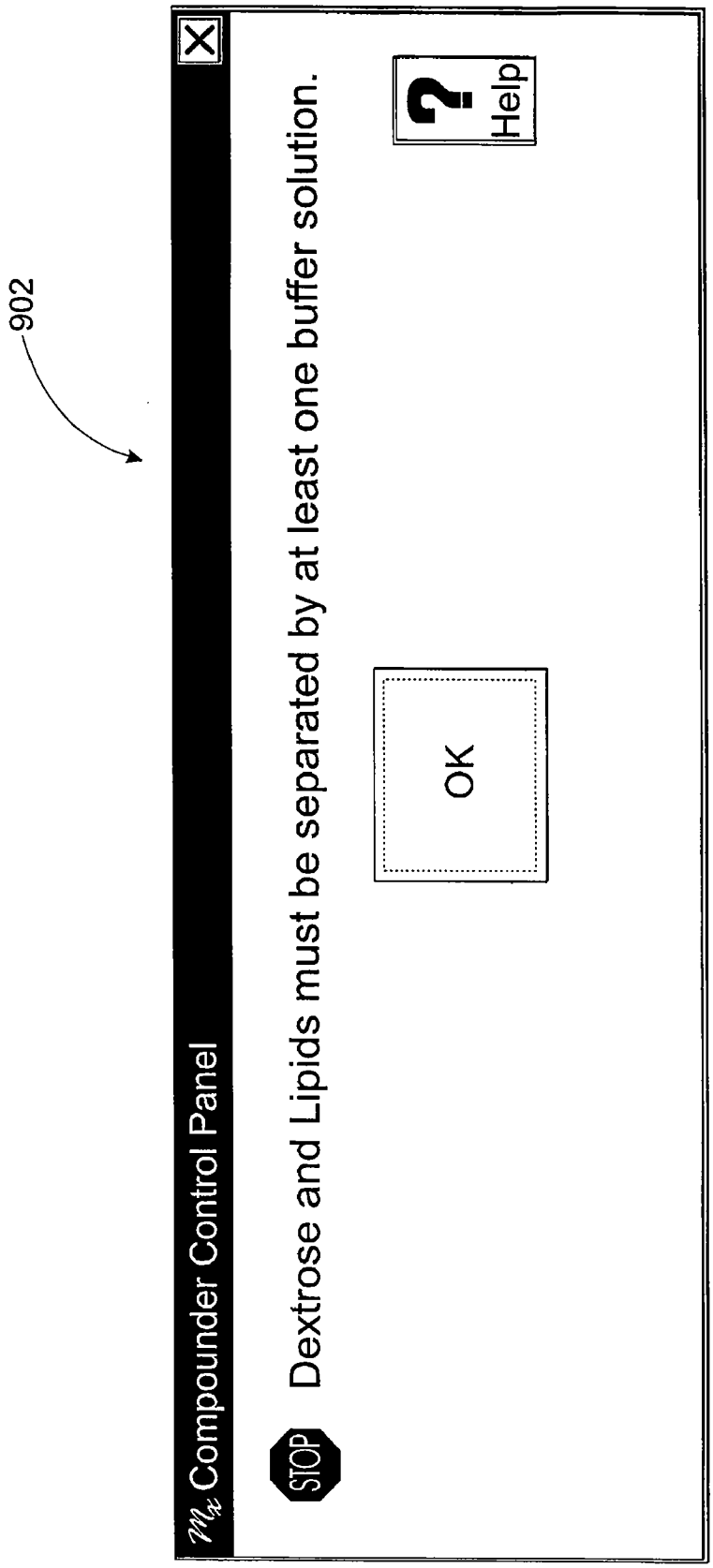

902
Mx Compounder Control Panel
STOP
Dextrose and Lipids must be separated by at least one buffer solution.
OK
Help

FIG. 9G(1)

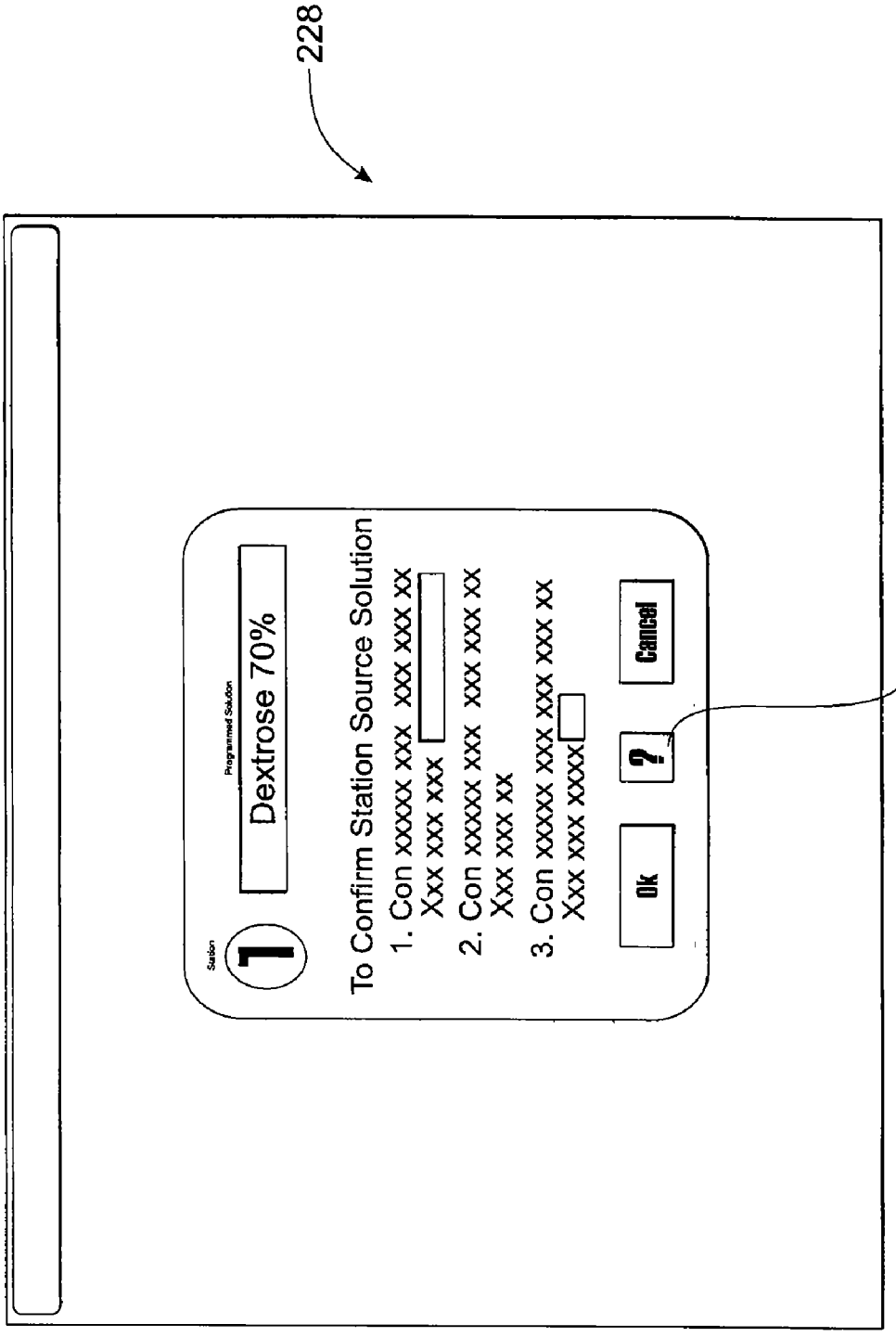

228
Station
1
Programmed Solution
Dextrose 70%
To Confirm Station Source Solution
1. Con xxxxx xxx xxx xx
Xxx xxx xxx
2. Con xxxxx xxx xxx xx
Xxx xxx xx
3. Con xxxxx xxx xxx xx
Xxx xxx xxxx
Ok
?
Cancel
264

FIG. 9H

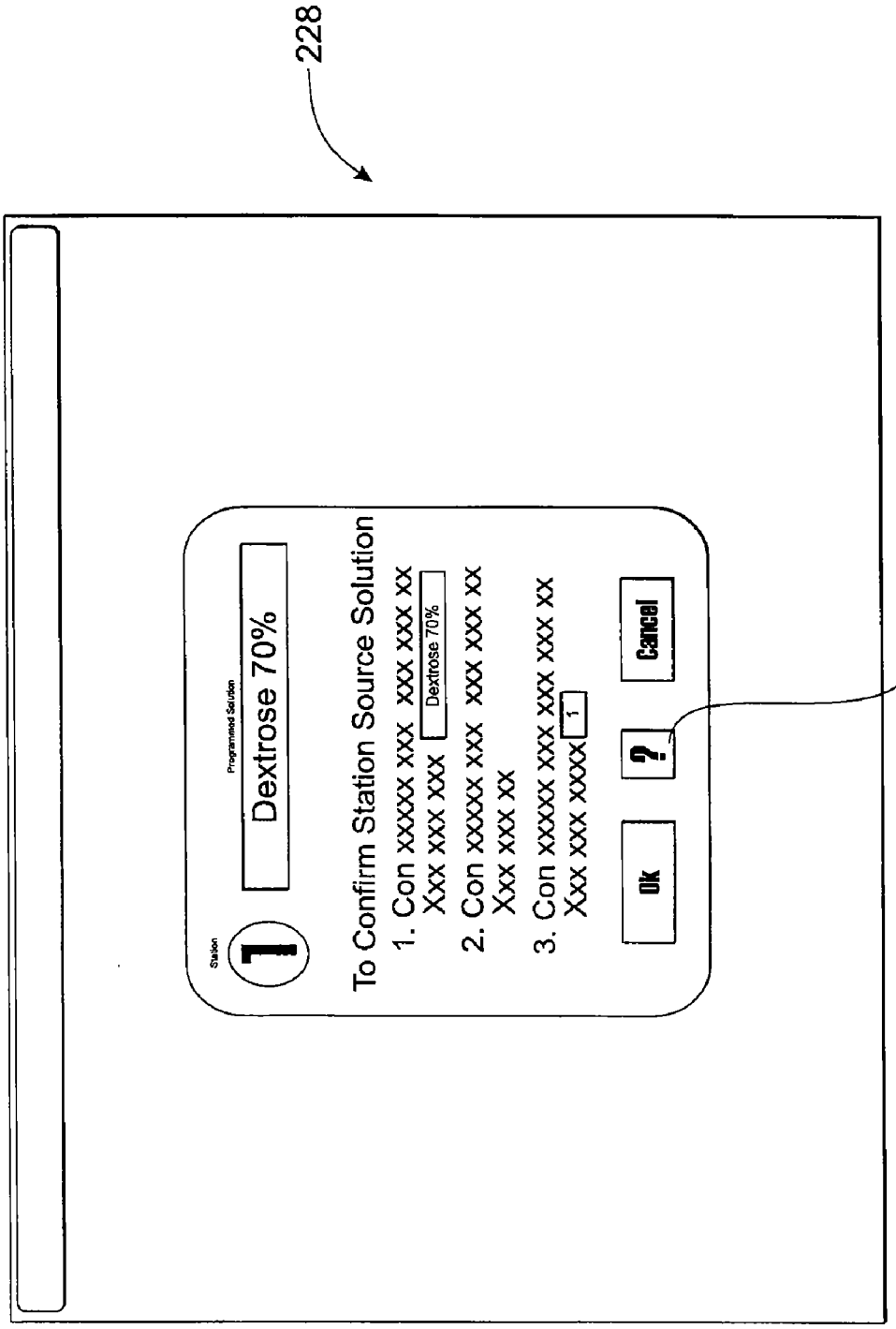

228
Station
1
Programmed Solution
Dextrose 70%
To Confirm Station Source Solution
1. Con xxxxx xxx xxx xxx xx
Xxx xxx xxx Dextrose 70%
2. Con xxxxx xxx xxx xxx xx
Xxx xxx xx
3. Con xxxxx xxx xxx xxx xx
Xxx xxx xxxx 1
Ok
?
Cancel
264

FIG. 9I(1)

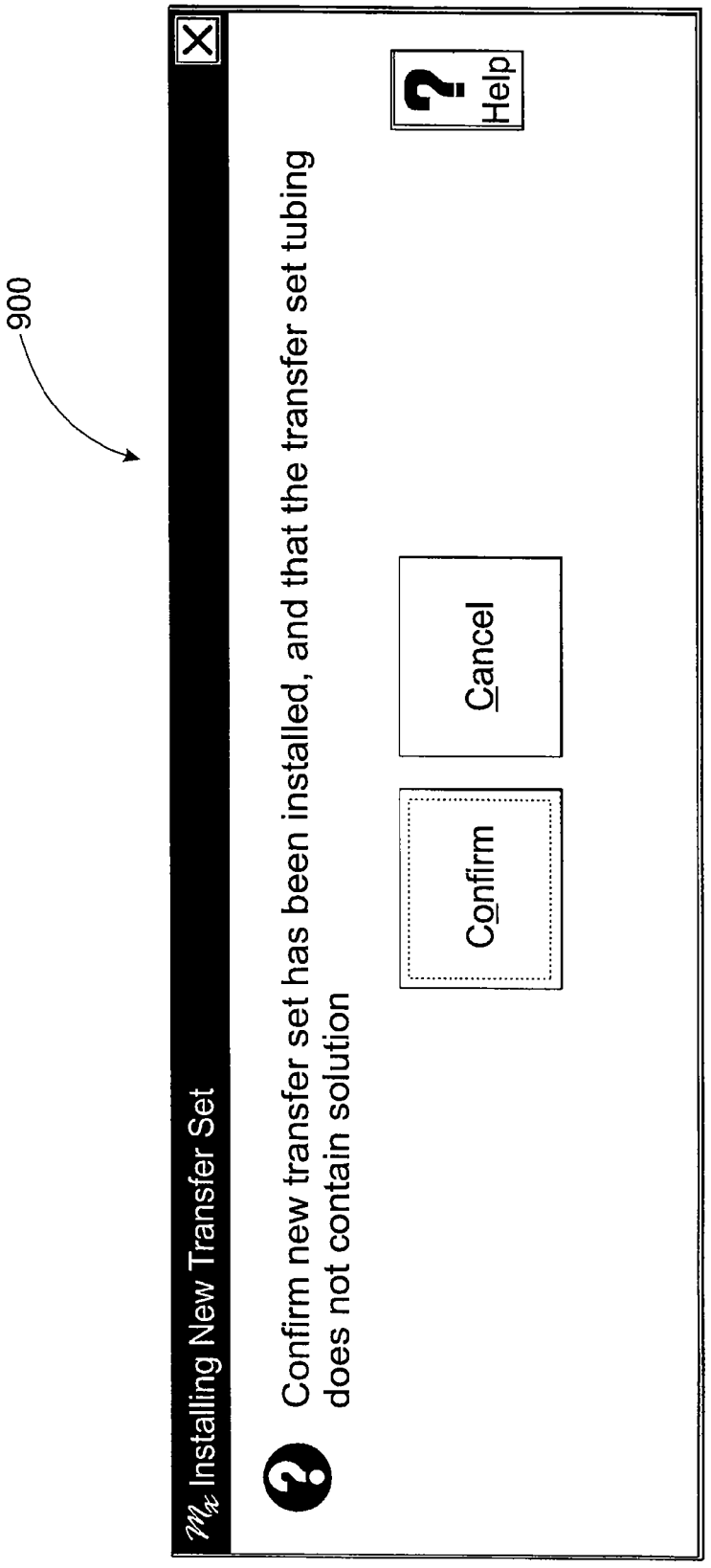

900
Installing New Transfer Set
Confirm new transfer set has been installed, and that the transfer set tubing does not contain solution
Help
Cancel
Confirm

FIG. 9I(2)

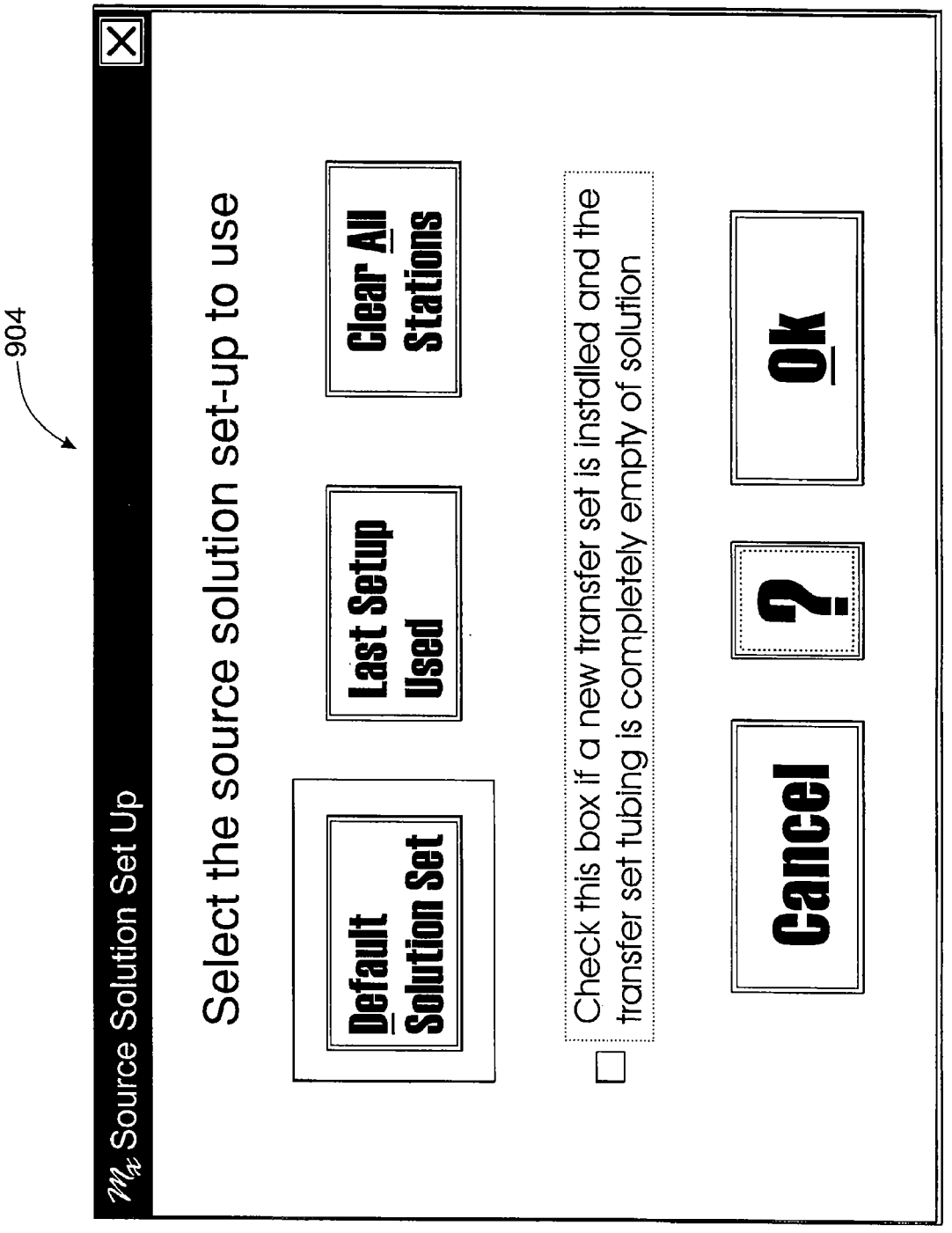

904
Source Solution Set Up
Select the source solution set-up to use
Default Solution Set
Last Setup Used
Clear All Stations
Check this box if a new transfer set is installed and the transfer set tubing is completely empty of solution
Cancel
?
Ok

FIG. 9I(3)

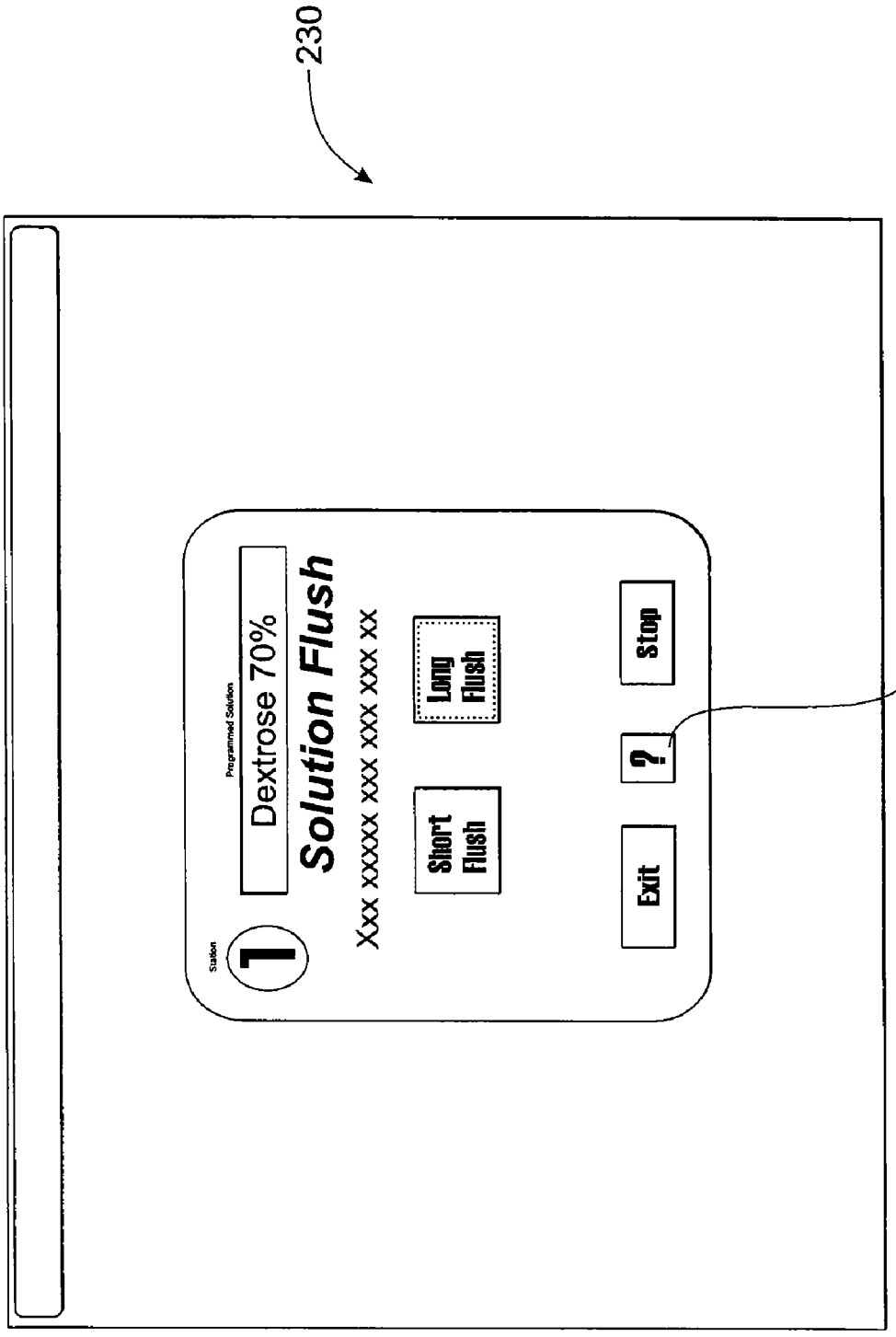

230
Station
1
Programmed Solution
Dextrose 70%
Solution Flush
Xxx xxxxx xxx xxx xxx xx
Short Flush
Long Flush
Exit
?
Stop
264

FIG. 9J

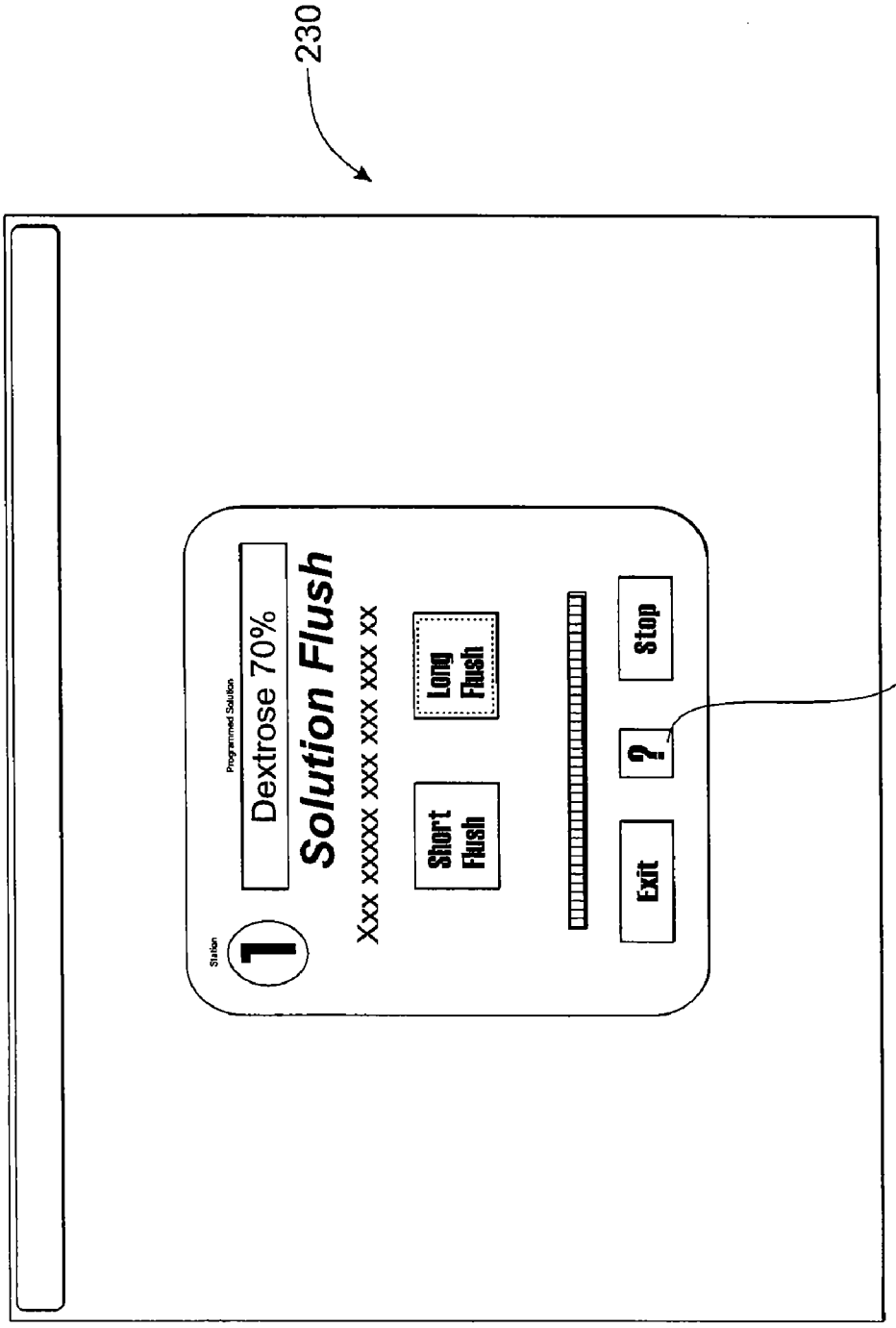

230
Station
1
Programmed Solution
Dextrose 70%
Solution Flush
Xxx xxxxx xxx xxx xxx xx
Short Flush
Long Flush
Exit
?
Stop
264

FIG. 9K

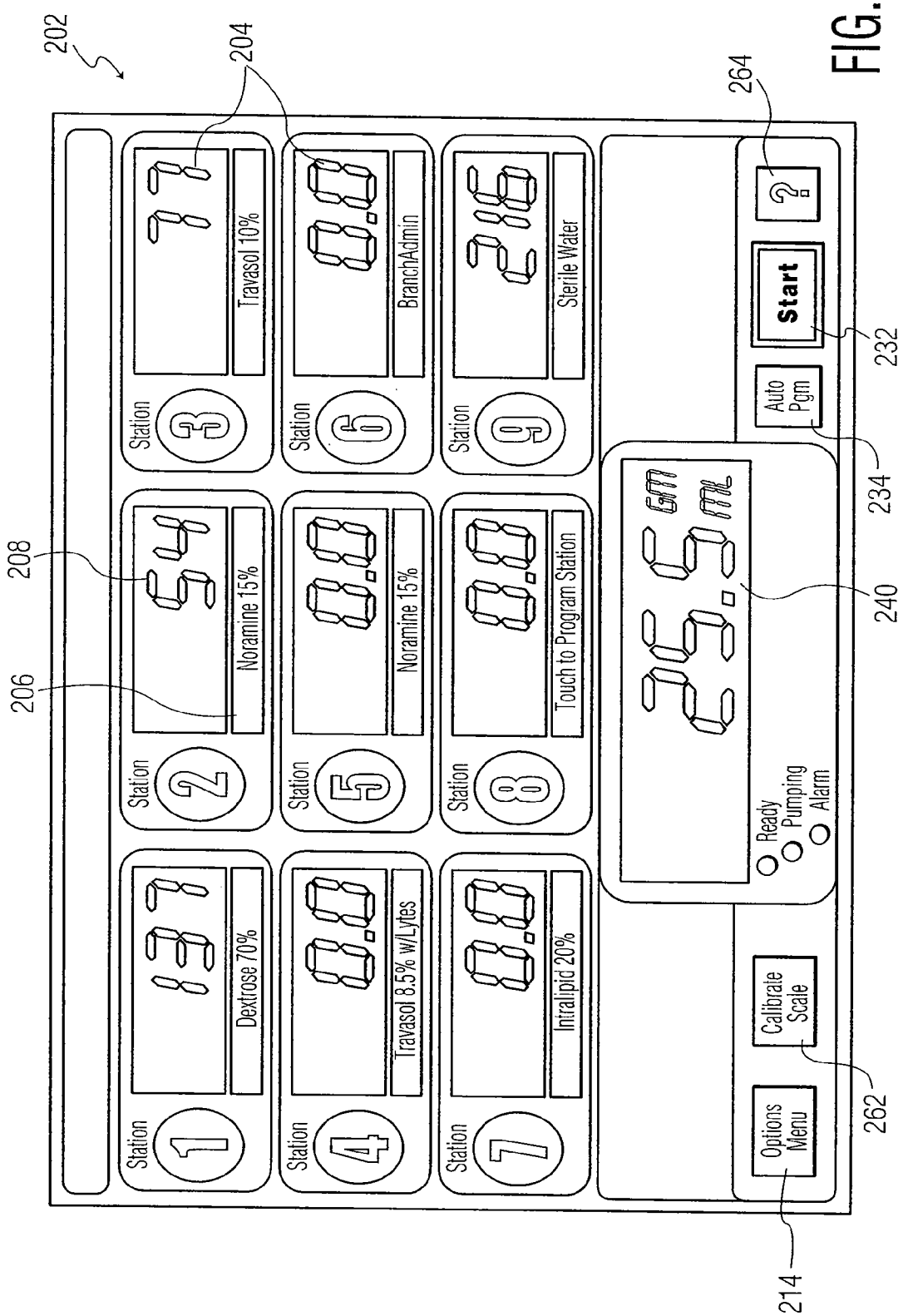

202
204
206
208
214
232
234
240
262
264
Station 1
Dextrose 70%
Station 2
Noramine 15%
Station 3
Travasol 10%
Station 4
Travasol 8.5% w/Lytes
Station 5
Noramine 15%
Station 6
BranchAdmin
Station 7
Intralipid 20%
Station 8
Touch to Program Station
Station 9
Sterile Water
Ready
Pumping
Alarm
Options Menu
Calibrate Scale
Auto Pgm
Start
?

FIG. 9L

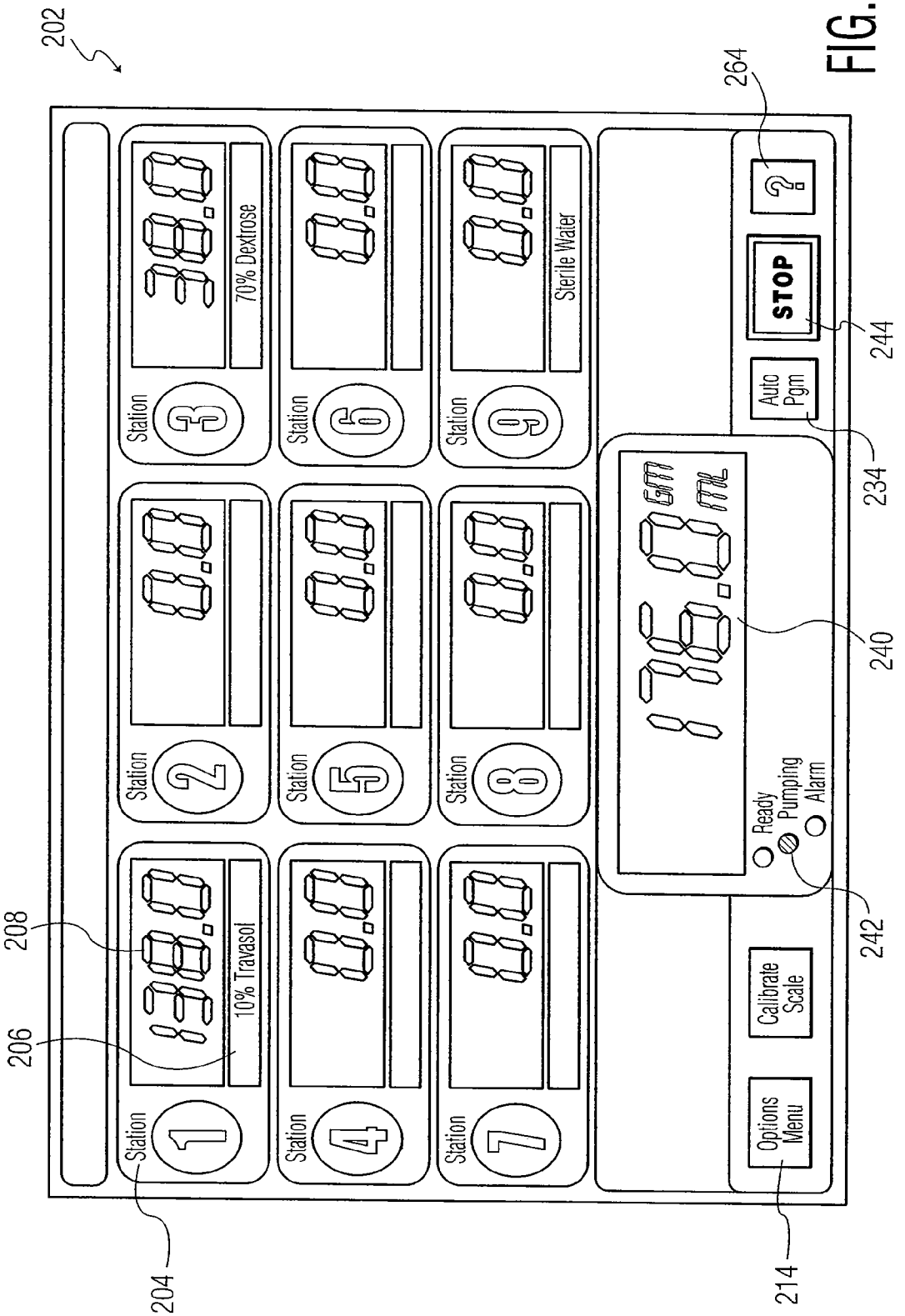

202
264
208
206
204
214
240
242
234
244
Station 1
10% Travasol
Station 2
Station 3
70% Dextrose
Station 4
Station 5
Station 6
Station 7
Station 8
Station 9
Sterile Water
Ready
Pumping
Alarm
Auto Pgm
STOP
Calibrate Scale
Options Menu

FIG. 9M

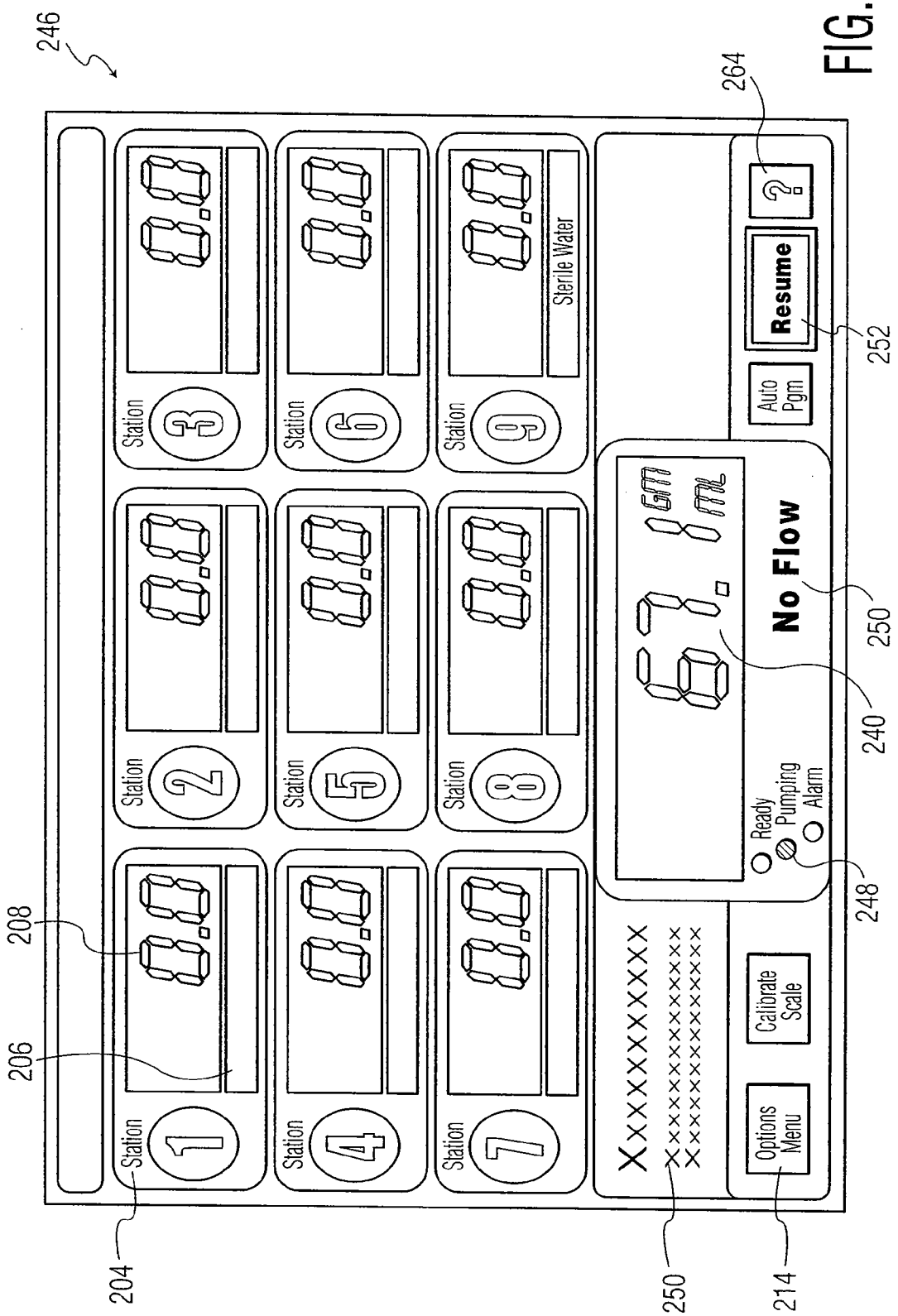

246
264
208
206
204
250
214
240
250
248
252
Station 1
Station 2
Station 3
Station 4
Station 5
Station 6
Station 7
Station 8
Station 9
Sterile Water
No Flow
Ready
Pumping
Alarm
Options Menu
Calibrate Scale
Auto Pgm
Resume
?

FIG. 9N

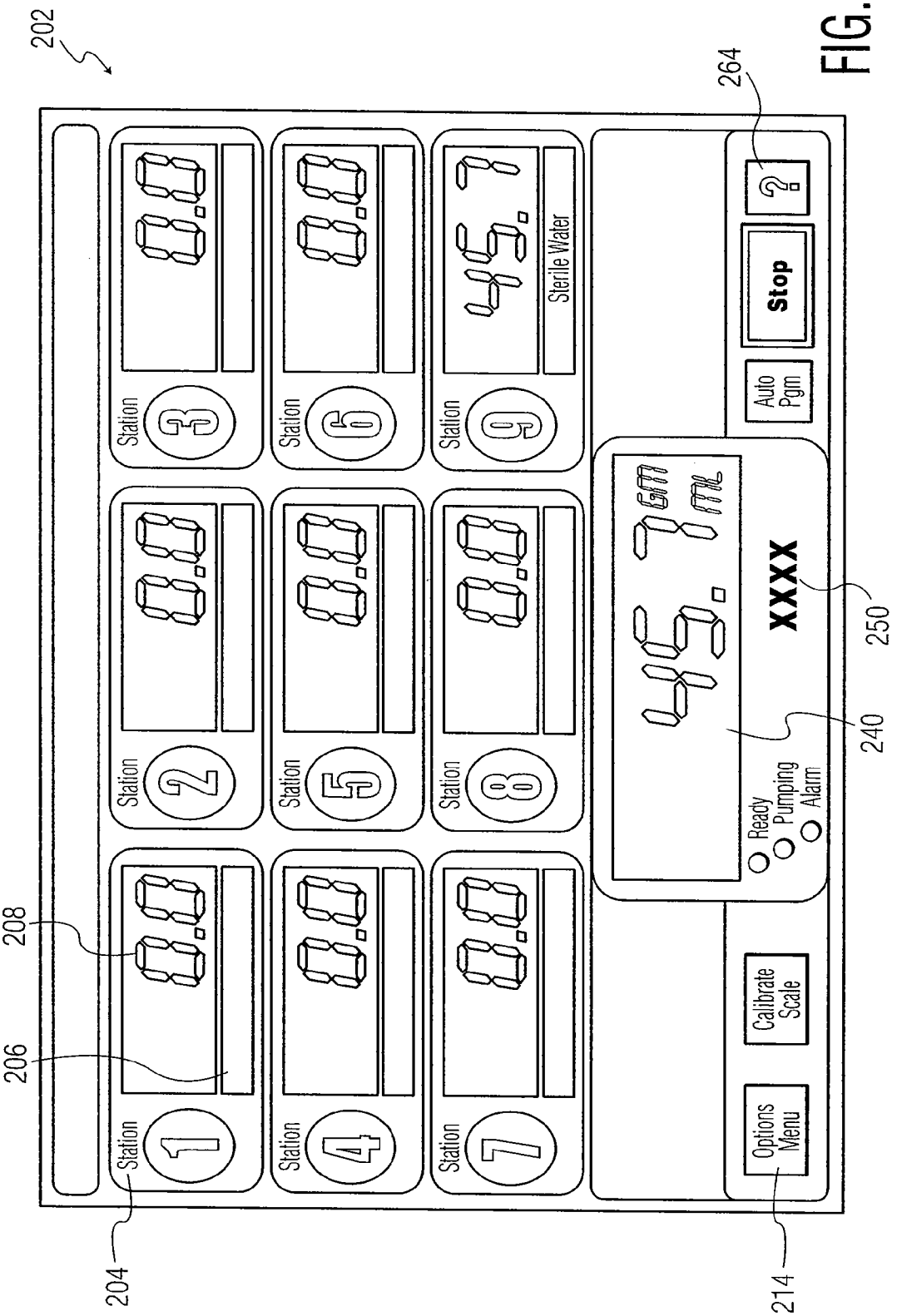

202
264
208
206
204
214
240
250
Station 1
Station 2
Station 3
Station 4
Station 5
Station 6
Station 7
Station 8
Station 9
Sterile Water
Options Menu
Calibrate Scale
Ready
Pumping
Alarm
XXXX
Auto Pgm
Stop
2

FIG. 90

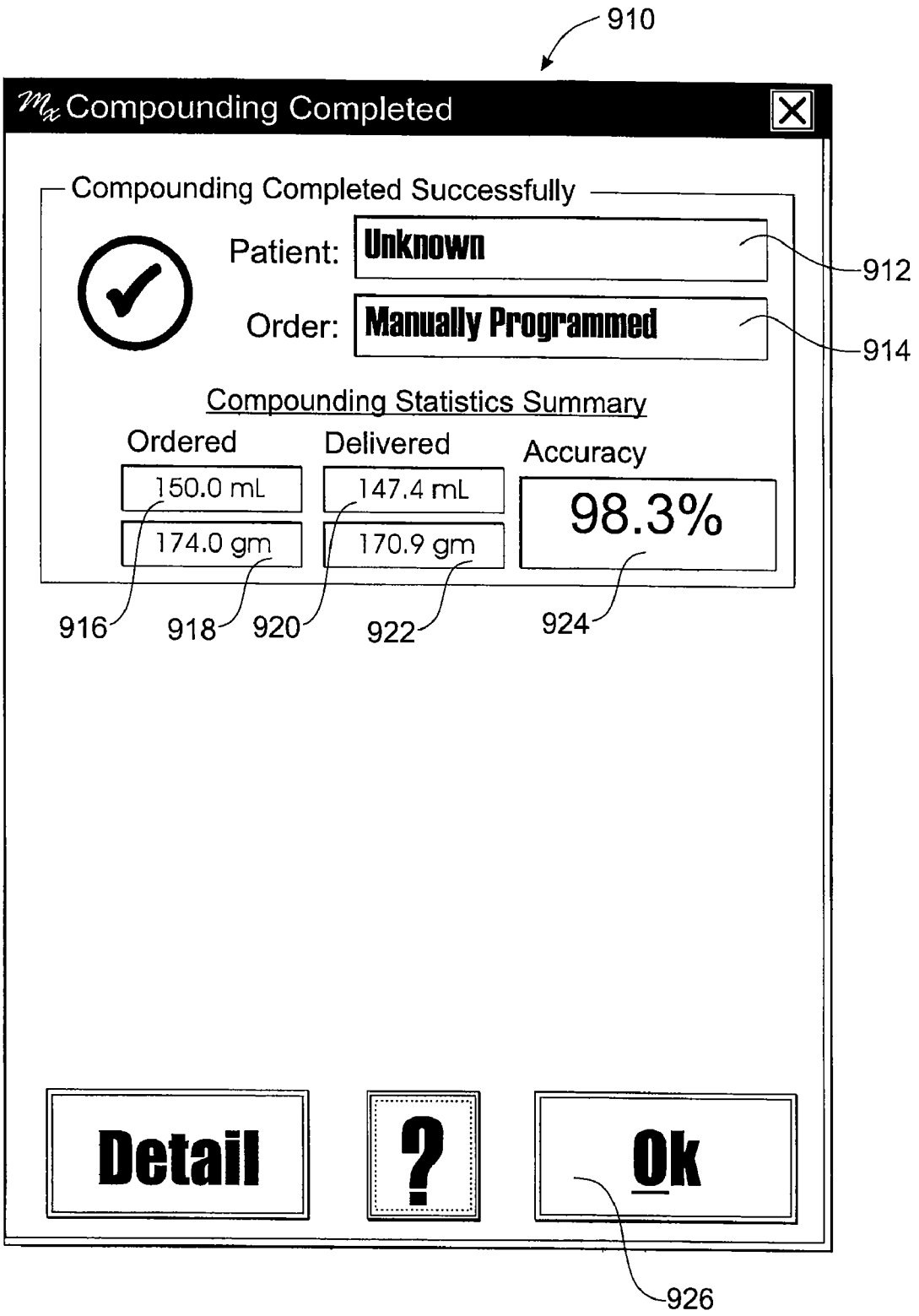

910
Compounding Completed
Compounding Completed Successfully
Patient:
Unknown
912
Order:
Manually Programmed
914
Compounding Statistics Summary
Ordered
Delivered
Accuracy
150.0 mL
147.4 mL
98.3%
174.0 gm
170.9 gm
916
918
920
922
924
Detail
?
Ok
926

FIG. 9O (1)

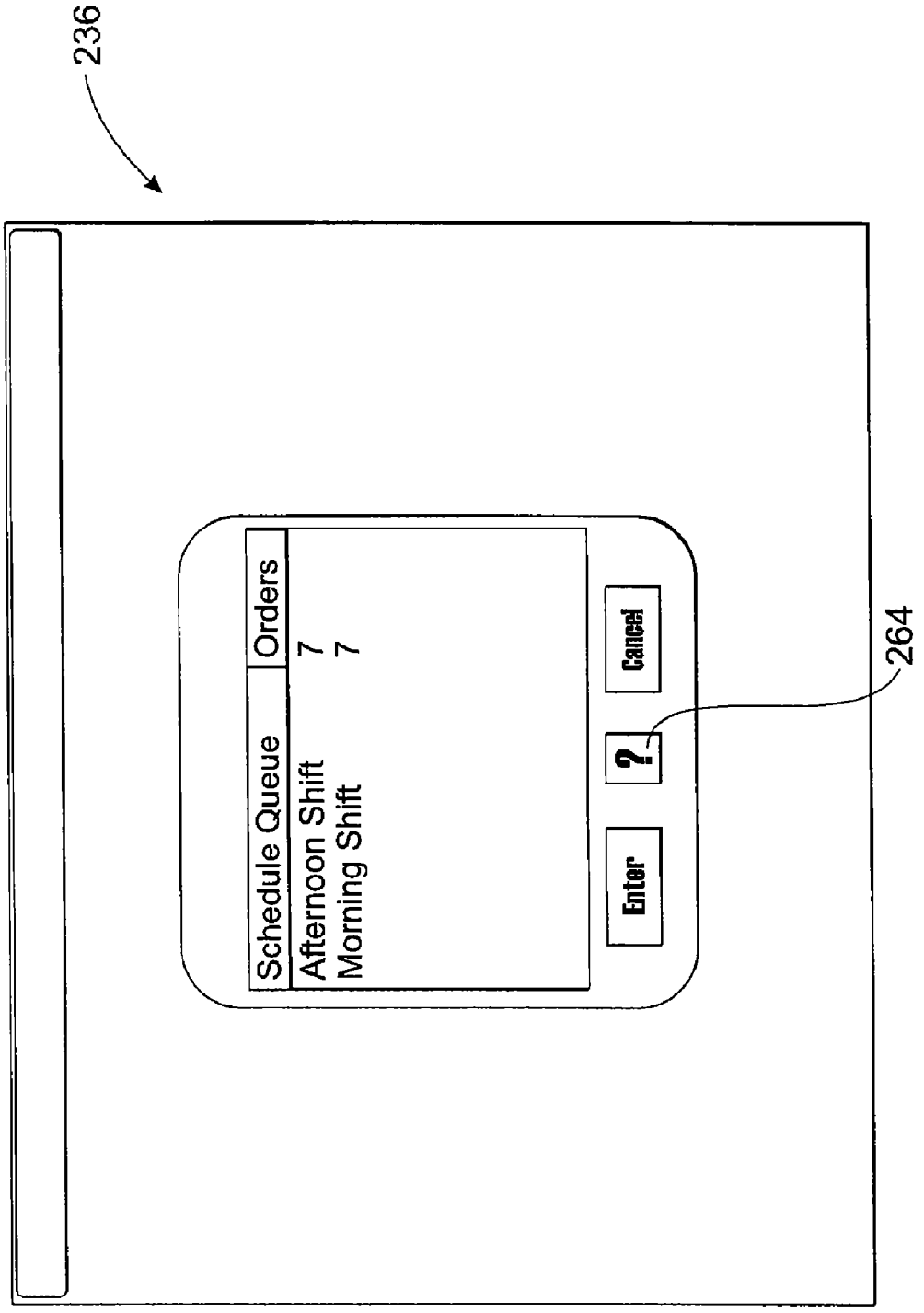

236
Schedule Queue
Orders
Afternoon Shift 7
Morning Shift 7
Enter
?
Cancel
264

FIG. 9P

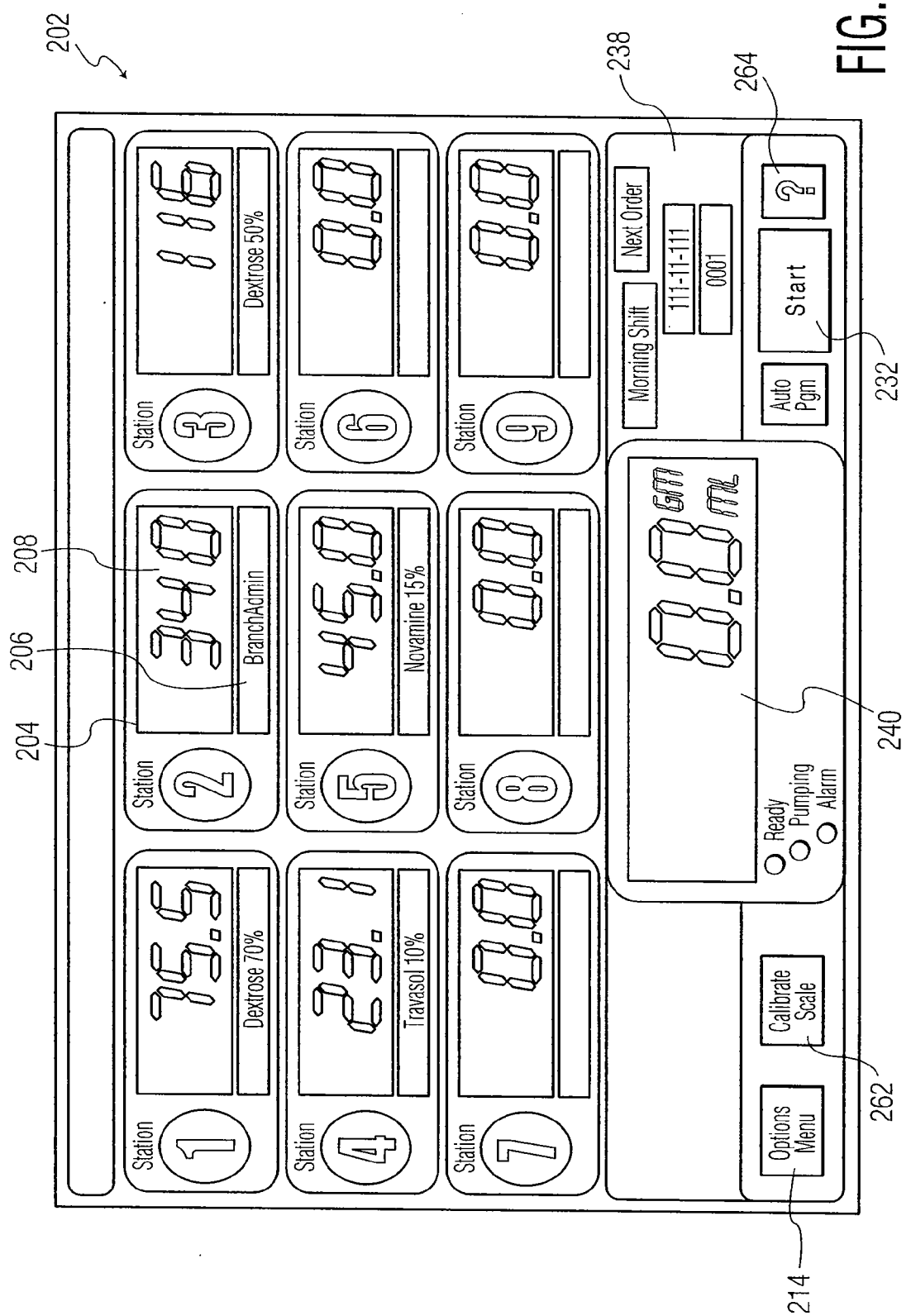

202
208
206
204
238
264
232
240
262
214
Station 1
85.5
Dextrose 70%
Station 2
3440
BranchAdmin
Station 3
1116
Dextrose 50%
Station 4
23.1
Travasol 10%
Station 5
450.0
Novamine 15%
Station 6
0.0
Station 7
0.0
Station 8
0.0
Station 9
0.0
Next Order
Morning Shift
111-11-111
0001
Start
Auto Pgm
2
gm
ml
Ready
Pumping
Alarm
Options Menu
Calibrate Scale

FIG. 9Q

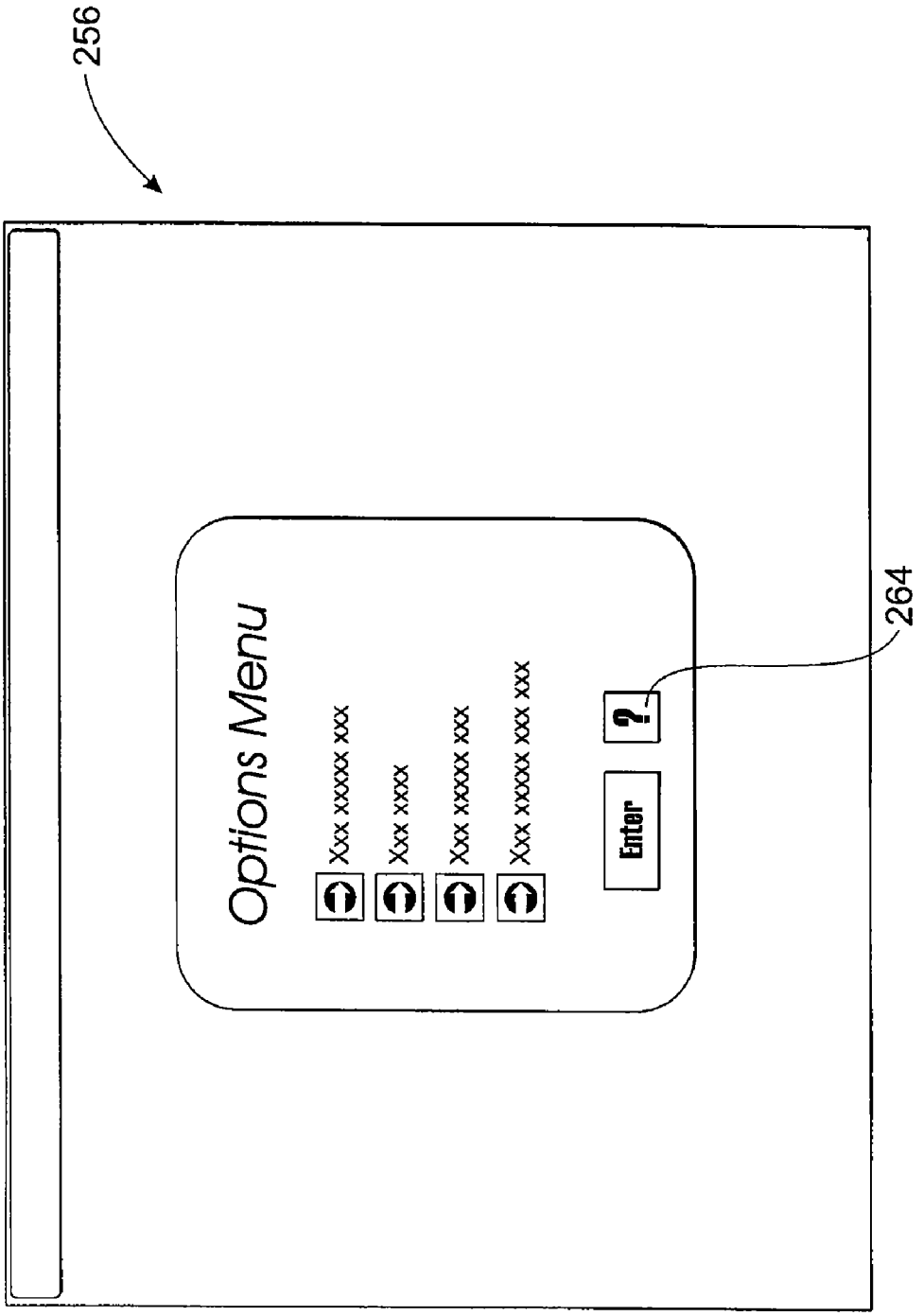

256
Options Menu
Xxx xxxxx xxx
Xxx xxxx
Xxx xxxxx xxx
Xxx xxxxx xxx xxx
Enter
?
264

FIG. 9R

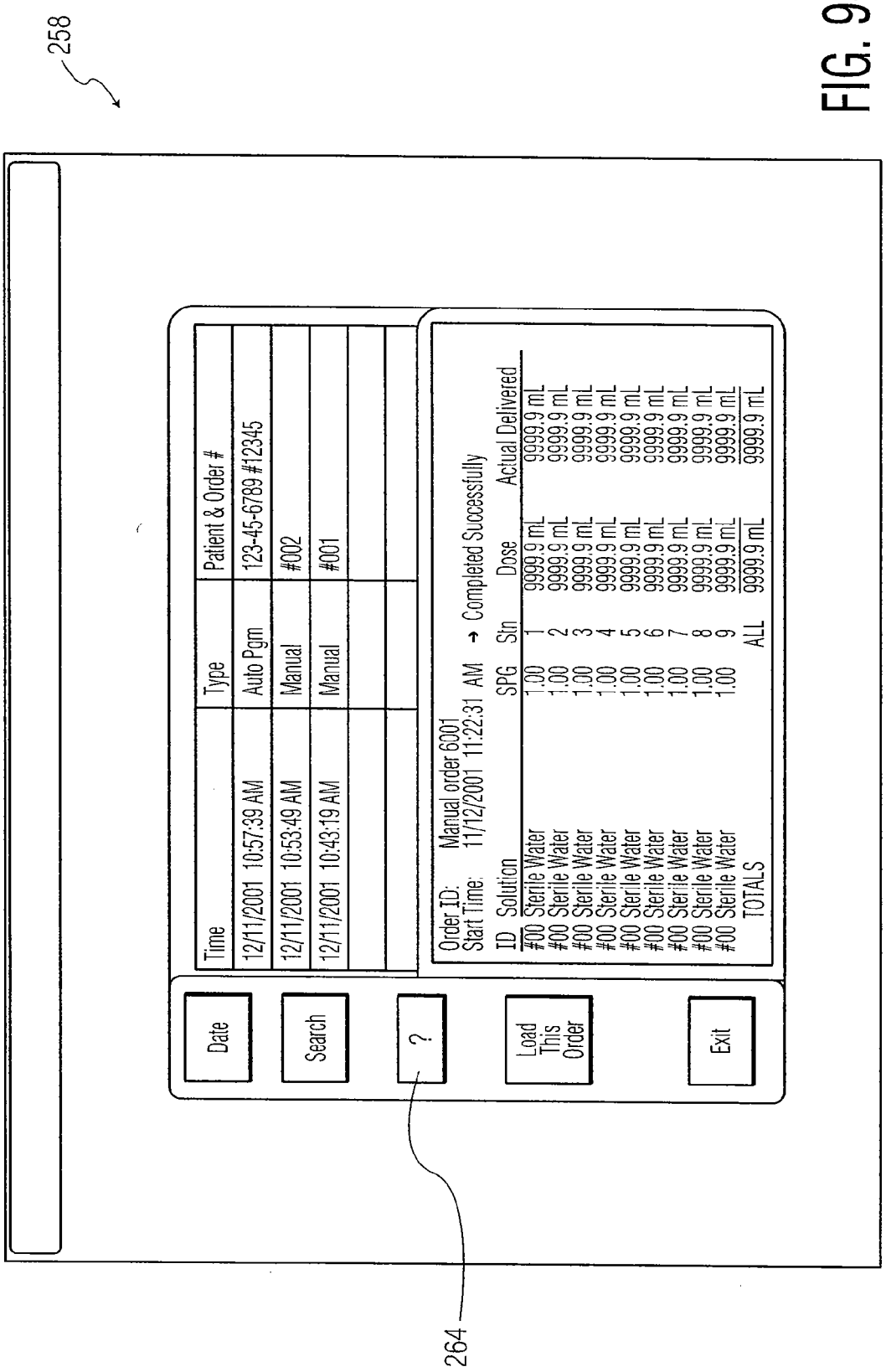

258
Date
Search
?
Load This Order
Exit
Time
Type
Patient & Order #
12/11/2001 10:57:39 AM
Auto Pgm
123-45-6789 #12345
12/11/2001 10:53:49 AM
Manual
#002
12/11/2001 10:43:19 AM
Manual
#001
Order ID: Manual order 6001
Start Time: 11/12/2001 11:22:31 AM → Completed Successfully
ID Solution SPG Stn Dose Actual Delivered
#00 Sterile Water 1.00 1 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 2 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 3 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 4 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 5 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 6 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 7 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 8 9999.9 mL 9999.9 mL
#00 Sterile Water 1.00 9 9999.9 mL 9999.9 mL
TOTALS ALL 9999.9 mL 9999.9 mL
264

FIG. 9S

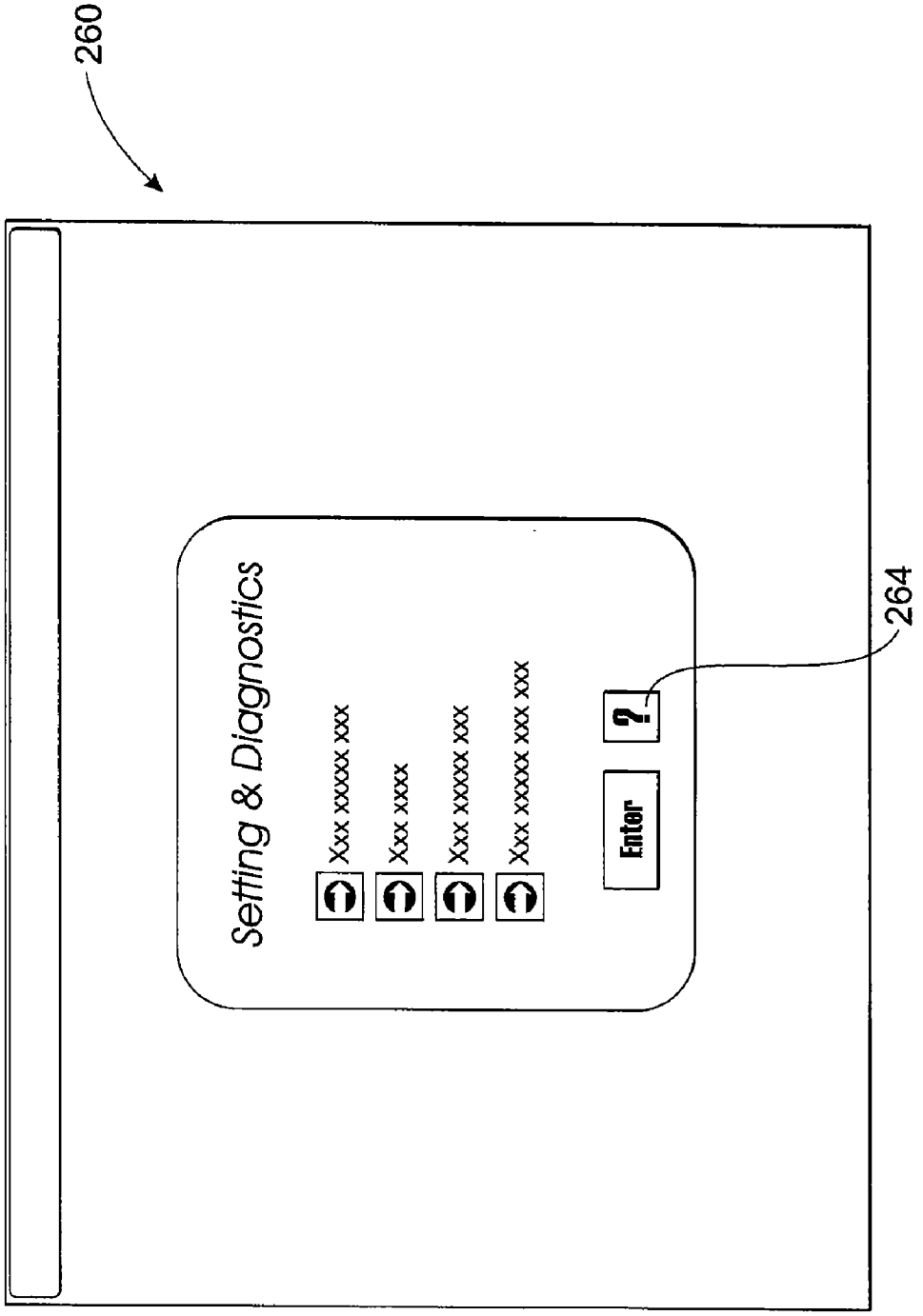

260
Setting & Diagnostics
Xxx xxxxx xxx
Xxx xxxx
Xxx xxxxx xxx
Xxx xxxxx xxx xxx
Enter
?
264

FIG. 9T

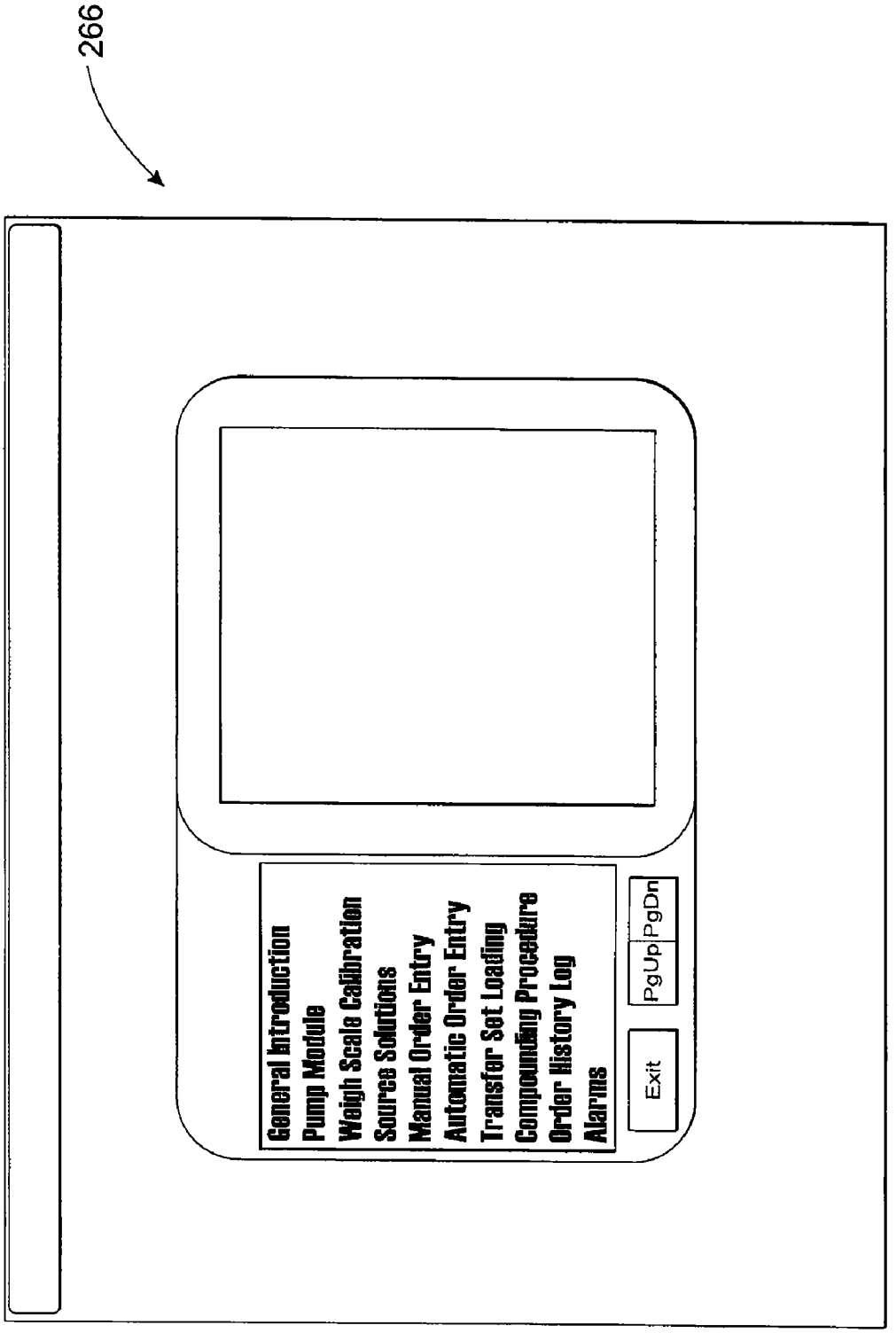

266
General Introduction
Pump Module
Weigh Scale Calibration
Source Solutions
Manual Order Entry
Automatic Order Entry
Transfer Set Loading
Compounding Procedure
Order History Log
Alarms
Exit
PgUp
PgDn

FIG. 9U

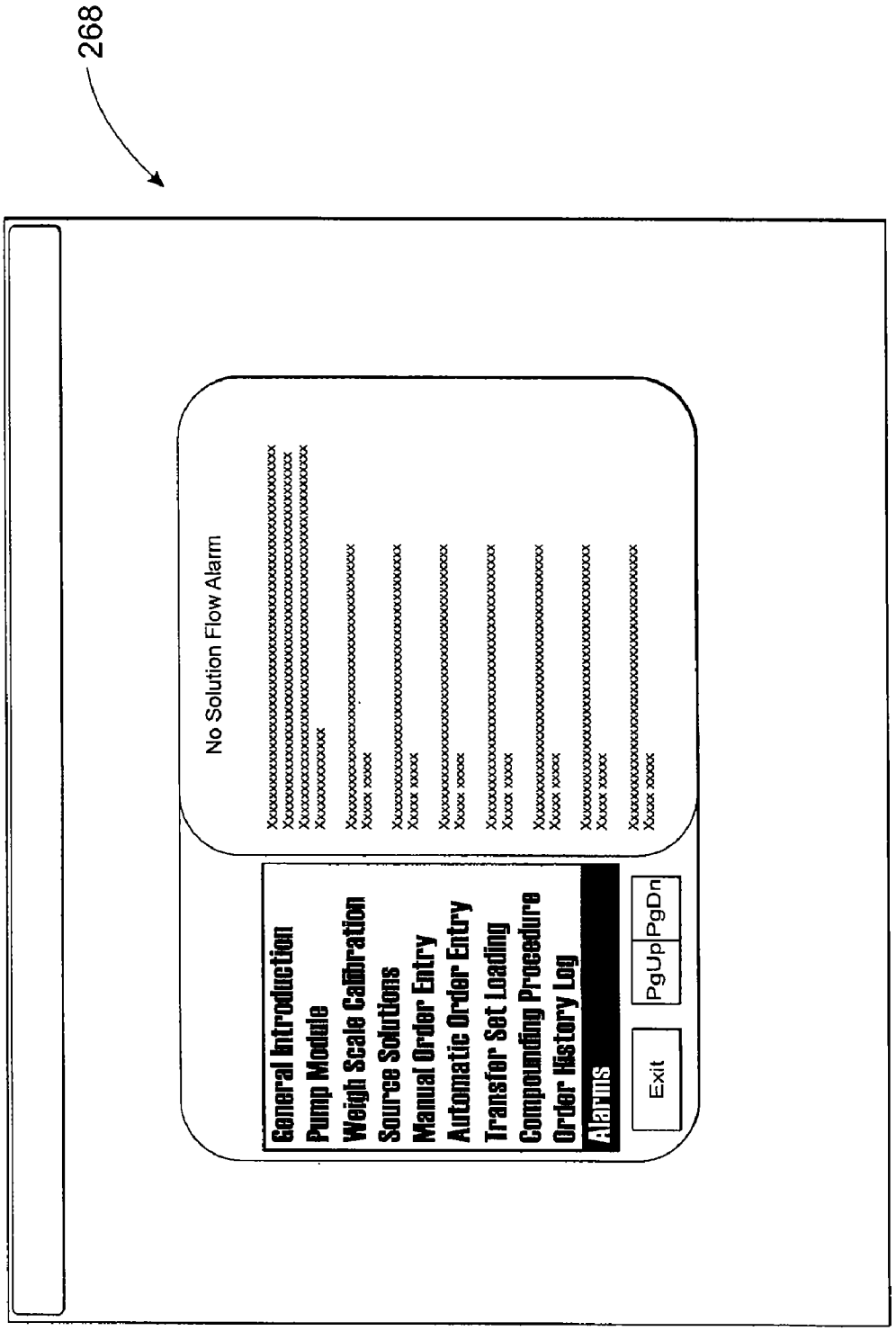

268
No Solution Flow Alarm
General Introduction
Pump Module
Weigh Scale Calibration
Source Solutions
Manual Order Entry
Automatic Order Entry
Transfer Set Loading
Compounding Procedure
Order History Log
Alarms
Exit
PgUp
PgDn

FIG. 9V

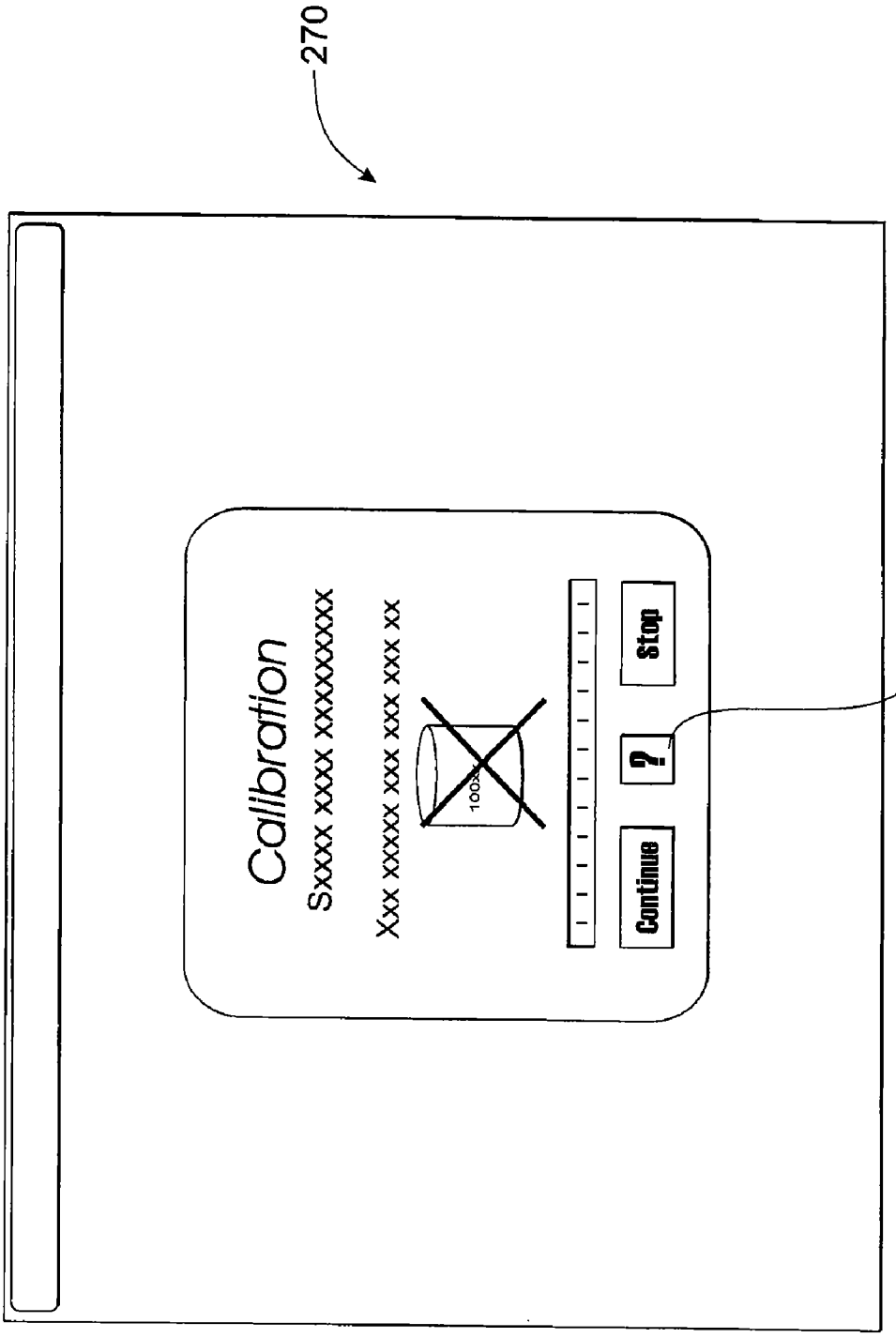

270
Calibration
Sxxxx xxxx xxxxxxxx
Xxx xxxxx xxx xxx xxx xx
100%
Stop
?
Continue
264

FIG. 9W

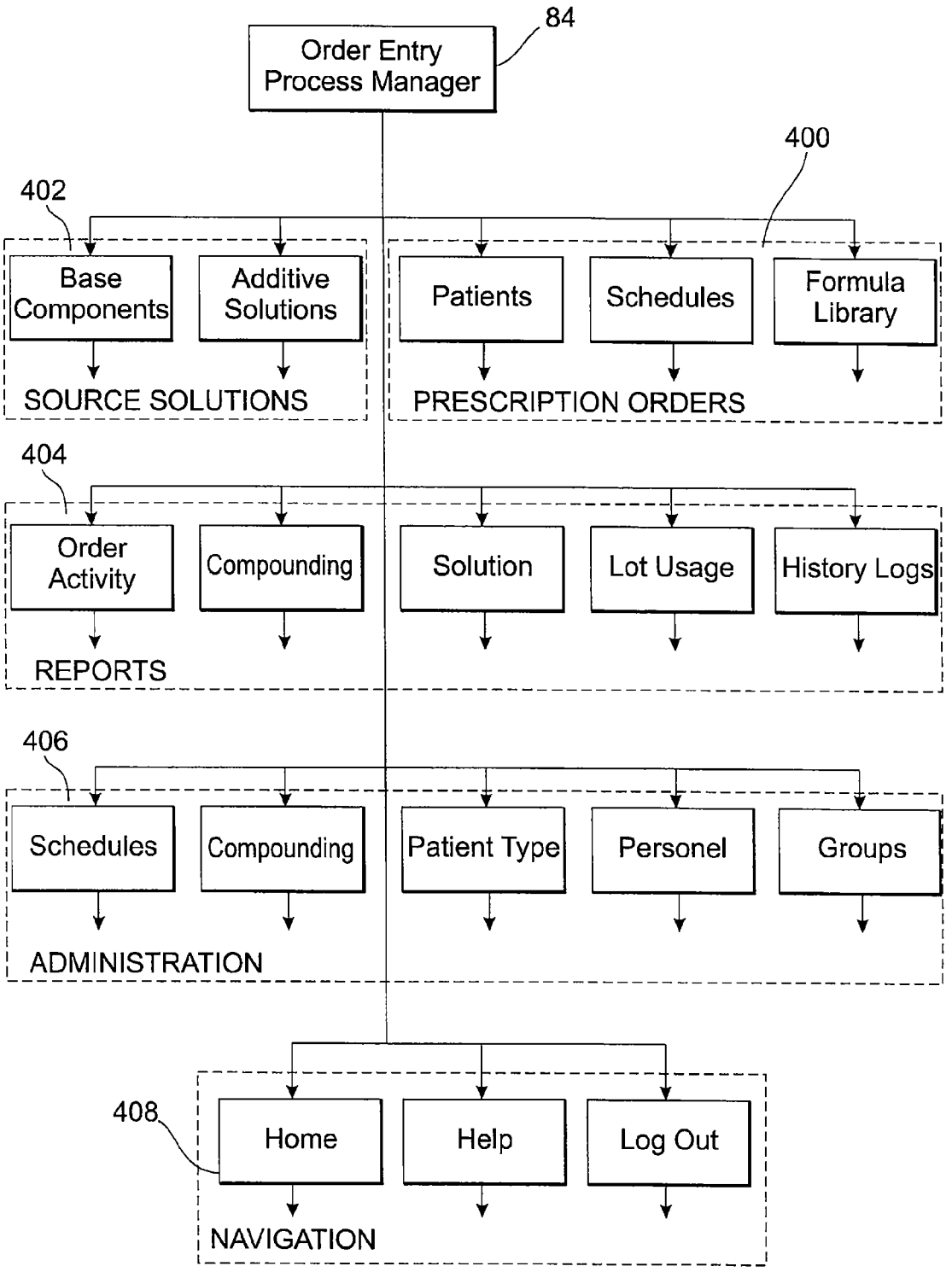
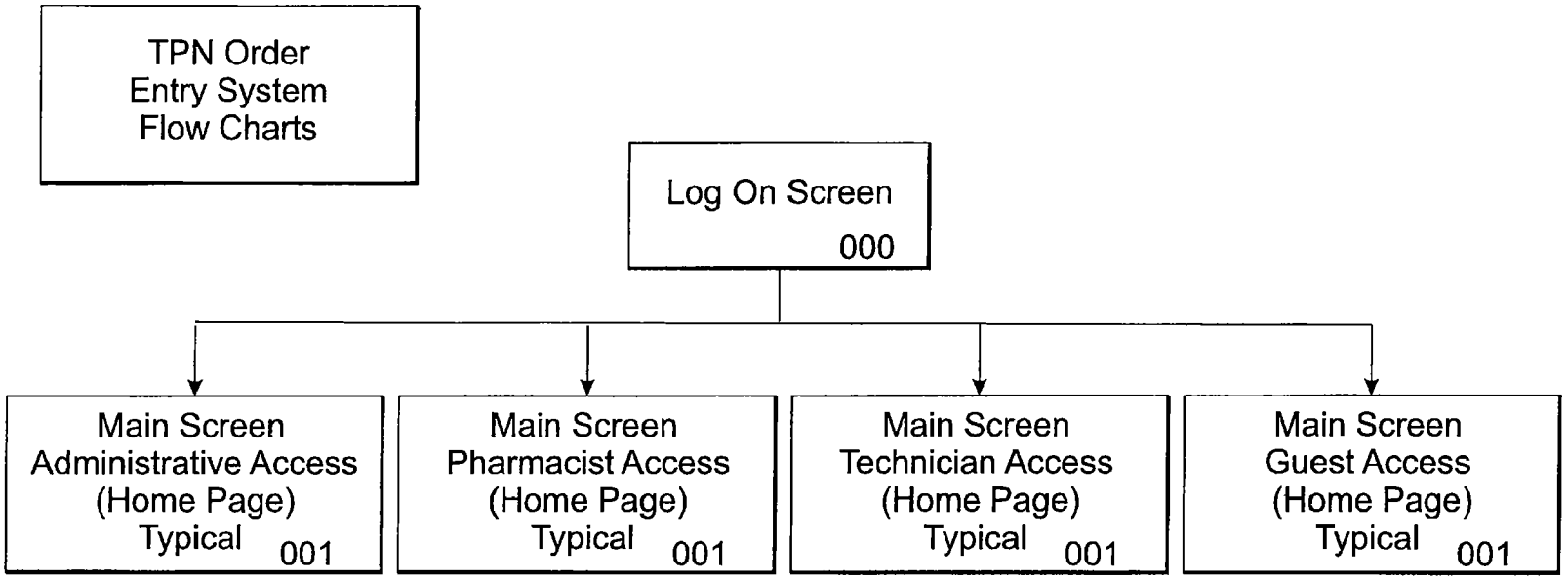

84
Order Entry Process Manager
400
402
Base Components
Additive Solutions
Patients
Schedules
Formula Library
SOURCE SOLUTIONS
PRESCRIPTION ORDERS
404
Order Activity
Compounding
Solution
Lot Usage
History Logs
REPORTS
406
Schedules
Compounding
Patient Type
Personel
Groups
ADMINISTRATION
408
Home
Help
Log Out
NAVIGATION

FIG. 10A(1)



Notes: Above access levels are "typical". Access to system functionality is a direct function of the individual's Granted access options.

Access titles (e.g., Administrative, Pharmacist, etc.) are not fixed and are instead examples of the type of levels that can be set up by the user.

Screen numbers are three digit code located in lower right corner of each flow chart box.

FIG. 10A(2)

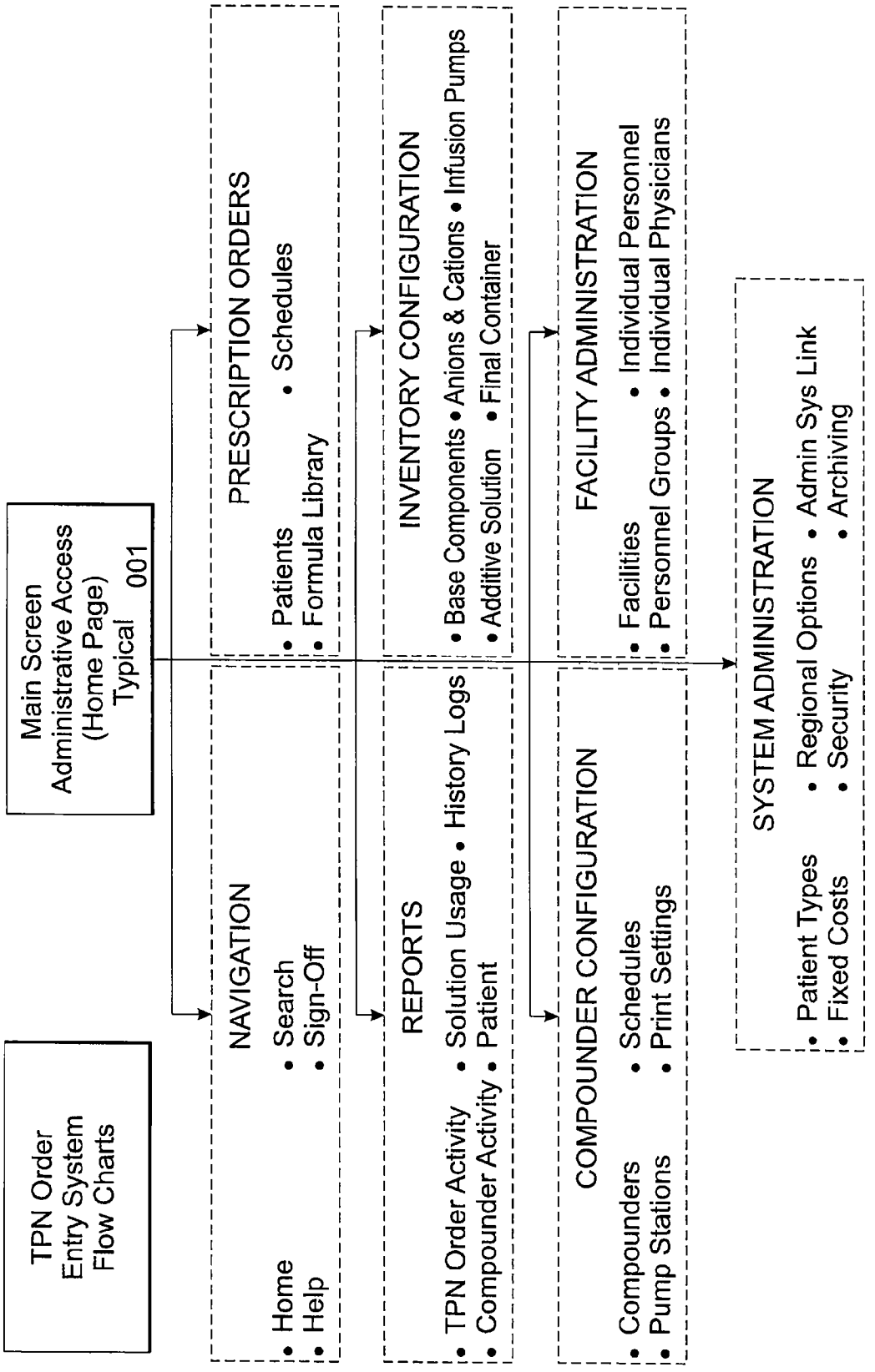

TPN Order Entry System Flow Charts
Main Screen Administrative Access (Home Page) Typical 001
NAVIGATION
• Home • Search
• Help • Sign-Off
PRESCRIPTION ORDERS
• Patients • Schedules
• Formula Library
REPORTS
• TPN Order Activity • Solution Usage • History Logs
• Compounder Activity • Patient
INVENTORY CONFIGURATION
• Base Components • Anions & Cations • Infusion Pumps
• Additive Solution • Final Container
COMPOUNDER CONFIGURATION
• Compounders • Schedules
• Pump Stations • Print Settings
FACILITY ADMINISTRATION
• Facilities • Individual Personnel
• Personnel Groups • Individual Physicians
SYSTEM ADMINISTRATION
• Patient Types • Regional Options • Admin Sys Link
• Fixed Costs • Security • Archiving

FIG. 10A(3)

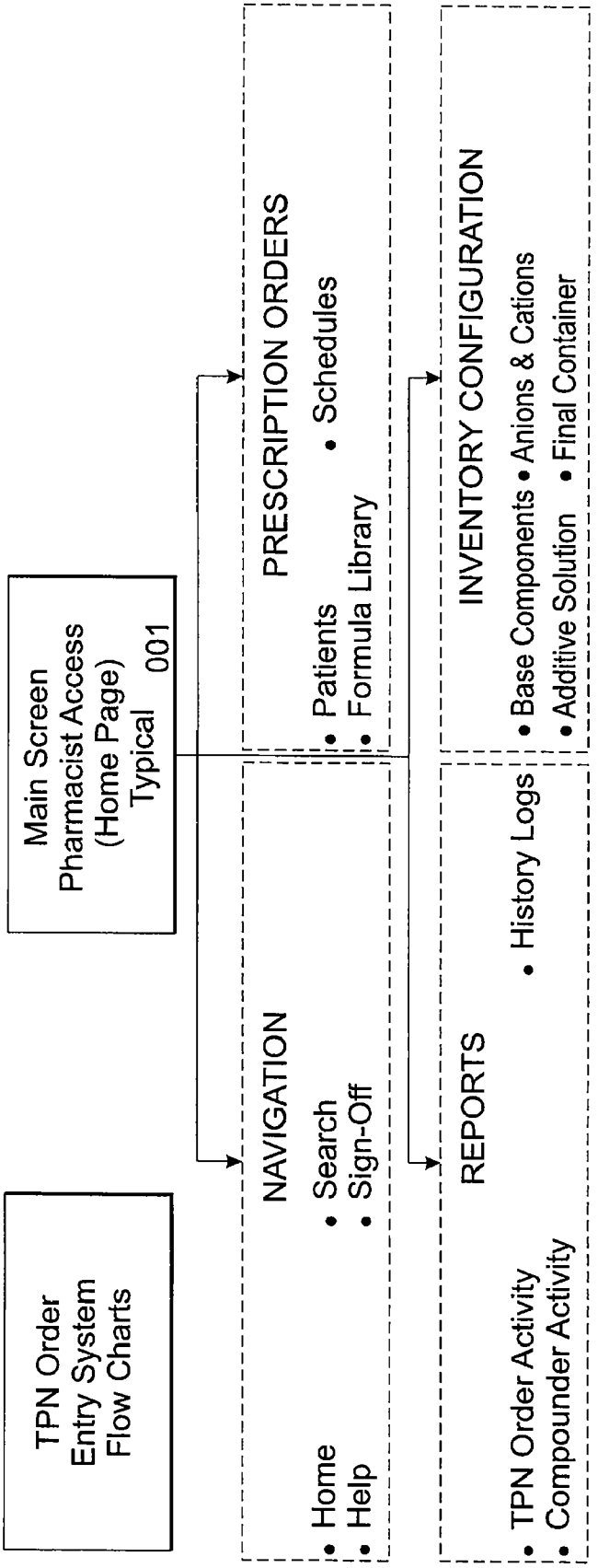

TPN Order Entry System Flow Charts
Main Screen Pharmacist Access (Home Page) Typical 001
NAVIGATION
• Home
• Help
• Search
• Sign-Off
PRESCRIPTION ORDERS
• Patients
• Formula Library
• Schedules
INVENTORY CONFIGURATION
• Base Components
• Additive Solution
• Anions & Cations
• Final Container
REPORTS
• TPN Order Activity
• Compounder Activity
• History Logs

FIG. 10A(4)

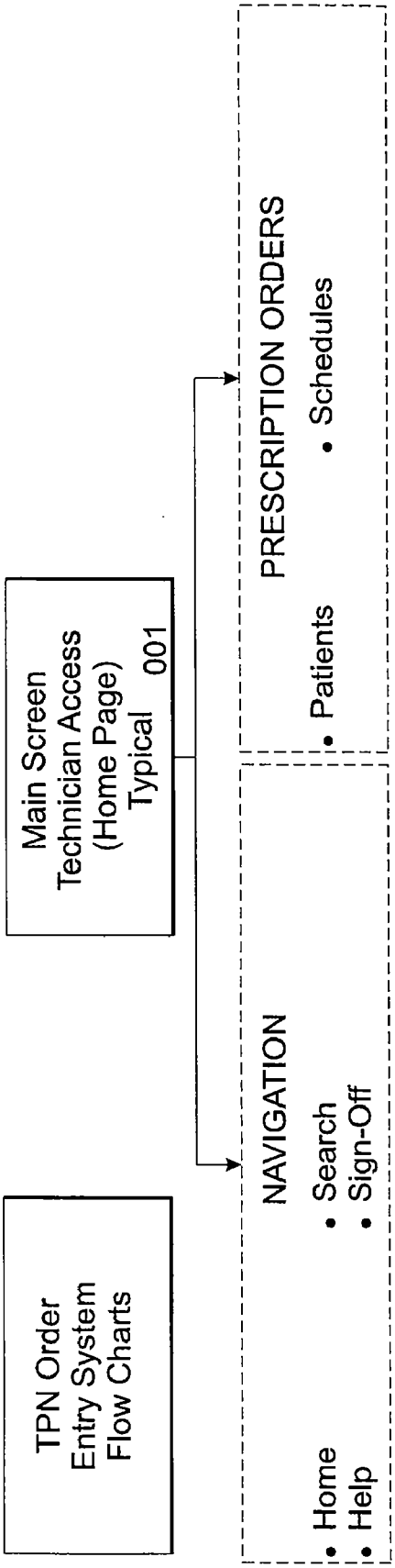

TPN Order Entry System Flow Charts
Main Screen Technician Access (Home Page) Typical 001
NAVIGATION
• Home
• Help
• Search
• Sign-Off
PRESCRIPTION ORDERS
• Patients
• Schedules

FIG. 10A(5)

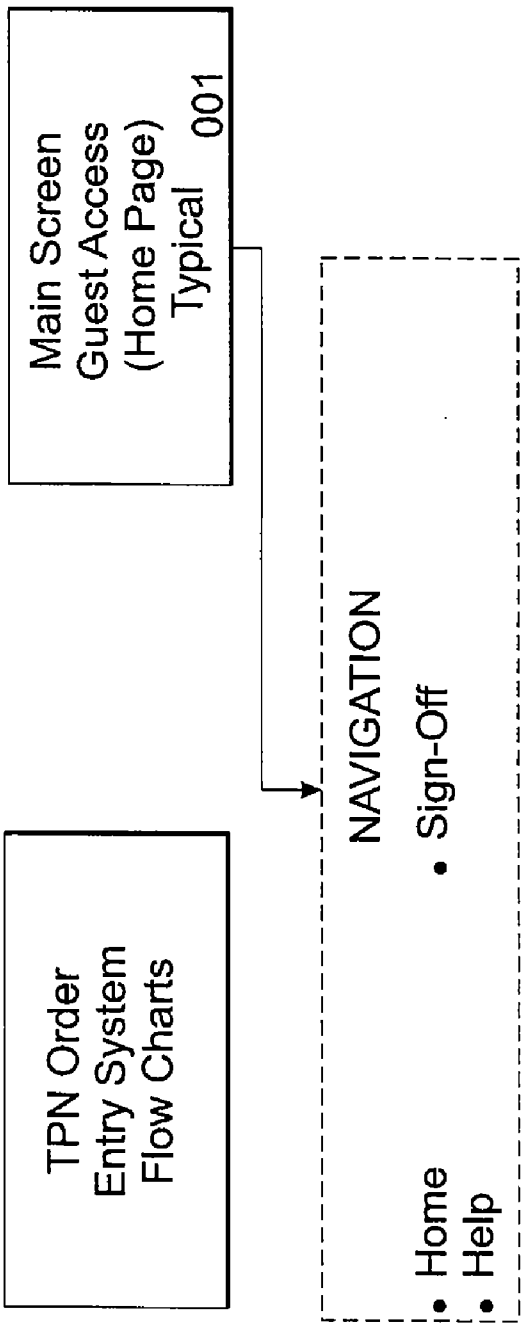

Main Screen
Guest Access
(Home Page)
Typical 001
TPN Order
Entry System
Flow Charts
NAVIGATION
• Sign-Off
• Home
• Help

FIG. 10A(6)

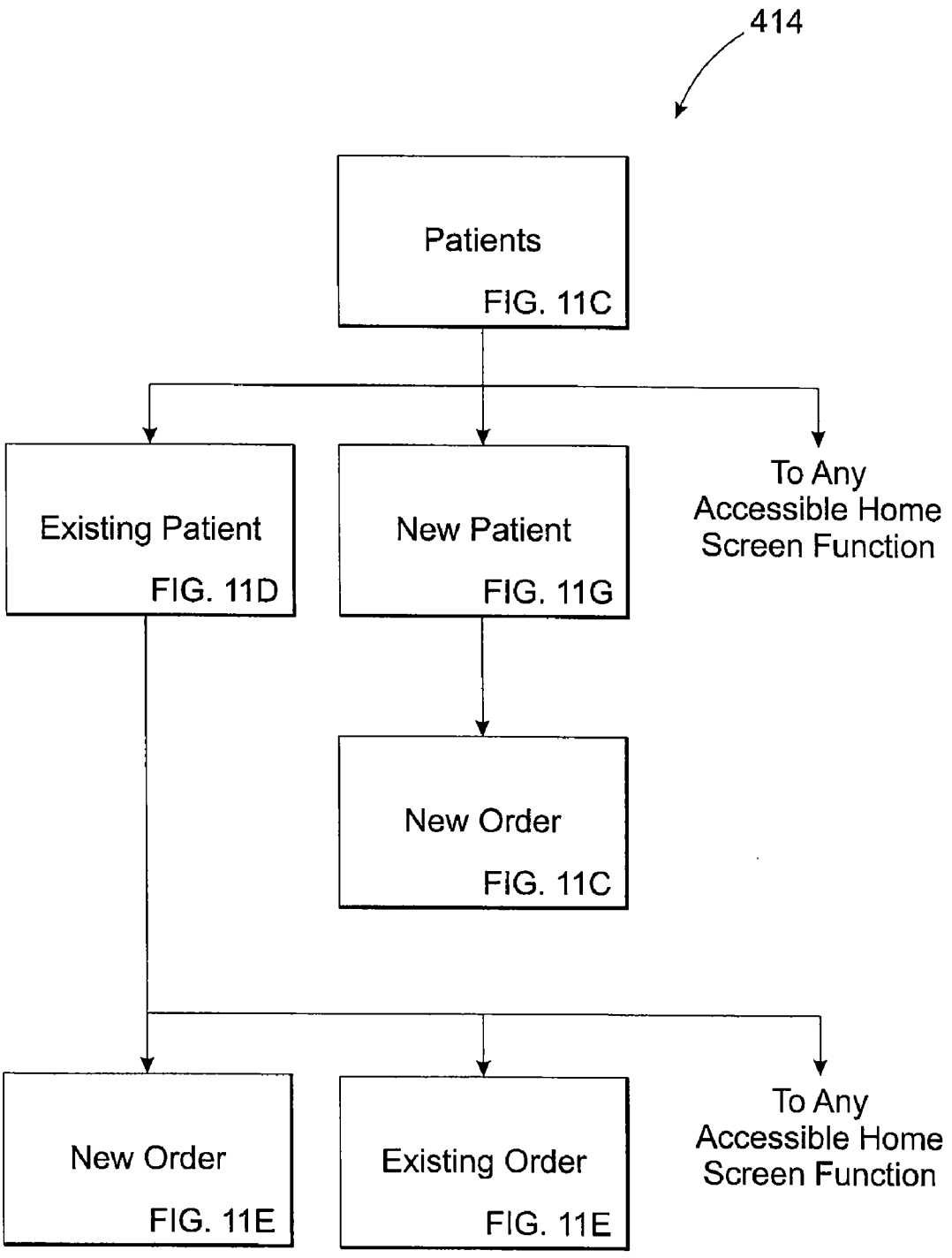

414
Patients
FIG. 11C
Existing Patient
FIG. 11D
New Patient
FIG. 11G
To Any Accessible Home Screen Function
New Order
FIG. 11C
New Order
FIG. 11E
Existing Order
FIG. 11E
To Any Accessible Home Screen Function

FIG. 10B

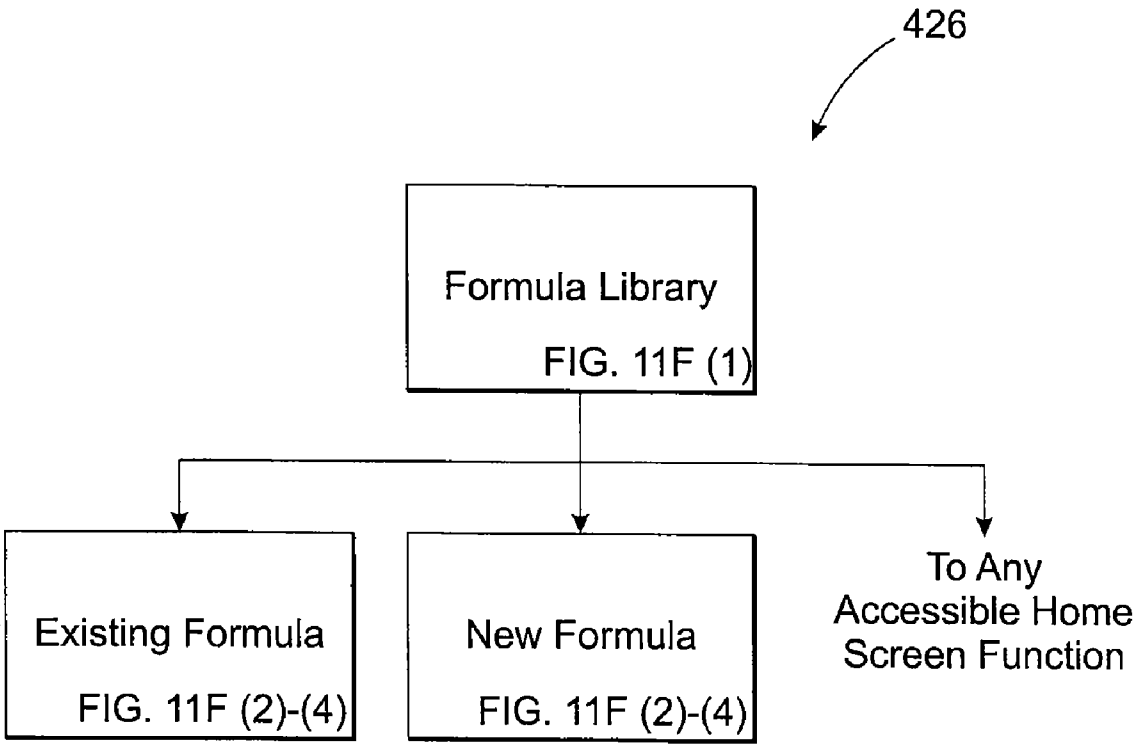

426
Formula Library
FIG. 11F (1)
Existing Formula
FIG. 11F (2)-(4)
New Formula
FIG. 11F (2)-(4)
To Any
Accessible Home
Screen Function

FIG. 10C

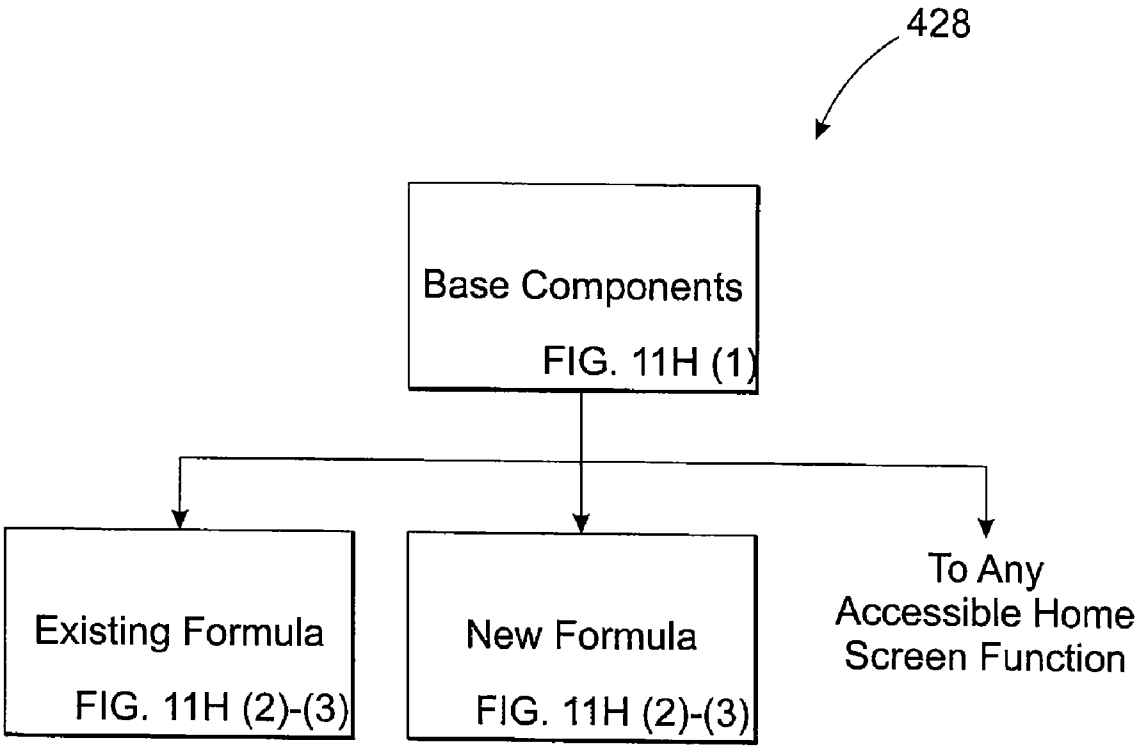

428
Base Components
FIG. 11H (1)
Existing Formula
FIG. 11H (2)-(3)
New Formula
FIG. 11H (2)-(3)
To Any
Accessible Home
Screen Function

FIG. 10D

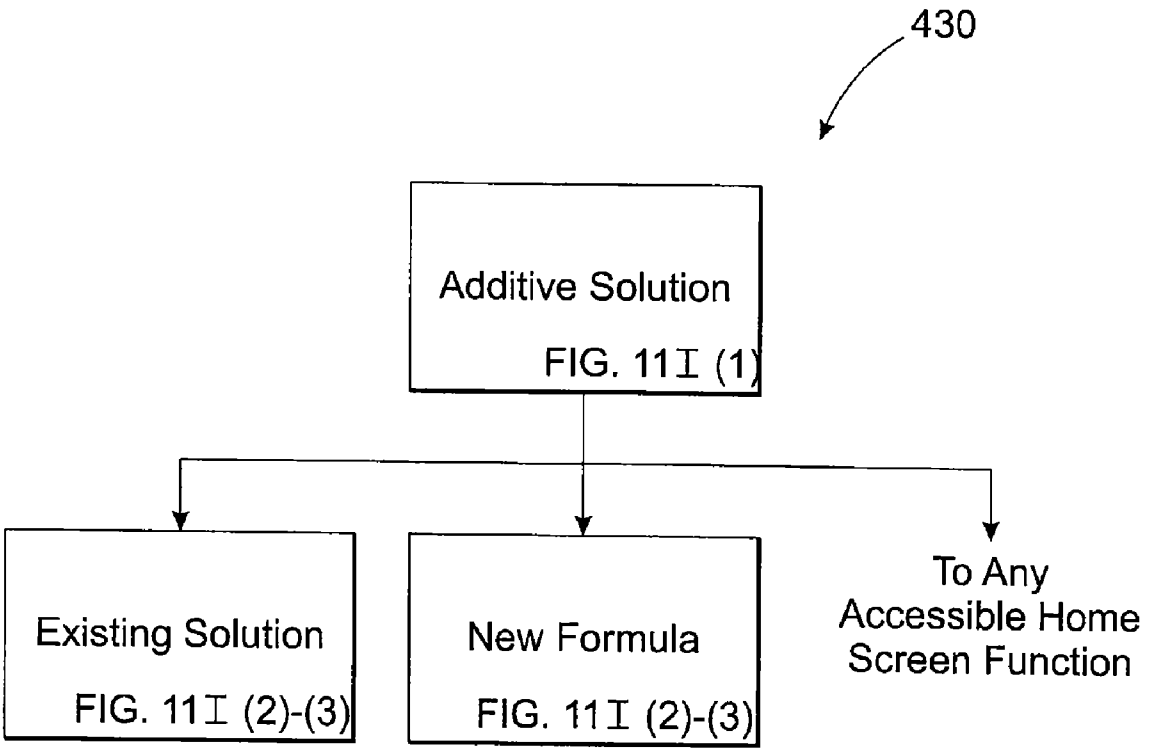

430
Additive Solution
FIG. 11I (1)
Existing Solution
FIG. 11I (2)-(3)
New Formula
FIG. 11I (2)-(3)
To Any
Accessible Home
Screen Function

FIG. 10E

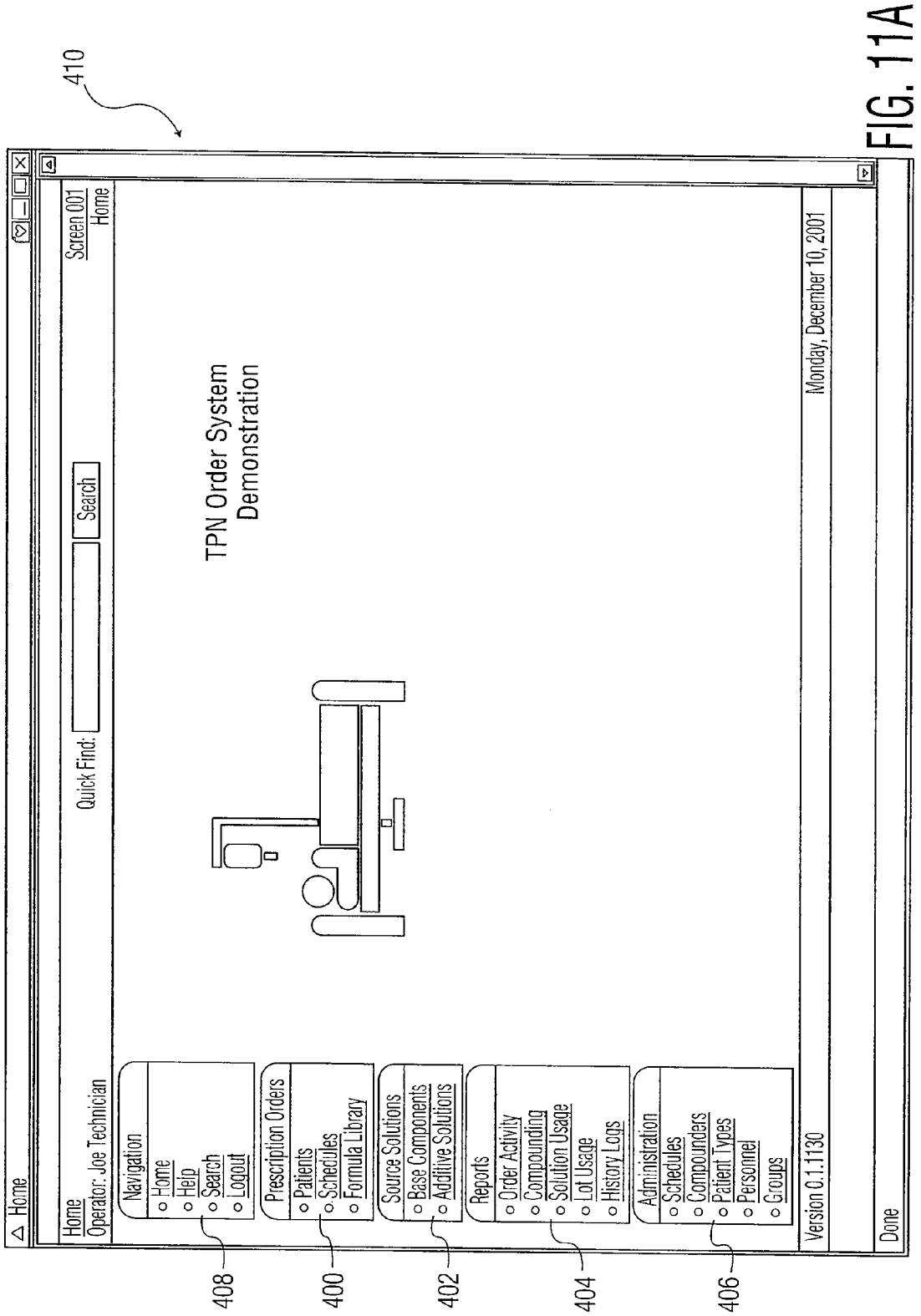

410
Home
Operator: Joe Technician
Quick Find:
Search
Screen 001
Home
TPN Order System
Demonstration
Navigation
Home
Help
Search
Logout
Prescription Orders
Patients
Schedules
Formula Library
Source Solutions
Base Components
Additive Solutions
Reports
Order Activity
Compounding
Solution Usage
Lot Usage
History Logs
Administration
Schedules
Compounders
Patient Types
Personnel
Groups
Monday, December 10, 2001
Version 0.1.1130
Done
408
400
402
404
406

FIG. 11A

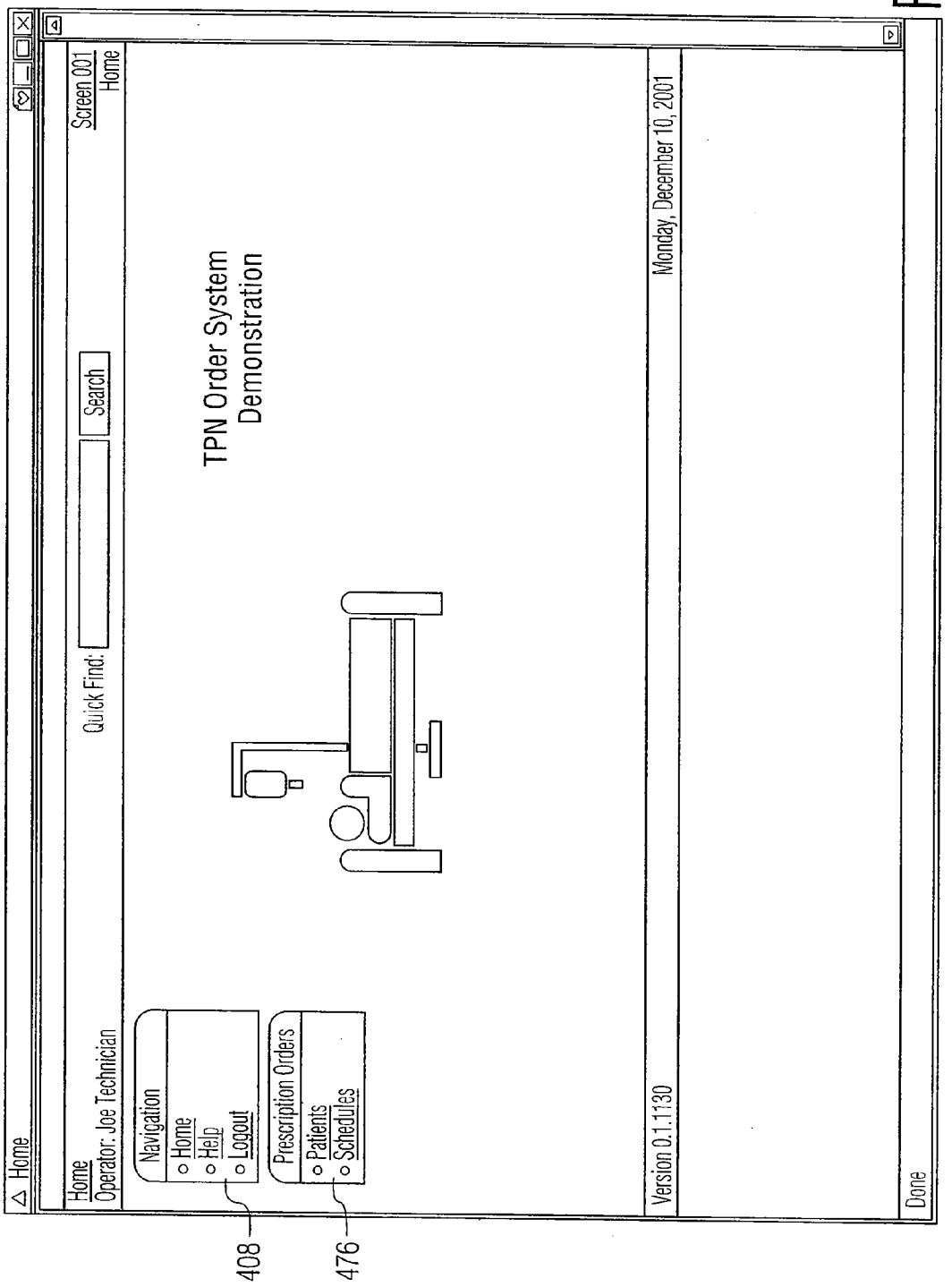

410'
Home
Home
Operator: Joe Technician
Screen 001
Home
Quick Find:
Search
TPN Order System
Demonstration
Navigation
Home
Help
Logout
Prescription Orders
Patients
Schedules
Monday, December 10, 2001
Version 0.1.1130
Done
408
476

FIG. 11B

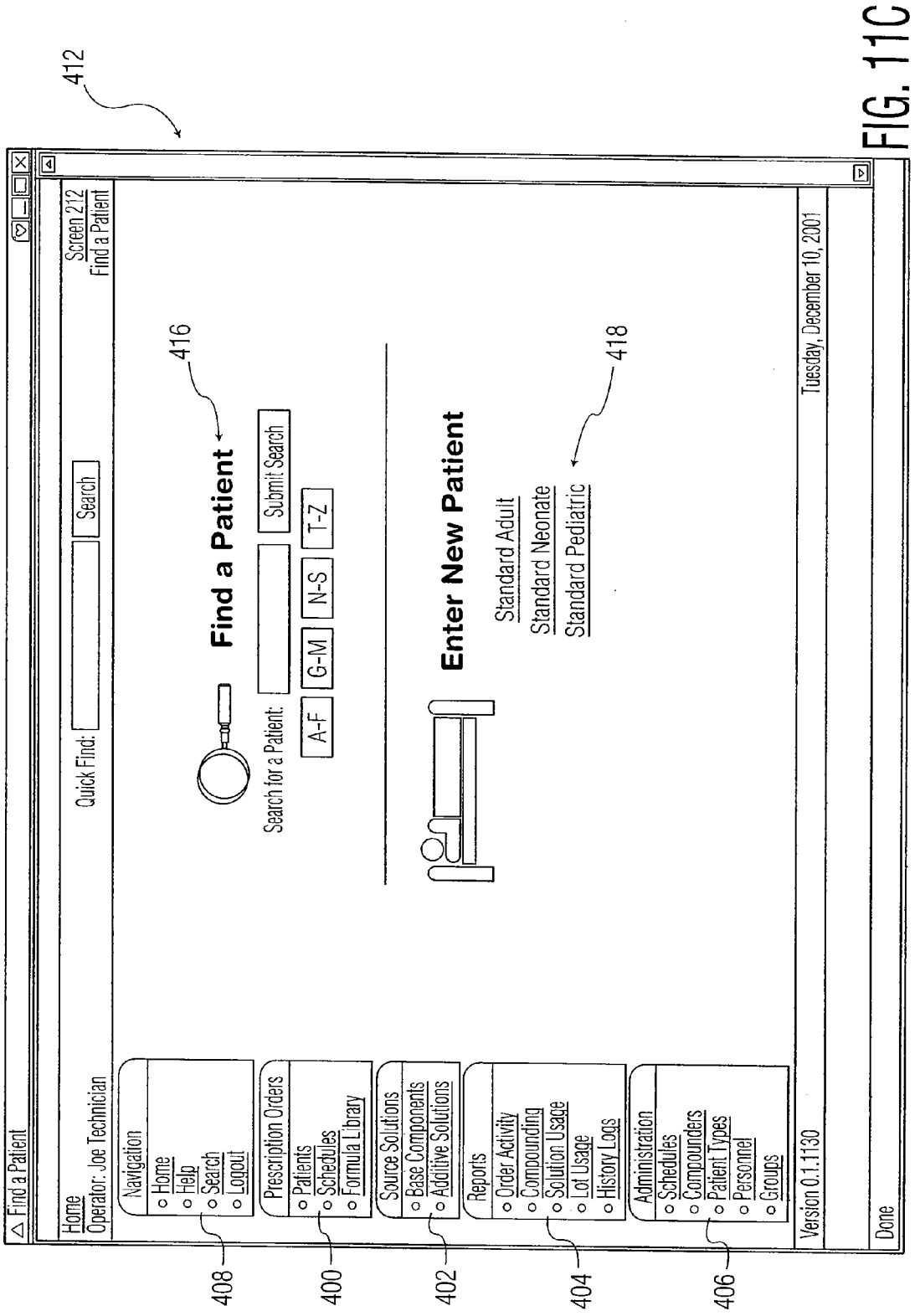

412
Find a Patient
Home
Operator: Joe Technician
Quick Find:
Search
Screen 212
Find a Patient
Navigation
Home
Help
Search
Logout
Prescription Orders
Patients
Schedules
Formula Library
Source Solutions
Base Components
Additive Solutions
Reports
Order Activity
Compounding
Solution Usage
Lot Usage
History Logs
Administration
Schedules
Compounders
Patient Types
Personnel
Groups
416
Find a Patient
Search for a Patient:
Submit Search
A-F
G-M
N-S
T-Z
Enter New Patient
418
Standard Adult
Standard Neonate
Standard Pediatric
Tuesday, December 10, 2001
Version 0.1.1130
Done
408
400
402
404
406

FIG. 11C

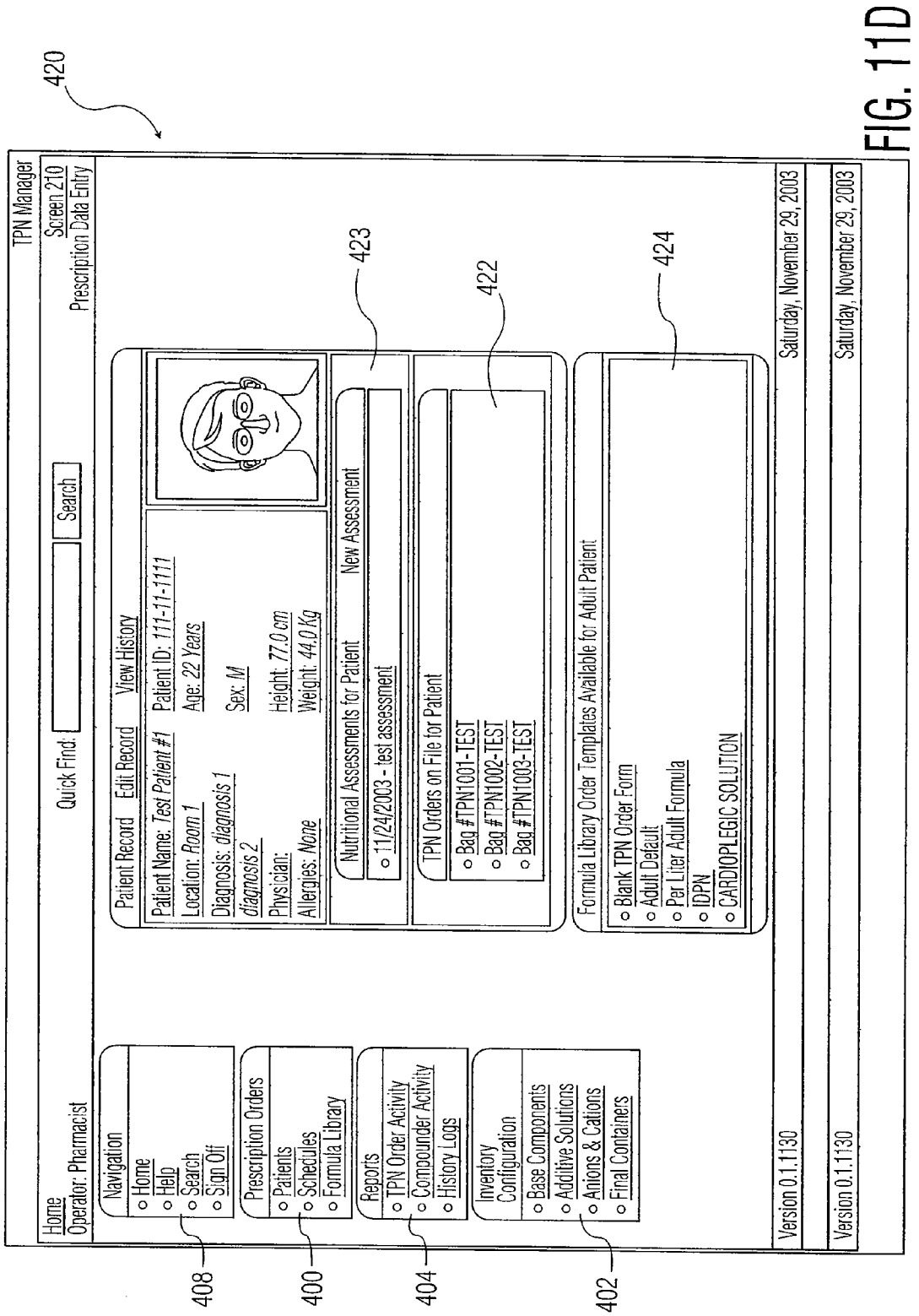

420
TPN Manager
Home
Operator: Pharmacist
Quick Find:
Search
Screen 210
Prescription Data Entry
Navigation
Home
Help
Search
Sign Off
Prescription Orders
Patients
Schedules
Formula Library
Reports
TPN Order Activity
Compounder Activity
History Logs
Inventory Configuration
Base Components
Additive Solutions
Anions & Cations
Final Containers
Patient Record
Edit Record
View History
Patient Name: Test Patient #1
Location: Room 1
Diagnosis: diagnosis 1
diagnosis 2
Physician:
Allergies: None
Patient ID: 111-11-1111
Age: 22 Years
Sex: M
Height: 77.0 cm
Weight: 44.0 Kg
Nutritional Assessments for Patient
New Assessment
11/24/2003 - test assessment
TPN Orders on File for Patient
Bag #TPN1001-TEST
Bag #TPN1002-TEST
Bag #TPN1003-TEST
Formula Library Order Templates Available for Adult Patient
Blank TPN Order Form
Adult Default
Per Liter Adult Formula
IDPN
CARDIOPLEGIC SOLUTION
Version 0.1.1130
Saturday, November 29, 2003
Version 0.1.1130
Saturday, November 29, 2003
423
422
424
408
400
404
402

FIG. 11D

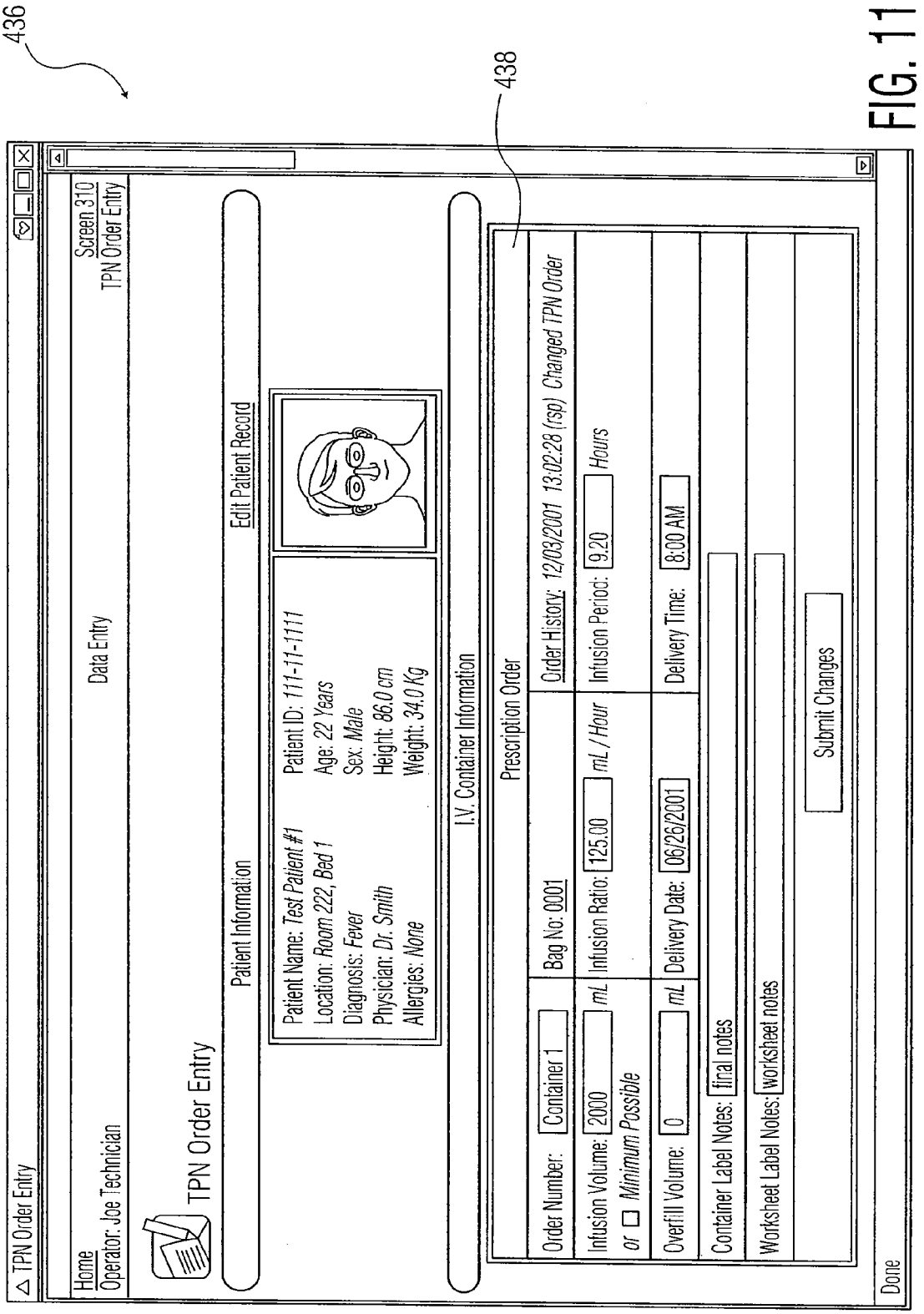

436
438
TPN Order Entry
Home
Operator: Joe Technician
Data Entry
Screen 310
TPN Order Entry
Patient Information
Edit Patient Record
Patient Name: Test Patient #1
Location: Room 222, Bed 1
Diagnosis: Fever
Physician: Dr. Smith
Allergies: None
Patient ID: 111-11-1111
Age: 22 Years
Sex: Male
Height: 86.0 cm
Weight: 34.0 Kg
I.V. Container Information
Prescription Order
Order Number: Container 1
Bag No: 0001
Order History: 12/03/2001 13:02:28 (rsp) Changed TPN Order
Infusion Volume: 2000 mL
or ☐ Minimum Possible
Infusion Ratio: 125.00 mL / Hour
Infusion Period: 9.20 Hours
Overfill Volume: 0 mL
Delivery Date: 06/26/2001
Delivery Time: 8:00 AM
Container Label Notes: final notes
Worksheet Label Notes: worksheet notes
Submit Changes
Done

FIG. 11E(1)

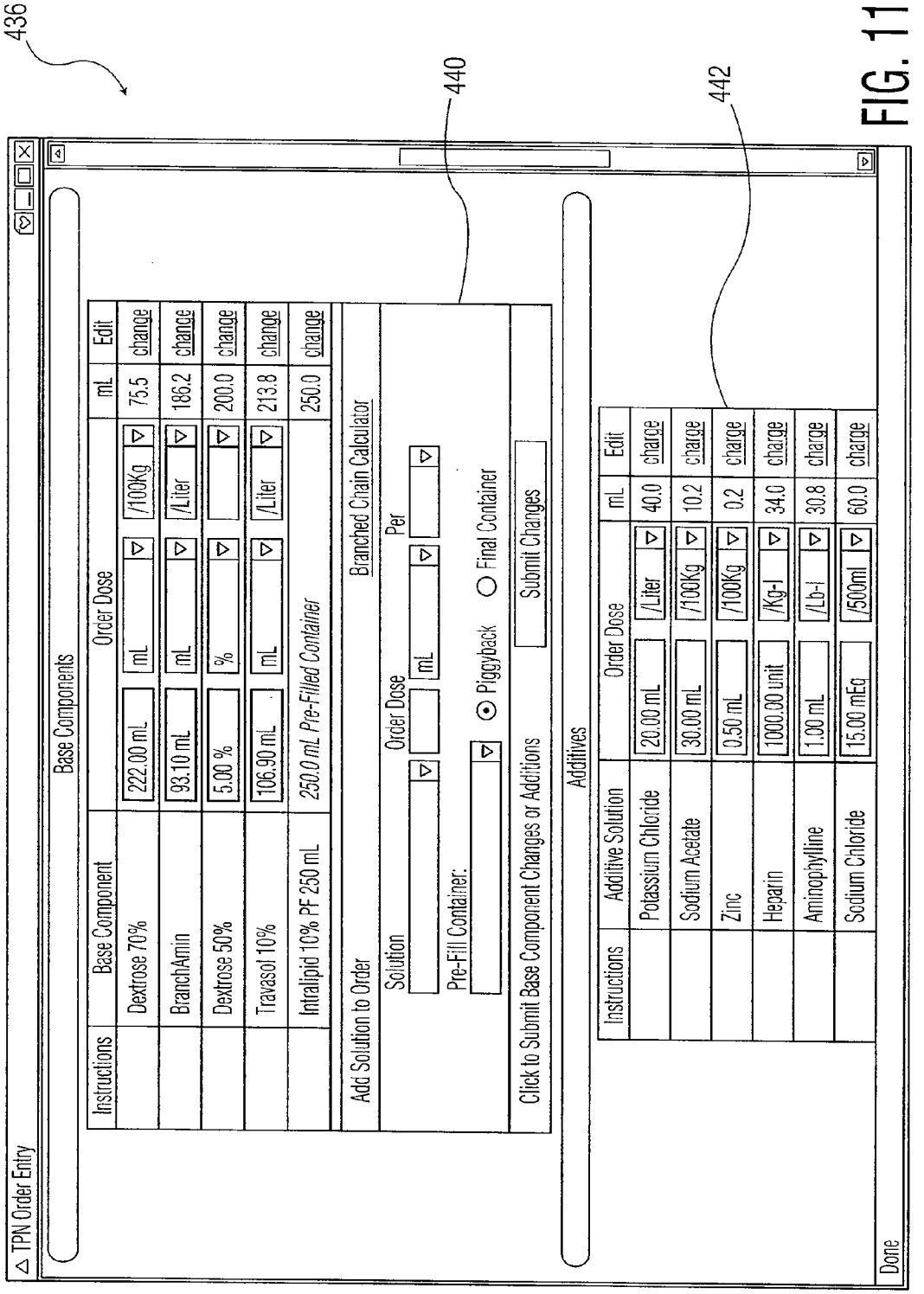

436
440
442
TPN Order Entry
Base Components
Instructions
Base Component
Order Dose
mL
Edit
Dextrose 70%
222.00 mL
mL
/100Kg
75.5
change
BranchAmin
93.10 mL
mL
/Liter
186.2
change
Dextrose 50%
5.00 %
%
200.0
change
Travasol 10%
106.90 mL
mL
/Liter
213.8
change
Intralipid 10% PF 250 mL
250.0 mL Pre-Filled Container
250.0
change
Add Solution to Order
Branched Chain Calculator
Solution
Order Dose
Per
mL
Pre-Fill Container:
Piggyback
Final Container
Click to Submit Base Component Changes or Additions
Submit Changes
Additives
Instructions
Additive Solution
Order Dose
mL
Edit
Potassium Chloride
20.00 mL
/Liter
40.0
charge
Sodium Acetate
30.00 mL
/100Kg
10.2
charge
Zinc
0.50 mL
/100Kg
0.2
charge
Heparin
1000.00 unit
/Kg-I
34.0
charge
Aminophylline
1.00 mL
/Lb-I
30.8
charge
Sodium Chloride
15.00 mEq
/500ml
60.0
charge
Done

FIG. 11E(2)

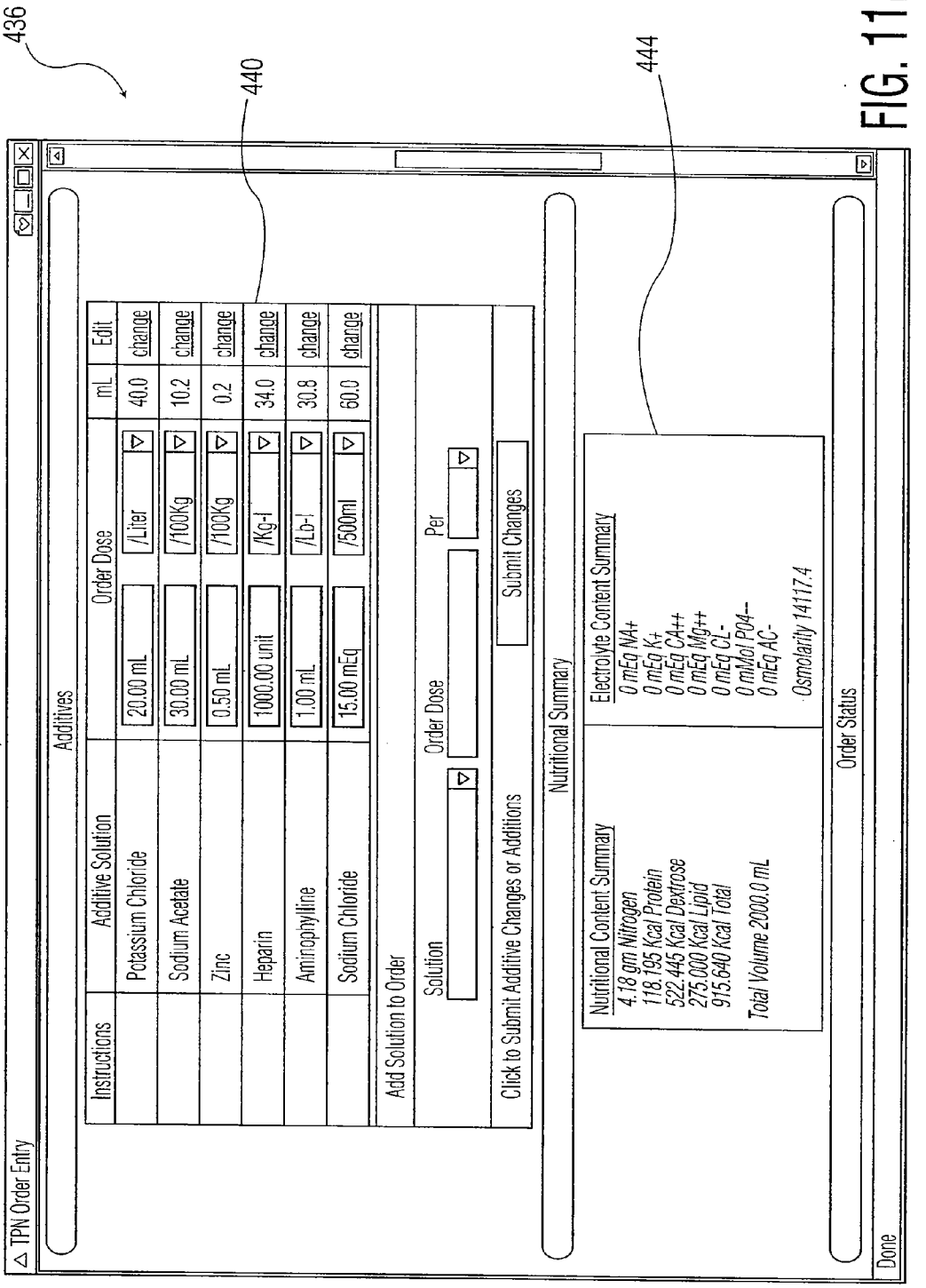

436
440
444
TPN Order Entry
Additives
Instructions
Additive Solution
Order Dose
mL
Edit
Potassium Chloride
20.00 mL
/Liter
40.0
change
Sodium Acetate
30.00 mL
/100Kg
10.2
change
Zinc
0.50 mL
/100Kg
0.2
change
Heparin
1000.00 unit
/Kg-I
34.0
change
Aminophylline
1.00 mL
/Lb-I
30.8
change
Sodium Chloride
15.00 mEq
/500ml
60.0
change
Add Solution to Order
Solution
Order Dose
Per
Click to Submit Additive Changes or Additions
Submit Changes
Nutritional Summary
Nutritional Content Summary
4.18 gm Nitrogen
118.195 Kcal Protein
522.445 Kcal Dextrose
275.000 Kcal Lipid
915.640 Kcal Total
Total Volume 20000.0 mL
Electrolyte Content Summary
0 mEq NA+
0 mEq K+
0 mEq CA++
0 mEq Mg++
0 mEq CL-
0 mMol PO4--
0 mEq AC-
Osmolarity 14117.4
Order Status
Done

FIG. 11E(3)

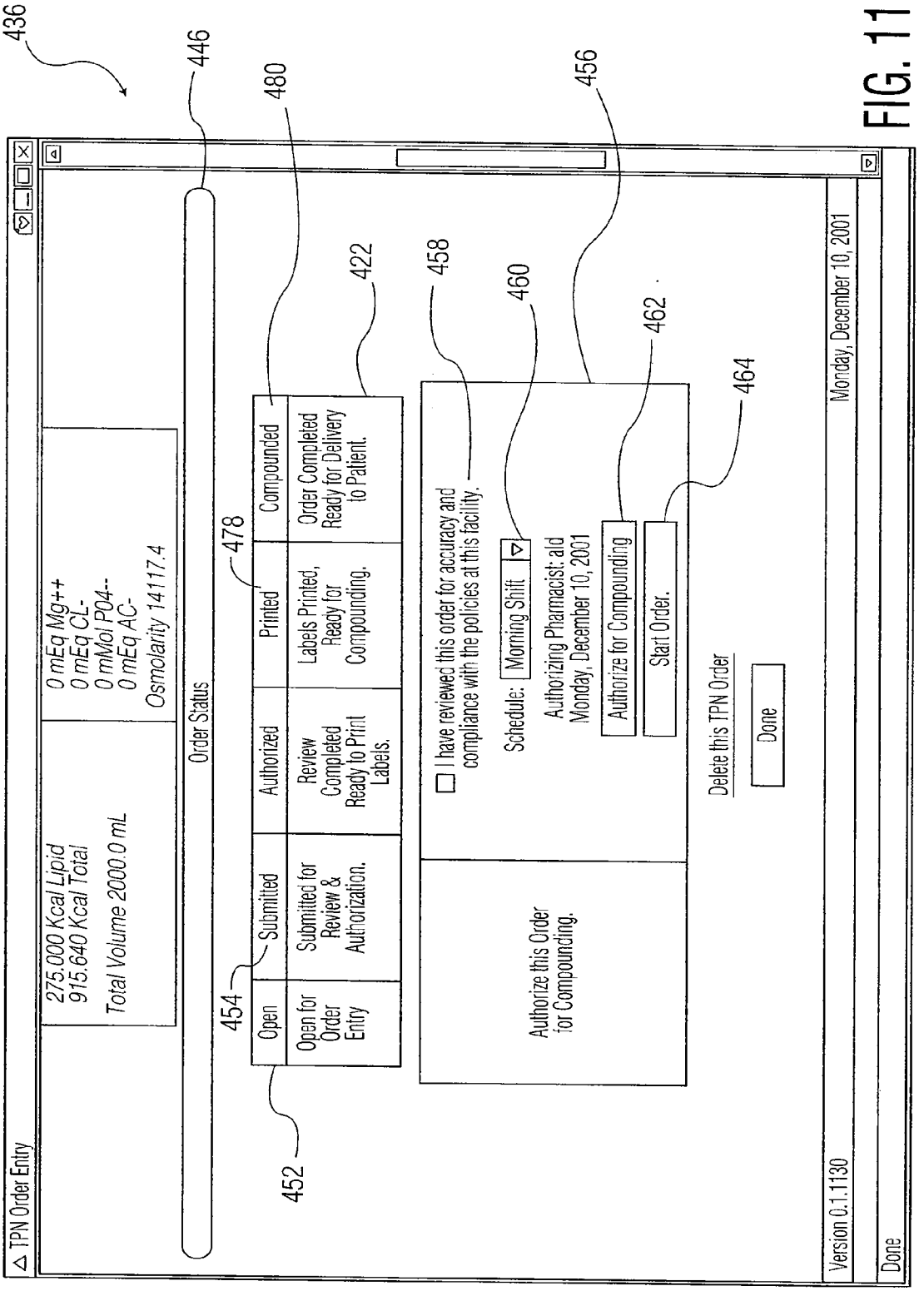

436
446
480
456
422
458
460
462
464
478
454
452
TPN Order Entry
275.000 Kcal Lipid
915.640 Kcal Total
Total Volume 2000.0 mL
0 mEq Mg++
0 mEq CL-
0 mMol PO4--
0 mEq AC-
Osmolarity 14117.4
Order Status
Open
Submitted
Authorized
Printed
Compounded
Open for Order Entry
Submitted for Review & Authorization.
Review Completed Ready to Print Labels.
Labels Printed, Ready for Compounding.
Order Completed Ready for Delivery to Patient.
I have reviewed this order for accuracy and compliance with the policies at this facility.
Schedule: Morning Shift
Authorizing Pharmacist: ald
Monday, December 10, 2001
Authorize for Compounding
Start Order.
Authorize this Order for Compounding.
Delete this TPN Order
Done
Version 0.1.1130
Monday, December 10, 2001
Done

FIG. 11E(4)

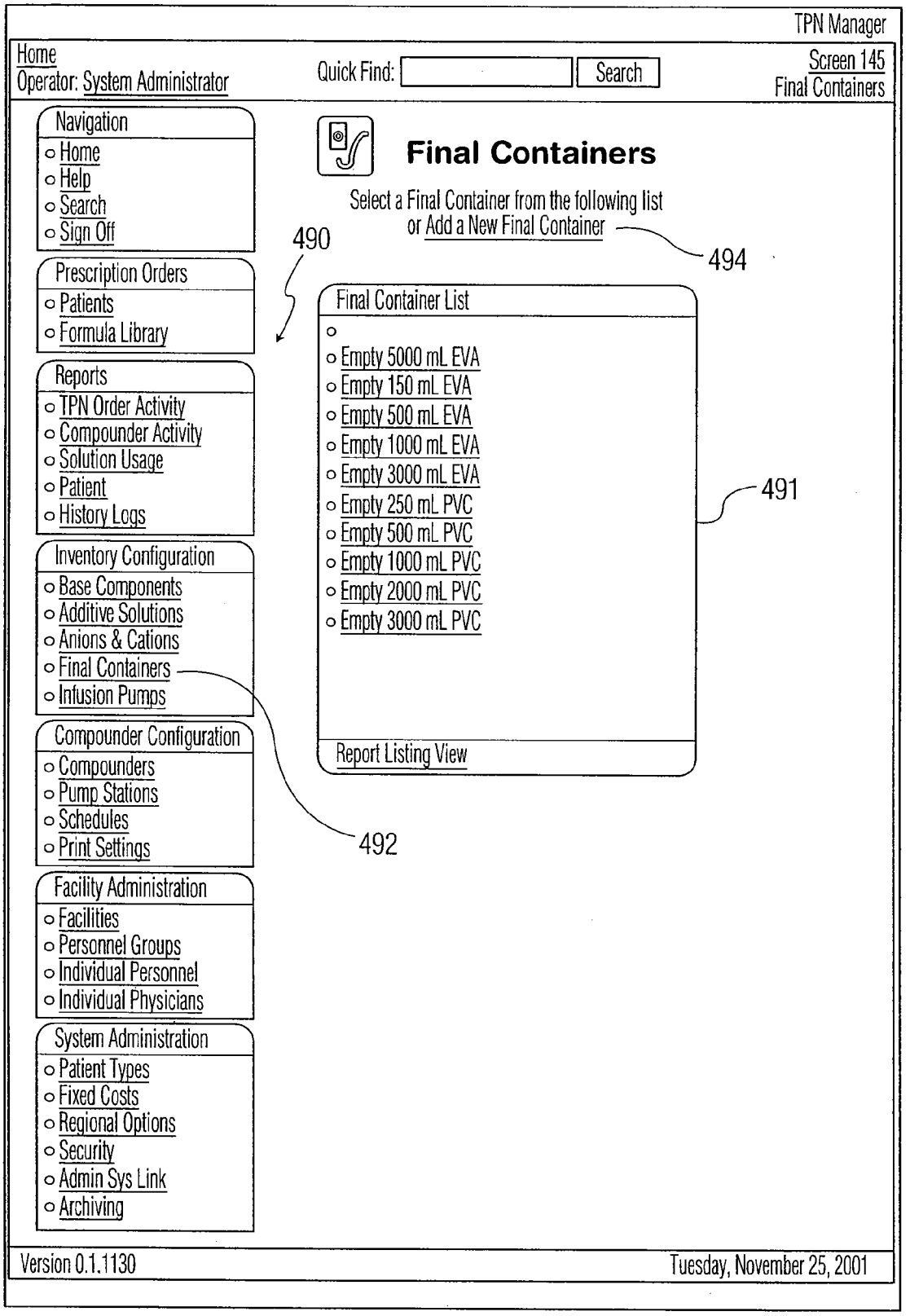

TPN Manager
Home
Operator: System Administrator
Quick Find:
Search
Screen 145
Final Containers
Navigation
Home
Help
Search
Sign Off
Prescription Orders
Patients
Formula Library
Reports
TPN Order Activity
Compounder Activity
Solution Usage
Patient
History Logs
Inventory Configuration
Base Components
Additive Solutions
Anions & Cations
Final Containers
Infusion Pumps
Compounder Configuration
Compounders
Pump Stations
Schedules
Print Settings
Facility Administration
Facilities
Personnel Groups
Individual Personnel
Individual Physicians
System Administration
Patient Types
Fixed Costs
Regional Options
Security
Admin Sys Link
Archiving
Final Containers
Select a Final Container from the following list
or Add a New Final Container
490
494
Final Container List
Empty 5000 mL EVA
Empty 150 mL EVA
Empty 500 mL EVA
Empty 1000 mL EVA
Empty 3000 mL EVA
Empty 250 mL PVC
Empty 500 mL PVC
Empty 1000 mL PVC
Empty 2000 mL PVC
Empty 3000 mL PVC
491
Report Listing View
492
Version 0.1.1130
Tuesday, November 25, 2001

FIG. 11E(5)

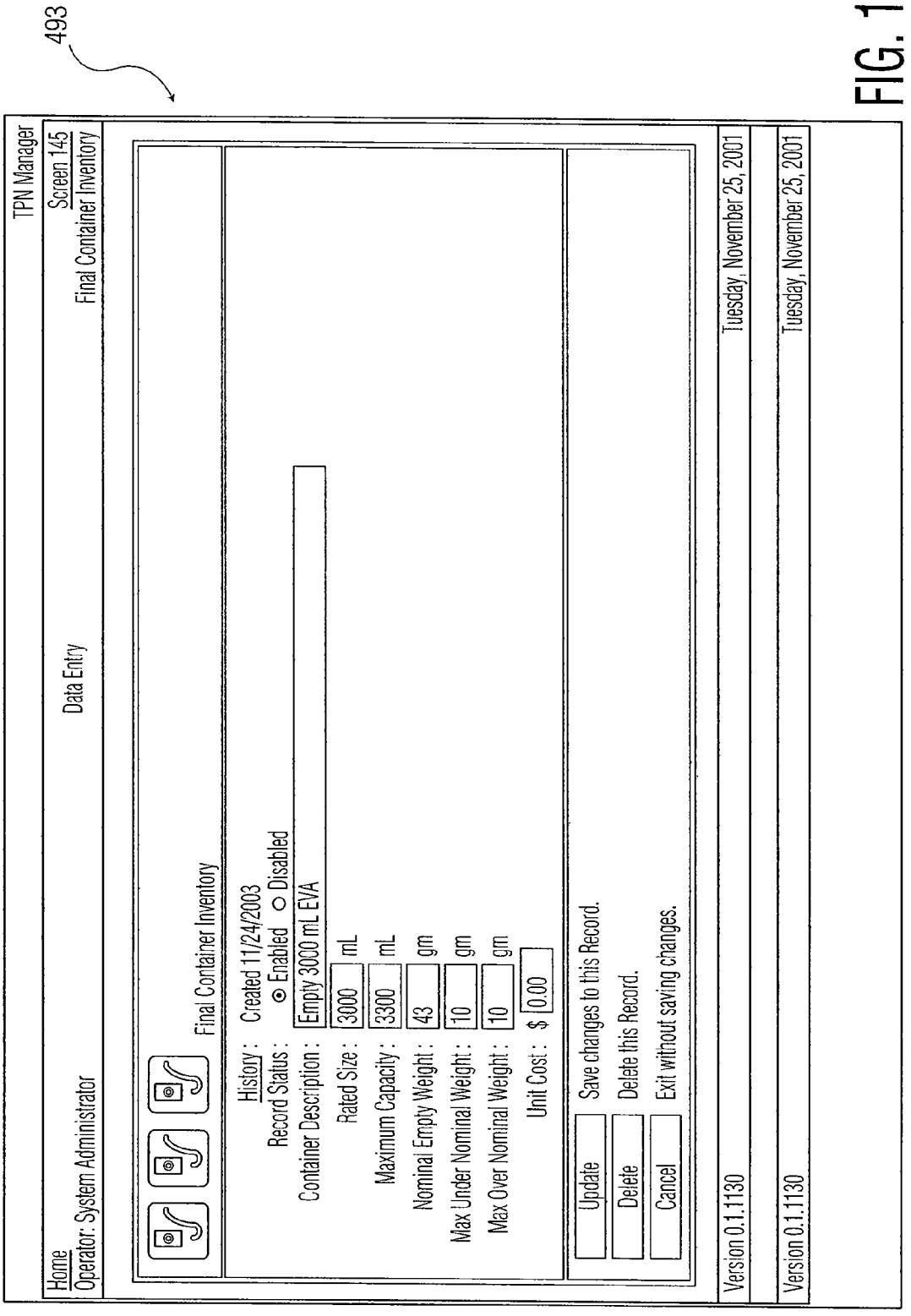

493
TPN Manager
Home
Operator: System Administrator
Data Entry
Screen 145
Final Container Inventory
Final Container Inventory
History : Created 11/24/2003
Record Status : Enabled Disabled
Container Description : Empty 3000 mL EVA
Rated Size : 3000 mL
Maximum Capacity : 3300 mL
Nominal Empty Weight : 43 gm
Max Under Nominal Weight : 10 gm
Max Over Nominal Weight : 10 gm
Unit Cost : $ 0.00
Update
Save changes to this Record.
Delete
Delete this Record.
Cancel
Exit without saving changes.
Version 0.1.1130
Tuesday, November 25, 2001
Version 0.1.1130
Tuesday, November 25, 2001

FIG. 11E(6)

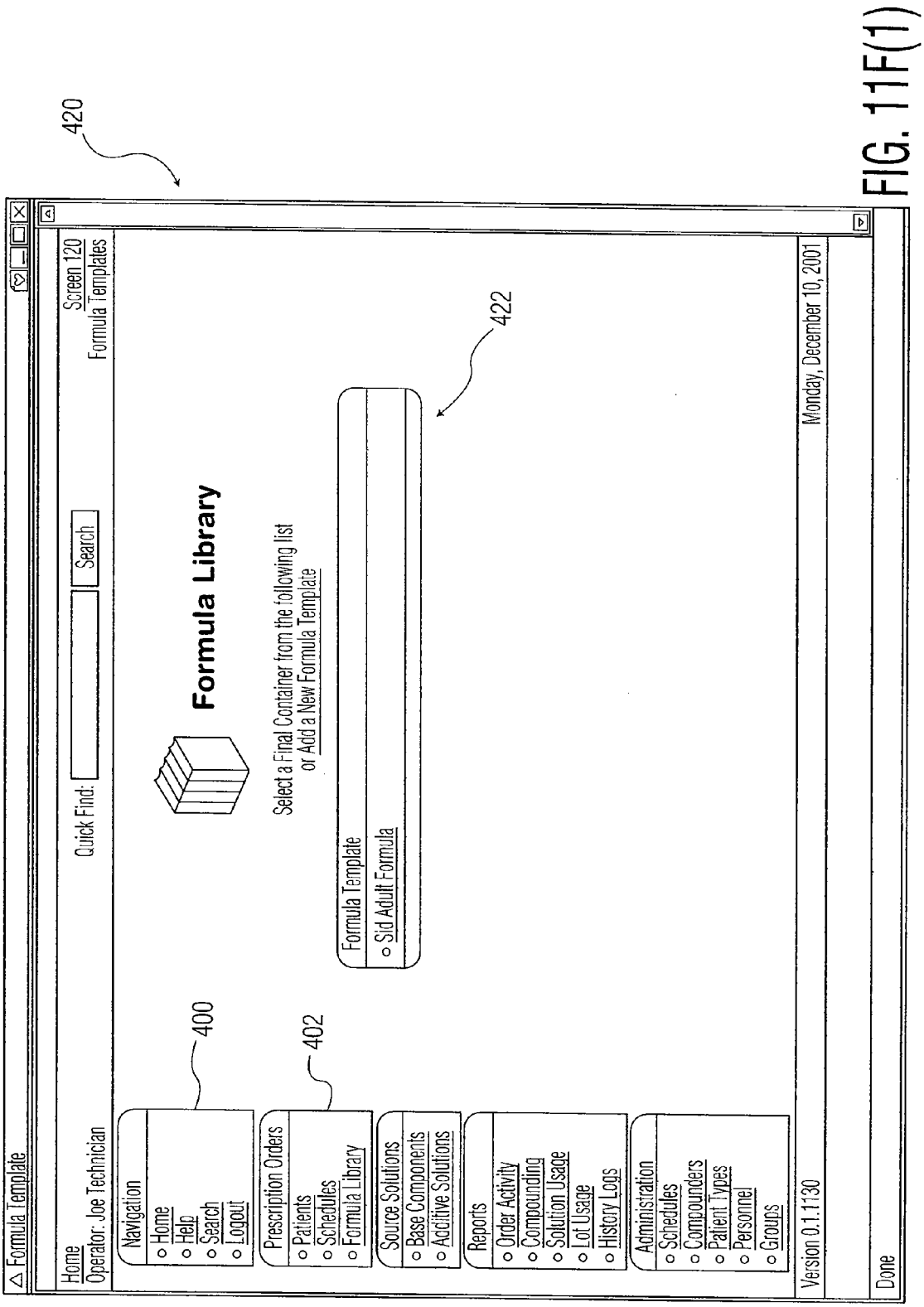

420
Formula Template
Home
Operator: Joe Technician
Quick Find:
Search
Screen 120
Formula Templates
Formula Library
Select a Final Container from the following list
or Add a New Formula Template
422
Formula Template
Sid Adult Formula
400
Navigation
Home
Help
Search
Logout
402
Prescription Orders
Patients
Schedules
Formula Library
Source Solutions
Base Components
Additive Solutions
Reports
Order Activity
Compounding
Solution Usage
Lot Usage
History Logs
Administration
Schedules
Compounders
Patient Types
Personnel
Groups
Version 0.1.1130
Monday, December 10, 2001
Done

FIG. 11F(1)

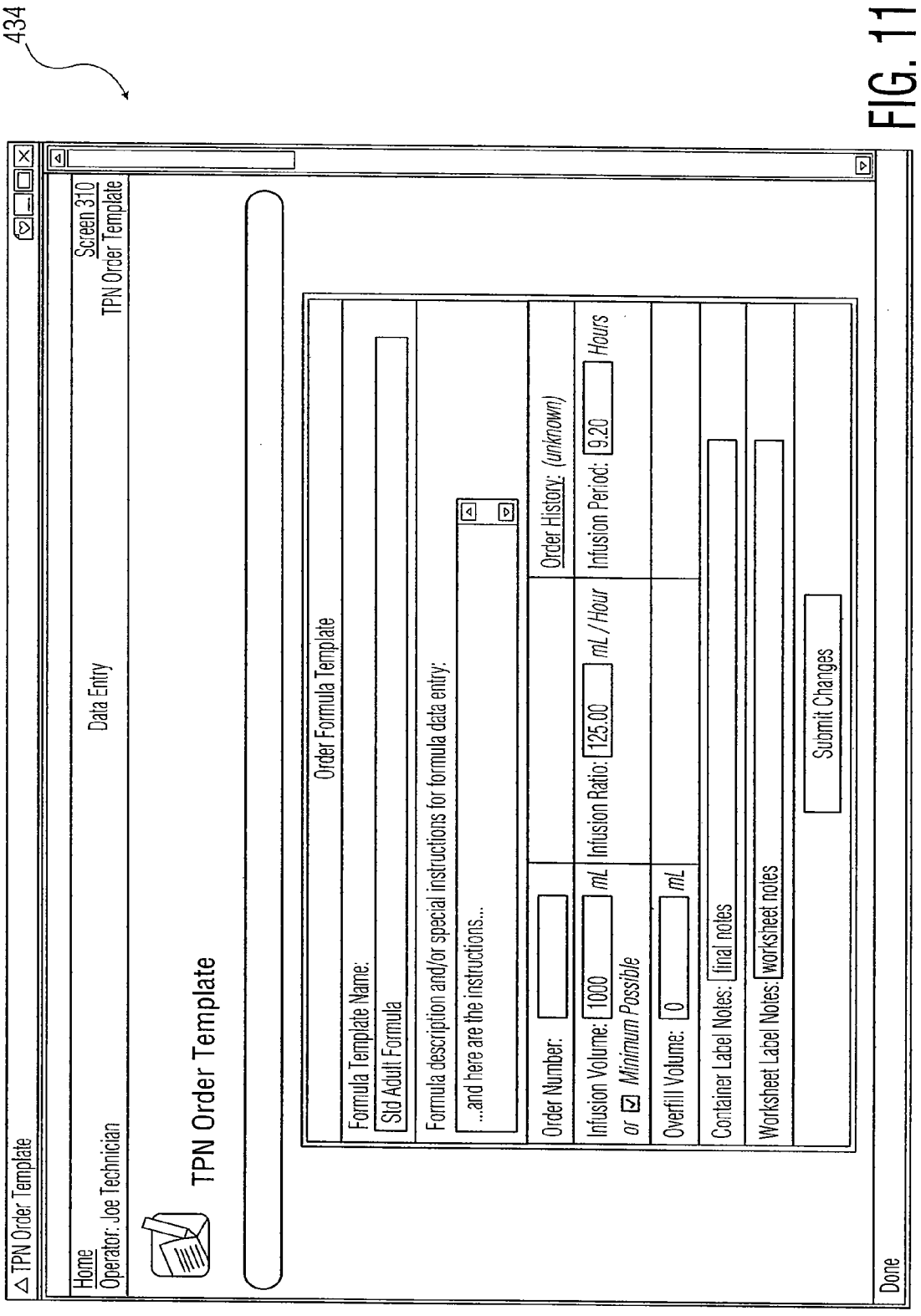

434
TPN Order Template
Home
Operator: Joe Technician
Data Entry
Screen 310
TPN Order Template
TPN Order Template
Order Formula Template
Formula Template Name:
Std Adult Formula
Formula description and/or special instructions for formula data entry:
...and here are the instructions...
Order Number:
Order History: (unknown)
Infusion Volume: 1000 mL
or Minimum Possible
Infusion Ratio: 125.00 mL / Hour
Infusion Period: 9.20 Hours
Overfill Volume: 0 mL
Container Label Notes: final notes
Worksheet Label Notes: worksheet notes
Submit Changes
Done

FIG. 11F(2)

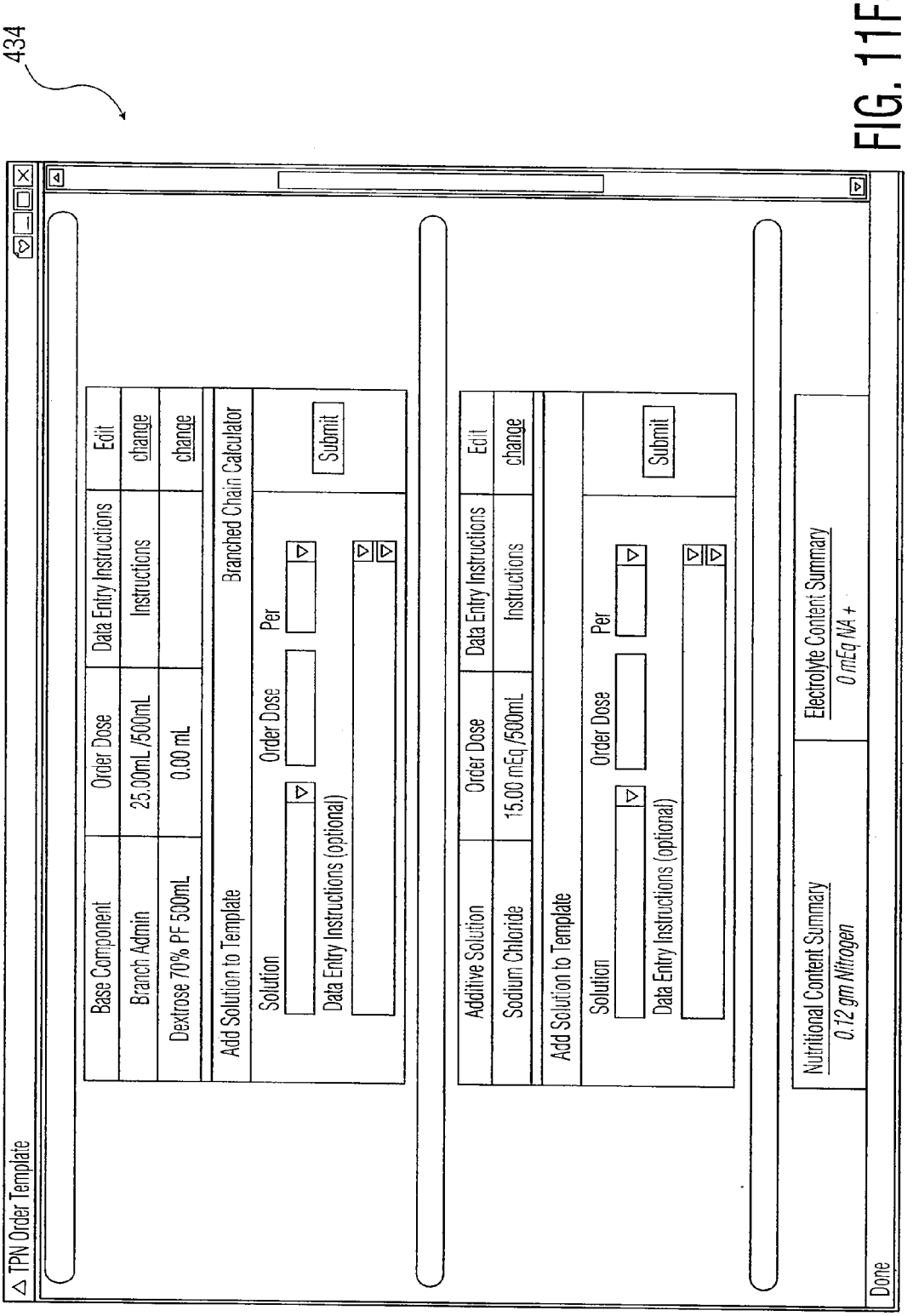

434
TPN Order Template
Base Component
Order Dose
Data Entry Instructions
Edit
Branch Admin
25.00mL /500mL
Instructions
change
Dextrose 70% PF 500mL
0.00 mL
change
Add Solution to Template
Branched Chain Calculator
Solution
Order Dose
Per
Data Entry Instructions (optional)
Submit
Additive Solution
Order Dose
Data Entry Instructions
Edit
Sodium Chloride
15.00 mEq /500mL
Instructions
change
Add Solution to Template
Solution
Order Dose
Per
Data Entry Instructions (optional)
Submit
Nutritional Content Summary
0.12 gm Nitrogen
Electrolyte Content Summary
0 mEq NA +
Done

FIG. 11F(3)

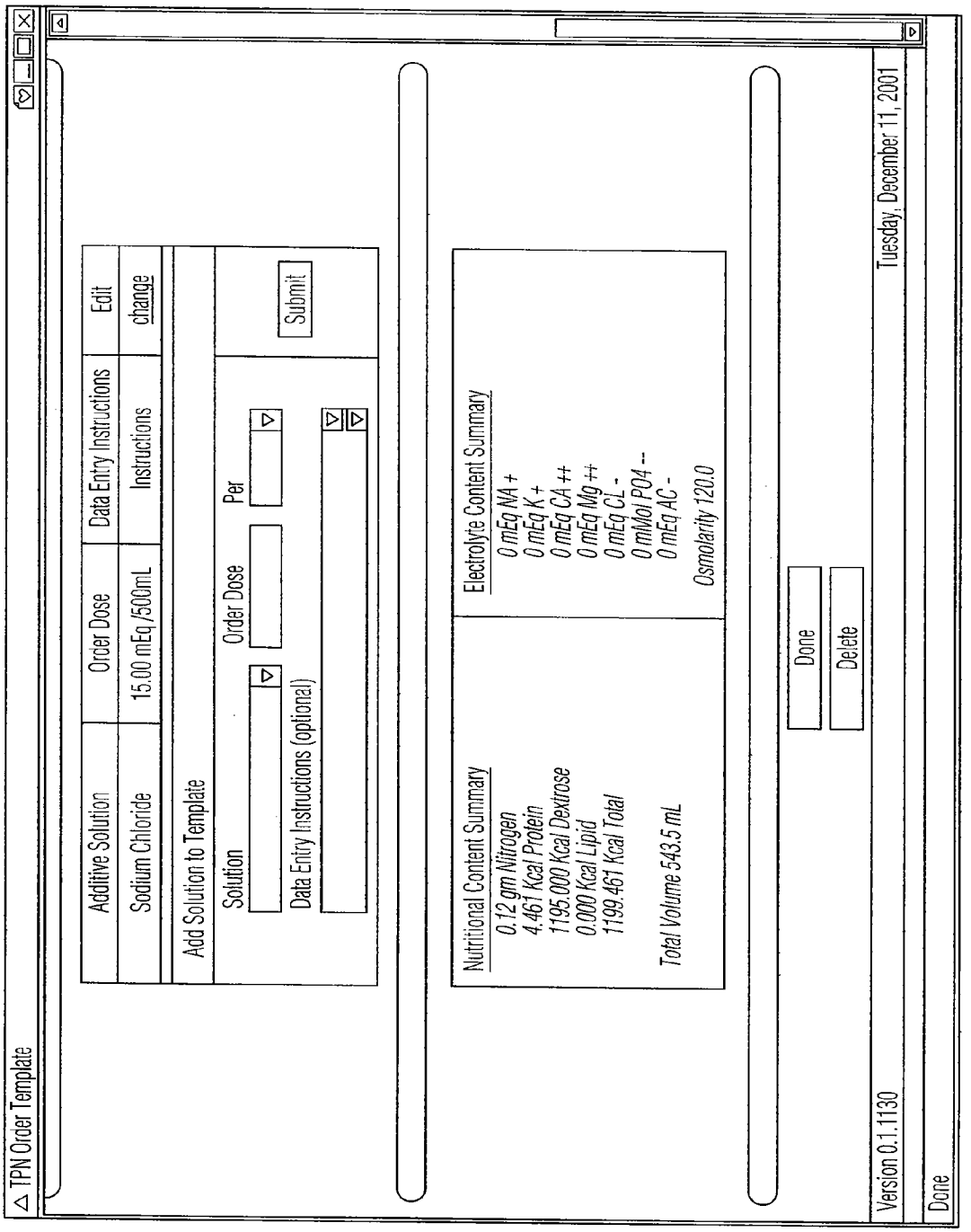

434
TPN Order Template
Additive Solution
Order Dose
Data Entry Instructions
Edit
Sodium Chloride
15.00 mEq /500mL
Instructions
change
Add Solution to Template
Solution
Order Dose
Per
Submit
Data Entry Instructions (optional)
Nutritional Content Summary
0.12 gm Nitrogen
4.461 Kcal Protein
1195.000 Kcal Dextrose
0.000 Kcal Lipid
1199.461 Kcal Total
Total Volume 543.5 mL
Electrolyte Content Summary
0 mEq NA +
0 mEq K +
0 mEq CA ++
0 mEq Mg ++
0 mEq CL -
0 mMol PO4 --
0 mEq AC -
Osmolarity 120.0
Done
Delete
Version 0.1.1130
Tuesday, December 11, 2001
Done

FIG. 11F(4)

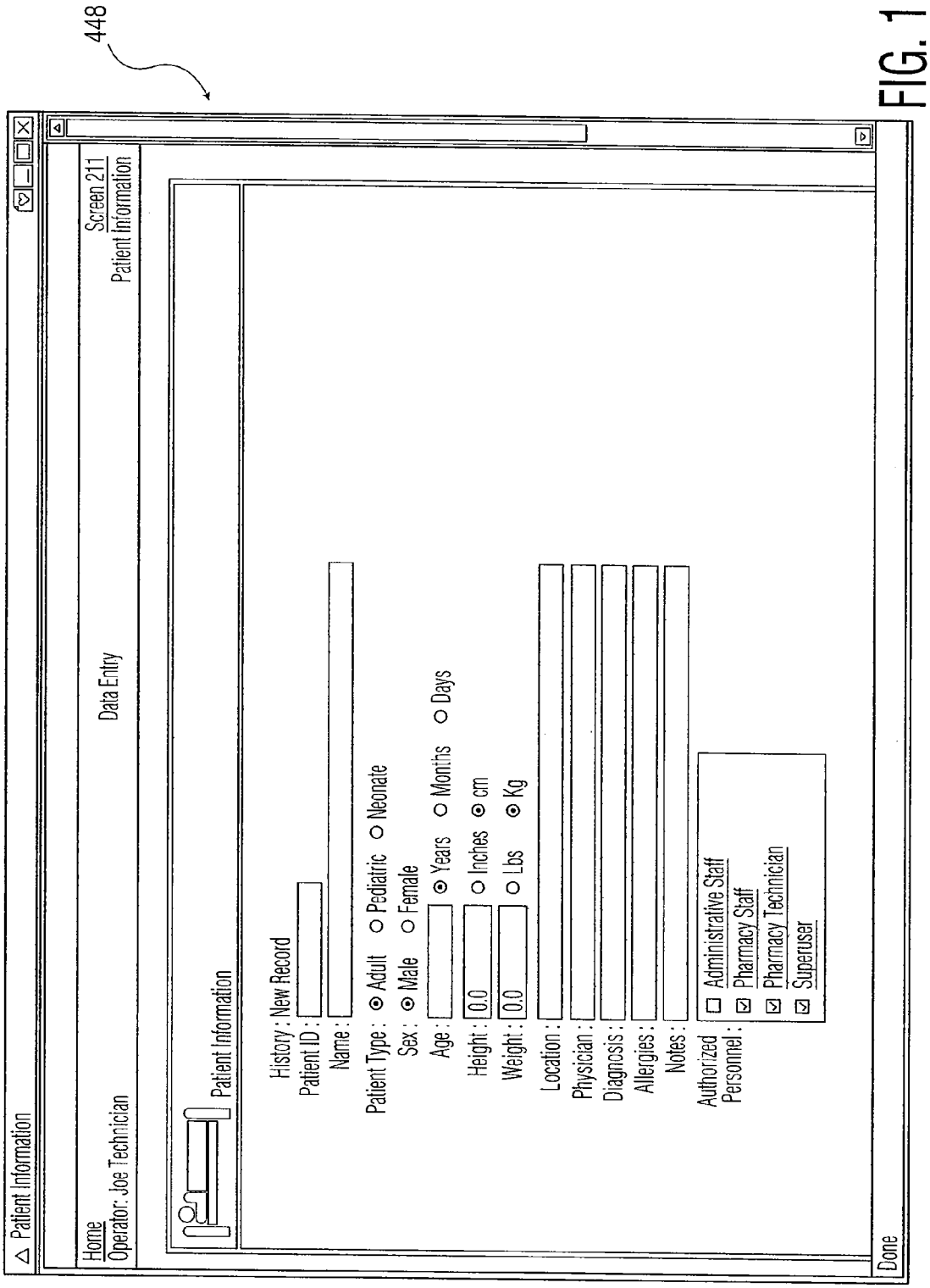

448
Patient Information
Home
Operator: Joe Technician
Data Entry
Screen 211
Patient Information
Patient Information
History: New Record
Patient ID:
Name:
Patient Type: Adult Pediatric Neonate
Sex: Male Female
Age: Years Months Days
Height: 0.0 Inches cm
Weight: 0.0 Lbs Kg
Location:
Physician:
Diagnosis:
Allergies:
Notes:
Authorized Personnel:
Administrative Staff
Pharmacy Staff
Pharmacy Technician
Superusar
Done

FIG. 11G(1)

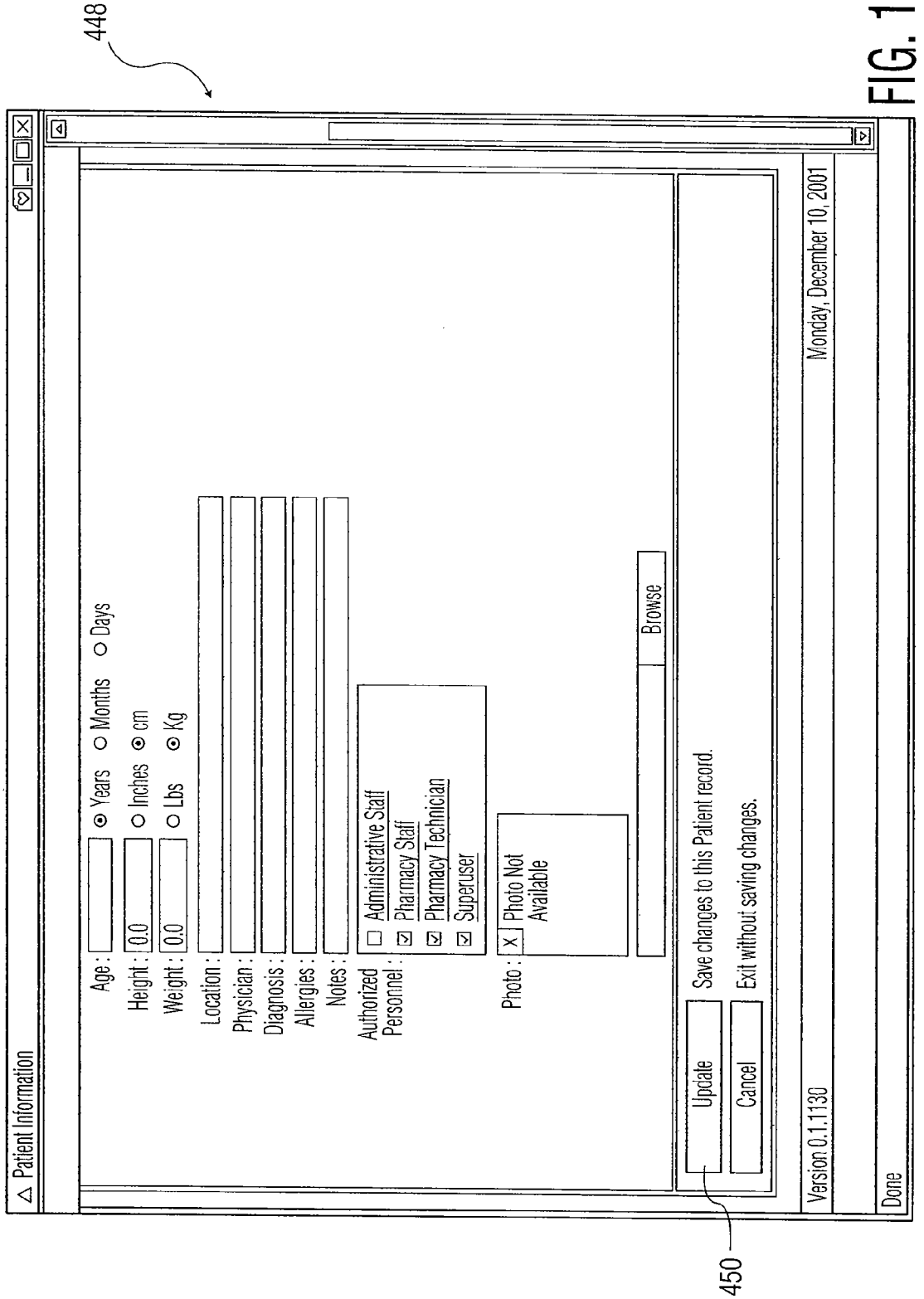

448
Patient Information
Age :
Years
Months
Days
Height : 0.0
Inches
cm
Weight : 0.0
Lbs
Kg
Location :
Physician :
Diagnosis :
Allergies :
Notes :
Authorized Personnel :
Administrative Staff
Pharmacy Staff
Pharmacy Technician
Superuser
Photo : X Photo Not Available
Browse
Update
Save changes to this Patient record.
Cancel
Exit without saving changes.
Version 0.1.1130
Monday, December 10, 2001
Done
450

FIG. 11G(2)

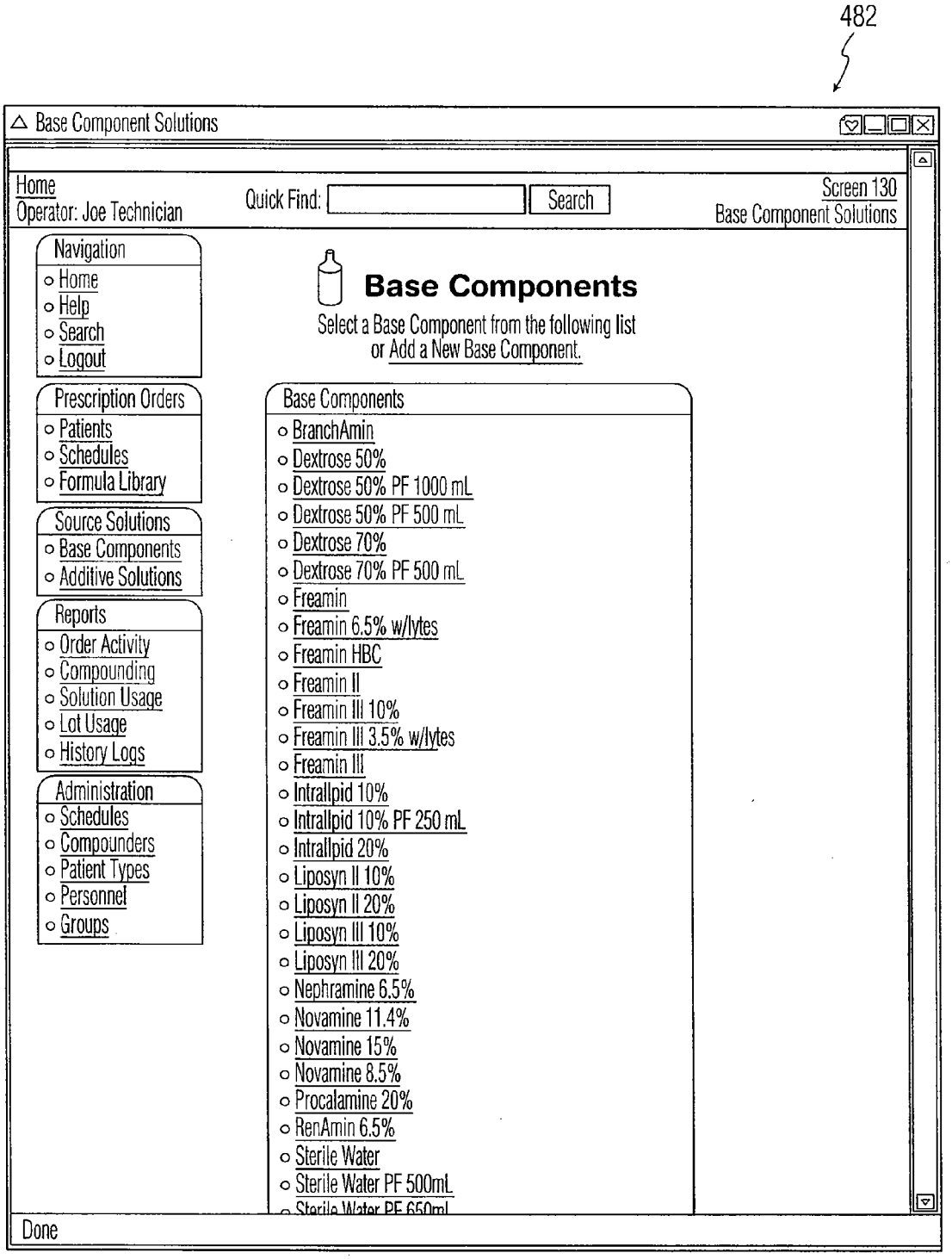

482
Base Component Solutions
Home
Operator: Joe Technician
Quick Find:
Search
Screen 130
Base Component Solutions
Navigation
Home
Help
Search
Logout
Prescription Orders
Patients
Schedules
Formula Library
Source Solutions
Base Components
Additive Solutions
Reports
Order Activity
Compounding
Solution Usage
Lot Usage
History Logs
Administration
Schedules
Compounders
Patient Types
Personnel
Groups
Base Components
Select a Base Component from the following list
or Add a New Base Component.
Base Components
BranchAmin
Dextrose 50%
Dextrose 50% PF 1000 mL
Dextrose 50% PF 500 mL
Dextrose 70%
Dextrose 70% PF 500 mL
Freamin
Freamin 6.5% w/lytes
Freamin HBC
Freamin II
Freamin III 10%
Freamin III 3.5% w/lytes
Freamin III
Intrallpid 10%
Intrallpid 10% PF 250 mL
Intrallpid 20%
Liposyn II 10%
Liposyn II 20%
Liposyn III 10%
Liposyn III 20%
Nephramine 6.5%
Novamine 11.4%
Novamine 15%
Novamine 8.5%
Procalamine 20%
RenAmin 6.5%
Sterile Water
Sterile Water PF 500mL
Done

FIG. 11H(1)

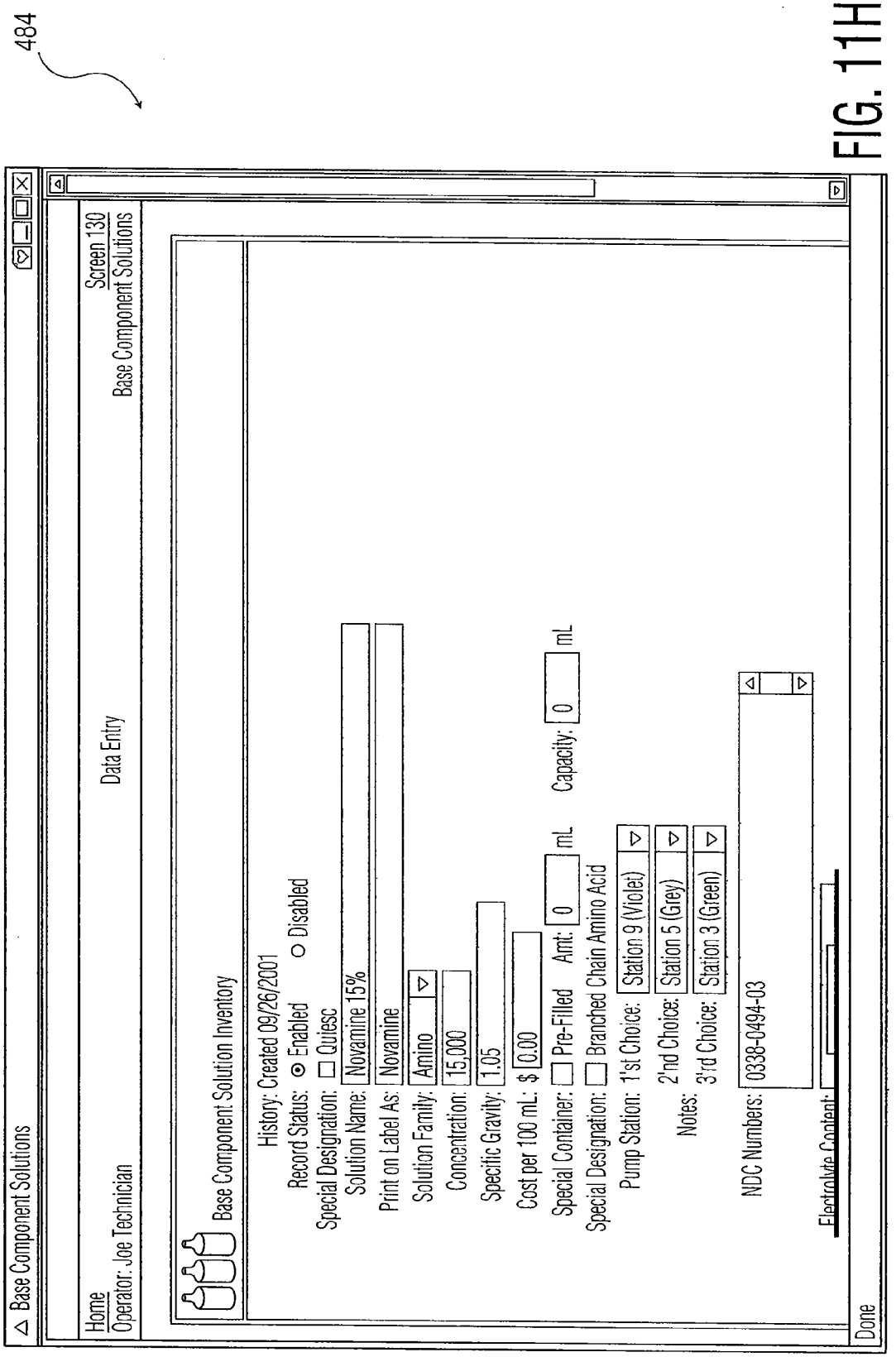

484
Base Component Solutions
Home
Operator: Joe Technician
Data Entry
Screen 130
Base Component Solutions
Base Component Solution Inventory
History: Created 09/26/2001
Record Status: Enabled Disabled
Special Designation: Quiesc
Solution Name: Novamine 15%
Print on Label As: Novamine
Solution Family: Amino
Concentration: 15.000
Specific Gravity: 1.05
Cost per 100 mL: $ 0.00
Special Container: Pre-Filled Amt: 0 mL Capacity: 0 mL
Special Designation: Branched Chain Amino Acid
Pump Station: 1st Choice: Station 9 (Violet)
2nd Choice: Station 5 (Grey)
Notes: 3rd Choice: Station 3 (Green)
NDC Numbers: 0338-0494-03
Electrolyte Content:
Done

FIG. 11H(2)

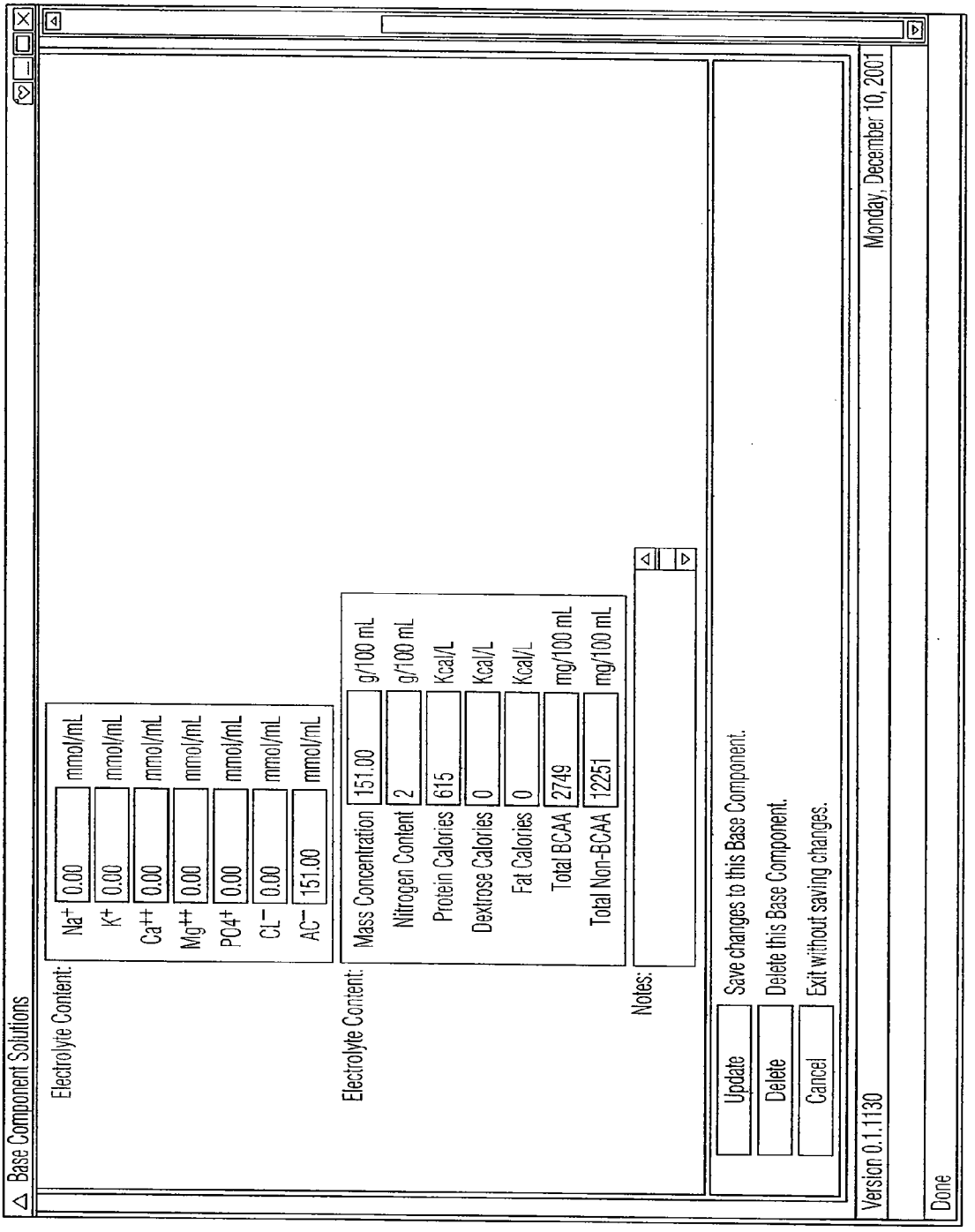

484
Base Component Solutions
Electrolyte Content:
Na+ 0.00 mmol/mL
K+ 0.00 mmol/mL
Ca++ 0.00 mmol/mL
Mg++ 0.00 mmol/mL
PO4+ 0.00 mmol/mL
CL− 0.00 mmol/mL
AC− 151.00 mmol/mL
Electrolyte Content:
Mass Concentration 151.00 g/100 mL
Nitrogen Content 2 g/100 mL
Protein Calories 615 Kcal/L
Dextrose Calories 0 Kcal/L
Fat Calories 0 Kcal/L
Total BCAA 2749 mg/100 mL
Total Non-BCAA 12251 mg/100 mL
Notes:
Update
Save changes to this Base Component.
Delete
Delete this Base Component.
Cancel
Exit without saving changes.
Version 0.1.1130
Monday, December 10, 2001
Done

FIG. 11H(3)

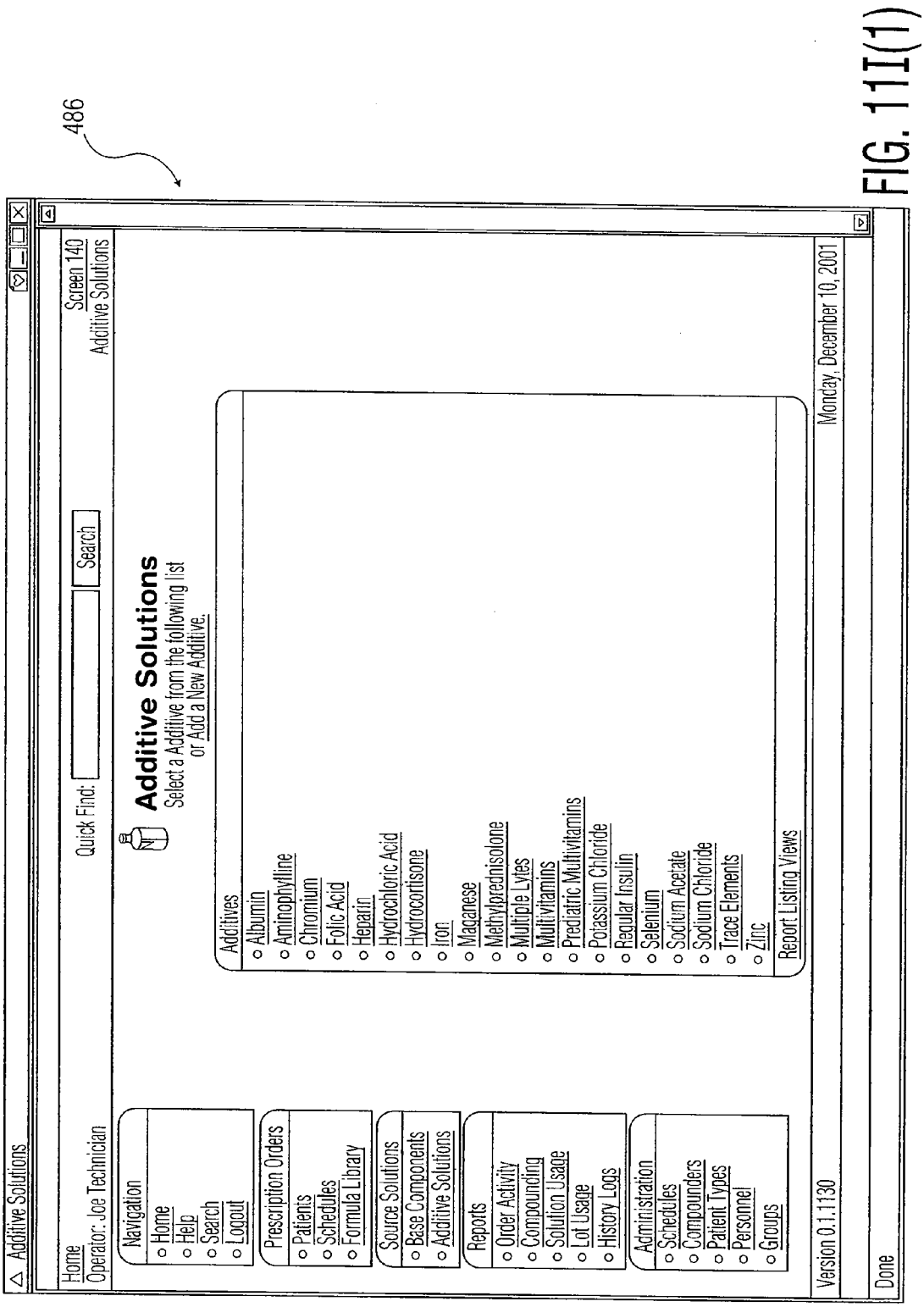

486
Additive Solutions
Home
Operator: Joe Technician
Quick Find:
Search
Screen 140
Additive Solutions
Navigation
Home
Help
Search
Logout
Prescription Orders
Patients
Schedules
Formula Library
Source Solutions
Base Components
Additive Solutions
Reports
Order Activity
Compounding
Solution Usage
Lot Usage
History Logs
Administration
Schedules
Compounders
Patient Types
Personnel
Groups
Additive Solutions
Select a Additive from the following list
or Add a New Additive.
Additives
Albumin
Aminophylline
Chromium
Folic Acid
Heparin
Hydrochloric Acid
Hydrocortisone
Iron
Maganese
Methylprednisolone
Multiple Lytes
Multivitamins
Prediatric Multivitamins
Potassium Chloride
Regular Insulin
Selenium
Sodium Acetate
Sodium Chloride
Trace Elements
Zinc
Report Listing Views
Version 0.1.1130
Monday, December 10, 2001
Done

FIG. 11I(1)

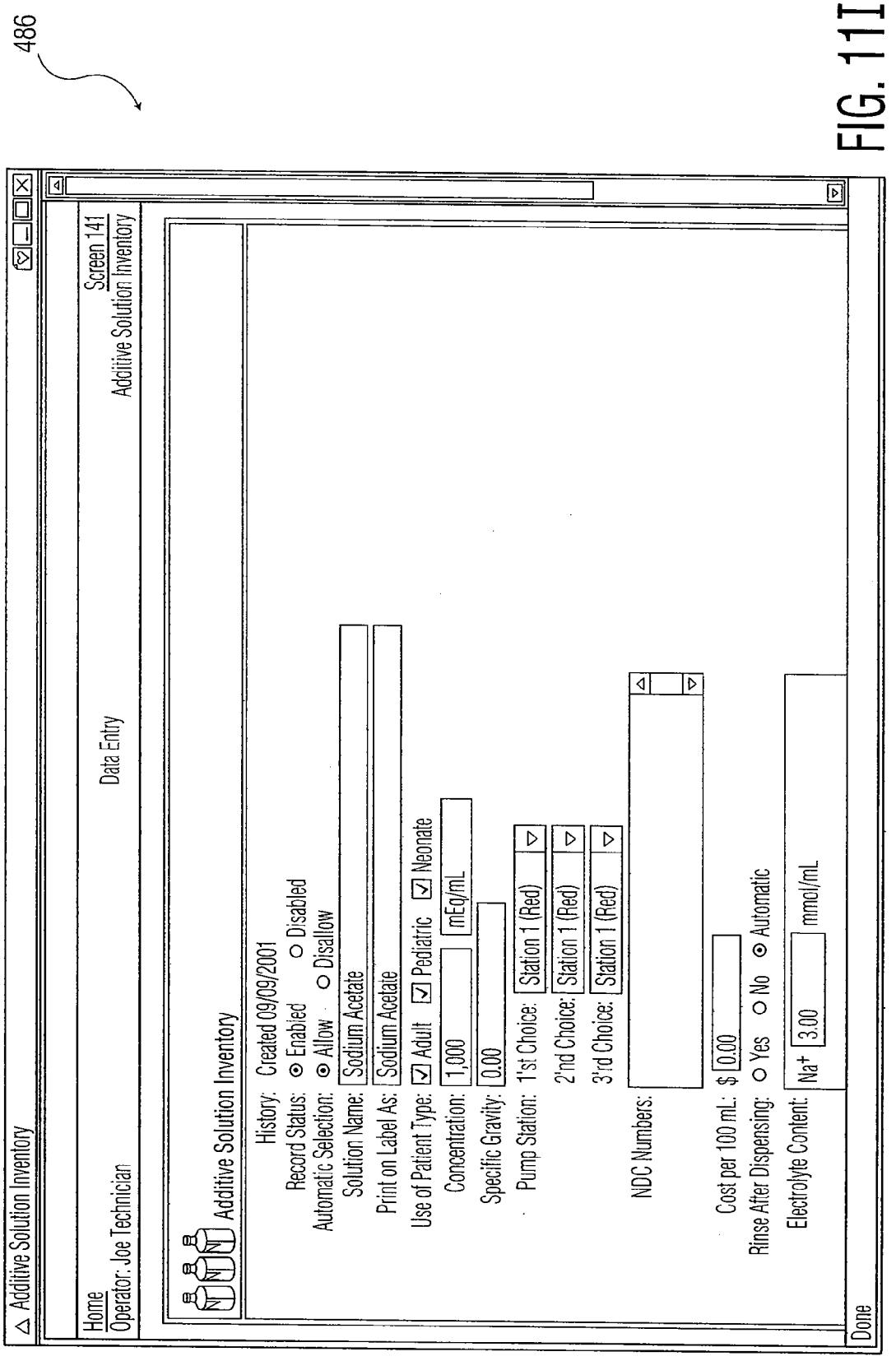

486
Additive Solution Inventory
Home
Operator: Joe Technician
Data Entry
Screen 141
Additive Solution Inventory
Additive Solution Inventory
History: Created 09/09/2001
Record Status: Enabled Disabled
Automatic Selection: Allow Disallow
Solution Name: Sodium Acetate
Print on Label As: Sodium Acetate
Use of Patient Type: Adult Pediatric Neonate
Concentration: 1,000 mEq/mL
Specific Gravity: 0.00
Pump Station: 1st Choice: Station 1 (Red)
2nd Choice: Station 1 (Red)
3rd Choice: Station 1 (Red)
NDC Numbers:
Cost per 100 mL: $ 0.00
Rinse After Dispensing: Yes No Automatic
Electrolyte Content: Na+ 3.00 mmol/mL
Done

FIG. 11I(2)

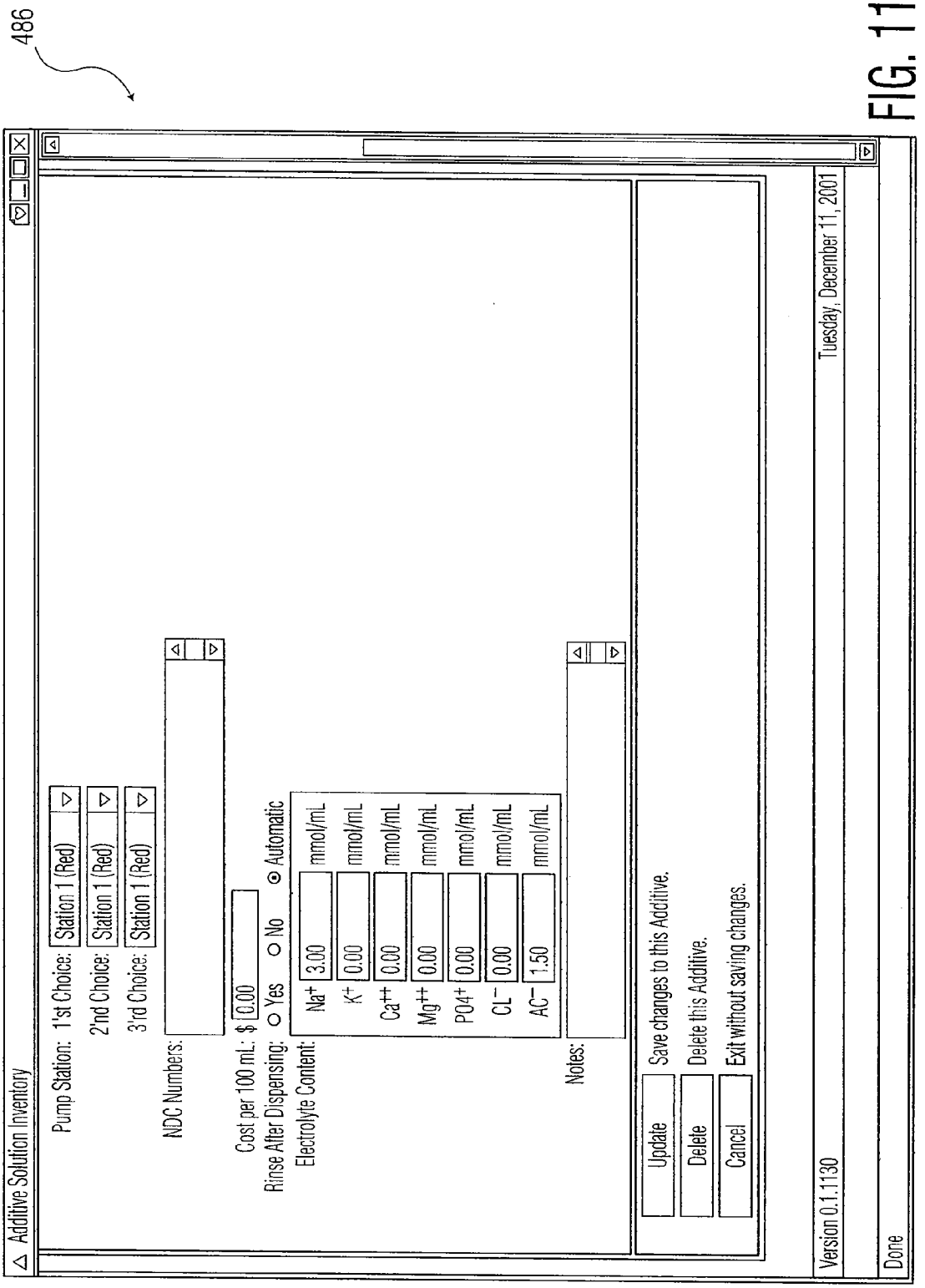

486
Additive Solution Inventory
Pump Station: 1'st Choice: Station 1 (Red)
2'nd Choice: Station 1 (Red)
3'rd Choice: Station 1 (Red)
NDC Numbers:
Cost per 100 mL: $ 0.00
Rinse After Dispensing: Yes No Automatic
Electrolyte Content:
Na+ 3.00 mmol/mL
K+ 0.00 mmol/mL
Ca++ 0.00 mmol/mL
Mg++ 0.00 mmol/mL
PO4+ 0.00 mmol/mL
CL- 0.00 mmol/mL
AC- 1.50 mmol/mL
Notes:
Update Save changes to this Additive.
Delete Delete this Additive.
Cancel Exit without saving changes.
Version 0.1.1130
Tuesday, December 11, 2001
Done

FIG. 11I(3)

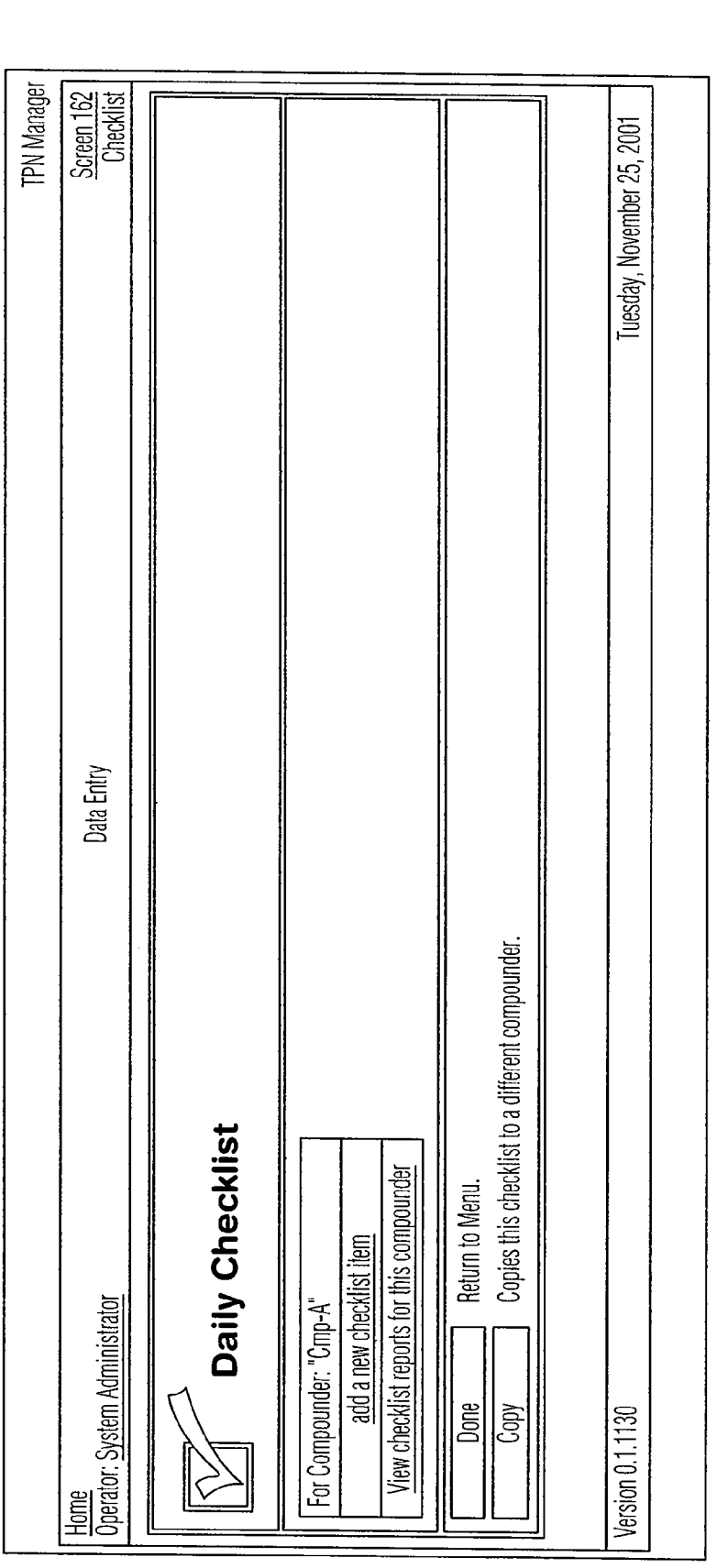

500
TPN Manager
Home
Operator: System Administrator
Data Entry
Screen 162
Checklist
Daily Checklist
For Compounder: "Cmp-A"
add a new checklist item
View checklist reports for this compounder
Done
Return to Menu.
Copy
Copies this checklist to a different compounder.
Version 0.1.1130
Tuesday, November 25, 2001

FIG. 11J(1)

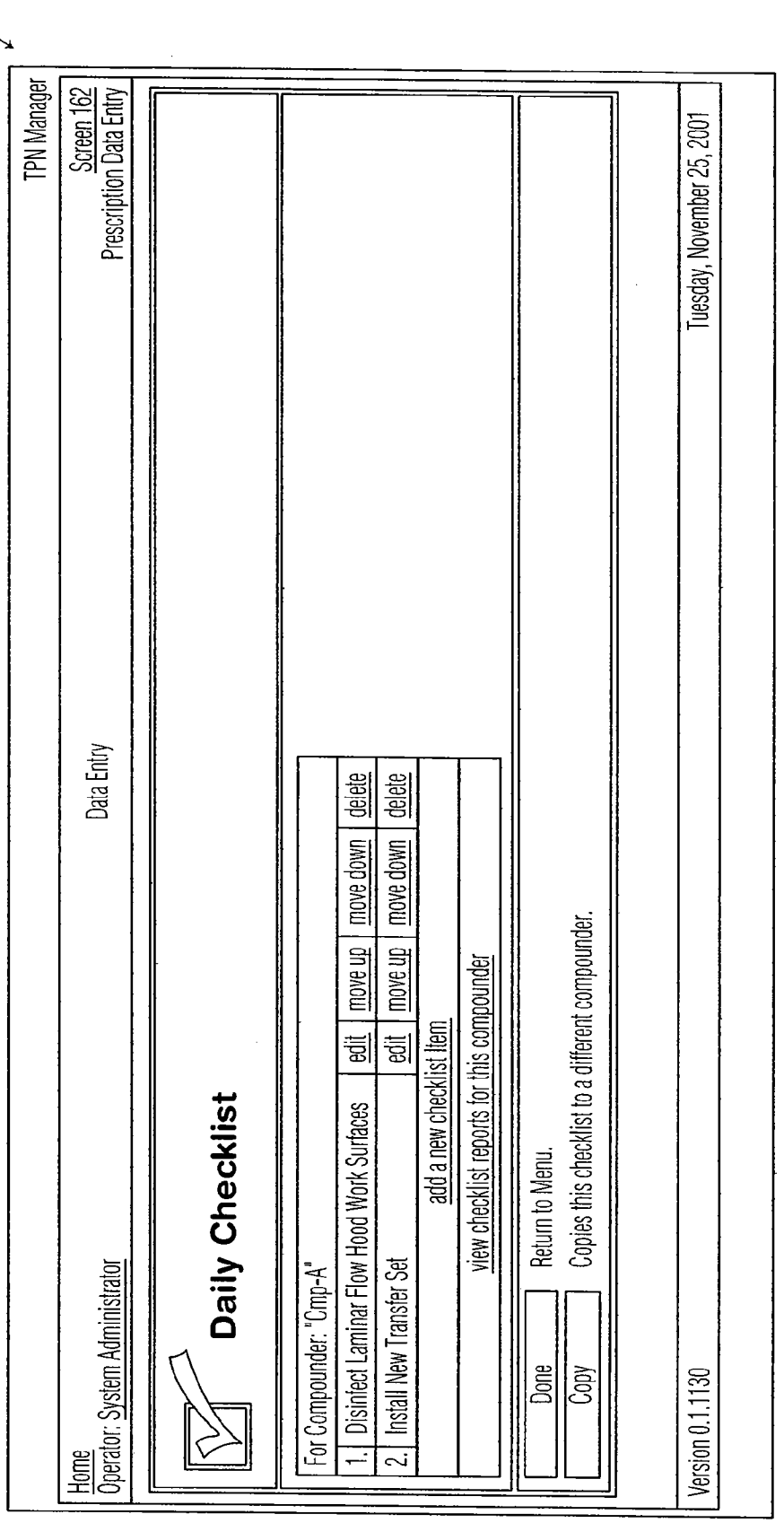

500
TPN Manager
Home
Operator: System Administrator
Data Entry
Screen 162
Prescription Data Entry
Daily Checklist
For Compounder: "Cmp-A"
1. Disinfect Laminar Flow Hood Work Surfaces
edit
move up
move down
delete
2. Install New Transfer Set
edit
move up
move down
delete
add a new checklist item
view checklist reports for this compounder
Done
Return to Menu.
Copy
Copies this checklist to a different compounder.
Version 0.1.1130
Tuesday, November 25, 2001

FIG. 11J(2)

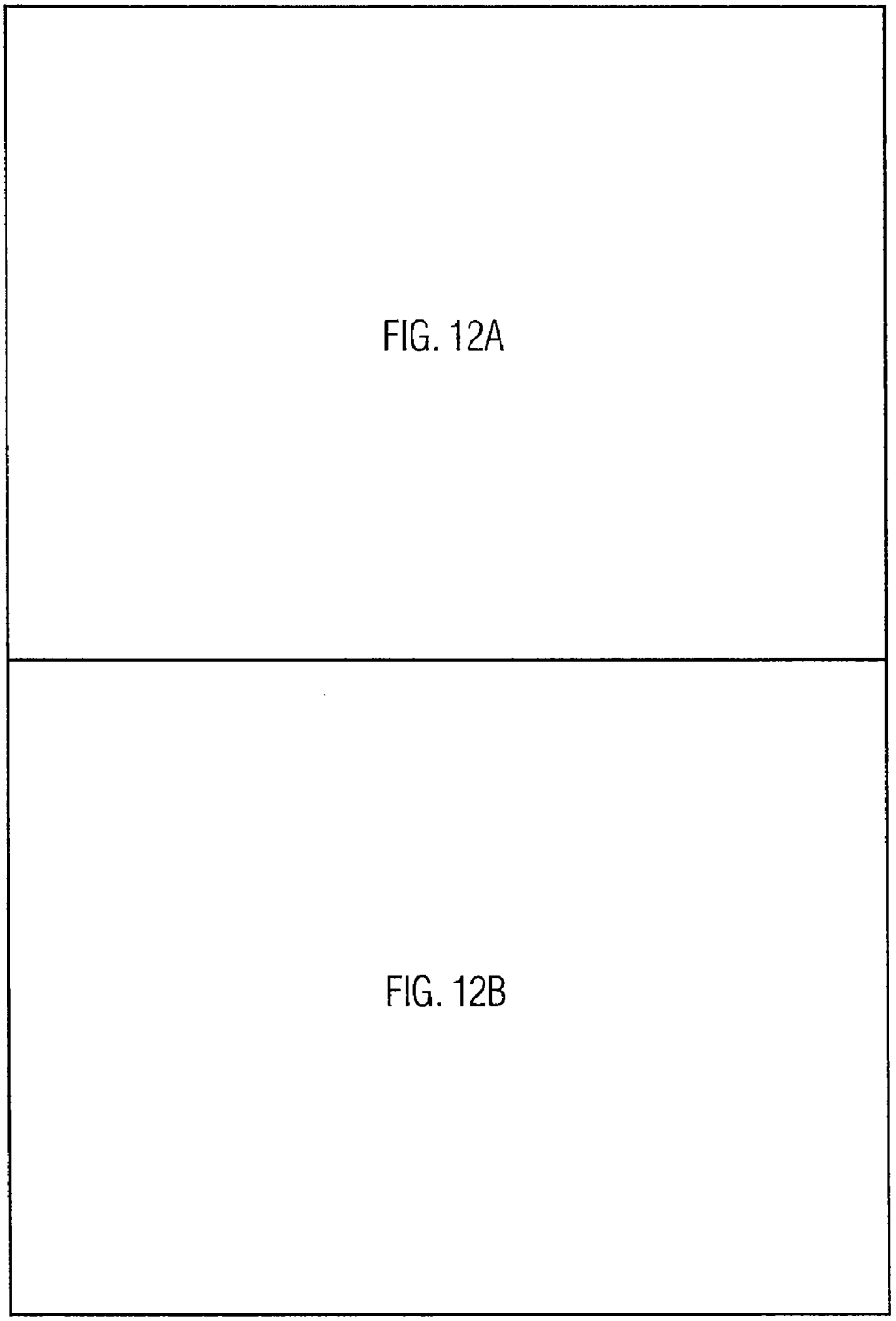


FIG. 12

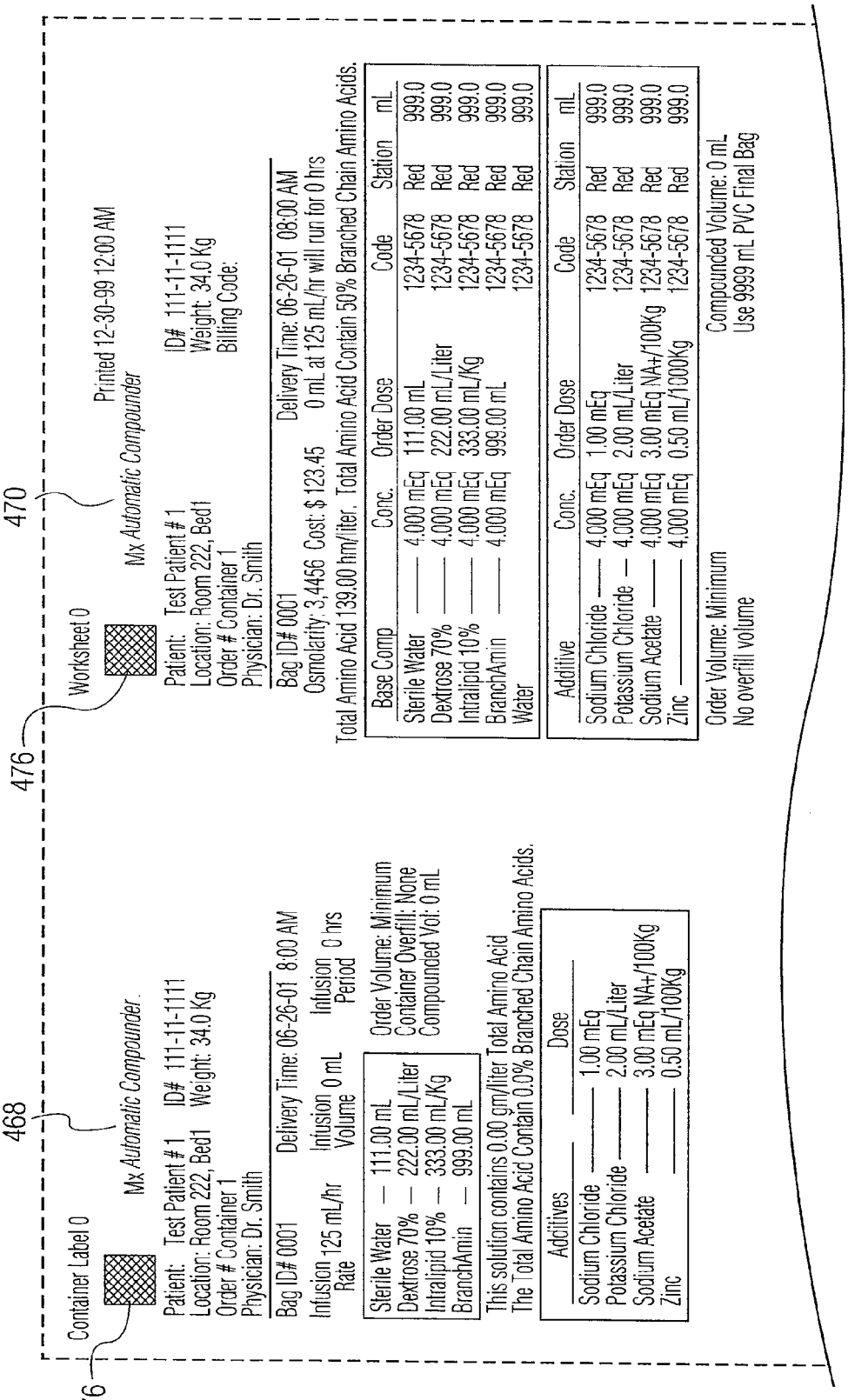

476
Container Label 0
468
Mx Automatic Compounder
Patient: Test Patient # 1 ID# 111-11-1111
Location: Room 222, Bed1 Weight: 34.0 Kg
Order # Container 1
Physician: Dr. Smith
Bag ID# 0001 Delivery Time: 06-26-01 8:00 AM
Infusion Rate 125 mL/hr Infusion Volume 0 mL Infusion Period 0 hrs
Sterile Water — 111.00 mL
Dextrose 70% — 222.00 mL/Liter
Intralipid 10% — 333.00 mL/Kg
BranchAmin — 999.00 mL
Order Volume: Minimum
Container Overfill: None
Compounded Vol: 0 mL
This solution contains 0.00 gm/liter Total Amino Acid
The Total Amino Acid Contain 0.0% Branched Chain Amino Acids.
Additives Dose
Sodium Chloride — 1.00 mEq
Potassium Chloride — 2.00 mL/Liter
Sodium Acetate — 3.00 mEq NA+/100Kg
Zinc — 0.50 mL/100Kg
476
Worksheet 0
470
Mx Automatic Compounder
Printed 12-30-99 12:00 AM
Patient: Test Patient # 1 ID# 111-11-1111
Location: Room 222, Bed1 Weight: 34.0 Kg
Order # Container 1 Billing Code:
Physician: Dr. Smith
Bag ID# 0001 Delivery Time: 06-26-01 08:00 AM
Osmolarity: 3,4456 Cost: $ 123.45 0 mL at 125 mL/hr will run for 0 hrs
Total Amino Acid 139.00 hm/liter. Total Amino Acid Contain 50% Branched Chain Amino Acids.
Base Comp Conc. Order Dose Code Station mL
Sterile Water — 4.000 mEq 111.00 mL 1234-5678 Red 999.0
Dextrose 70% — 4.000 mEq 222.00 mL/Liter 1234-5678 Red 999.0
Intralipid 10% — 4.000 mEq 333.00 mL/Kg 1234-5678 Red 999.0
BranchAmin — 4.000 mEq 999.00 mL 1234-5678 Red 999.0
Water 1234-5678 Red 999.0
Additive Conc. Order Dose Code Station mL
Sodium Chloride — 4.000 mEq 1.00 mEq 1234-5678 Red 999.0
Potassium Chloride — 4.000 mEq 2.00 mL/Liter 1234-5678 Red 999.0
Sodium Acetate — 4.000 mEq 3.00 mEq NA+/100Kg 1234-5678 Rec 999.0
Zinc — 4.000 mEq 0.50 mL/100Kg 1234-5678 Red 999.0
Order Volume: Minimum
No overfill volume
Compounded Volume: 0 mL
Use 9999 mL PVC Final Bag

FIG. 12A

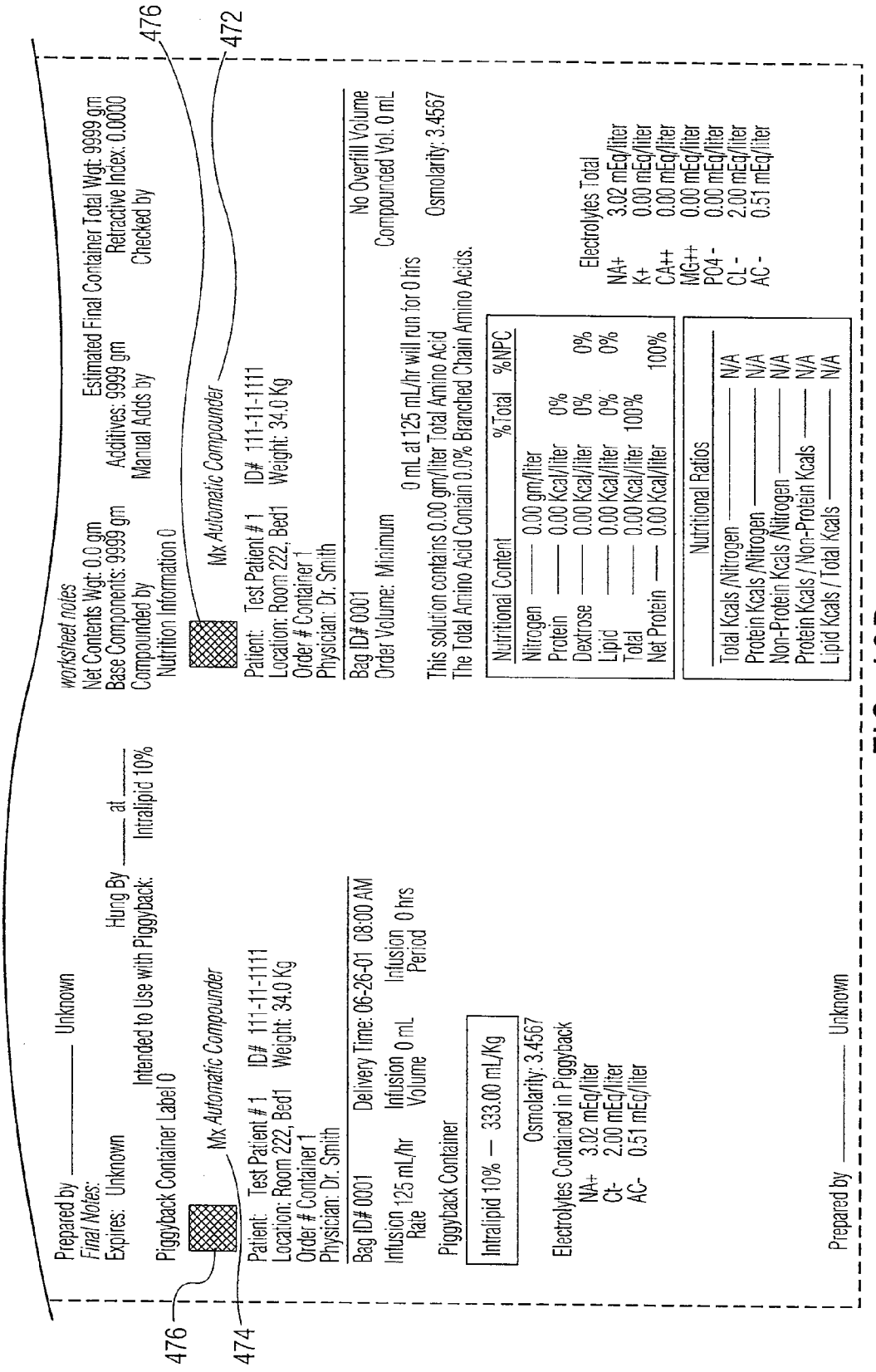

476
474
476
472
Prepared by _____ Unknown
Final Notes:
Expires: Unknown
Hung By _____ at _____
Intended to Use with Piggyback: Intralipid 10%
Piggyback Container Label 0
Mx Automatic Compounder
Patient: Test Patient # 1 ID# 111-11-1111
Location: Room 222, Bed1 Weight: 34.0 Kg
Order # Container 1
Physician: Dr. Smith
Bag ID# 0001 Delivery Time: 06-26-01 08:00 AM
Infusion Rate 125 mL/hr
Infusion Volume 0 mL
Infusion Period 0 hrs
Piggyback Container
Intralipid 10% — 333.00 mL/Kg
Osmolarity: 3.4567
Electrolytes Contained in Piggyback
NA+ 3.02 mEq/liter
Ct- 2.00 mEq/liter
AC- 0.51 mEq/liter
Prepared by _____ Unknown
worksheet notes
Net Contents Wgt: 0.0 gm
Base Components: 9999 gm
Compounded by
Nutrition Information 0
Estimated Final Container Total Wgt: 9999 gm
Additives: 9999 gm
Manual Adds by
Retractive Index: 0.0000
Checked by
Mx Automatic Compounder
Patient: Test Patient # 1 ID# 111-11-1111
Location: Room 222, Bed1 Weight: 34.0 Kg
Order # Container 1
Physician: Dr. Smith
Bag ID# 0001
Order Volume: Minimum
No Overfill Volume
Compounded Vol. 0 mL
0 mL at 125 mL/hr will run for 0 hrs
This solution contains 0.00 gm/liter Total Amino Acid
The Total Amino Acid Contain 0.0% Branched Chain Amino Acids.
Osmolarity: 3.4567
Nutritional Content %Total %NPC
Nitrogen 0.00 gm/liter
Protein 0.00 Kcal/liter 0%
Dextrose 0.00 Kcal/liter 0% 0%
Lipid 0.00 Kcal/liter 0% 0%
Total 0.00 Kcal/liter 100%
Net Protein 0.00 Kcal/liter 100%
Electrolytes Total
NA+ 3.02 mEq/liter
K+ 0.00 mEq/liter
CA++ 0.00 mEq/liter
MG++ 0.00 mEq/liter
PO4 - 0.00 mEq/liter
CL - 2.00 mEq/liter
AC - 0.51 mEq/liter
Nutritional Ratios
Total Kcals /Nitrogen N/A
Protein Kcals /Nitrogen N/A
Non-Protein Kcals /Nitrogen N/A
Protein Kcals / Non-Protein Kcals N/A
Lipid Kcals / Total Kcals N/A

FIG. 12B

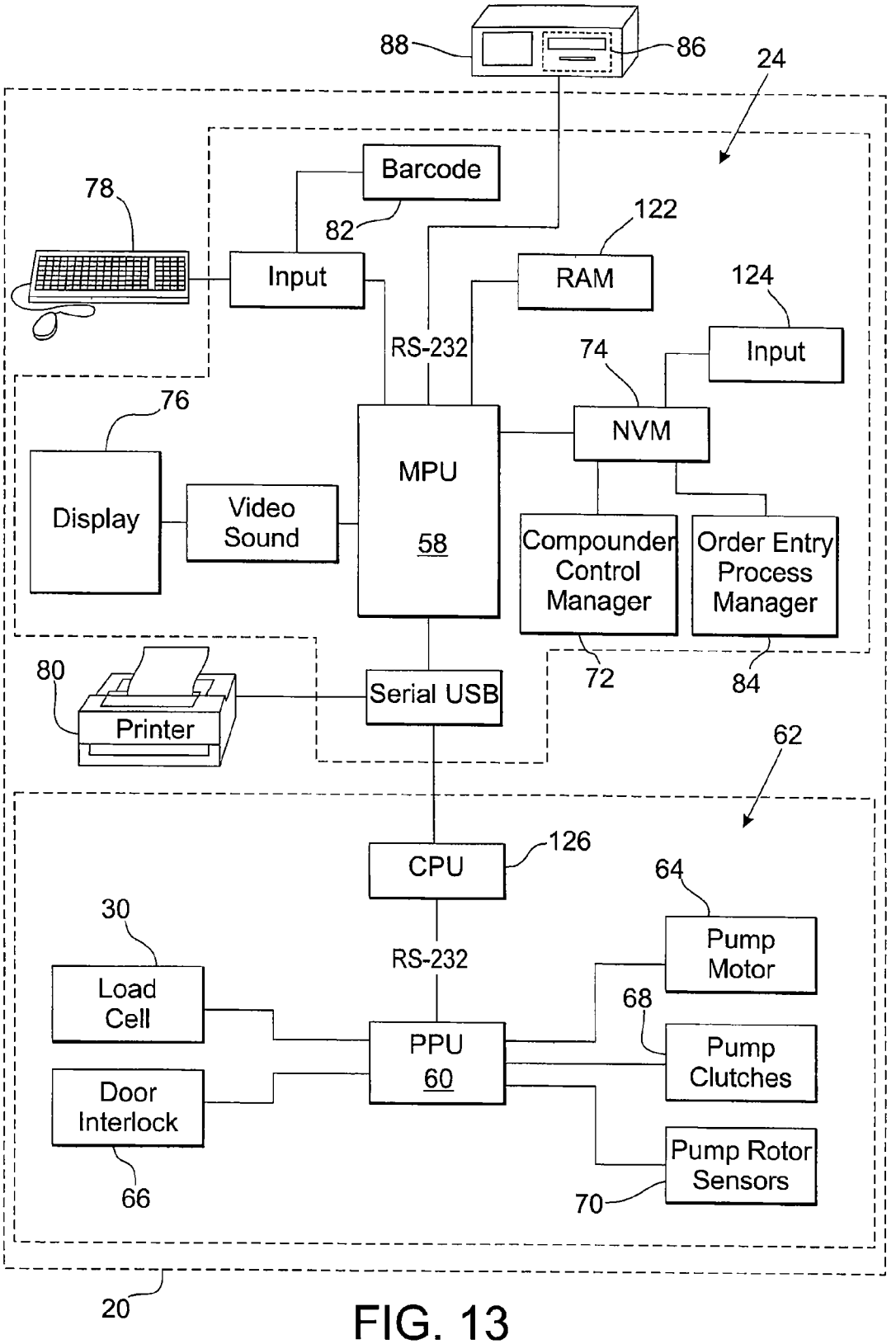

88
86
24
Barcode
82
78
122
Input
RAM
124
Input
RS-232
74
NVM
76
MPU
58
Display
Video
Sound
Compounder
Control
Manager
Order Entry
Process
Manager
72
84
80
Printer
Serial USB
62
CPU
126
64
30
Pump
Motor
RS-232
Load
Cell
68
PPU
60
Pump
Clutches
Door
Interlock
Pump Rotor
Sensors
66
70
20

FIG. 13

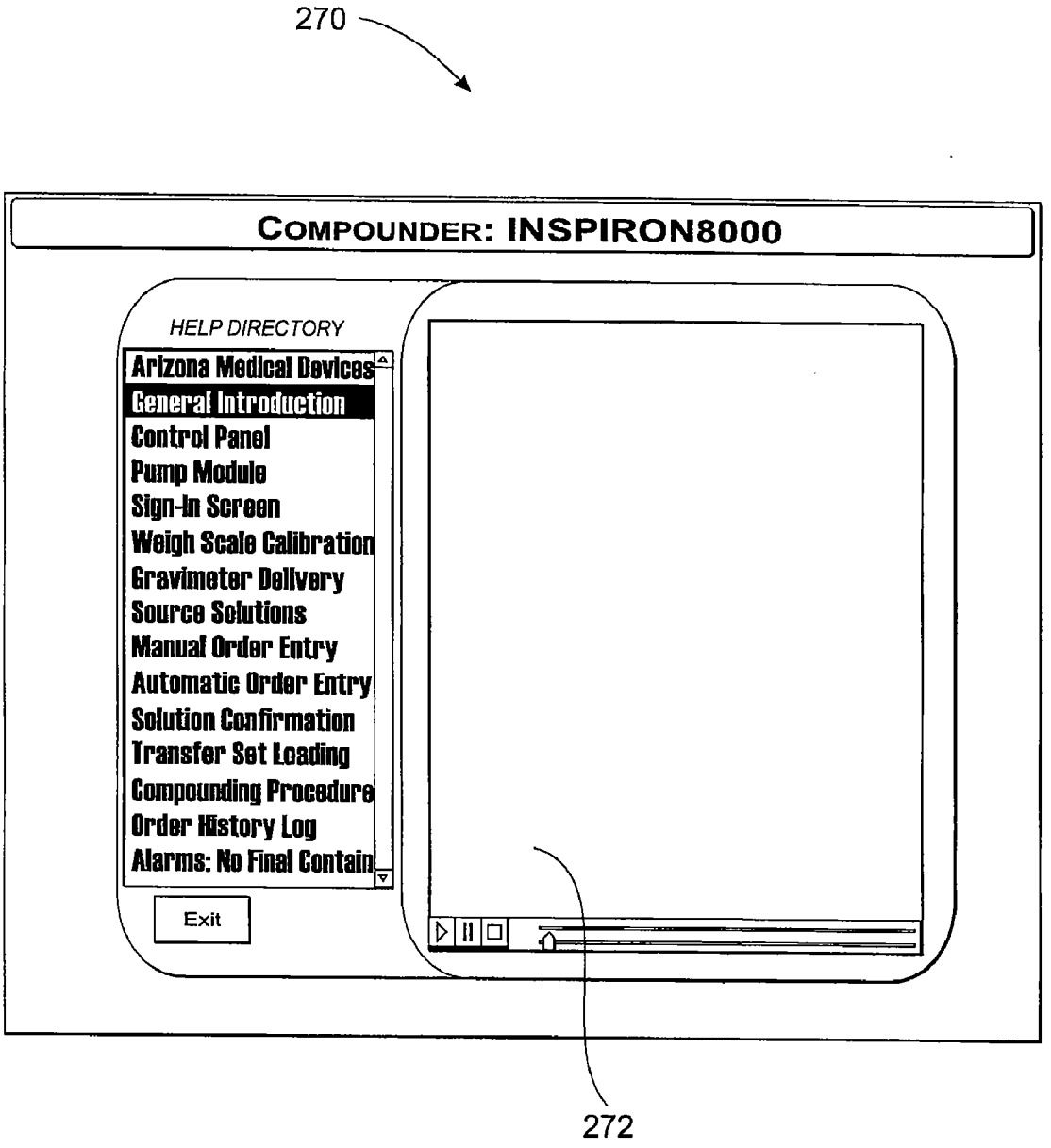

270
COMPOUNDER: INSPIRON8000
HELP DIRECTORY
Arizona Medical Devices
General Introduction
Control Panel
Pump Module
Sign-In Screen
Weigh Scale Calibration
Gravimeter Delivery
Source Solutions
Manual Order Entry
Automatic Order Entry
Solution Confirmation
Transfer Set Loading
Compounding Procedure
Order History Log
Alarms: No Final Contain
Exit
272

FIG. 14A

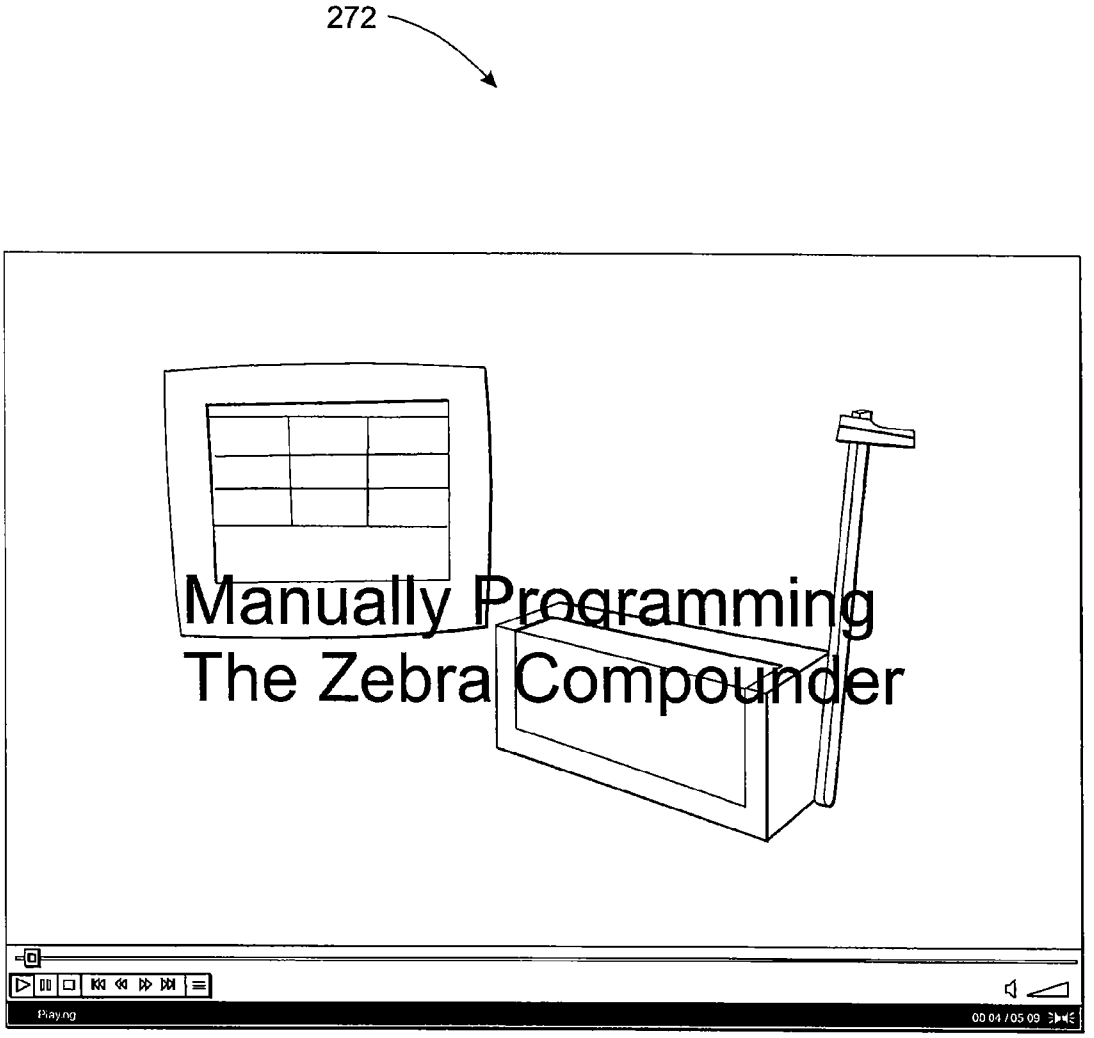

272
Manually Programming
The Zebra Compounder
Playing
00:04 / 05:09

FIG. 14B (1)

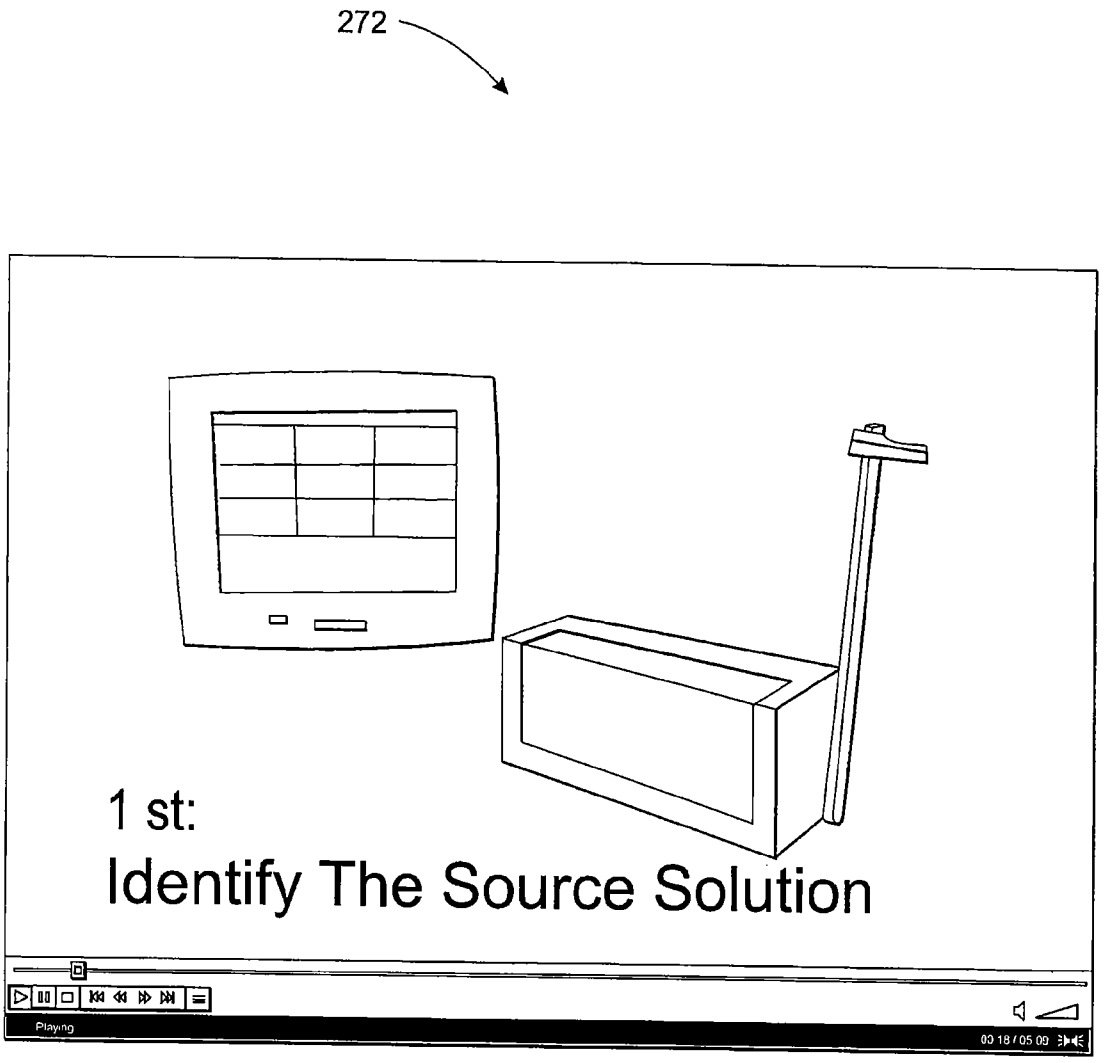


FIG. 14B (2)

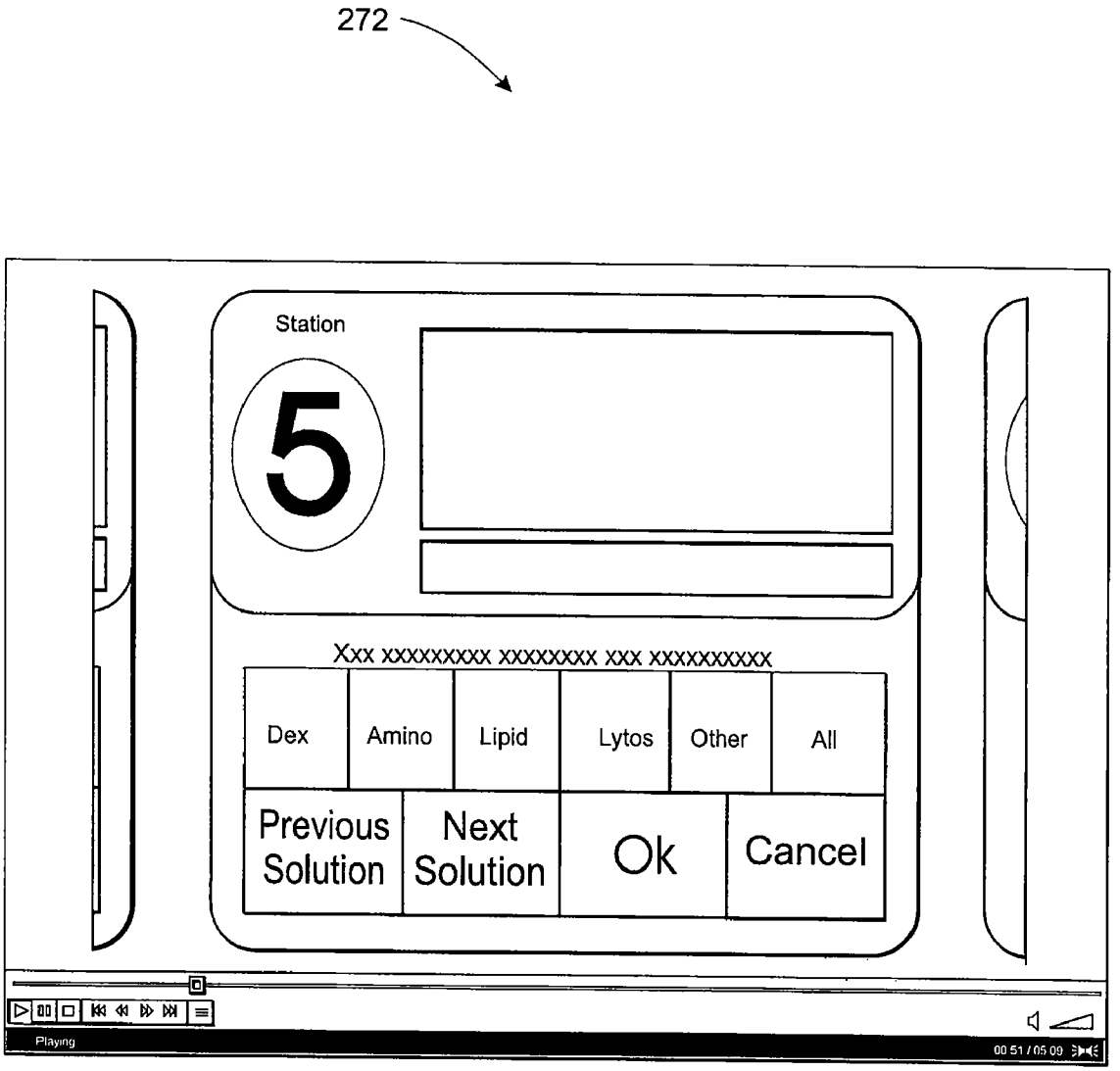

272
Station
5
Xxx xxxxxxxxx xxxxxxxx xxx xxxxxxxxxx
Dex
Amino
Lipid
Lytos
Other
All
Previous Solution
Next Solution
Ok
Cancel
Playing

FIG. 14B (3)

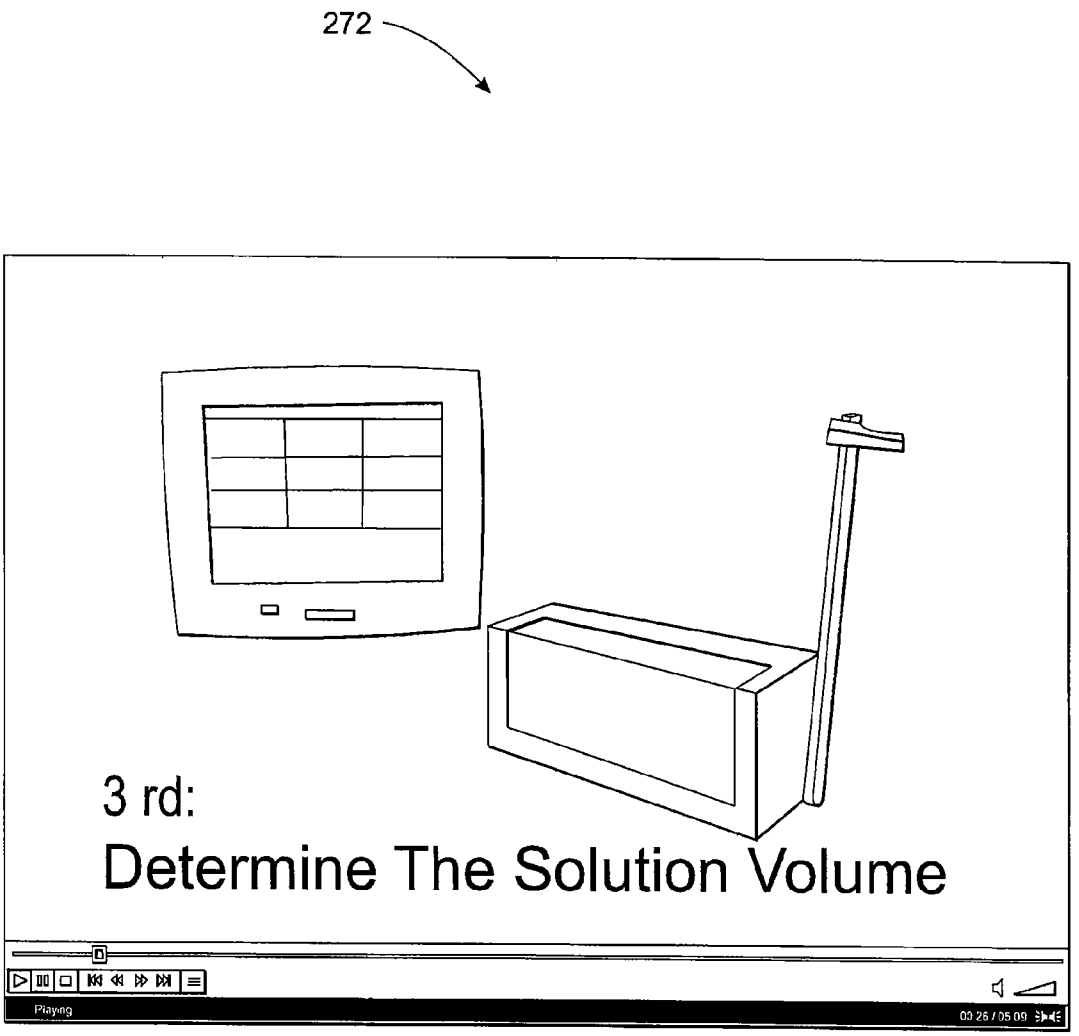


FIG. 14B (4)

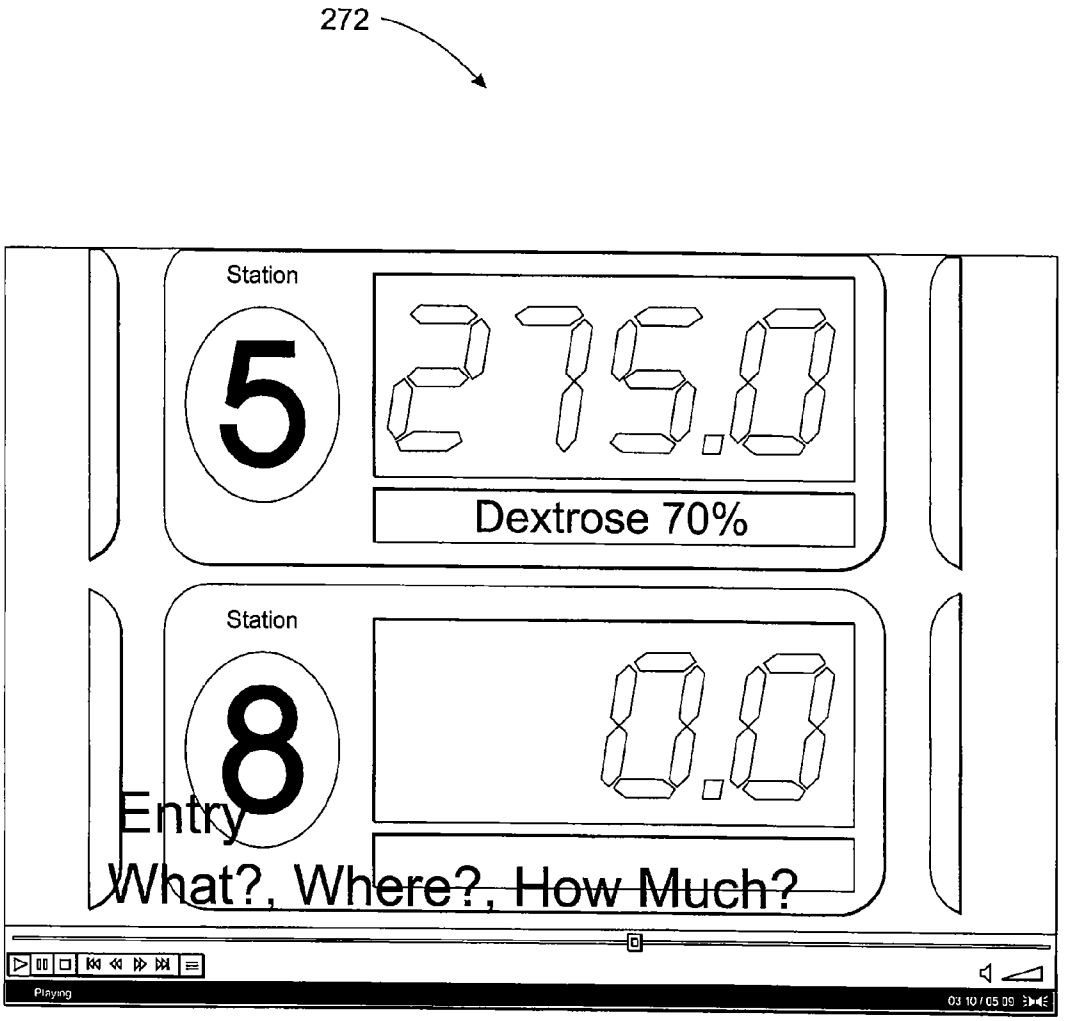

272
Station
5
275.0
Dextrose 70%
Station
8
0.0
Entry
What?, Where?, How Much?
Playing

FIG. 14B (5)

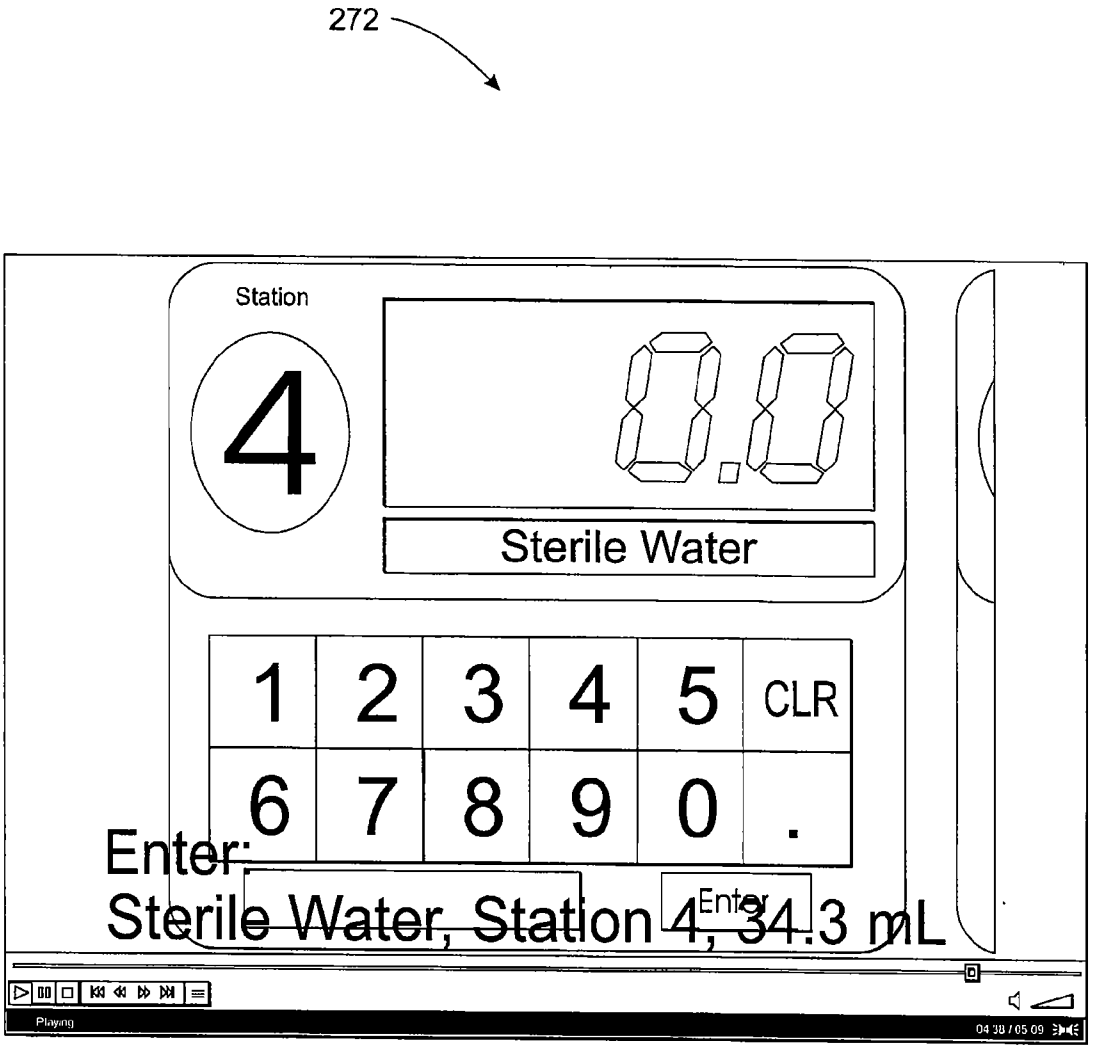

272
Station
4
0.0
Sterile Water
1 2 3 4 5 CLR
6 7 8 9 0 .
Enter:
Sterile Water, Station 4, 34.3 mL
Enter
Playing

FIG. 14B (6)

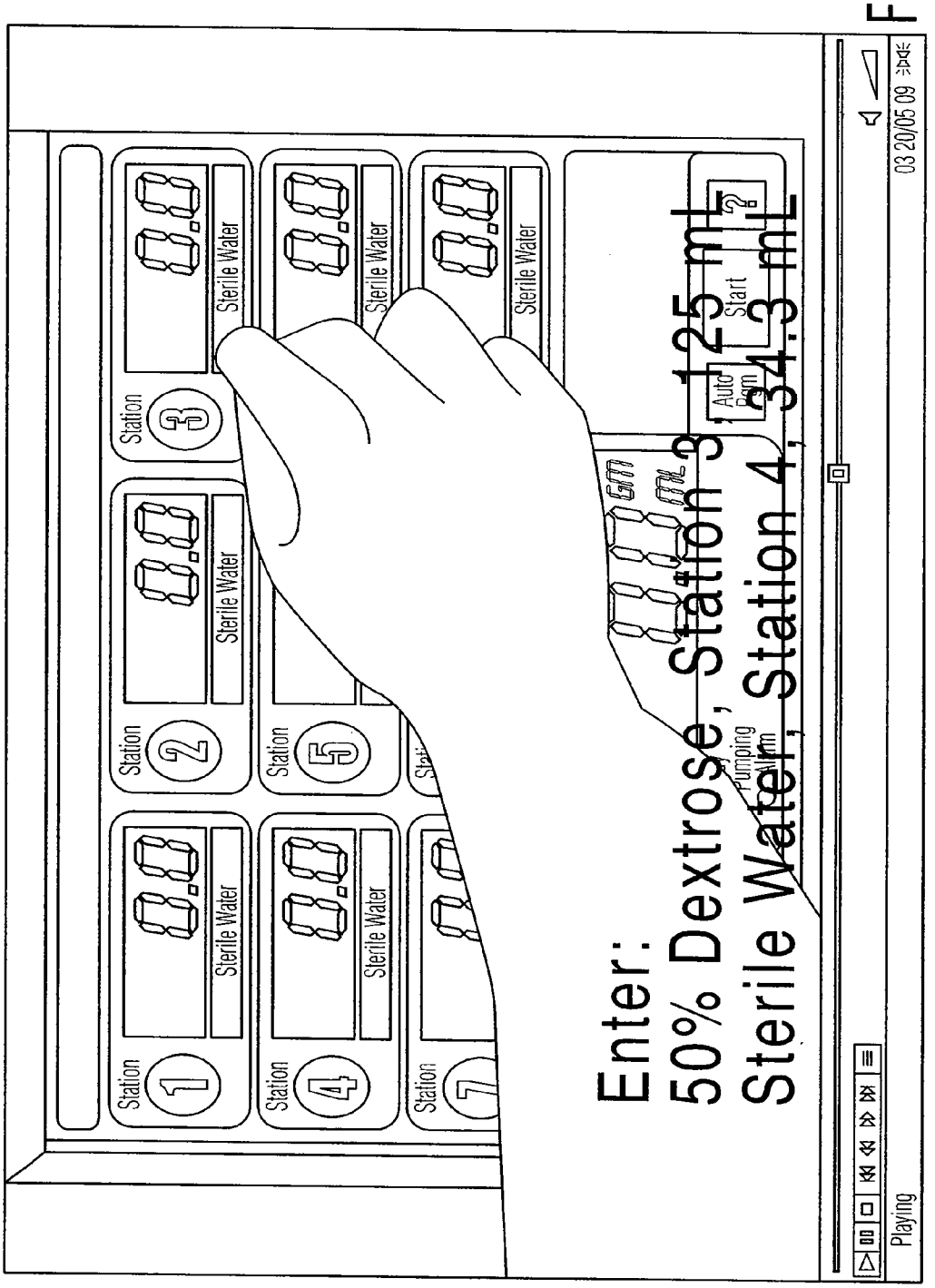

272
Station 1
Sterile Water
Station 2
Sterile Water
Station 3
Sterile Water
Station 4
Sterile Water
Station 5
Sterile Water
Station 7
Sterile Water
Enter:
50% Dextrose, Station 3, 125 mL
Sterile Water, Station 4, 34.3 mL
Start
Auto Pump
Pumping
Playing
03 20/05 09

FIG. 14B (7)

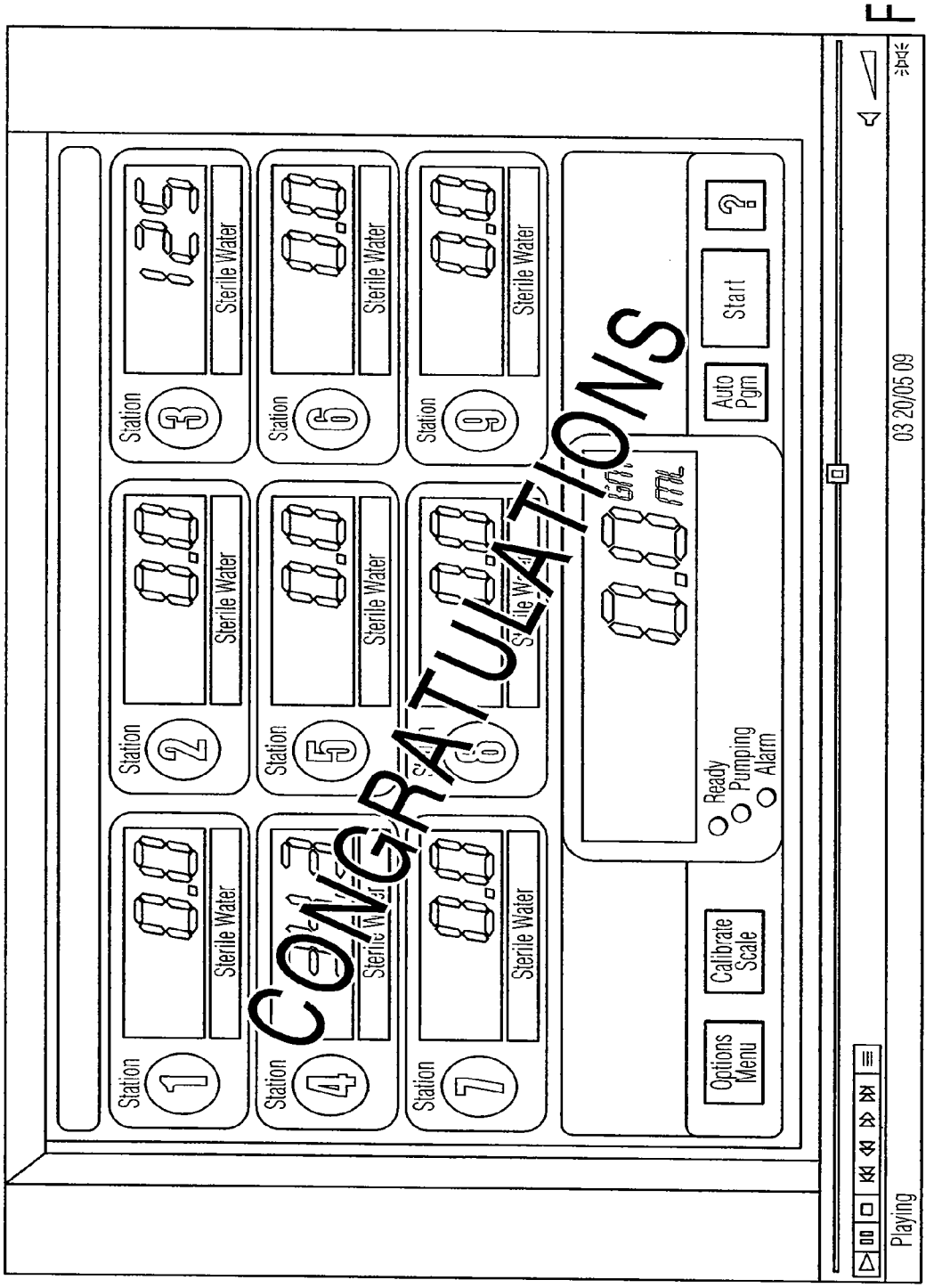

272
Station 1
Sterile Water
Station 2
Sterile Water
Station 3
Sterile Water
Station 4
Sterile Water
Station 5
Sterile Water
Station 6
Sterile Water
Station 7
Sterile Water
Station 8
Sterile Water
Station 9
Sterile Water
CONGRATULATIONS
Options Menu
Calibrate Scale
Ready
Pumping
Alarm
Auto Pgm
Start
?
Playing
03 20/05 09

FIG. 14B (8)

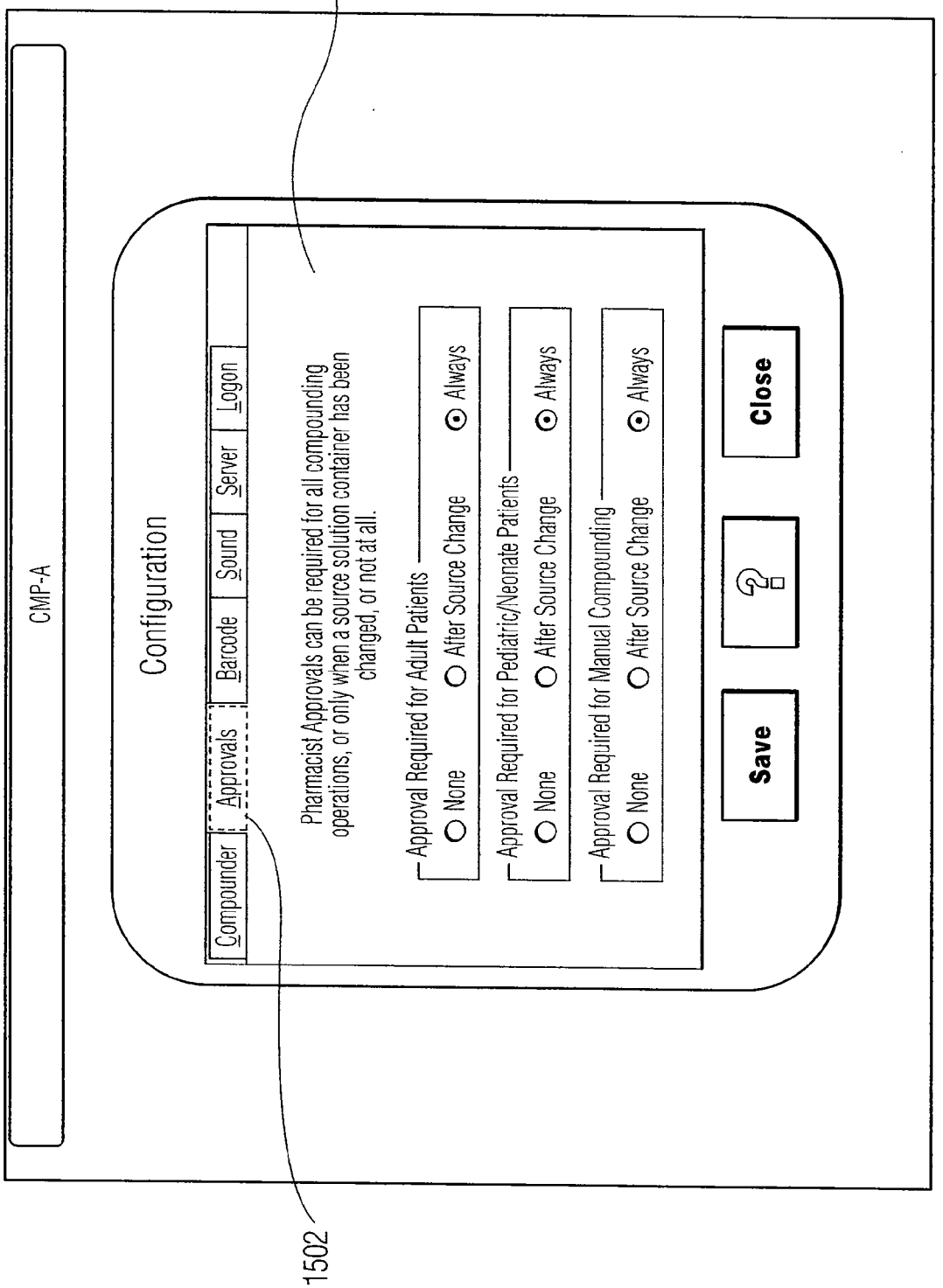

1500
1502
CMP-A
Configuration
Compounder
Approvals
Barcode
Sound
Server
Logon
Pharmacist Approvals can be required for all compounding operations, or only when a source solution container has been changed, or not at all.
Approval Required for Adult Patients
None
After Source Change
Always
Approval Required for Pediatric/Neonate Patients
None
After Source Change
Always
Approval Required for Manual Compounding
None
After Source Change
Always
Save
Close

FIG. 15A

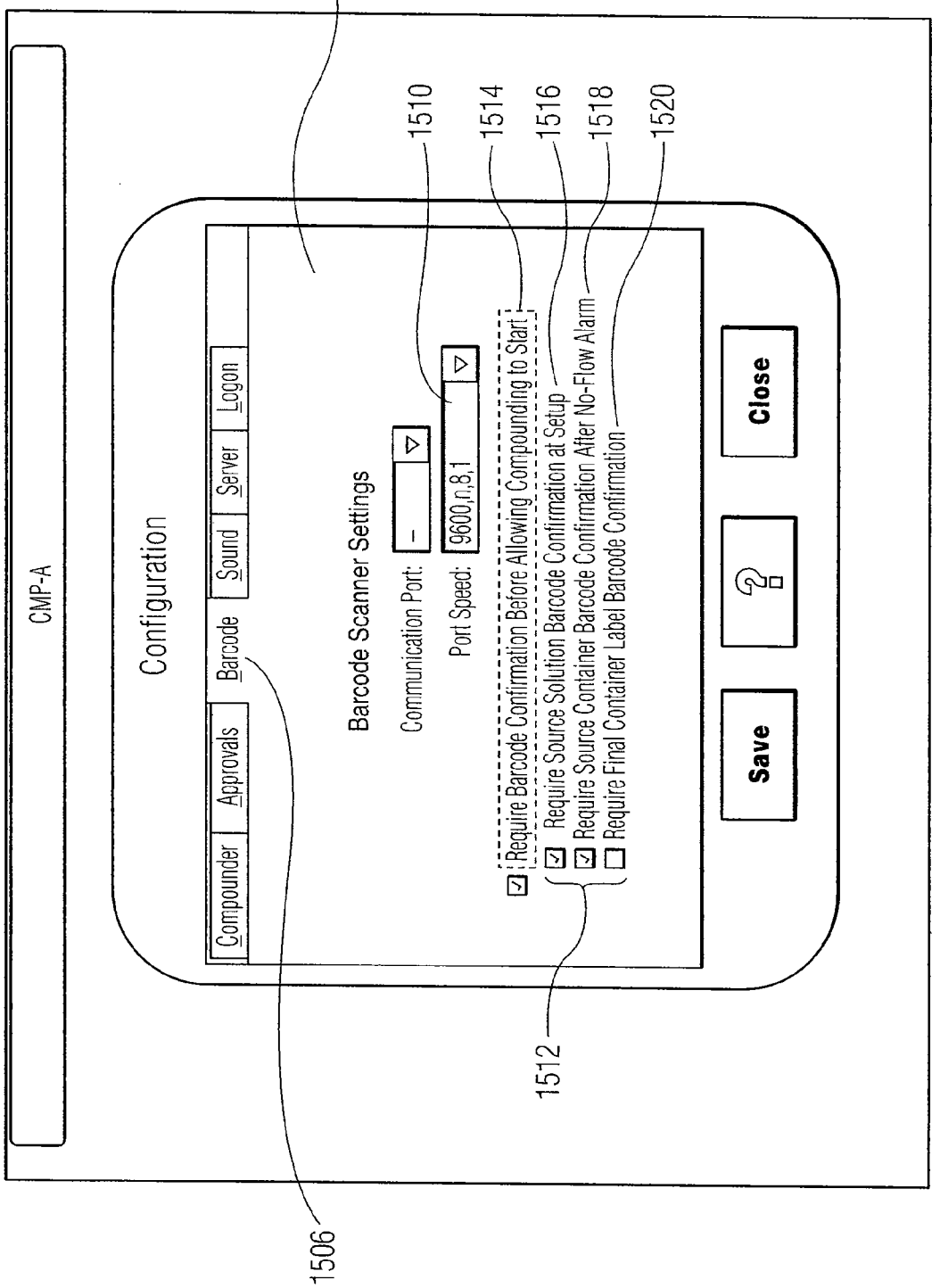

CMP-A
Configuration
Compounder
Approvals
Barcode
Sound
Server
Logon
Barcode Scanner Settings
Communication Port:
Port Speed:
9600,n,8,1
Require Barcode Confirmation Before Allowing Compounding to Start
Require Source Solution Barcode Confirmation at Setup
Require Source Container Barcode Confirmation After No-Flow Alarm
Require Final Container Label Barcode Confirmation
Save
Close
1504
1506
1510
1512
1514
1516
1518
1520

FIG. 15B

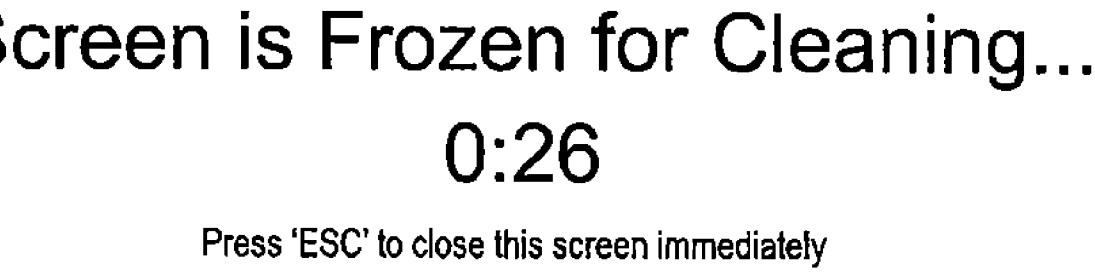

Screen is Frozen for Cleaning...
0:26
Press 'ESC' to close this screen immediately

FIG. 16

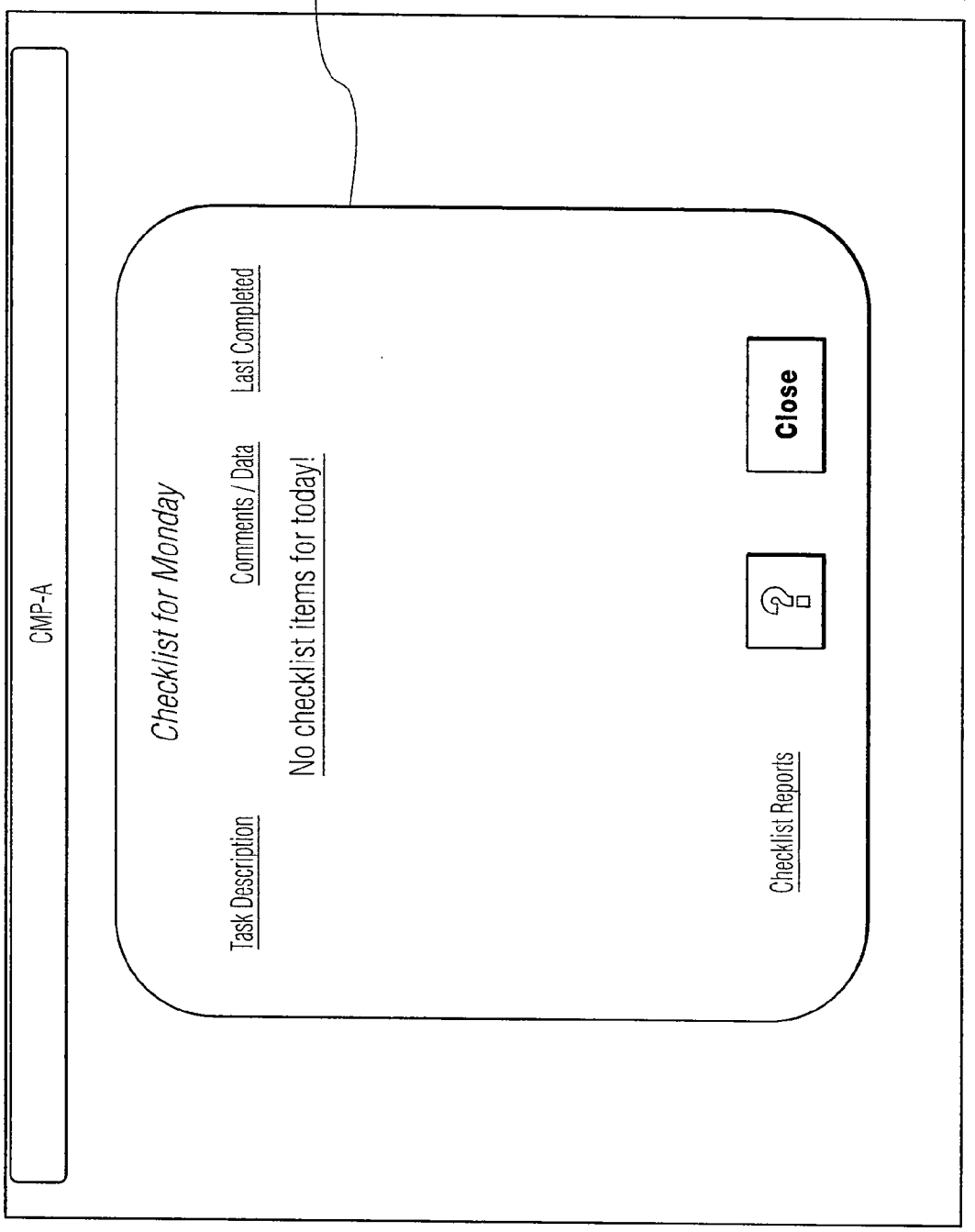

1700
CMP-A
Checklist for Monday
Task Description
Comments / Data
Last Completed
No checklist items for today!
Checklist Reports
Close

FIG. 17

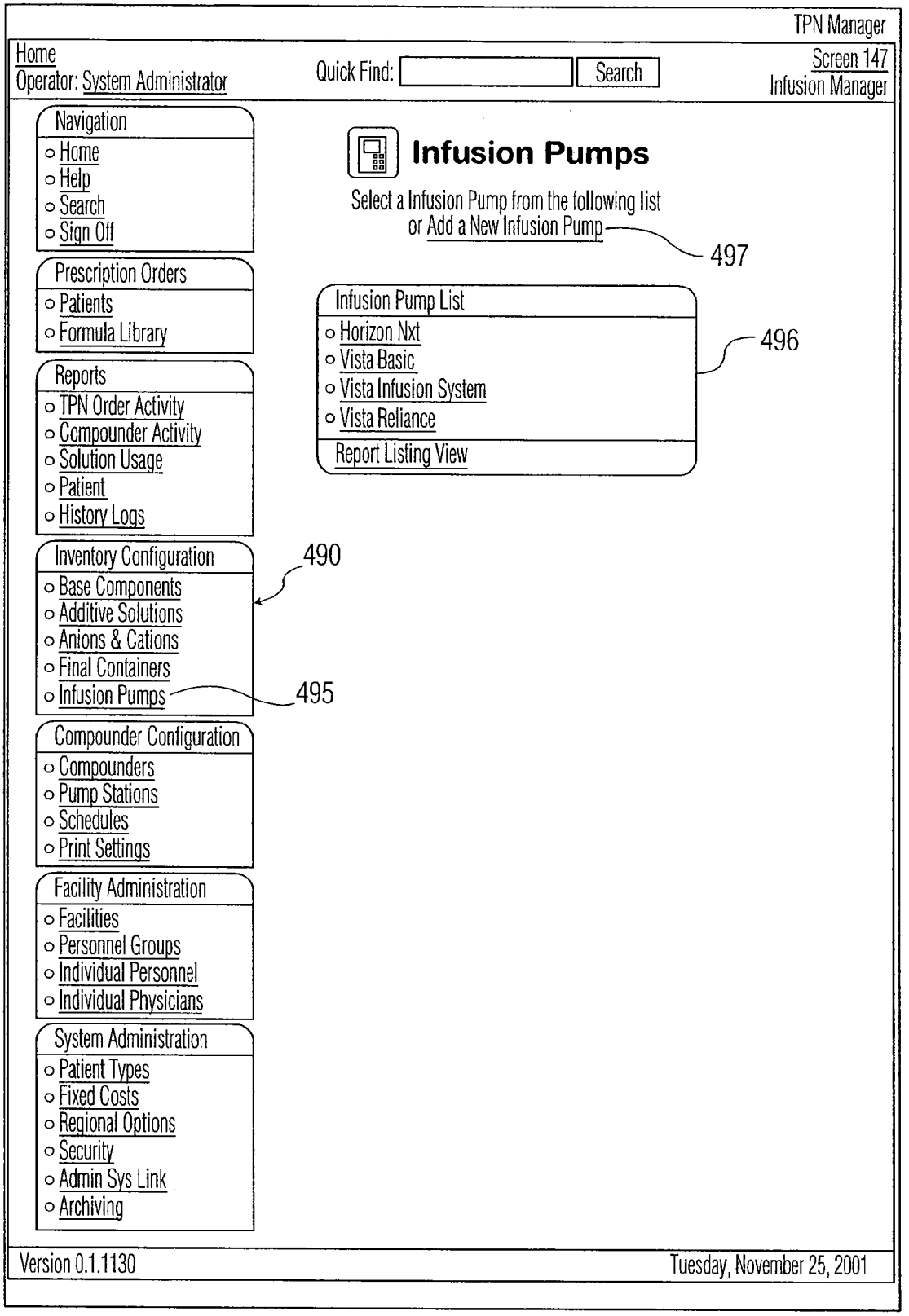

TPN Manager
Home
Operator: System Administrator
Quick Find:
Search
Screen 147
Infusion Manager
Navigation
Home
Help
Search
Sign Off
Prescription Orders
Patients
Formula Library
Reports
TPN Order Activity
Compounder Activity
Solution Usage
Patient
History Logs
Inventory Configuration
Base Components
Additive Solutions
Anions & Cations
Final Containers
Infusion Pumps
Compounder Configuration
Compounders
Pump Stations
Schedules
Print Settings
Facility Administration
Facilities
Personnel Groups
Individual Personnel
Individual Physicians
System Administration
Patient Types
Fixed Costs
Regional Options
Security
Admin Sys Link
Archiving
Infusion Pumps
Select a Infusion Pump from the following list
or Add a New Infusion Pump
497
Infusion Pump List
Horizon Nxt
Vista Basic
Vista Infusion System
Vista Reliance
496
Report Listing View
490
495
Version 0.1.1130
Tuesday, November 25, 2001

FIG. 18A

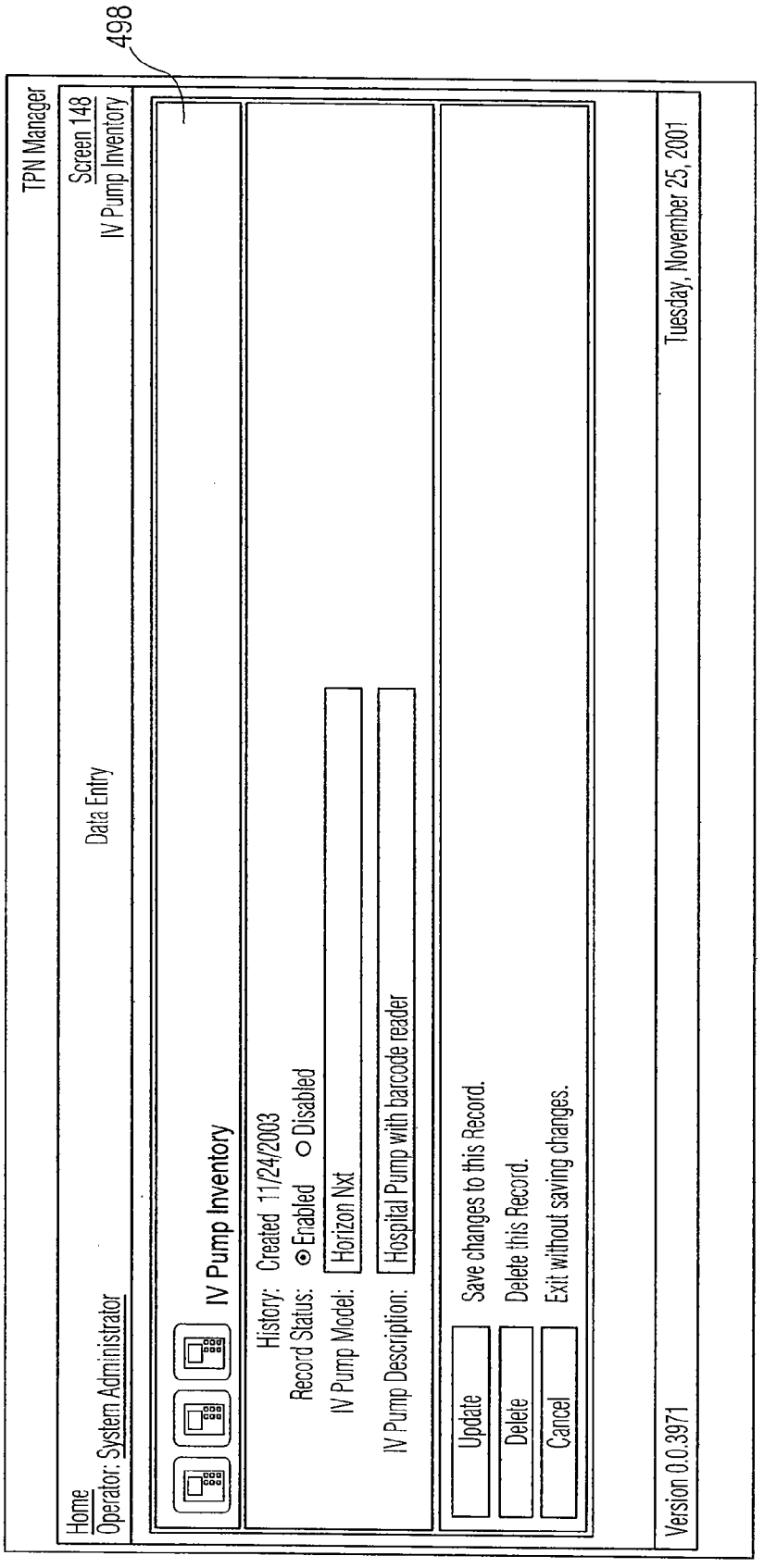

498
TPN Manager
Home
Operator: System Administrator
Data Entry
Screen 148
IV Pump Inventory
IV Pump Inventory
History: Created 11/24/2003
Record Status: Enabled Disabled
IV Pump Model: Horizon Nxt
IV Pump Description: Hospital Pump with barcode reader
Update
Save changes to this Record.
Delete
Delete this Record.
Cancel
Exit without saving changes.
Version 0.0.3971
Tuesday, November 25, 2001

FIG. 18B

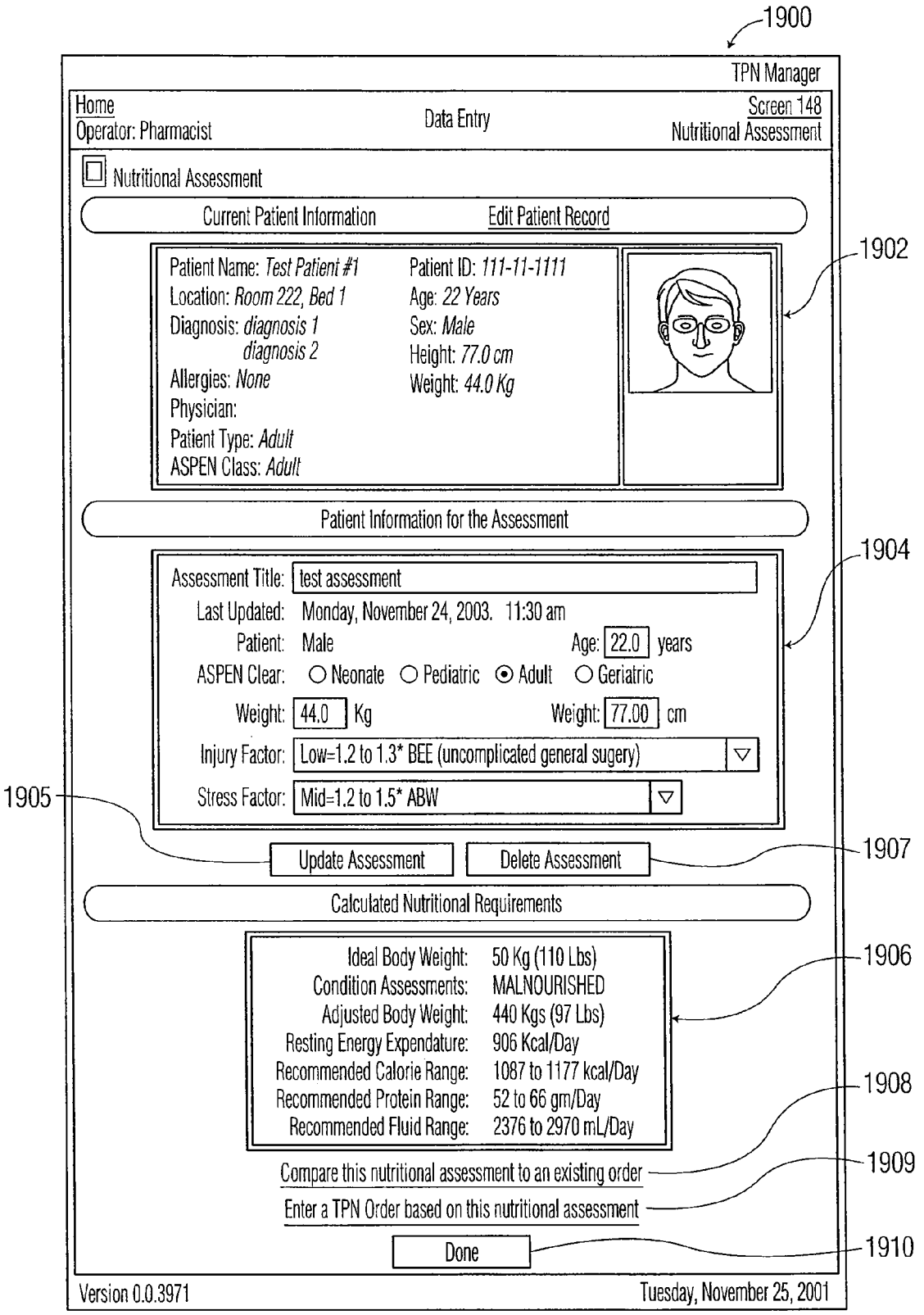

1900
TPN Manager
Home
Operator: Pharmacist
Data Entry
Screen 148
Nutritional Assessment
Nutritional Assessment
Current Patient Information
Edit Patient Record
Patient Name: Test Patient #1
Location: Room 222, Bed 1
Diagnosis: diagnosis 1
diagnosis 2
Allergies: None
Physician:
Patient Type: Adult
ASPEN Class: Adult
Patient ID: 111-11-1111
Age: 22 Years
Sex: Male
Height: 77.0 cm
Weight: 44.0 Kg
1902
Patient Information for the Assessment
1904
Assessment Title: test assessment
Last Updated: Monday, November 24, 2003. 11:30 am
Patient: Male
Age: 22.0 years
ASPEN Clear: Neonate Pediatric Adult Geriatric
Weight: 44.0 Kg
Weight: 77.00 cm
Injury Factor: Low=1.2 to 1.3* BEE (uncomplicated general sugery)
Stress Factor: Mid=1.2 to 1.5* ABW
1905
Update Assessment
Delete Assessment
1907
Calculated Nutritional Requirements
Ideal Body Weight: 50 Kg (110 Lbs)
Condition Assessments: MALNOURISHED
Adjusted Body Weight: 440 Kgs (97 Lbs)
Resting Energy Expendature: 906 Kcal/Day
Recommended Calorie Range: 1087 to 1177 kcal/Day
Recommended Protein Range: 52 to 66 gm/Day
Recommended Fluid Range: 2376 to 2970 mL/Day
1906
1908
Compare this nutritional assessment to an existing order
1909
Enter a TPN Order based on this nutritional assessment
Done
1910
Version 0.0.3971
Tuesday, November 25, 2001

FIG. 19

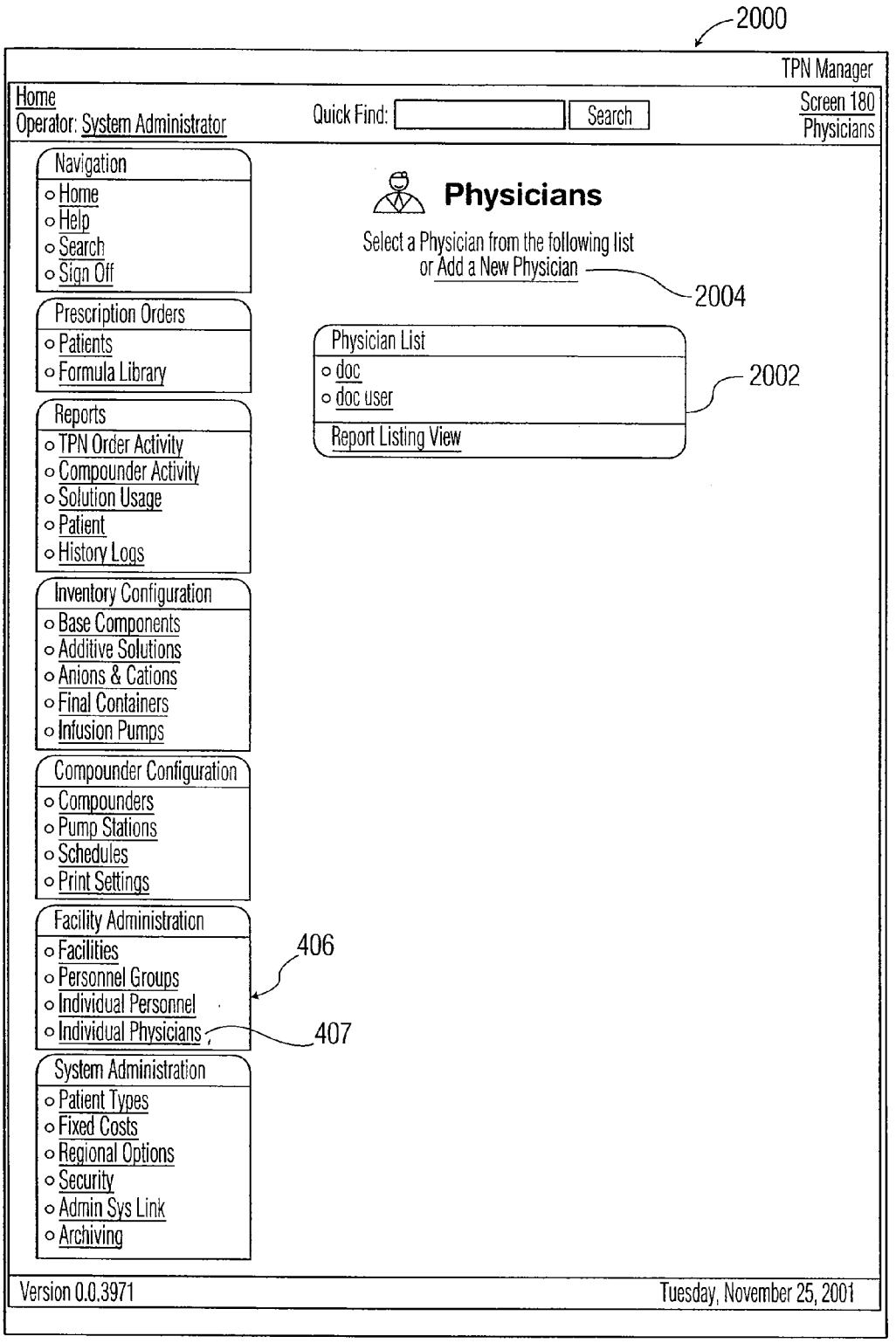

2000
TPN Manager
Home
Operator: System Administrator
Quick Find:
Search
Screen 180
Physicians
Navigation
Home
Help
Search
Sign Off
Prescription Orders
Patients
Formula Library
Reports
TPN Order Activity
Compounder Activity
Solution Usage
Patient
History Logs
Inventory Configuration
Base Components
Additive Solutions
Anions & Cations
Final Containers
Infusion Pumps
Compounder Configuration
Compounders
Pump Stations
Schedules
Print Settings
Facility Administration
Facilities
Personnel Groups
Individual Personnel
Individual Physicians
System Administration
Patient Types
Fixed Costs
Regional Options
Security
Admin Sys Link
Archiving
Physicians
Select a Physician from the following list
or Add a New Physician
2004
Physician List
doc
doc user
2002
Report Listing View
406
407
Version 0.0.3971
Tuesday, November 25, 2001

FIG. 20A

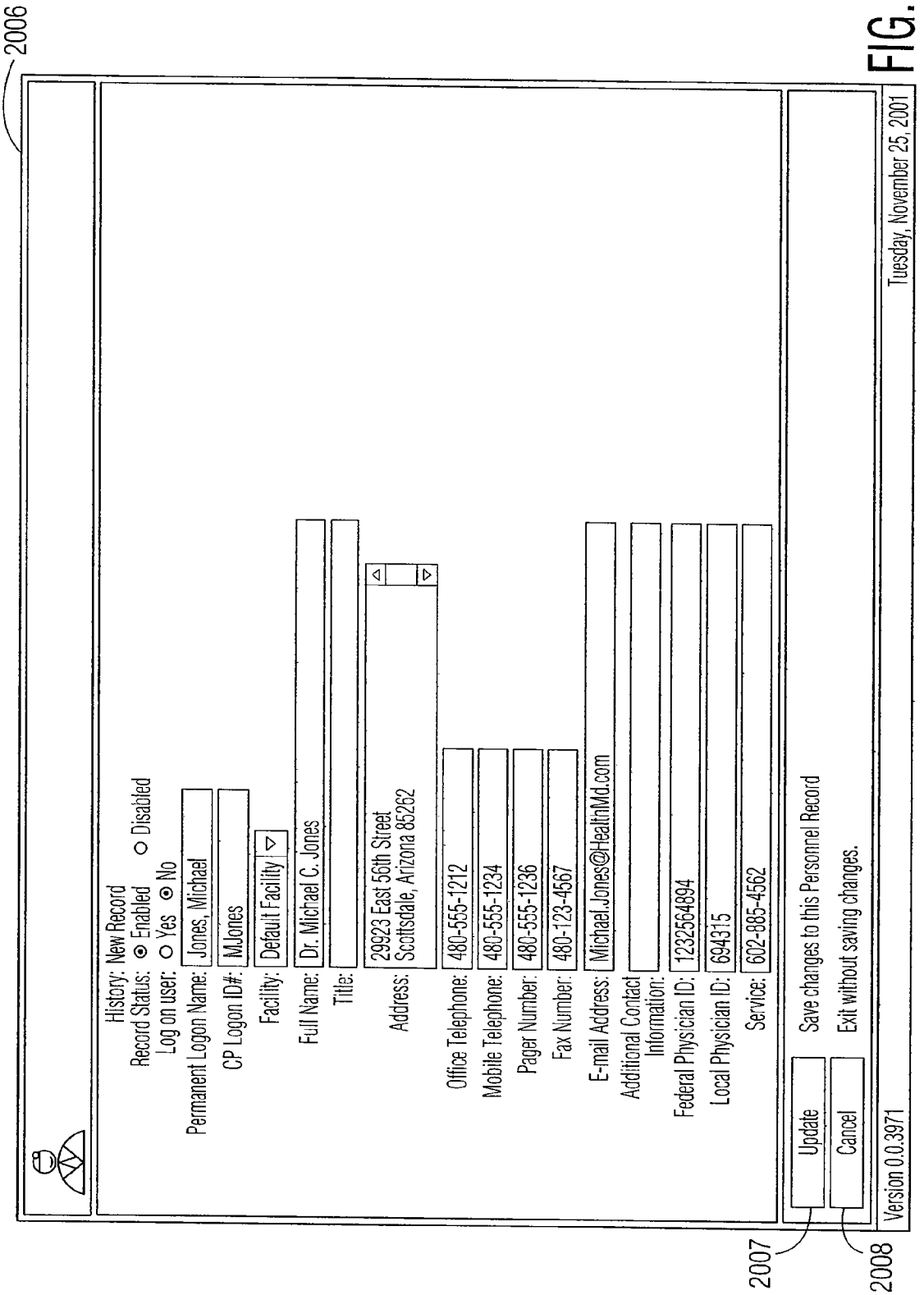

2006
History: New Record
Record Status: Enabled Disabled
Log on user: Yes No
Permanent Logon Name: Jones, Michael
CP Logon ID#: MJones
Facility: Default Facility
Full Name: Dr. Michael C. Jones
Title:
Address: 29923 East 56th Street Scottsdale, Arizona 85262
Office Telephone: 480-555-1212
Mobile Telephone: 480-555-1234
Pager Number: 480-555-1236
Fax Number: 480-123-4567
E-mail Address: Michael.Jones@HealthMd.com
Additional Contact Information:
Federal Physician ID: 1232564894
Local Physician ID: 694315
Service: 602-885-4562
Update
Save changes to this Personnel Record
Cancel
Exit without saving changes.
Version 0.0.3971
Tuesday, November 25, 2001
2007
2008

FIG. 20B

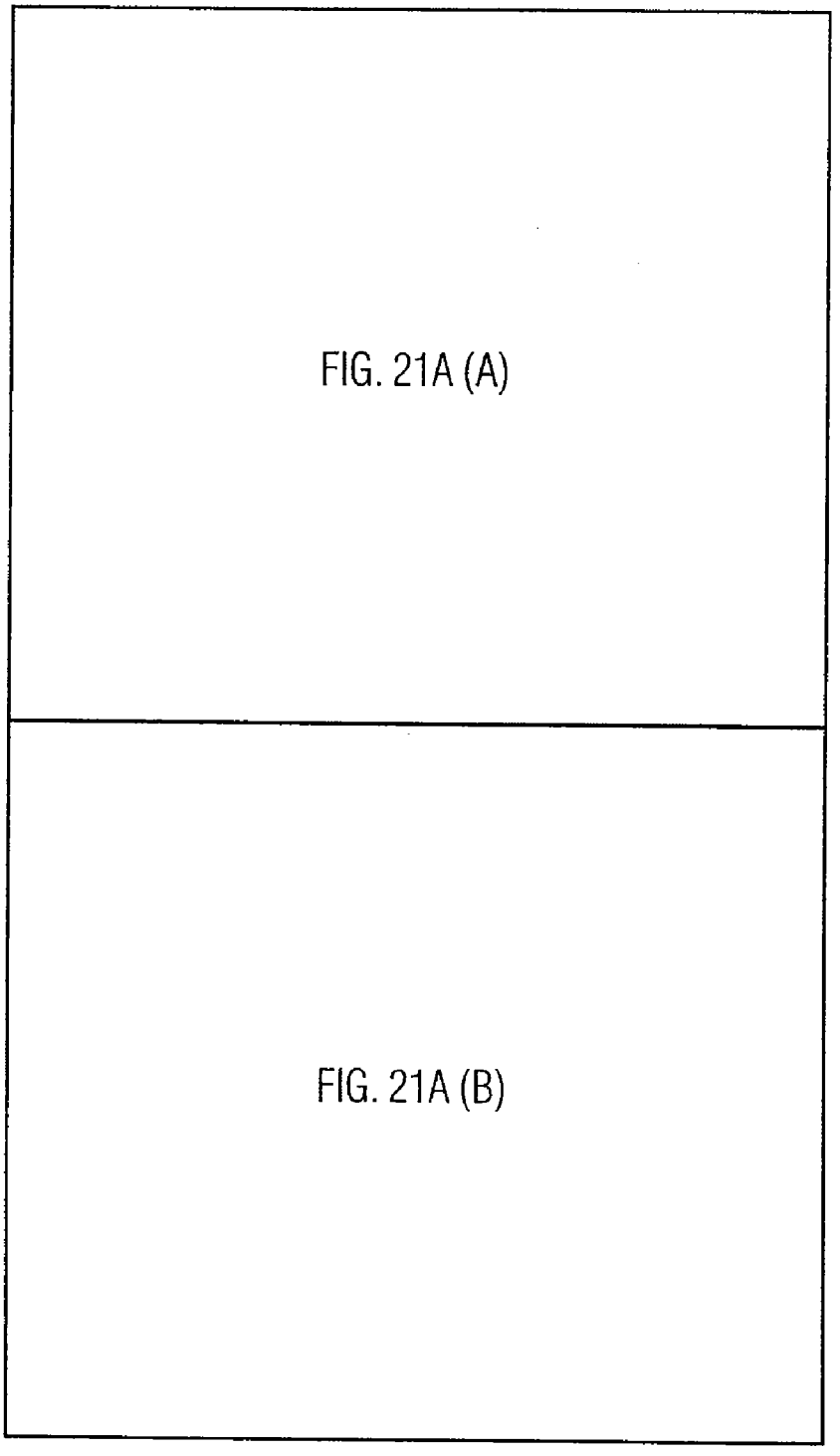


FIG. 21A

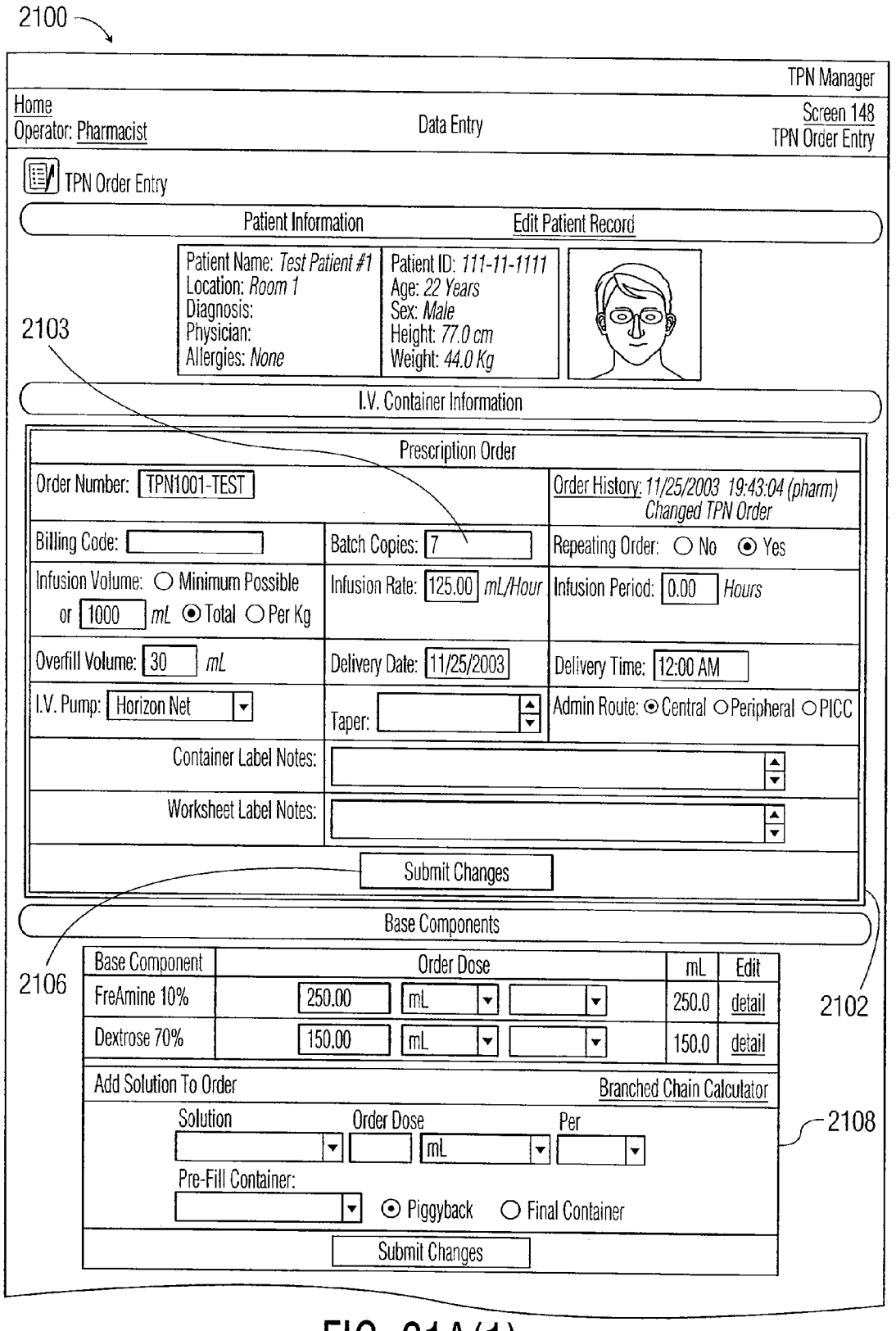

2100
TPN Manager
Home
Operator: Pharmacist
Data Entry
Screen 148
TPN Order Entry
TPN Order Entry
Patient Information
Edit Patient Record
Patient Name: Test Patient #1
Location: Room 1
Diagnosis:
Physician:
Allergies: None
Patient ID: 111-11-1111
Age: 22 Years
Sex: Male
Height: 77.0 cm
Weight: 44.0 Kg
2103
I.V. Container Information
Prescription Order
Order Number: TPN1001-TEST
Order History: 11/25/2003 19:43:04 (pharm) Changed TPN Order
Billing Code:
Batch Copies: 7
Repeating Order: No Yes
Infusion Volume: Minimum Possible
or 1000 mL Total Per Kg
Infusion Rate: 125.00 mL/Hour
Infusion Period: 0.00 Hours
Overfill Volume: 30 mL
Delivery Date: 11/25/2003
Delivery Time: 12:00 AM
I.V. Pump: Horizon Net
Taper:
Admin Route: Central Peripheral PICC
Container Label Notes:
Worksheet Label Notes:
Submit Changes
Base Components
2106
Base Component
Order Dose
mL
Edit
FreAmine 10%
250.00
mL
250.0
detail
Dextrose 70%
150.00
mL
150.0
detail
2102
Add Solution To Order
Branched Chain Calculator
Solution
Order Dose
Per
mL
2108
Pre-Fill Container:
Piggyback
Final Container
Submit Changes

FIG. 21A(1)

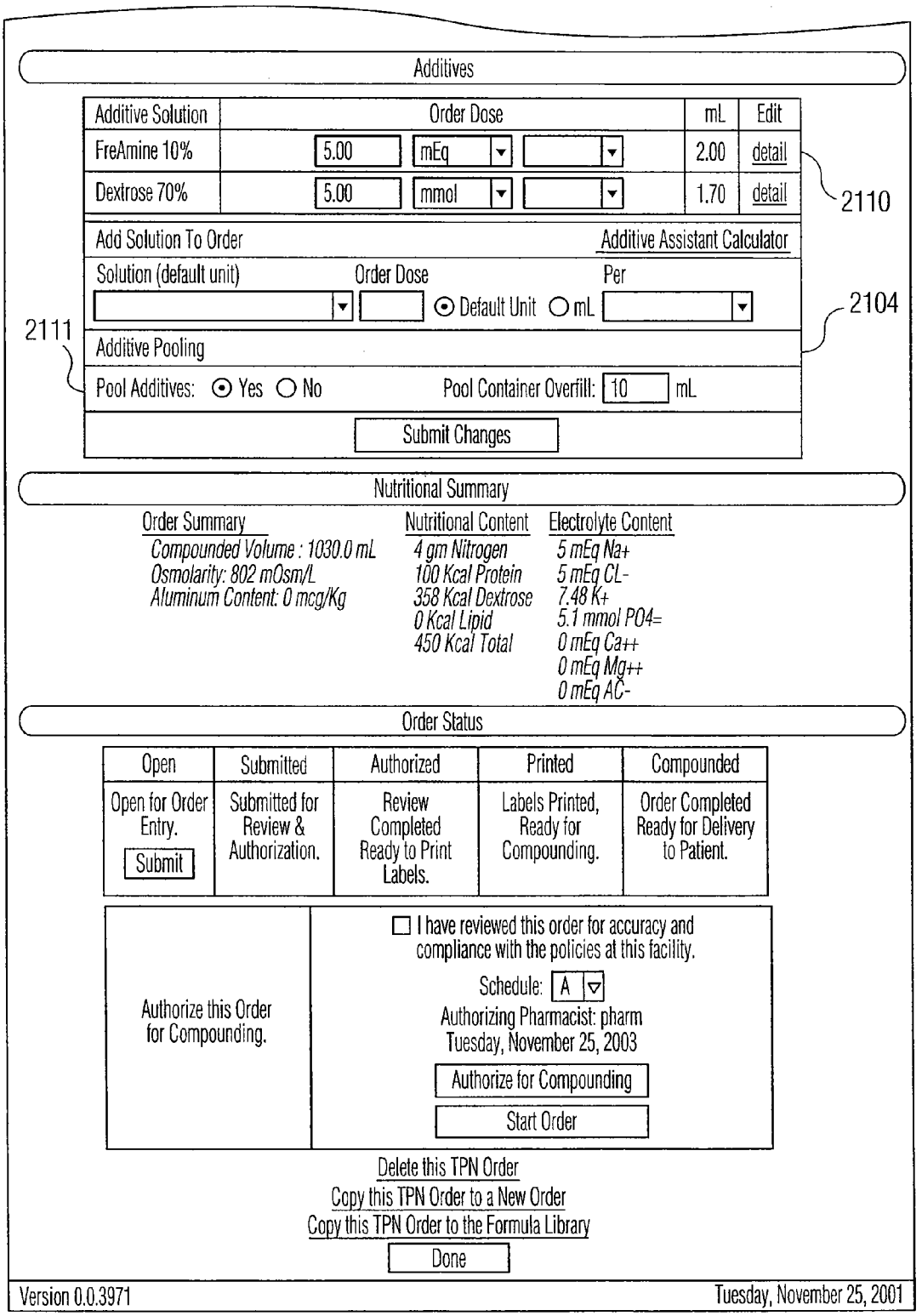

Additives
Additive Solution
Order Dose
mL
Edit
FreAmine 10%
5.00
mEq
2.00
detail
Dextrose 70%
5.00
mmol
1.70
detail
2110
Add Solution To Order
Additive Assistant Calculator
Solution (default unit)
Order Dose
Per
Default Unit
mL
2104
2111
Additive Pooling
Pool Additives: Yes No
Pool Container Overfill: 10 mL
Submit Changes
Nutritional Summary
Order Summary
Compounded Volume : 1030.0 mL
Osmolarity: 802 mOsm/L
Aluminum Content: 0 mcg/Kg
Nutritional Content
4 gm Nitrogen
100 Kcal Protein
358 Kcal Dextrose
0 Kcal Lipid
450 Kcal Total
Electrolyte Content
5 mEq Na+
5 mEq CL-
7.48 K+
5.1 mmol PO4=
0 mEq Ca++
0 mEq Mg++
0 mEq AC-
Order Status
Open
Submitted
Authorized
Printed
Compounded
Open for Order Entry.
Submit
Submitted for Review & Authorization.
Review Completed Ready to Print Labels.
Labels Printed, Ready for Compounding.
Order Completed Ready for Delivery to Patient.
Authorize this Order for Compounding.
I have reviewed this order for accuracy and compliance with the policies at this facility.
Schedule: A
Authorizing Pharmacist: pharm
Tuesday, November 25, 2003
Authorize for Compounding
Start Order
Delete this TPN Order
Copy this TPN Order to a New Order
Copy this TPN Order to the Formula Library
Done
Version 0.0.3971
Tuesday, November 25, 2001

FIG. 21A(2)

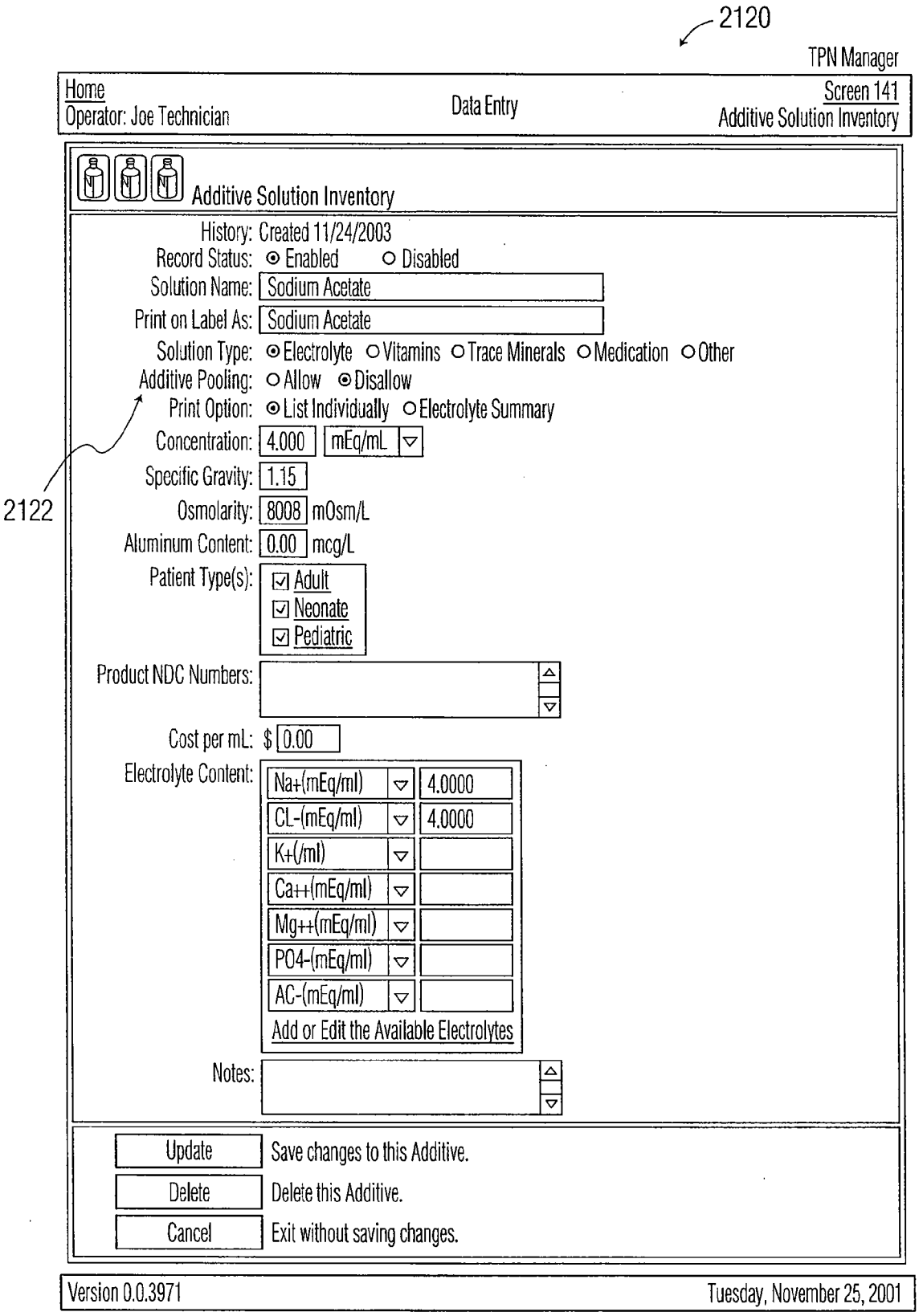

2120
TPN Manager
Home
Operator: Joe Technician
Data Entry
Screen 141
Additive Solution Inventory
Additive Solution Inventory
History: Created 11/24/2003
Record Status: Enabled Disabled
Solution Name: Sodium Acetate
Print on Label As: Sodium Acetate
Solution Type: Electrolyte Vitamins Trace Minerals Medication Other
Additive Pooling: Allow Disallow
Print Option: List Individually Electrolyte Summary
Concentration: 4.000 mEq/mL
Specific Gravity: 1.15
2122
Osmolarity: 8008 mOsm/L
Aluminum Content: 0.00 mcg/L
Patient Type(s): Adult Neonate Pediatric
Product NDC Numbers:
Cost per mL: $ 0.00
Electrolyte Content:
Na+(mEq/ml) 4.0000
CL-(mEq/ml) 4.0000
K+(/ml)
Ca++(mEq/ml)
Mg++(mEq/ml)
PO4-(mEq/ml)
AC-(mEq/ml)
Add or Edit the Available Electrolytes
Notes:
Update
Save changes to this Additive.
Delete
Delete this Additive.
Cancel
Exit without saving changes.
Version 0.0.3971
Tuesday, November 25, 2001

FIG. 21B

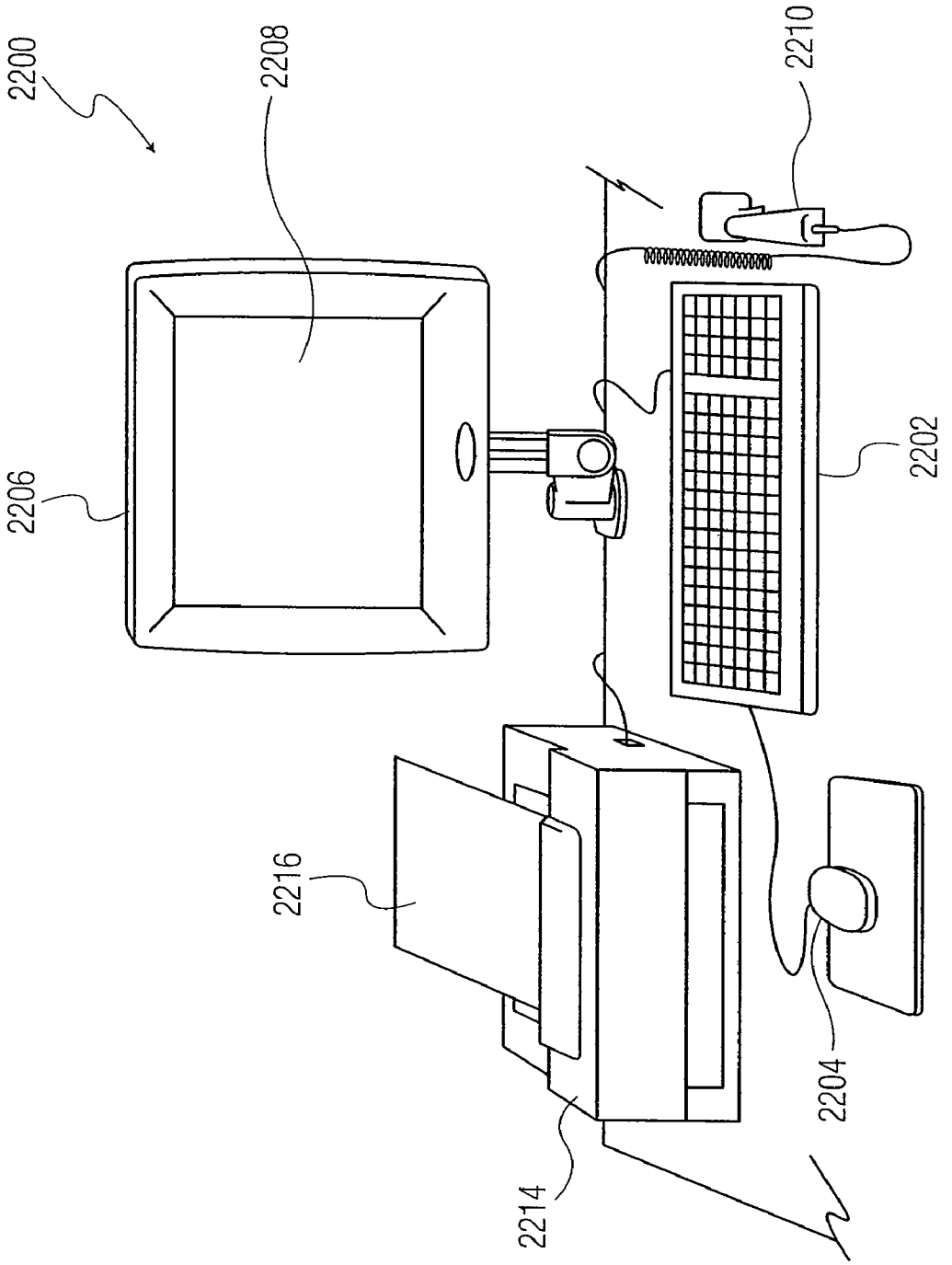


FIG. 22

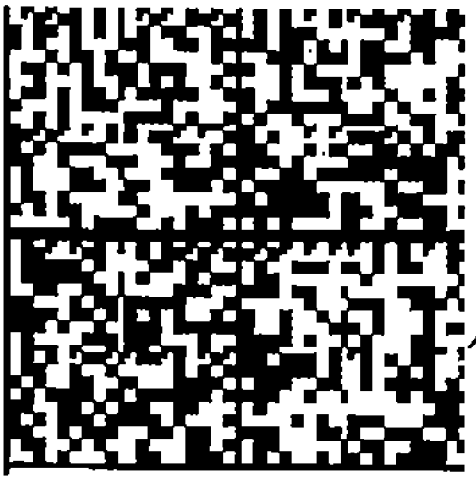


FIG. 23A

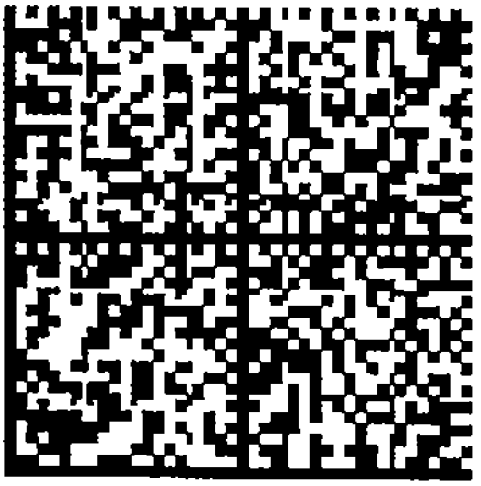


FIG. 23B

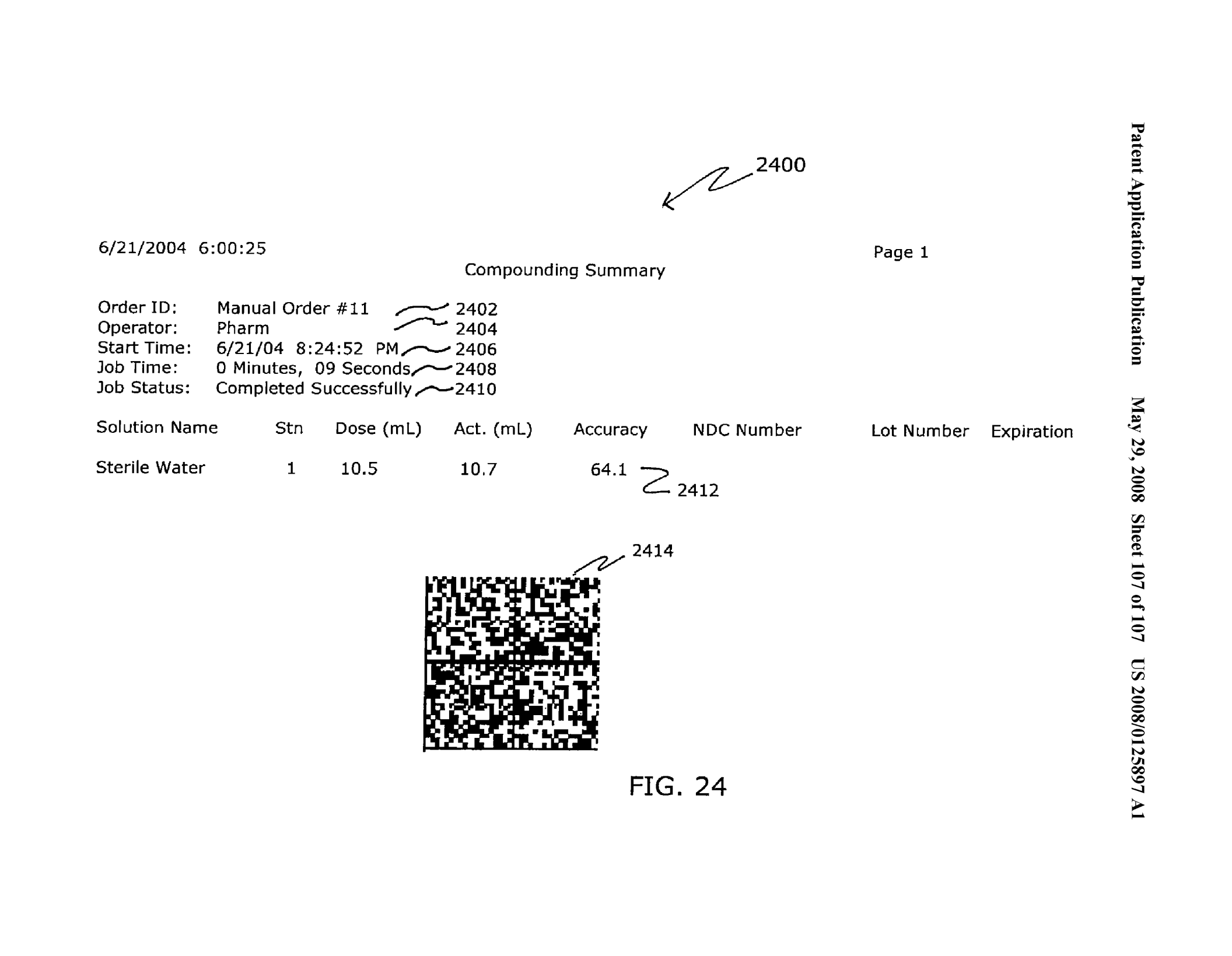

2400
6/21/2004 6:00:25
Page 1
Compounding Summary
Order ID: Manual Order #11 2402
Operator: Pharm 2404
Start Time: 6/21/04 8:24:52 PM 2406
Job Time: 0 Minutes, 09 Seconds 2408
Job Status: Completed Successfully 2410
Solution Name Stn Dose (mL) Act. (mL) Accuracy NDC Number Lot Number Expiration
Sterile Water 1 10.5 10.7 64.1 2412
2414

FIG. 24

METHOD FOR TRANSFERRING DATA TO A PHARMACEUTICAL COMPOUNDING SYSTEM

[0001] This application is a Continuation of U.S. patent application Ser. No. 11/003,232 filed on Dec. 3, 2004, which is a Continuation-in-Part of U.S. patent application Ser. No. 10/728,560 filed on Dec. 5, 2003 which is a Continuation-in-Part of U.S. patent application Ser. No. 10/335,552 filed on Dec. 31, 2002 which claims the benefit of priority of U.S. Provisional Patent Application Ser. No. 60/344,869, filed Dec. 31, 2001, and entitled "Pharmaceutical Compounder and Information Management System".

[0002] A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever.

FIELD OF THE INVENTION

[0003] This invention relates to a method for interfacing a compounder used to compound liquids and/or drugs intended to be administered to a human being or an animal with a prescription/order entry system.

BACKGROUND OF THE INVENTION

[0004] Pharmaceutical compounding involves the transfer of two or more of individual prescribed liquids and/or drugs from multiple source containers into a single collecting container, for the purpose of administering the mix of liquids and/or drugs intravenously to an individual in need. Presently, the pharmaceutical compounding of liquids and/or drugs takes places primarily at one of three sites. There are: (1) hospital based compounding performed by pharmacists or pharmacy technicians in the hospital pharmacy; (2) alternate site based compounding performed primarily by pharmacists or pharmacy technicians in the home care company pharmacy; and (3) compounding centers operated by any one of several major pharmaceutical or hospital supply companies.

[0005] The operational and performance demands upon these compounding systems and methodologies are becoming increasingly more complex and sophisticated, in terms of, e.g., safety, speed, reliability, accuracy, and overall user friendliness and ergonomics. The operational and performance demands upon these compounding systems and methodologies are also becoming increasingly more complex and sophisticated with regard to the management of patient and prescription information, in terms of providing an information path that starts with the clinician and finishes with the final product delivery to the end patient.

[0006] Interfacing of the system used by the doctor for example to enter a compound prescription/order for a patient has become a problem. Especially so where the order system is part of a larger system to which the compounder is not connected. Conventionally, in these situations the order is written or otherwise entered into the ordering system. The written order is then checked by the prescribing doctor or clinical pharmacist for accuracy. After approval, this printed order is provided to the pharmacy where it must now be reentered into the compounder system. The transcription of the written order is a source for errors resulting in a compound that does not match the intended prescription.

[0007] Alternatively, there are systems in place that electronically couple the order entry system and the pharmaceutical compounder. These systems, however, are complex and in the case of systems that do not share a common data protocol, require a translation interface. Further, these systems may not be desirable where autonomy of existing systems is required.

[0008] Therefore, what is needed is a system and method that addressed the problems of the prior art and provides for inputting of compounding data into a pharmaceutical compounded such that transcription errors are minimized if not eliminated entirely.

SUMMARY OF THE INVENTION

[0009] In view of the shortcomings of the prior art, the present invention is a system and method providing input data to a pharmaceutical compounding device having an associated plurality of source solutions.

[0010] One method comprising the steps of generating with said data entry system includes a first label comprising first indicia defining an allocation of said plurality of source solutions conforming to either a predetermined or undefined configuration; providing said first indicia to said pharmaceutical compounding device as an input; and generating a pharmaceutical compound based on said indicia input into said pharmaceutical compounding device.

[0011] According to another aspect of the invention, further steps include generating a second label comprising second indicia indicative of at least said pharmaceutical compound; providing said second indicia to said at data entry device as an input; and comparing said allocation of said plurality of source solutions with said second indicia in said data entry device.

[0012] Another aspect of the invention provides generating a first output if it is determined that a mismatch of said allocation of said plurality of source solutions and said pharmaceutical compound has occurred.

[0013] Another aspect of the invention provides generating a second output if it is determined that the allocation of said plurality of source solutions and matches the allocation of source solution in the pharmaceutical compound.

[0014] According to another aspect of the invention the second indicia also compromises information relating to a patient for which the pharmaceutical compound is intended.

[0015] According to another aspect of the invention at least one of the first indicia and/or the second indicia comprises a bar code.

[0016] According to yet another aspect of the invention, either or both labels are RFID tags and the indicia associated with the tags is stored in electronic form therein.

[0017] Another aspect of the invention is a system for providing input data to a pharmaceutical compounding device having an associated plurality of source solutions. The system comprises means for generating a first output comprising first information defining at least an allocation of said plurality of source solutions conforming to a predetermined configuration; means for transferring said first information into said pharmaceutical compounding device; means for generating a pharmaceutical compound based on said first information; means for generating a second output comprising second information indicative of at least said pharmaceutical compound; means for comparing said second information with

said first information; and means for determining if said pharmaceutical compound matches said predetermined configuration.

[0018] According to another aspect of the invention, either or both of the first and second information are in electronic form stored in respective RFID tags.

[0019] Other features and advantages of the inventions are set forth in the following specification and attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The invention is best understood from the following detailed description when read in connection with the accompanying drawing. It is emphasized that, according to common practice, the various features of the drawing are not to scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawing are the following Figures:

[0021] FIG. **1** is a perspective view of a pharmaceutical compounding system that includes a compounding device that, in use, mixes or compounds two or more selected liquids and/or drugs intended to be administered to a human being or an animal.

[0022] FIG. **2**A is a view of a disposable transfer set that can be used in association with the compounding device shown in FIG. **1**.

[0023] FIGS. **2**B and **2**C are enlarged views, partially broken away and in section, of an embodiment of a manifold that the transfer set shown in FIG. **2**A can incorporate to mediate against back flow of liquid in the manifold and lipid hazing.

[0024] FIGS. **2**D and **2**E are enlarged views, partially broken away and in section, of another embodiment of a manifold that the transfer set shown in FIG. **2**A can incorporate to mediate against lipid hazing.

[0025] FIG. **2**F is a view of a portion of the disposable transfer set shown in FIG. **2**A, which includes a transfer tube organizer to facilitate use of the transfer set with the compounding device shown in FIG. **1**.

[0026] FIG. **3** is a perspective view of the system shown in FIG. **1** with the transfer set shown in FIG. **2**A mounted for use on the compounding device.

[0027] FIG. **4** is a perspective view of the compounding device shown in FIG. **1**, with its peristaltic pumping station open for loading a transfer set of the type shown in FIG. **2**A.

[0028] FIG. **5** is a perspective view of a compounding device shown in FIG. **4**, with a transfer set mounted in the peristaltic pumping station.

[0029] FIG. **6**A is a perspective side view of the compounding device shown in FIG. **4** with its exterior case removed to show the peristaltic pump components and other internal components.

[0030] FIG. **6**B is an exploded perspective view of the peristaltic pump components shown in FIG. **6**A.

[0031] FIG. **7** is a top view of the compounding device shown in FIG. **6**A.

[0032] FIGS. **8**A to **8**F are schematic views of alternative configurations of linked and/or networked systems that incorporate the compounding device shown in FIG. **1**.

[0033] FIGS. **9**A to **9**W are representative screens of a graphical user interface that a compounding control manager function residing on the compounding device shown in FIG. **1** can generate in the process of enabling and controlling a compounding procedure.

[0034] FIGS. **10**A to **10**E are system flow charts of representative functional modules of an order entry process manager function that, when used in association with the compounding control manager function of the compounding device shown in FIG. **1**, provides enhanced compounding order entry and processing capabilities that can be accessed by browsers installed on remote workstations.

[0035] FIGS. **11**A to **11**J are representative screens of a browser-based graphical user interface that makes accessible to a remote workstation the functional modules of the order entry process manager shown in FIGS. **10**A to **10**E.

[0036] FIG. **12** is a representative view of labeling that the order entry process manager shown in FIGS. **10**A to **10**E and FIGS. **11**A to **11**I can generate.

[0037] FIG. **13** is a schematic view of a controller that the compounding device shown in FIG. **1** can incorporate, which can execute the compounding control manager and order entry process manager functions shown in FIGS. **9**A to **9**W; **10**A to **10**E; **11**A to **11**I.

[0038] FIGS. **14**A-**14**B are representative screens of a training/help video-audio function that can be integrated with the compounding control manager of the compounding device shown in FIG. **1**.

[0039] FIG. **15**A-**15**B are representative screens related to configuration of the exemplary system.

[0040] FIG. **16** is a representative screen illustrating the freeze screen function of the exemplary system.

[0041] FIG. **17** is a representative screen illustrating the check list function of the exemplary system.

[0042] FIG. **18**A-**18**B are representative screens illustrating the infusion pump selection function of the exemplary system.

[0043] FIG. **19** is a representative screen illustrating the nutritional assessment function of the exemplary system.

[0044] FIG. **20**A-**20**B are representative screens illustrating the physician entry/selection function of the exemplary system.

[0045] FIG. **21**A-**21**B are representative screens illustrating the additive solution function of the exemplary system.

[0046] FIG. **22** is a block diagram of an exemplary embodiment illustrating transfer of information for an ordering system to a pharmaceutical compounder of the present invention.

[0047] FIGS. **23**A-**23**B are examples of a barcode output from the order entry device of the exemplary data transfer system.

[0048] FIG. **24** is an example of an output from the pharmaceutical compounder of the exemplary data transfer system.

DETAILED DESCRIPTION OF THE INVENTION

[0049] FIG. **1** shows a pharmaceutical compounding system **10**. The system **10** can be used for mixing or compounding two or more selected liquids and/or drugs intended to be administered to a human being or an animal. In use, the system **10** serves to transfer two or more of individual prescribed liquids and/or drugs from multiple source containers (e.g., individual vials, bottles, syringes, or bags) into a single collecting container (e.g., a bottle, syringe, or bag), so that the mix of liquids and/or drugs can be administered (e.g., intravenously) to an individual in need.

[0050] As one example, due to injury, disease, or trauma, a patient may need to receive all or some of their nutritional requirements intravenously. In this situation, the patient will typically receive a basic solution containing a mixture of amino acids, dextrose, and fat emulsions, which provide a major portion of the patient's nutritional needs, which is

called total parenteral nutrition, or, in shorthand, TPN. In this arrangement, a physician will prescribe a mixture of amino acids, dextrose, and fat emulsions to be administered, as well as the frequency of administration. To maintain a patient for an extended period of time on TPN, smaller volumes of additional additives, such as vitamins, minerals, electrolytes, etc., are also prescribed for inclusion in the mix. Using the system **10**, under the supervision of a pharmacist, the prescription order is entered and individual doses of the prescribed liquids, drugs, and/or additives are accordingly transferred from separate individual source containers for mixing in a single container for administration to the individual.

[0051] There are other environments where the system **10** is well suited for use. For example, in the medical field, the system **10** can be used to compound liquids and/or drugs in support of chemotherapy, cardioplegia, therapies involving the administration of antibiotics and/or blood products therapies, and in biotechnology processing, including diagnostic solution preparation and solution preparation for cellular and molecular process development. Furthermore, the system **10** can be used to compound liquids outside the medical field.

[0052] Nevertheless, for the purpose of explaining the features and benefits of the system **10**, the illustrated embodiment describes use of the system **10** in support of TPN.

I. System Overview

[0053] The system **10** includes three principal components. These are (i) a liquid transfer set **12** (see FIG. **2**A), which, in use, couples a final solution container **14** to individual solution source containers **16**; (ii) a compounding or solution mixing device **18** (see FIG. **1**), which, in use (see FIG. **3**), interacts with the transfer set **12** to transfer liquids from the solution source containers **16** into the final solution container **14**; and (iii) a controller **20** (see FIG. **1**) that governs the interaction to perform a compounding or solution mixing procedure prescribed by a physician, which is typically carried out by a trained clinician at a compounding site under the supervision of a pharmacist.

[0054] The compounding device **18** and controller **20** are intended to be durable items capable of long-term use. In the illustrated embodiment (see FIG. **1**), the compounding device **18** is mounted inside a housing or case **22**, and the controller **20** is mounted, in most part, within a control panel **24** mounted to a surface outside the case **22**. The case **22** presents a compact footprint, suited for set up and operation upon a tabletop or other relatively small surface. The case **22** and panel **24** can be formed into a desired configuration, e.g., by molding or forming. The case **22** and panel **24** are preferably made from a lightweight, yet durable material, e.g., plastic or metal.

[0055] The transfer set **12** (FIG. **2**A) is intended to be a sterile, single use, disposable item. As FIG. **3** shows, before beginning a given compounding procedure, the operator loads the various components of the transfer set **12** in association with the device **18**.

[0056] As illustrated, the device **18** includes a weigh station **26** that, in use, carries the final solution container **14** (as FIG. **3** shows). The weigh station **26** includes a support arm **28** (as FIG. **4** shows), which in the illustrated embodiment, is attached to a side or bottom of the case **22**. The weigh station **26** also includes a conventional load cell **30**, which suspends from a top of the support arm **28**. During compounding, the final solution container **14** hangs from a hanger H on the load cell **30** (see FIG. **3**). As also illustrated, the device **18** may include, but does not require, a source solution support frame **32**. The support frame **32** carries several individual hangers H, which, during compounding, support the individual source containers **16**. When a source solution support frame **32** is not included in device **18**, other means can be used to support the individual source containers **16**.

[0057] As illustrated, the support frame **32** comprises a separate component; however, the support frame **32** can be attached in a suitable manner to the case **22**. Typically, during compounding, the device **18**, with source containers **16** and final container **14**, are located within a laminar flow hood in a "clean room" environment.

[0058] The transfer set **12** shown in FIG. **2**A can in general include lengths of source transfer tubing **34**, which are joined at one end to a common junction or manifold **36**. The opposite ends of the source transfer tubing **34** each includes a spike **38** or suitable releasable coupling, which can be inserted in conventional fashion through a diaphragm carried by the associated source solution container **16**, to open flow communication between that source solution container **16** and the respective source transfer tubing **34**. A length of final transfer tubing **40** is coupled to the final solution container **14**. The opposite end of the final transfer tubing **40** includes a spike **42** or suitable releasable coupling, which can be inserted into an outlet **44** in the manifold **36**, to couple the final solution container **14** to the source solution containers **16**. The source transfer tubing **34** and the final transfer tubing **40** can be made from flexible, medical grade plastic material, such as polyvinyl chloride plasticized with di-2-ethylhexyl-phthalate. One or more of the source containers **16** or final containers **14** can likewise be made from medical grade plastic material selected for inertness and compatibility with the intended source solution. Likewise, one or more of the source or final containers **16** or **14** can be made from glass.

[0059] Each source transfer tubing **34** includes an in-line pump segment **46** between the spike **38** and the manifold **36**. The pump segments **34** can be made, e.g., from silicone rubber. Each source transfer tubing **34** also includes an in-line, one way valve **48** (e.g., a duckbill, disk, or umbrella valve)—which, in the illustrated embodiment, is carried within the manifold **36** (see FIG. **2**B)—which permits liquid flow from the source containers **16** toward the manifold **36**, but prevents backflow from the manifold **36** toward any of the source containers **16**. Each valve **48** opens in response to forward fluid flow, to allow liquid flow into the manifold **36** and through the spike-receiving outlet **44** (i.e., toward the final solution container **14**). Each valve **48** closes in response to back flow of liquid in the manifold **36** from the outlet **44** or other source transfer tubing **34**.

[0060] Each pump segment **46** is designed for use in association with a peristaltic pump rotor. Accordingly, as FIG. **4** shows, the compounding device **18** includes a peristaltic pumping station **50**. As FIG. **4** shows, the peristaltic pumping station **50** occupies a pump bay **52** or compartment formed in the device. As shown, the peristaltic pumping station **50** includes an axial array of individual peristaltic pump rotor assemblies **54**, although non-axial arrays can be used. Furthermore, the pumping station **50** can include multiple side-by-side banks of peristaltic pump rotor assemblies **54**.

[0061] The peristaltic pumping station **50** includes a door **56**, which opens and closes the pump bay **52**. The door **56** opens (as FIG. **4** shows) to allow loading of a selected one of the pump segments **46** in association with a selected one of the peristaltic pump rotor assemblies **54**, as FIG. **5** shows. The

door closes (as FIG. **3** shows) to enclose the peristaltic pumping station **50** during operation. Desirably, the controller **20** is coupled to an electrical interlock **66** (see FIG. **13**) to prevent operation of the peristaltic pump rotor assemblies **54** when the door **56** is opened.

[0062] The controller **20** executes a compounding protocol or procedure based upon prescribed data entry orders and preprogrammed pump control rules, which also can include other input from the operator. During operation, the peristaltic pump rotor assemblies **54** are individually, selectively operated in series—or simultaneously, selectively operated in parallel—as dictated by the controller **20**, to transfer desired amounts of source solutions from the individual source containers **16** through the manifold **36** and into the final container **14**. The load cell **30** is coupled to the controller **20**, to gravimetrically monitor the incremental transfer of the individual source solutions into the final container **14**. The controller **20** monitors incremental changes in weight, which are processed according to preprogrammed rule to govern the speed at which a given peristaltic pump assembly **54** is operated and, ultimately, stopped when the prescribed amount of source solution is delivered.

[0063] The controller **20** (see FIG. **13**) comprises a main processing unit (MPU) **58**. The MPU **58** comprises a conventional PC that is, in the illustrated embodiment, mounted within the control panel **24**, outside the case **22** of the compounding device **18**. Alternatively, the MPU **58** could be mounted within the case **22** of the compounding device **18**. The MPU **58** can comprise one or more conventional microprocessors that support the Microsoft.®. Windows.®. operating environment. The MPU **58** includes conventional RAM **122** and a conventional nonvolatile memory device **74**, such as a hard disk drive. The MPU **58** includes an input device **124** to upload programs into the memory device **74**, e.g., a CD-reader. In the illustrated embodiment, a compounding control manager function **72** resides as process software in the memory device **74** of the MPU **58**.

[0064] In the illustrated embodiment, the controller **20** also includes a supervisor CPU **126** and peripheral processing unit (PPU) **60**. Both the CPU **126** and PPU **60** are desirably implemented on a printed circuit board. The CPU comprises a conventional microprocessor capable of running the uC/OS-II operating system. The PPU is a dedicated microchip PIC, driven by firmware specific to its processing tasks and control functions. In the illustrated embodiment, the CPU **126** and PPU **60** are mounted inside an electronics bay **62** or compartment with the case **22** of the compounding device **18** (see FIGS. **6**A, **6**B, and **7**). An AC power supply (not shown) supplies electrical power to the CPU **126**, PPU **60**, and other electrical components of the device **18**.

[0065] The CPU **126** is coupled via a USB, RS-232, or Ethernet port, or other connective means, to the MPU **58** (see FIG. **13**). The CPU **126** receives high-level instructions from the MPU **58** generated by the compounding control manager **72**. The PPU **60** (see FIG. **13**) is coupled via an RS-232 link to the CPU **126**. The high-level instructions generated by the compounding control manager **72** are conveyed by the CPU **126** as medium level commands to the PPU **60**. The PPU **60** is connected to various hardware of the peristaltic pump station **50** and weigh station **26**—e.g., the door interlock **66** (as previously described), a pump motor **64** (see also FIG. **6**A, as will be described later), pump clutches **68** (a will be described later), Hall effect pump rotor sensors **70** (as will also be described later), the load cell **30** (previously described), etc. The PPU **60** provides hardware-specific commands, based upon the medium level control commands generated by the CPU **126**, as well as a first level of safeguards (e.g., to stop the pump motor **64** if the door **56** is open, as previously described). The PPU **60** and CPU **126** communicate with and monitor each other, to backup individual failures and take corrective action.

[0066] The compounding control manager **72** resides on the MPU **58**. The compounding control manager **72** includes preprogrammed rules that prescribe procedures for receiving and manipulating input data, monitoring device status and operating conditions, outputting or storing data, and commanding operation of the peristaltic pump station **50** to achieve prescribed compounding tasks. The MPU **58** communicates high level instructions to the CPU **126** (e.g., the amount of liquid each peristaltic pump assembly **54** is to convey), which are created by the compounding control manager **72** in response to operator input. The CPU **126**, in turn, communicates medium level instructions to the PPU **60**, which communicates specific pump commands to the peristaltic pump assemblies **54** to carry out the pumping instructions, well as receives and evaluates operational status data from sensors and the load cell, to generate closed-loop feedback control and corresponding alarms. The PPU **60** also relays operational status data to the CPU **126**, which also evaluates the operational status data in parallel with the PPU **60**. In this respect, the CPU **126** provides a second level of safeguards if an alarm condition is not detected by the PPU **60** (e.g., to halt pumping if over-delivery—not otherwise sensed by the PPU **60**—is occurring).

[0067] In the illustrated embodiment (see FIG. **1**), the controller **20** includes a display device **76**, which is part of the control panel **24**, data entry devices **78** (e.g., a keyboard and a mouse), and a data output station **80** (e.g., a printer), which are coupled via appropriate inputs and outputs to the MPU **58**. In the illustrated embodiment (see FIG. **1**), the display device **76** also desirably serves as another data entry device using, e.g., conventional touch screen methodologies implemented by the compounding control manager **72** using a Windows.®.-based operating platform resident in the compounding control manager **72**. The combined data display and data entry capabilities that the compounding control manager **72** executes in this arrangement provide an interactive user interface on the display device **76** that, under preprogrammed rules resident in the compounding control manager **72**, accepts data entry and displays for the operator information prompting or confirming the entered data, as well as monitored operational status and conditions of the compounding device **18**. The compounding control manager **72** also provides a third level of safeguards by verification of the original order with the actual pump delivery results. The display can be in alpha-numeric format and/or as graphical or pictorial images, as desired. The compounding control manager **72** also enables output of selected information to the printer **80** in a desired format, e.g., as activity reports. The interactive user interface of the compounding control manager **72** allows the operator to conveniently enter, view, and assimilate information regarding the operation of the system **10**. Further details of the compounding control manager **72** and the touch screen interactive user interface that can be implemented by the compounding control manager **72** will be described later.

[0068] As also shown in FIG. **1**, the MPU **58** also includes an input for a bar code reader **82** or the like, for scanning information into the compounding control manager **72**. In

embodiments that include RFID tags, rather than bar coded indicia, a commercially available RFID reader (not shown) is substituted for bar code reader **82**. Further details of this aspect of the system **10** will be described later.

[0069] As FIG. **1** also shows, the MPU **58** also includes input for keyboard and mouse data entry devices **78**. These devices **78** allow the operator to enter data for manipulation by the compounding control manager **72** and to interact with information presented by the display device **76** in different ways, and without use of the touch screen data entry capabilities of the compounding control manager **72**. In this arrangement (see FIG. **13**), the controller **20** desirably includes an order entry process manager **84**, which can reside on the memory device **74** of the MPU **58** in the control panel **24**. The order entry manager **84** makes possible other forms of interactive data entry and data viewing platforms, as well as other forms of data output to the printer **80** in a selected format, e.g., as labeling for the final solution container **14**, as will be described in greater detail later.

[0070] Desirably (as FIG. **13** shows), the order entry process manager **84** can be accessed by browser software **86** residing on one or more external microprocessors **88** linked to the compounding control manager **72** of the device controller **20**. In this arrangement, the controller **20** desirably includes an RS-232 link or another alternative data communication connections (e.g., radio, microwave, infrared, or other electromagnetic wave communication systems), to enable electronic or electromagnetic data communication between the compounding control manager **72** and external input or output devices (e.g., other data entry workstations and/or printers), using, e.g., single-station hubless local area network connections, multiple-station hub or switch local area network connections, multiple-station hub connections with facility network servers, and/or multiple-station connections through the public internet. Conversely, or in addition, multiple compounding devices **18** can be linked through their onboard controllers to multiple data entry workstations or sites. These capabilities of the controller **20** make diverse arrangements of fully networked pharmaceutical compounding possible. Further details of these networked forms (e.g., internet, intranet, or loopback) of interactive data entry and data viewing platforms, that can be accommodated by the controller **20** in association with the compounding control manager **72**, will be described later.

[0071] Upon completing a compounding procedure, the operator seals the inlet tubing **40** of the final solution container **14** and detaches the final transfer tubing spike **42** from the manifold **36**. When there are a series of compounding orders that require mixtures of at least some of the same source solutions, which typically is the case, the operator will proceed to the next compounding order by attaching the spike **42** of the inlet tubing **40** of a new final solution container **14** to the manifold **36** and executing another compounding procedure. Otherwise, the operator can decouple the source transfer tubing **34** from the source containers **16** and remove the transfer set **12** and source containers **16** from association with the device **18**. The transfer set **12** can be discarded. Each final solution container **14**, and its compounded liquid contents, is retained for storage, infusion, transfusion, or further processing.

II. Technical Features of the Compounding Device

[0072] FIGS. **6**A, **6**B, and **7** best show the details of construction of a representative embodiment of the compounding device **18**. As illustrated, the device **18** includes a frame **90** that is divided into the pump bay **52** and the electronics bay **62**, as previously described. Hardware components of the peristaltic pumping station **50** occupy the pump bay **52**. The electrical components of the pumping station **50** the load cell **30**, as well as the PPU **60**, occupy the electronics bay **62**. The case **22** shown, e.g., in FIGS. **4** and **5**, encloses the frame **90** and the components it carries.

[0073] A. The Peristaltic Pumping Station

[0074] Within the pump bay **52**, the peristaltic pumping station **50** includes an array of peristaltic pump rotor assemblies **54**, as already generally described. The number and configuration of peristaltic pump rotor assemblies **54** can vary according to design considerations and the compounding requirements of the device **18**. In the illustrated embodiment (shown in FIG. **4**), there are nine peristaltic pump rotor assemblies **54**.

[0075] As illustrated (see FIGS. **6**A and **6**B), each peristaltic pump rotor assembly **54** is constructed in the same manner. Each assembly **54** is supported on a bearing plate **92** secured to the frame **90**. The bearing plates **92** are arranged sequentially in an axial spaced relationship along a drive shaft **94**. The drive shaft **94** is coupled at one end to the electric drive motor **64** (see FIG. **6**A) (carried in the electronics bay **62**) via a drive belt **96** and drive pulley **98**. Alternatively, the drive shaft **94** can be coupled directly to the drive motor **64**. Operation of the drive motor **64**, which is governed by the controller **20**, rotates the drive shaft **94** at a desired rate of rotation. In a representative implementation, the drive motor can rotate the drive shaft **94** at variable rates. Each pump rotor assembly **54** includes a drive gear **100**, which is carried by a bearing **102** on the drive shaft **94**. A conventional electro-magnetic clutch assembly **68** is coupled to each drive gear **100**. Each clutch assembly **68** is individually coupled to the controller **20** (as FIG. **13** shows). When actuated by the controller **20**, a given clutch assembly **68** frictionally couples the drive gear **100** to the drive shaft **94**, causing rotation of the drive gear **100**. When the clutch assembly **68** is not actuated by the controller **20**, rotation of the drive shaft **94** is not imparted to the associated drive gear **100**.

[0076] A fixed idler shaft **104** extends through the bearing plates **92** on a bushing **108**, spaced from and offset from the drive shaft **94**. Each pump rotor assembly **54** also includes a driven gear **106**. The driven gears **106** are individually coupled to the drive gears **100**, such that rotation of a given drive gear **100** will impart rotation to its respective driven gear **106**. In this arrangement, each pump rotor assembly **54** includes a pump rotor **110** coupled (e.g., by gear attachment screws **112**) for rotation with each driven gear **106**. Each pump rotor **110** carries an array of pump rollers **114**, which, in use, engage an in-line pump segment **46** of the transfer tubing **34**.

[0077] Actuation of a given clutch assembly **68** by the controller **20** couples the associated drive gear **100** to the drive shaft **94**—to which rotation is imparted by the drive motor **64**—which, in turns, imparts rotation through the driven gear **106** to the associated pump rotor **110**. During rotation of the pump rotor **110**, the pump rollers **114** engage the associated pump segment **46** and convey liquid through the transfer tubing **34** by well-understood peristaltic pumping action.

[0078] Each pump rotor assembly **54** includes a pair of holding brackets **116** aligned with the associated pump rotor **110**. The holding brackets **116** are sized and configured to

releasably mate with mounts **118** (see FIG. **2**A) formed on opposite ends of each pump segment **46**. The holding brackets **116** frictionally engage the pump segment mounts **118**, and thereby hold the pump segments **46** in desired operative association with the pump rollers **114** during use, as FIG. **5** shows.

[0079] As will be described in greater detail later, the holding brackets **116** of the pump rotor assemblies **54** and pump segment mounts **118** of the transfer tubing **34** are desirably uniquely coded (e.g., by matching numbers and/or by a matching color or the like) to prompt a desired order to the mounting of a selected pump segment **46** in relation to a selected pump rotor **110**. The unique matching code is also carried by the spike **38** of the associated transfer tubing **34** (e.g., by a numbered, colored tab **120**), to prompt a desired coupling of the transfer tubing **34** in relation to a selected source container **16**. As will be described in greater detail later, the graphics of the user interface generated by the compounding control manager **72** desirably incorporates this unique code, thereby matching the disposable components of the transfer set **12** with the hardware components of the pump station **50**, as well as with the desired software functionality provided by the compounding control manager **72**.

[0080] Desirably, the unique matching code includes for example bar-code indicia, e.g., one or two-dimensional bar code. Alternate embodiments may employ other types of indicia, such as RFID tags for example, into which the information is stored. In this arrangement, the compounding control manager **72** can require the operator to perform the physical act of scanning in bar code indicia on a source solution container and on the transfer set, to eliminate potential error sources prior to compounding. This marriage between software, hardware, and disposable components minimizes sources of compounding errors due to human error. Bar code scanning can also desirably include determining lot number recording prior to compounding, and warning/preventing use of a source solution that has an expired date or will become expired within a predetermined period. As such, recording of solution lot numbers can be automated and tied to the compounded bag and the waste of valuable source solutions is avoided as well as avoiding the possibility of providing a final solution that may not be as effective as a solution that did not contain an expired component.

[0081] As shown in FIG. **2**F, the transfer set **12** can also include a tubing organizer **128**, which comprises a molded or fabricated strip of plastic sized and configured to capture, as a unit, all the transfer tubing **34** between the pump segments **46** and the spikes **38** in a desired order. In this arrangement, the organizer **128** requires the operator to mount the pump segments **46** as a unit to the holding brackets **116**, with the order of the transfer tubing **24** with respect to the pump rotor assemblies **54** preordained by the organizer **128**. The organizer **128** further assures that the transfer tubing **34** is loaded in a desired order on the compounding device **18**.

[0082] The system **10** makes possible systematic process control at every stage of the compounding process, starting at the physician order point and continuing through compounding and final product delivery and receipt. As above described, orders can be received from the patient site via hospital based electric ordering systems. Upon the electronic receipt of data, such data can be entered or transmitted electronically into the compounding control manager **72**. Final solution containers **14** can be labeled automatically as the step preceding the compounding process. The compounding process can thereafter be controlled and verified through labeling on the final solution container **14** in combination with source container labeling and bar coding.

[0083] B. Pump Control Criteria

[0084] As has been generally described, and as will be described later in greater detail, a desired compounding order is entered by an operator, and the compounding control manager **72** in the MPU **58** of the control panel **24** executes the compounding order. Typically, the compounding order identifies the source solutions and the amounts of each source solution (by weight or volume) that are to be mixed in the final solution. The compounding control manager **72** can operate the individual pump rotor assemblies **54** (through the PPU **60** in the compounding device **18**) in a serial compounding mode, i.e., operating a first pump rotor assembly **54** to convey the desired amount of a first source solution into the final container **14**, then next operating a second pump rotor assembly **54** to convey the desired amount of a second source solution into the final container **14**, and so on until the desired amount of each source solution has been delivered to comprise the desired mixture.

[0085] In controlling the individual pump rotor assemblies **54**, the preprogrammed rules of the compounding control manager **72** desirably take into account pre-established delivery accuracy criteria. The criteria can vary according to the compounding tasks to be accomplished. For example, for TPN, delivery accuracy criteria can be established of +/−5%, or better, for any ingredient of 0.2 mL or more. A delivery accuracy criteria of +5%/−0% could be established to eliminate the possibility of underfills.

[0086] The preprogrammed rules of the compounding control manager **72** also desirably include a delivery time criteria that takes into account the delivery volume. Keeping absolute errors as small as possible is mandated at smaller delivery volumes to achieve a system delivery accuracy goal of +/−5% or better. Such smaller absolute delivery errors require the compounding control manager **72** to incorporate tighter process control, which, for smaller delivery volumes, can result in longer delivery times per mL of delivery. However, larger absolute errors are acceptable at larger delivery volumes to achieve a system delivery accuracy goal of +/−5% or better. For example, a 1% error on a 10 mL delivery is 0.1 mL. The same 1% error on a 1000 mL delivery is 10 mL. Thus, the compounding control manager **72** can institute different process control for larger volumes, which, for larger delivery volumes, can result in a faster delivery times per mL of delivery.

[0087] The compounding control manager **72** can also accommodate parallel processing of the same source solution. For example, if the same source solution is present on two pump rotor assemblies **54**, both source solutions can be pumped in parallel (at the same time) to shorten overall delivery time. Thus, if it takes two minutes to fill a single container using serial compounding (i.e., one solution after the other), it is expected that parallel compounding can potentially reduce this time requirement down to one minute, depending upon the solution components that comprise the final product.

[0088] The preprogrammed rules of the compounding control manager **72** institute desirable closed-loop control of the pump drive motor **64**. The closed-loop control desirably implement convention proportional-integral-derivative (PID) control schemes to control pump speed to achieve a desired target delivery. The PID control schemes generate pump correction commands that take into account not only the absolute difference between the present delivery amount and the target

amount, but also the how quickly the absolute difference is changing over time. The control schemes can use a purely mathematical PID model, or they can incorporate "fuzzy logic" techniques, making use of estimations and interpolations to determine how to adjust the motor speed to obtain the desired flow rate. Use of fuzzy logic techniques permit a motor speed control function without use of multiply and divide instructions, thereby minimizing processing complexity.

[0089] Shown below is the fundamental PID equation is, where 'e' is the error between the desired motor speed and the actual motor speed and 'u' is the new motor drive power level to try to adjust for the error:

$$u = K_P e + K_I \int e dt + K_D \frac{de}{dt} \quad \text{Eq. 1}$$

[0090] where:

[0091] (P)roportional—The proportional (direct) response to motor speed error.

[0092] (I)ntegral—The integral (quick speed change) to difference between the desired speed and actual speed. This normally comes into play at motor start-up, where the motor power needs to go from zero to full power very quickly.

[0093] (D)erivative—The derivative (accumulated) response to motor speed error. This is what causes the motor power to steadily increase as necessary in the presence of high loads, for example.

[0094] In Eq. 1, an integer math approximation of the error between the desired motor speed and the projected motor speed is performed based on the current motor speed and acceleration. This error value is then used to adjust the motor drive power level up or down as appropriate.

[0095] By using the absolute error value (scaled appropriately) as the motor power adjustment value, the (P)roportional part of the PID equation is approximated.

[0096] By the choice of value ranges and scales, the (I)ntegral part of the PID equation is approximated. This is accomplished by making the error value scale large compared to the motor drive power, so that a moderate error value (much less than the maximum possible error) drives the motor power level to saturation.

[0097] Furthermore, by adjusting the motor drive power level instead of determining a new motor drive power level at each PID control loop iteration, the (D)erivative contribution of the PID equation is approximated.

[0098] This results in a motor control algorithm that performs like a conventional PID algorithm, with improved transient response and smooth control.

Quadrature Decoder Implementation

[0099] Unlike a conventional quadrature decoder, our decoder does not generate Up and Down pulses to pump drive motor **64**; rather it simply determines the direction that pump drive motor **64** is currently spinning. The PPU **60** monitors the direction signal and statistically determines if the motor is spinning in the programmed direction, and generates an alarm if not. This results in the use of a minimum number of parts to implement the quadrature decoding function, which in conventional systems, require additional PPU inputs or more expensive external parts.

[0100] In one representative implementation, the compounding control manager **72** conducts a high speed flow rate control regime until the absolute difference between the volume delivered and the target approaches a preset amount. At this "slow down" point, the compounding control manager **72** ramp-downs the flow rate and conducts a low speed flow rate control regime. During this regime, the correction commands become successively smaller as the difference between the volume delivered and the target diminishes. The rate of the flow rate reduction during this regime can be linear or non-linear, and the slope of the non-linear reduction can be either concave, or convex, or a combination thereof.

[0101] In a desired implementation, the compounding control manager **72** steps or pulses the respective pump rotor assembly as the target volume is approached. In this arrangement, the PPU **60** can communicate with rotor rotation sensors **70**, such as Hall effect sensors coupled to each rotor, so that a rotor revolution can be correlated with a number of incrementally sensed steps, which, in turn, can be correlated with incremental degrees of rotor rotation—e.g., one full revolution (360 degrees) equals five hundred incrementally sensed steps, so each incrementally sensed step equals 0.72 degrees of rotation. In this way, the PPU **60** can generate very precise pump commands in terms of small incremental units of pump rotor rotation when the target volume is approached, to prevent an overfill such as that caused by hydraulic effect whereby the tubing of the transfer set will return to its normal cross-section after pressure from pumping is removed.

[0102] The PPU **60** monitors the output of the Hall effect sensors to determine which rotor(s) are spinning. This information is used to generate appropriate alarms, such as:

[0103] 1. Rotor moving when it shouldn't be—this is a potential hazard because it can cause incorrect solution to be delivered to the final container. The exemplary system monitors for this condition and issues an alarm when it occurs, and advises the operator that the final container should not be used to treat a patient.

[0104] 2. Rotor not moving when it should be—this is not a hazard, but is detected and reported to the operator as a malfunction.

III. Technical Features of the Transfer Set

[0105] As before described, for a typical compounding session, there are usually a series of compounding orders that require mixtures of at least some of the same source solutions. In this arrangement, an operator will repeatedly exchange final solution containers **14** with the same manifold **36**.

[0106] In these circumstances, a compounding order that requires a fat emulsion as a source solution can leave a fat emulsion residue in the manifold **36**. This residue left in the manifold **36**, although small in volume, can be introduced into the final solution container **14** of a subsequent compounding order, which may not specify a fat emulsion. The unintended residue causes what is generally called "lipid hazing" in the final solution container **14** of a compounding order that is supposed to be free of a fat emulsion.

[0107] To minimize the lipid hazing effect, in FIG. **2**B, there is one transfer tubing **34'** that is intended, during use, to be dedicated to the conveyance of a fat emulsion. As before explained, a unique coding arrangement, coupled with required bar code scanning (or RFID scanning where appropriate), can be incorporated to assure that this transfer tubing **34'** is dedicated during use to the conveyance of fat emulsion from a source container. During compounding, fat emulsion

is conveyed into the final solution container **14** in advance of the other source solutions. Thus, the compounding of other source solutions after the fat emulsion serves to flush residual fat emulsion from the manifold **36** and into the final solution container **14**.

[0108] Following compounding, when the spike **42** is withdrawn from the outlet **44**, a temporary vacuum is created within the manifold **36**. The valves **48** can open in response to the temporary vacuum created by withdrawal of the spike **42** from the outlet **44**, drawing a small bolus of source solutions into the manifold **36**. A residue of fat emulsion can be included in this bolus.

[0109] In the illustrated arrangement, the valve **48'** in the manifold **36** that is in-line with the fat emulsion transfer tubing **34'** is sized and configured to have a valve opening or "cracking" pressure that is greater than the valve opening or cracking pressure of the other valves **48** in the manifold **36**, which are in-line with transfer tubing **34** that is not coupled to a fat emulsion source container. The greater cracking pressure of the valve **48'** that is in-line with the fat emulsion transfer tubing **34'** is selected to keep the valve **48'** closed when the spike **42** is withdrawn from the outlet **44**.

[0110] In use (as FIG. **2**C shows), when a spike **42** is withdrawn from the outlet **44**, due to the lesser cracking pressures of the valves **48** that are not in-line with the fat emulsion transfer tubing **34'**, these valves **48** can open in response to the temporary vacuum created by withdrawal of the spike **42** from the outlet **44**. However, due to the greater cracking pressure of the valve **48'** that is in-line with the fat emulsion transfer tubing **34'**, the valve **48'** remains closed when the spike **42** is withdrawn from the outlet **44**. Thus, as the spike **42** is withdrawn and the temporary vacuum is created within the manifold **36**, the small bolus of source solutions from all the source containers that may be drawn into the manifold **36** will not include the fat emulsion. Thus, a residue of fat emulsion is prevented from entering the manifold **36** when the final solution container **14** is exchanged.

[0111] In an alternative arrangement (see FIGS. **2**D and **2**E), the peristaltic pump rotor assembly **54'** serving the one transfer tubing **34'** dedicated to the conveyance of fat emulsion can be capable of reverse rotation under the direction of the controller **20**. Reverse rotation creates a negative pressure and draws the in-line valve **48'** closed. In this arrangement, the controller **20** commands reverse rotation of the fat emulsion pump assembly **54'** prior to the operator removing the spike **42** from the outlet **44**. As FIG. **2**E shows, removal of the spike **42** can open the valves **48**, except the valve **48'** in the fat emulsion tubing **34'**, which remains closed due to the counterforce of negative pump pressure. As before described, as the spike **42** is removed, a bolus of source solutions from all the source containers can be drawn into the manifold **36**, except for the fat emulsion.

[0112] The vacuum created by removal of the spike **42** can be augmented by pulsing the other peristaltic pump rotor assemblies **54** in a forward direction as the spike **42** is withdrawn. In this arrangement, the cracking pressure of the valve **48'** serving the fat emulsion transfer tubing **34'** need not be different that the cracking pressure of the other valves **48**.

IV. Technical Features of the Controller

[0113] A. The Compounding Control Manager

[0114] The compounding control manager **72** resides in the MPU **58** in the control panel **24**. The compounding control manager **72** allows a clinician to enter, view, adjust and offload information pertaining to a given compounding protocol.

[0115] In general, the compounding control manager **72** is the program language that provides the operator with real time feedback and interaction with the compounding device through graphic user interface (GUI) elements. The GUI elements, created in a Windows.®.-based graphical format, display the various inputs and outputs generated by the compounding control manager **72** and allow the user to input and adjust the information used by the compounding control manager **72** to operate the compounding device **18**.

[0116] To develop the GUI elements, the compounding control manager **72** can utilize certain third party, off-the-shelf components and tools. Once developed, the compounding control manager **72** can reside as a standard window-based software program on a memory device.

[0117] FIGS. **9**A to **9**W, **15**A-**15**B, **16**, and **17** are a walk-through of display screens generated by a representative embodiment of the compounding control manager **72**, which demonstrate various features of the compounding control manager **72**.

[0118] After an initial start-up mode of software initialization, a main work **10** area is created on the display device **76**, which initially opens a log-in screen **200** (FIG. **9**A). The log-in screen **200** prompts the operator to identify himself, either by using the bar code or RFID scanner to scan an operator badge number, or by entry of a badge number or other selected form of identification on the graphical touch screen entry pad. This identification procedure is required for logging-in and/or assessing the operator's level of security clearance. Desirably, a system administrator would have previously established a list of authorized users, against which the sign-in data is compared.

[0119] The system desirably includes various set-up procedures that provide various safeguards for the operation of the system. FIG. **15**A is one such configuration screen **1500** for setting up approvals required for all compounding operations. As shown in FIG. **15**A, upon selection of tab **1502**, screen **1500** is presented to the operator, such as the administrator of the system or another individual that has such high level system administrative access. In this example, Screen **1500** presents a three tier selection for each of several classes of patients. Approval requirements are independent of one another across patient classes. Examples of approval levels are "NONE"—no approval necessary of any compounding function; "After Source Change"—Requiring approval from an upper level employee, such as a pharmacist, after any of the various source solutions are changed and/or replaced; "ALWAYS"—Requiring approval from an upper level employee for all compounding functions. The latter approval setting may be invoked for example for a new or junior level technician, or whenever such oversight is desired.

[0120] FIG. **15**B illustrates Barcode Configuration screen **1504**. As shown in FIG. **15**B, screen **1504** is presented to the operator upon selection of tab **1506** and allows the operator to set up the communication port via pull down **1508**, as well as permitting the selection of other attributes of the port, such as Port Speed, parity, word length, etc., via pull down **1510**. The operator is also presented with a variety of check boxes **1512** allowing the operator to select other check routines, such as requiring barcode confirmation before allowing compounding to start (**1514**); requiring source solution barcode confirmation at setup (**1516**); requiring source container barcode

confirmation after a no-flow alarm is indication (**1518**); and requiring final container label barcode confirmation (**1520**). The checks provide additional means to help avoid human error in the preparation of the final solution.

[0121] Once an authorized identification is entered, the log-in screen **200** is replaced by a main screen **202** (FIG. **9**B). The main screen **202** displays sequentially numbered pump station data fields **204**. The pump station data fields **204** are desirably numbered according to the left to right placement of the peristaltic pump rotor assemblies **54** in the compounding device. The numbers are also desirably color-coded according to the color code assigned to the peristaltic pump rotor assemblies **54** in the compounding device **18**, as previously described.

[0122] Each pump station data field **204** includes a solution field **206** for the operator to identify what solution is to be delivered, as well as an amount field **208** to identify how much of that solution is to be delivered. The solution field **206** includes a touch button **210** that prompts TOUCH TO PROGRAM STATION. Touching the prompt button **210** allows to operator to enter data in the solution and amount fields **206** and **208** required by the compounding control manager **72**.

[0123] Touching the prompt button **210** first opens a solution programming box **212** (FIG. **9**C). The solution programming box **212** displays within the main screen **202** an array of touch buttons that either contain a specific identification of a solution type—e.g., DEX (dextrose); AMINO (amino acid); LIPID (fat emulsion); LYTES (electrolytes)—or allow the operator to specify another solution type (OTHER), or ask for a list of available solutions (LIST). Desirably, a system administrator would have previously established a list of solutions, using the OPTIONS MENU touch button **214** on the main screen **202**, as will be described later. Other touch buttons in the solution programming box allow the operator to scroll through a list of solutions (PREVIOUS SOLUTION, NEXT SOLUTION). Another button (OK) allows for a verification of the identified solution and entry of that solution in the solution field **206**, or an exit button (CANCEL) that closes the solution programming box **212** with no data entry in the solution field **206**. Selection of a specific solution type button (e.g., DEX) (see FIG. **9**D) either enters the only solution of its type on the list (i.e., Dextrose 70%), or, if there are various selections to be made (e.g., by selecting AMINO), displays a solution listing box **216** for that solution type (see FIG. **9**E), from which the operator selects by touch.

[0124] Once the solution type has been selected, the operator selects the OK button on the solution programming box **212**, and the solution type appears (see FIG. **9**F) in the solution field **206** of the pump station data field **204**. An amount programming box **218** is also opened (FIG. **9**F), which replaces the solution programming box **212**. The amount programming box **218** comprises a graphical numeric keypad, by which the operator can enter an amount expressed in a selected unit which is to be transferred by the selected pump station from the source solution container into the final container (e.g., volume, expressed in mL). The unit for the amount can also be specified by use of the DOSE CALCULATOR touch button **220**. Once the numeric amount is entered, pressing the ENTER touch button in the amount programming box **218** enters the entered amount in the amount field **208** of the pump station data field **204** (see FIG. **9**F), and the amount programming box **218** closes.

[0125] The station control box **222** (FIG. **9**G) can also be optionally selected by pressing the station number identification icon **224**. The station control box **222** requires that the transfer of the solution identified in the solution field **206** be confirmed by the operator pressing the CONFIRM SOLUTION touch button **226**. Pressing the CONFIRM SOLUTION touch button **226** opens a solution confirmation box **228** (FIG. **9**H). The operator is prompted to scan a bar code on the source solution container (using the bar scanner input device **82**). This bar code identifies, e.g., the solution type, the lot number of the solution, and its expiration date. By scanning the bar code, the compounding control manager **72** links this information to a specific compounding order for verification and solution tracking purposes. Furthermore, the compounding control manager **72** can implement expiration date control, locking out the use of expired solutions. The integration of the bar code scanning function with the compounding control manager **72** integrates lot number and expiration date tracking and/or verification to the operation of the compounding device **18**.

[0126] The operator is also prompted to visually assure that the transfer tubing **34** having the unique coding corresponding to the pump station number is coupled to the source container from which the bar code is scanned, as well as scan the bar code component of the unique code on the transfer tubing **24** for that pump station. As confirmation of the correct source solution container **15** and transfer tubing **24** is made by the operator by scanning bar codes, information in the solution confirmation box **228** is updated (see FIG. **9**I(**1**)). The operator is also prompted by screen **900**, as shown in FIG. **9**I(**2**), to confirm that the new transfer set has been installed and that it does not contain any solution is presented as option choice. Alternatively, if the operator is continuing to use the previous set up or a default setup to compound, the source solution setup screen **904** (FIG. **9**I(**3**)) is presented at start-up asking the operator to make the appropriate selection as well as asking the operator to confirm that if a new transfer set was as installed, to ensure that the transfer set tubing is free of all solutions before proceeding. After full confirmation is accomplished, the operator can press an OK touch button in the solution confirmation box **228**.

[0127] The solution flush box **230** (see FIG. **9**J) can also be optionally selected by pressing the FLUSH station control button on the station control box **222** (see FIG. **9**G). The solution flush box **230** includes touch buttons that prompt the operator to conduct a SHORT FLUSH (e.g., 2 seconds) or a LONG FLUSH (e.g., 5 seconds), during which time the compounding control manager **72** operates the corresponding peristaltic pump rotor assembly **54** for the selected pump station. The load cell **30** can also monitor for weight changes, indicating entry of solution into the final container **14**, to verify (if desired) that flow communication exists between the source solution container **16** and the final container **14**. The solution flush box **230** indicates completion of the flush (see FIG. **9**K), and the operator is prompted to by an EXIT touch button to return to the main screen **202**. Flush is not required prior to the start of compounding, but is available as an optional set up step.

[0128] The operator is prompted to follow the above prescribed sequence for each source solution and each pump station, until programming is complete. FIG. **9**L shows the main screen **202** after (i) the operator has programmed the compounding control manager **72** to mix 137 mL of 70% dextrose (pump station **1**), 54 mL of 15% novamine (pump station **2**), 77 mL of 10% Travasol (pump station **3**), and 216 mL of sterile water (pump station **9**) from source solution

containers into the final container, and (ii) the operator has also verified for each pump station that the proper source solution and transfer tubing set up are present. As FIG. **9**L shows, the main screen **202** lists the solutions and amounts in the respective fields **206** and **208** of each pump station box **204** and, further, prompts the operator to press a highlighted START touch button **232**. Upon selection of the START touch button, compounding immediately commences under the control of the compounding control manager **72**. If one or more of the source solutions have not been confirmed at the time the operator presses the START button **232**, the compounding control manager **72** will automatically prompt the operator to confirm each remaining source solution before compounding is allowed to begin. The START touch button **232** is not enabled by the compounding control manager **72** until all required preliminary steps have been satisfactorily completed.

[0129] Alternatively, the operator can select an AUTO PGM touch button **234** on the main screen **202** (see FIG. **9**L). This opens a queue selection screen **236** (FIG. **9**P), which displays a list of preprogrammed schedule queues established by the system administrator. The operator selects the desired queue and presses the ENTER touch button on the queue selection screen **236**. The compounding control manager **72** holds the order queue list in memory, and the main screen **202** (see FIG. **9**Q) allows the operator to view the current order queue list, one order at a time, in a queue box **238**. In this arrangement, the operator selects the order from the programmed order queue list on the main screen **202**, and then starts compounding. Alternatively, the operator can scan a bar code on a final solution container to be compounded. The compounding control manager **72** uploads and presents the compounding order for that final container.

[0130] If, during the selection process outlined above, the operator programs a dextrose source solution and a Lipid source solution screen as part of the same compound with one immediately proceeding or following the other, the process recognizes this and displays screen **902** (FIG. **9**G(**1**)) to the operator to avoid a situation whereby a breakdown (or cracking) of the lipid may occur without the introduction of the buffer solution. Also, and as it relates to additive solutions discussed below, a check whether calcium and/or phosphate are added to the final solution is conducted to avoid the formation of an insoluble precipitate. In the event that an improper concentration of these components is detected, the operator will be alerted with a display screen (not shown) similar to screen **902**.

[0131] It may be the case that certain source solution are contained in small vials, rather than large bags or bottles. As such, these vials will necessarily have a small stopper end from which the solution will be extracted. Such a small stopper will limit the flow rate of the solution when compared to other types of source solution containers and may result in a flow rate that will fall below the normal flow rate that the system expects, thereby resulting in an alarm condition. To overcome this problem the system allows the operator to instruct the system though an appropriate screen selection that the source solution is being sourced from a vial or other reduced flow container. In response, the system will limit the upper speed on the pump when that particular source solution is pumped to avoid the false indication of reduced flow.

[0132] As compounding proceeds, the compounding control manager **72** updates the number TOTAL DELIVERED field **240** (by incrementing up) and amount field **208** (by incrementing up) of the respective pump station field **204** of the main screen **202** (FIG. **9**M), to indicate the series transfer of liquid from the several source containers **16** into the final container **14**. In FIG. **9**M, pump stations **1**, **3**, and **9** have been programmed. Station **1** has completed its pumping (having delivered the desired 138 mL. Station **3** has begun to pump (having pumped 38 mL). Station **9** is waiting to begin. The TOTAL DELIVERED field **240** shows 176 mL, which is the current sum of amounts pumped by pump stations **1**, **2**, and **3**. The PUMPING icon **242** is illuminated to indicate that compounding is proceeding. The operator can, if desired, terminate compounding by pressing the illuminated STOP touch button **244**.

[0133] If, during the course of compounding, the load cell **30** indicates that there is no liquid transfer into the final container **14**, the compounding control manager **72** generates a pumping alarm. The compounding control manager **72** interrupts the compounding procedure when this alarm condition occurs. The compounding control manager **72** opens a pumping alarm screen **246** (FIG. **9**N). The INTERRUPTED icon **248** is also illuminated to indicate that compounding is not proceeding. An information field **250** displays information pertaining to the alarm condition. The information field **250** prompts the operator to take corrective action and, by pressing a RESUME touch button **252**, to commence compounding once again.

[0134] When compounding is complete, the compounding control manager **72** displays a COMPLETE message in the information field **250** (see FIG. **9**O) and prompts the operator to remove the final container **14**. In an alternate representation, once compounding is complete screen **910** (FIG. **9**O(**1**)) is displayed. As shown in FIG. **9**O(**1**), screen **910** includes patient name **912**, the type of order **914**, the amount ordered by volume (**916**) and/or weight (**918**), the amount of compound delivered by volume (**920**) and/or weight (**922**), and accuracy **924**. The operator may close this screen by selecting "OK" **926** to continue.

[0135] The operator can then reprogram the compounding control manager **72** to carry out another compounding regime by following the above sequences of steps.

[0136] There are other graphical buttons on the main screen **202** (see FIG. **9**B), which may be used to carry out various support functions. For example, by pressing the OPTIONS MENU touch button **214**, the options menu screen (FIG. **9**R) is displayed. The option menu screen prompts the operator to select among a list of administrative functions that, in the illustrated embodiment, include REPEAT LAST ORDER, ORDER HISTORY, SETTINGS AND DIAGNOSTICS, and SIGN OFF. Pressing the REPEAT LAST ORDER button automatically configures the compounding control manger to compound according to the most recent order. Pressing the ORDER HISTORY button displays an order history screen **258** (FIG. **9**S), that lists the compounding orders that have been executed by the compounding control manager **72**. These compounding orders are maintained in memory by the compounding control manager **72**. Pressing the SETTINGS AND DIAGNOSTICS button displays the settings and diagnostic screen **260** (FIG. **9**T) that displays additional administrative functions that the system administrator can perform, such as establishing the list of available source solutions for the solution programming box **212** (FIGS. **9**D and **9**E), previously discussed. Other additional administrative functions can also be accessed through this screen. Pressing the SIGN

OFF button displays a fresh log-in screen, and the compounding control manager **72** awaits a new order sequence from an operator.

[0137] In the illustrated embodiment, the main screen **202** also includes a CALIBRATE SCALE touch button **262** (see FIG. **9**B). When pressed, the button **262** opens an instruction screen **270** (FIG. **9**W), that leads the operator through a sequence of steps that calibrate the load cell. Alternatively, this function (CALIBRATE SCALE) may be provided within or as part of other screens (not shown) presented to the operator.

[0138] Also displayed on the main screen **202** is a HELP icon **264** (identified by a question mark—?). Pressing the HELP icon **264** on the main screen **202** opens a main screen help screen **266** (FIG. **9**U), which displays a list of available help topics pertaining to the compounding control manager **72** and operation of the compounding device **18** in general. Desirably, a HELP icon **264** is also present on every other functional screen or box generated by the compounding control manager **72** (see, e.g., FIGS. **9**A, **9**E, **9**H, **9**P). Pressing the HELP icon **264** on any given screen opens a context sensitive help screen, which provides guidance pertaining to the particular function that the given screen performs. For example, FIG. **9**V shows a context sensitive help screen **268** that opens when the HELP icon **264** on the pump alarm screen **246** (FIG. **9**N) is pressed. As can be seen, the context specific help topic is NO SOLUTION FLOW ALARM, and the screen provides instructions for correcting the alarm condition.

[0139] In a desired implementation, the compounding control manager **72** incorporates within its preprogrammed structure an integrated selection of training and/or help video files, e.g., in MPEG format. The integrated training and/or help video files contain stored formatted video footage and streaming audio. When presented by the compounding control manager **72** on the display screen **76**, the files communicate information to the operator in a direct visual and audible way. This platform of communication, which forms an integrated part of the compounding control manager **72**, provides the operator direct, real time access to context specific information in an effective, first person, visual and audible format, eliminating the need to resort to offline training manuals or separate CD's.

[0140] In a representative implementation, pressing the HELP icon **264** on the main screen **202** opens a main screen video training/help screen **270** (FIG. **14**A). The screen **270** displays a list of available training/help topics pertaining to the compounding control manager **72** and operation of the compounding device **18** in general. The screen incorporates **270** a MPEG viewing area **272**, in which the training and/or help video files in the compounding control manager **72** are displayed. Selecting an instruction/help topic runs the associated MPEG file.

[0141] As an example, FIGS. **14**B(**1**) to **14**B(**8**) show representative screen captures from a training/help video for "Programming the Compounder." The training/help video, with associated streaming sound file, walk an operator through the steps of entering a compounding order using the graphical user interface of the compounding control manager **72**. These steps have been previously described, with reference to FIGS. **9**B to **9**F. The training/help video explain that the first step is to identify the source solution (FIG. **14**B(**2**)), and then proceed (FIG. **14**B(**3**)), by visual and audible instructions, the procedure for using the Solution Programming Box **212** (previously described in the context of FIGS. **9**C and **9**D). The training/help video then explain that the next step is to determine the solution volume (FIG. **14**B(**4**)), and then proceed (FIGS. **14**B(**5**) to **14**B(**7**)), by visual and audible instructions, the procedure for using the Amount Programming Box **218** (previously described in the context of FIG. **9**F). The training/help video concludes (FIG. **14**B(**8**)) by congratulating the operator for successfully accomplishing the programming procedure.

[0142] As can by now be appreciated, the compounding control manager **72** serves to generate an interactive user interface that presents as much information/control on one screen as possible without making the screen too busy. Among its features are (i) to minimize user entry errors by making their entry points very focused and utilizing large display and keypad areas; (ii) to minimize keystrokes for the experienced user; (iii) to provide as much help as possible for the inexperienced user; and (iv) to minimize calls to service by making "smart help" available.

[0143] The compounding control manager **72** makes possible the operation of a gravimetric compounding device **18** under direct software process control, while utilizing barcodes as a process quality control mechanism.

[0144] Other useful features of the system include, for example, the activation of a process to freeze entry display screen **76** (or any other touch screen used to enter data and/or commands into the system). FIG. **16** illustrates this. As shown in FIG. **16**, screen **1600** may be invoked as desired via a selection from the main system screen (not shown). Once activated, the display screen **76** is frozen and will not interpret tactile input on the display screen **76** as an attempt to enter data or otherwise instruct the system. In this way, the operator may clean the screen without jeopardizing an ongoing process or begin an unintended process, thereby avoiding waste of valuable source solutions and/or final solutions. The time that display screen **76** is frozen is preferably predetermined, such as 30 seconds, but may be adjustable if desired in a particular configuration.

[0145] Additionally, and as shown in FIG. **17**, the process can also include screen **1700** that will advise the operator of items that need to be completed on that particular day. It is also possible to configure the checklist such that it advises the operator of items that span multiple days if desired.

[0146] B. The Order Entry Process Manager

[0147] The order entry process manager **84** can be installed on the MPU **58** of the controller **20** and/or on another workstation linked to the controller **20**. The order entry process manager **84** provides an array of enhanced order entry functions for the compounding control manager **72**. The order entry process manager **84** also provides an information management function and label printing function, that make possible simplified and consolidated order data record storage and control on a patient-by-patient basis. This function is integrated with the communication of the order data to the compounding control manager **72** of a compounding device **18**, to thereby facilitate set-up, operation, and management of an overall compounding system in a reliable fashion that minimizes error. The order entry process manager **84** makes possible a centralized or distributed order data entry, order data storage, order data manipulation, and order data communication system.

[0148] The order entry process manager **84** desirably receives data input through keyboard/mouse devices **78**, and provides data output either through the display screen **76** of

the control panel **24** (as shown in FIG. **8**A), or a separate, dedicated display device **376** (as shown in FIGS. **8**B to **8**F). The order entry process manager **84** also is desirably linked to a printer **302** (or **80**), for providing reports and labeling in paper form.

[0149] The order entry process manager **84** can be developed to generate its own proprietary user interface (like the compounding control manager **72**). Desirably, however, the order entry process manager **84** is developed in a graphics-based environment (e.g., Windows.®., Linux.®., etc.) using, e.g., an Apache.®. or Java.®. Operating Environment that can be used in association with conventional web-server or browser software **86**, such as Microsoft.®. Internet Explorer, Netscape.®. Navigator, or an equivalent public accessible browser. In this arrangement, the order entry process manager **84** desirably comprises the program language that provides the operator with real time feedback and interaction with the controller **20** of the compounding device through browser-based graphic user interface (GUI) elements. The browser-based GUI elements allow an operator to input and adjust the information used by the compounding control manager **72** to operate the compounding device. This makes possible the linkage of the proprietary compounding control manager **72** of the compounding device to one, several, or an entire network of conventional browser data entry and output platforms, which can comprise a single local site or a network of remote sites. Implemented in this manner, the order entry process manager **84** and browser software **86** make fully networked compounding possible. Furthermore, the order entry process manager **84** makes possible a network appliance function, whereby all an authorized operator has to do is couple a browser to the MPU **58** of the compounding device **18** to be able to control the compounding device **18**. The network appliance function significantly enhances the usability and flexibility of the compounding device **18**.

[0150] To develop the browser-based GUI elements, the order entry process manager **84** utilizes certain third party, off-the-shelf components and tools, available in e.g., Apache.®. or Java.®. Operating Environments. Once developed, the order entry process manager **84** can reside as a software program on a memory device. The order entry process manager **84** can be accessed by a laptop or desktop workstation computer, PDA device, or any other device that can run a browser, to provide different order entry platforms.

[0151] C. Associations with the Compounding Control Manager

[0152] The order entry process manager **84** and browser software **86** accommodate diversely different associations with the compounding control manager **72** installed on the controller **20** of the compounding device **18**.

[0153] In a basic form (see FIG. **8**A), the order entry process manager **84** and browser software can be installed in the MPU **58** in the control panel **24** of the compounding device **18**, to constitute a single control panel configuration. In this arrangement, the display device **76** on the control panel **24** supports the browser-based interface of the order entry process manager **84** for order entry to the compounding device and label printing, as well as supporting the proprietary touch screen interface of the compounding control manager **72** during operation of the compounding device.

[0154] In another arrangement (see FIG. **8**B), the browser software **86** can be installed on a data entry workstation **304** positioned in the same facility as the compounding device **18**. The data entry workstation **304** can be placed near the compounding device **18**, or it can be physically separated from the compounding device within the facility. In this arrangement, the browser software **86** of the data entry workstation **304** is linked, e.g., via a hubless local area network connection to the order entry process manager **84** residing in the MPU **58** in the control panel **24** of the compounding device **18**, to constitute a single data entry station configuration. In this arrangement, the display device **376** of the data entry workstation **304** supports the browser-based interface of the order entry process manager **84** for order entry to the compounding device and label printing. The display device **76** of the control panel **24** supports the proprietary touch screen interface of the compounding control manager **72** during operation of the compounding device **18**.

[0155] In another arrangement (see FIG. **8**C), the browser software **86** can be installed on several data entry workstations **304** positioned in the same facility as the compounding device **18**. The browser software **86** of the data entry workstations **304** can be linked, e.g., via a hub **306** or switch as a local area network to the order entry process manager **84** residing in the MPU **58** in the control panel **24** of the compounding device **18**, to constitute a multiple data entry station configuration. In this arrangement, the display device **376** of each data entry workstation **304** supports the browser-based interface of the order entry process manager **84** for order entry to the compounding device **18** and label printing by the printer **302**. A single compounding device **18** can thereby be linked to several order entry workstations **304**. The display device **76** on the control panel **24** of the compounding device **18** supports the proprietary touch screen interface of the compounding control manager **72** during operation of the compounding device.

[0156] In another arrangement (see FIG. **8**D), the browser software **86** can be installed on several data entry workstations **304** positioned in the same facility as several compounding devices **18**. The browser software **86** of the data entry workstations **304** can be linked, e.g., via a server **308** to form an intranet facility network **310**, and the order entry process manager **84** residing in the MPU's **58** in the control panels **24** of the several compounding devices **18** can be linked to the server **308** via a hub **312**, to constitute a fully networked data entry, multiple compounding station configuration. In this arrangement, the display device **300** of each data entry workstation **304** supports the browser-based interface of the order entry process manager **84** for order entry to the compounding device **18** and label printing by the printer **302**. Multiple compounding devices **18** can thereby be linked to multiple order entry workstations **304**. The display device **76** in the control panel **24** of each compounding device **18** supports the proprietary touch screen interface of the compounding control manager **72** during operation of the respective compounding device. As shown in FIG. **8**D, the browser software can be installed in a PDA device **314**; or any other device that can run a browser, to provide different order entry platforms.

[0157] In another arrangement (see FIG. **8**E), the browser software **86** can be installed on one or more data entry workstations **304** positioned in a data entry facility **316** that is remote to another facility **318** where one or more compounding devices **18** are located. The browser software **86** on one or more data entry workstations **304** at the remote data entry facility **316** can be linked to the order entry process manager **84** residing in the MPU(s) **58** in the control panel(s) **24** of the compounding device(s) **18** at the remote compounding facil-

ity **318** via the public internet **320**. Of course, other forms of remote linkage can be used. The browser software **56** can be installed, alone or with the installation on the remote workstations **304**, on one or more data entry workstations **304** at the local compounding facility **318**, and also linked to the order entry process manager **84** in the MPU(s) **58** in the control panel(s) **24** of the compounding device(s) **18** via the public internet **320**. If the facilities **316** and **318** are part of a common operating entity, the order entry process manager **84** and browser software **56** can be installed on a data collection/administration workstation **304** positioned in a data center facility **322** that is remote to both the data entry and compounding facilities **316** and **322**. The data center **322** maintains an information data base **324** of patient information and compounding resources for the compounding facility **318**, and also be linked to the data entry facility **316** and the compounding facility **318** via the public internet **320**.

[0158] In a variation to the arrangement shown in FIG. **8**E (see FIG. **8**F), a host data entry service facility **326**, where the order entry process manager **84** is installed, can be coupled via the public internet **320** to one or more remote data entry facilities **328**A, **328**B, **328**C, **328**D. The host data entry service facility **326** can also be linked via a virtual private network **328** through the public internet to a remote compounding facility **330**, where the compounding control manager **72** is installed in the MPU **58** in the control panel **24** of the compounding device **18**. The browser software **86** is installed on the data entry workstations **304** positioned in the remote data entry facilities **328**A to **328**D. The host data entry service facility **326** maintains the data collection and management data base **332** for the entire network. In this way, multiple order entry facilities **328**A to **328**D can be linked to a single compounding facility **330** via an intermediary service facility **326**, which can also maintain a central collection and management data base **332**.

[0159] B. Features of the Order Entry Process Manager

[0160] FIG. **10**A(**1**) shows a general schematic representation of the operator-selectable functional modules that a representative implementation of the order entry process manager **84** can possess. As illustrated, these functional modules include a prescription order module **400**, a source solution module **402**, a reports module **404**, an administration module **406**, and a navigation module **408**. The prescription order module **400** allows an operator to enter a prescription order for a given patient, with reference to a preexisting compound formula or to a new compound formula, as well as schedule the order for compounding. The source solution module **402** maintains an inventory of available base source solutions and additive source solutions that are cross-referenced in the formula library of the prescription order module **400**. The reports module **404** provides an operator the capability of tracking compounding activities and generating various administrative reports relating to these activities. The administration module **406** aids the operator in the performance of various administration tasks in support of the compounding activity. The navigation module **408** assists the operator in use of the order entry process manager **84**. Each module contains one or more functional components that an operator can select in using the module, as will be described in greater detail later.

[0161] FIGS. **10**A(**2**)-**10**A(**6**) illustrate a flow chart of the logon sequence and the level of access given to various users, such as the administrator (FIG. **10**A(**3**)), Pharmacist (FIG. **10**A(**4**)), Technician (FIG. **10**A(**5**), and Guest (FIG. **10**A(**6**)), for example. As shown in FIG. **10**A(**2**), the administrator has the highest level of access and can ultimately control access by any other user. The administrator can also create additional classes of users as well as subclasses within any class of users. For example, although technicians are given very restricted rights within the system to formulate compounds for instance, it may be that there are certain technicians that require less oversight and can thus be granted greater privileges.

[0162] A given operator can gain access to one or more of these functional modules, depending upon the access options that the system administrator grants a given operator, which depends upon the functions that the operator is required to perform. For example, a hierarchy of access options can be specified for use by a physician or pharmacist, who specifies or enters compounding orders; a compounding activity administrator, whose function is to oversee the compounding function from an administrative standpoint; and a compounding technician, whose function is to operate one or more compounding devices **18**. The available functional modules can be displayed as menu box selections on a main screen or home page, which opens once a given operator identifies itself by name and assigned password on an appropriate log-on screen.

[0163] For example, FIG. **11**A shows a representative main screen or home page **410** for an operator who has a physician or pharmacist access option. As FIG. **11**A shows, all functional modules **400** to **408** are available for selection at this access level, because performance of that person's function may require access to all features of the order entry process manager **84**. As a comparative example, FIG. **11**B shows a representative main screen or home page **410'** for a compounding technician, which offers access to a lesser selection of functional modules, because the technician's function does not require access to all the functional features of the order entry process manager **84**. The functional module menu boxes which a given individual may access may appear in a column along the left side of other screens generated by the order entry process manager **84**.

[0164] Assuming that the operator is at a physician or pharmacist access level, and is thereby viewing the home page shown in FIG. **11**A, the operator can, with a mouse click, select a desired functional module. Assuming the operator seeks to enter a prescription order for a given patient, the operator mouse-clicks on the Patients component of the PRESCRIPTION ORDER menu box **400**, which opens the PATIENT MAIN PAGE **412** shown on FIG. **11**C. This window **412** provides access to the features of the Patient Data Base Component **414** of the order entry process manager **84**, the functional units of which are shown schematically in FIG. **10**B.

[0165] The Patient Data Base Component **414** allows a user to either select an existing patient by a last name search of a list of patient information files created in a patient information data base maintained by the order entry process manager **84** (FIND A PATIENT box field **416**), or by entering the name of a new patient (ENTER NEW PATIENT box field **418**).

[0166] Upon finding an existing patient's name, the order entry process manager **84** provides a window displaying the contents of the corresponding Patient Information Record **420** (FIG. **11**D). The Patient Information Record **420** allows the operator to enter a new compounding order, based upon previous compounding orders retained in the patient data base for that patient (TPN ORDERS ON FILE FOR PATIENT box field **422**), or allows the operator to enter a new compounding

order for that patient based upon a standard default templates for a patient type that the patient matches (NEW TPN ORDER TEMPLATES AVAILABLE FOR STANDARD ADULT PATIENT TYPE box field **424**). The operator can also review an existing nutritional assessment or start a new nutritional assessment as desired. Nutritional assessments are discussed in detail below with respect to FIG. **19**.

[0167] The PRESCRIPTION ORDER MENU box **400** includes a Formula Library component. When selected, the Formula Library component provides access to the features of the Formula Library Data Base Component **426** of the order entry process manager **84**, the functional units of which are shown schematically in FIG. **10**C. Selection of the Formula Library component opens a Formula Library web page **420** shown in FIG. **11**F(**1**). The Formula Library web page **420** permits the operator to select an existing default formula template for display and selection in the Patient Information Record page **424**, or to add a new formula template for display in the Patient Information Record. Selection of template opens a scrollable Order Template web page **434** shown in FIGS. **11**F(**2**), **11**F(**3**), and **11**F(**4**), that allows the operator to specify base components (types and amounts) and additive solutions (types and amounts) for a template formula. Default data in an existing template formula can also be changed and submitted. The Order entry process manager **84** computes the nutritional requirements of the template formula based upon the selected types and amounts of base components and additives, drawing upon data contained in the source solutions module **402**, as will be described in greater detail later.

[0168] A mouse click selecting one of the order options **422** or **424** on the Patient information Record opens a scrollable Order Entry window **436** (FIGS. **11**E(**1**) to **11**E(**4**)). The Order Entry window **436** includes field boxes that contain details of the PRESCRIPTION ORDER (box **438**), the BASE COMPONENTS included in the order (type and amount) (box **440**), the ADDITIVES included in the order (type and amount) (box **442**), the NUTRITIONAL SUMMARY (based upon the types and amounts of the base components and additives included in the order) (box **444**), and the ORDER STATUS (which will be described later) (box **422**). The default listing of solutions and solution amounts in the BASE COMPONENTS and ADDITIVE field boxes **440** and **442** are provided based upon the selection on the Patient Information Record **420**—to base the order upon a previous order or a standard template. The default BASE COMPONENTS and ADDITIVES can be edited to change the previous order or template type and/or amount, or they can be submitted without change. The Order entry process manager **84** computes the NUTRITIONAL REQUIREMENTS (box **444**) based upon the selected types and amounts of base components and additives, drawing upon data contained in the source solutions module **402**.

[0169] It is also important that medical personnel be able to perform a nutritional assessment of the patient. That is, to make determinations of patient nutritional needs and compare those needs to the orders for the patient. As such, when the operator makes a selection in section **423** of the patient's record (see screen **420** shown in FIG. **11**D for example) he is provided with the Nutritional Assessment Screen **1900** (FIG. **19**). The selection in screen **420** may be either to review an existing assessment or to perform a new assessment. Screen **1900** is divided into three sections, Patient Demographic Information **1902**; Patient Assessment Information **1904**; and Calculated Nutritional Requirements **1906**.

[0170] The Patient Demographic Information Section **1902** includes certain demographic information concerning the selected patient and may include for example, Patient Name; Patient ID; Patient Age; Patient Sex; Patient Height; Patient Weight; Location of the Patient; Diagnosis; Physician; Allergies; and a Picture of the Patient.

[0171] The Assessment Section **1904** includes a brief patient descriptor composed of the patient's sex, age, and height. The screen desirably includes a Date/Time stamp for when the assessment was last updated. The Assessment Section **1904** also includes various input fields, such as a Text Box for the Assessment Title; a Numeric Text Box for Patient Weight in the local units (default value–weight in patient demographic data); a Pull-down List of Injury Factors, including for example, Low (uncomplicated, general surgery) (default); Moderate (complicated, extensive surgery); High (sepsis, burns); a Pull-down List of Stress Factors, such as Mild, Moderate, Severe, Renal Dysfunctional/Dialysis, and Renal Dysfunctional/Non-Dialysis.

[0172] The Assessment Section **1904** also includes two buttons **1905**, **1907**. When selected, the "Update Assessment" Button **1905** takes the information on the screen and uses it to calculate the nutritional requirements which will be presented in the Calculated Nutritional Requirements section and also updates the Assessment's Date/Time Stamp. If this is a new assessment, a Cancel Button is provided, that if selected will abort the assessment creation and return to the previous screen. If this is an existing assessment, a Delete Assessment Button **1907** can be used to remove the assessment from the list of assessments associated with the patient.

[0173] The Calculated Nutritional Requirements Section **1906** desirably provides the following information preferably calculated to two decimal places based on the patient information provided in the Patient Assessment Section **1904**, such as Ideal Body Weight; Condition Assessment; Adjusted Body Weight; Basil Energy Expenditure in Kcal/Day; Total Protein Requirements in gm/Day & gm/Kg/Day; Total Calories Requirement in Kcal/Day & Kcal/Kg/Day; and Fluid Requirement Range in mL/Day.

[0174] The Calculated Nutritional Requirements Section **1906** desirably provides a link **1908** to allow the user to compare the current nutritional assessment to existing orders for the patient. When exercised, a Nutritional Assessment Comparison Order Selection Screen appears.

[0175] The Calculated Nutritional Requirements Section **1906** also desirably provides a link **1909** to allow the user to enter a TPN order based on the current nutritional assessment. When selected, the TPN Order Screen (see FIG. **20**) is provided with the fields populated based on the current patient and the nutritional needs of the patient. When the operator is finished with this screen he activates the "Done" button **1910** to return to the calling screen. It is also contemplated that alternative or customized nutritional assessment calculations may be included as part of the exemplary system.

[0176] The operator can open the Order Entry window (FIGS. **11**E(**1**)) to **11**E(**4**)) to enter a compounding order for a new patient (i.e., a patient not previously entered into the patient data base) by selecting ENTER A NEW PATIENT field box **418** on the Patient Main Web Page **412** (FIG. **1**C). With this selection, the order entry process manager **84** opens a window displaying a New Patient web form **448** (FIGS. **11**G(**1**) and **11**G(**2**)), prompting the operator to enter data pertaining to the new patient. Upon entry of the new patient information, the operator saves the information to the patient

data base (selecting the UPDATE field box **450**—shown in FIG. **11**G(**2**)), at which time the scrollable Order Entry window **436** opens for entry of the compounding order(FIGS. **11**E(**1**) to **11**E(**4**)).

[0177] The next screen of the Order Entry window **436** (FIG. **11**E(**4**)) includes an ORDER STATUS box **422**. The ORDER STATUS box **422** comprises a listing of the functional steps in a compounding operation that must be executed between order entry and delivery of the compounded order to a patient. The ORDER STATUS box **422** also colors or highlights the steps to indicate which steps have been performed and which remain to be performed. The ORDER STATUS box **422** provides a check list of functions that must be performed to carryout the compounding process and, at a glance, informs an operator what function has been performed and what function still needs to be performed. In the illustrated embodiment (FIG. **11**E(**4**)) the function steps listed include OPEN, SUBMITTED, AUTHORIZED, PRINTED, and COMPOUNDED.

[0178] The OPEN step entails the opening of the Order Entry window **436**, and the entry of information making up the compounding order. In FIG. **11**E(**4**), the OPEN icon **452** is colored or highlighted, to indicate that this step has been accomplished.

[0179] As part of the order entry, a Final Container is automatically selected based on an inventory of available final containers. This list is desirably prepared by the system administrator or other individual having such rights. Set up of the inventory is illustrated in FIG. **11**E(**5**). As shown in FIG. **11**(E)**5**, upon selection of the final container line item **492** of the Inventory Configuration module **490** of the order entry process manager **84** a list **491** of available final containers is displayed. Through this screen, the administrator may review the listing of available containers, and if necessary delete a container no longer in stock, if desired.

[0180] In normal operation, a final container conforming to the volume of the final solution ordered will be automatically selected. Alternatively, through a manual operation the operator may select a final container presented through a list which may be similar to that of FIG. **11**(E)**5**. In the event that the operator selects a final container that is too small of the final solution, an error indication will be provided and the operator will be instructed to make an alternate selection.

[0181] If the administrator needs to add a new container to the inventory this may be accomplished by selecting "Add a New Final Container" selection **494**, whereupon screen **493** (FIG. **11**E(**6**)) is presented to the operator. As shown in FIG. **11**E(**6**), the administrator has the capability to enter a description for the new container, as well as particulars of the container, such as rated size, maximum capacity, nominal empty weight, maximum under normal weight, maximum over normal weight and unit cost. If the administrator decides to save the information into the inventory, he selects "Update," otherwise, the administrator can delete the record to start over again, or select "Cancel" to exit this screen without changing the inventory configuration. The data regarding the final containers is also available for access via the compounder control panel screen.

[0182] Although the majority of the final solution is comprised of portions of various source solutions, there are other components that may be necessary to complete the particular patient's nutritional needs. For example, there are a various additive solutions, such as electrolytes, vitamins, minerals, etc. that may need to be included based on the patient's nutritional assessment. In many cases, these individual additives may need to be added in such minute amounts that automated macro-compounding is not useful. To overcome this, it is possible to "pool" the various additive solutions into a pooled additive bag to be used as another source solution for use during the compounding process. For example, if a patient is to receive as part of his daily compounded solution 1 mL of a vitamin, 2 mL of sodium chloride, and 3 mL of potassium phosphate each day over a ten day period, a pooled solution consisting of 10 mL of the vitamin, 20 mL of sodium chloride, and 30 mL of potassium phosphate may be compounded with the present invention to create a 60 mL source solution. Then, when the daily final solutions need to be compounded, this additive source solution may be included and selected to provide 6 mL of the pooled solution. The details related to this are described below.

[0183] TPN Order Entry Screen **2100** (FIG. **21**A) desirably provides the Patient Name, Patient ID and Order ID (if linked to from the TPN Order Entry Screen) or the Formula Template name of which the Base Component Solution is a component (if linked to from the TPN Order Template Screen). As part of the Screen **2100**, a prescription order section **2102** is provided. Within section **2102** is a "Batch Copies" entry **2103** which is used to prepare multiples of a particular order. In this example, seven (7) identical batches are to be prepared. In addition, screen **2100** includes section **2104** relating to Additives to be used in the order. Section **2104** desirably presents for example the name of the Additive Solution in the selected color, the amount ordered and ordering units in the current formula, Dose Amount; a pull down for Dose Order Units with a default unit of measure (based on the unit in the database entry for the selected additive); Per Amount unit; mL (default); Lb; 500 mL; 100 Lb; 250 mL; 100 mL; Kg; 100 Kg; Liter; Kg-mL; Kg-l; Lb-mL; Lb-l.

[0184] If these additives are selected to be part of the active pooling inventory (see FIG. **21**B), upon the user selecting Pool Additives **2111** and then activating the "Submit Changes" button, the system will automatically create a pooled additive solution. Upon completion of the pooled additive solution, the system will identify the pooled additive solution with an identifier desirably including the patient's name and a bar code identifier. This pooled additive will now be considered as another source solution for compounding and added to Base Compounds section **2108** of screen **2100**.

[0185] Section **2104** also provides access to the additive source inventory screen **2120** (FIG. **21**B) by selecting the Edit detail link **2110**. Depending on the user's permission level, the user may review the details of a particular additive or edit those details. Of significance to the pooling function is the "Additive Pooling" selection **2122**. If an additive is allowed to be part of the pooling process the "Allow" selection is enabled, otherwise, the "disallow" selection is enabled.

[0186] User screen control options include for example, a button to Submit ("Update") the changes, thereby updating the individual order/order template; a button to Return ("Cancel") without making any changes, and a "Delete" function to delete this particular additive from the inventor (assuming the required permission level). Desirably, the screen provides the following exemplary information regarding the current additive solution from the database: Name of the Additive Solution; Concentration; Specific Gravity; Osmolarity—mOsm/L; Cost—Localized Current Value/mL; and Electrolyte Content Details.

[0187] The SUBMITTED step entails mouse-clicking the DONE button, which places the information in the database and thereby makes the Order Entry window containing the pending compounding order available for viewing on any workstation with a proper operator access level, which, in this case, would be a designated authorizing pharmacist. The SUBMITTED icon **454** is colored or highlighted on the Order Entry window **436** when the step has been completed. The order entry process manager **84** desirably keeps track in the database of the compounding orders submitted by the various order entry workstations that are awaiting authorization, so that they can be accessed in an organized fashion by the browser software at the workstation of the authorizing pharmacist. The authorizing pharmacist knows to periodically run the browser software to access this queue of pending orders, to review each pending order, and indicate authorization of each order in the AUTHORIZE THIS ORDER FOR COMPOUNDING field box **456** on the Order Entry window **436**.

[0188] In another arrangement, the order entry process manager **84** can include a notification function, which provides a pop-up message at the workstation of the authorizing pharmacist to alert the individual that there are entered compounding orders awaiting authorization. Clicking on the pop-up message opens a list of the orders awaiting authorization that the authorizing pharmacist can access.

[0189] In the illustrated embodiment, authorization entails clicking the authorization statement (box **458**), selecting the shift in which the compounding is to be performed (box **460**), and selecting the AUTHORIZE FOR COMPOUNDING icon **462**. A STAT ORDER icon **464** is provided if the compounding order is to be performed as soon as possible. The AUTHORIZED icon **466** is colored or highlighted on the Order Entry window **436** when the authorization step has been completed.

[0190] The order entry process manager **84** desirably keeps track of the compounding orders that are in the database that have been authorized and are awaiting the printing of labeling, so that this subset of orders can be accessed in an organized fashion at a workstation where printing occurs. These compounding orders are accessed at the workstation where labeling for the final solution container **14** is to be printed.

[0191] In another arrangement, the order entry process manager **84** can include a notification function, which provides a pop-up message at the workstation where printing occurs to alert the operator that there are authorized compounding orders awaiting printing Clicking on the pop-up message opens a list of the orders awaiting label printing that the operator can access to perform the printing function.

[0192] The order entry process manager **84** formats the labeling (see FIG. **12**) based upon the information entered in the Order Entry window **436**. The labeling includes a label **470** for the final solution container **14**, a worksheet **468** identifying the source solutions and targeted compounding volumes, a worksheet **472** providing nutritional information for the contents of the final solution container **14**, and a label **474** for a piggyback container, if ordered. The labeling also includes the bar codes **476** that the compounding control manager **72** requires to verify the compounding order and perform the actual compounding process. The final container bar code **476** (on the final solution container label **470**) can also be used to electronically transfer formula information after compounding to a capable medication dispensing device (e.g., such as an infusion pump).

[0193] Upon completion of the printing step, the compounding order is made available for electronic transfer to a compounding control manager **72** of a compounding device **18**. The PRINTED icon **478** is colored or highlighted on the Order Entry window **436** when the labeling printing step has been completed and the order has been made available for transfer to the compounding control manager **72** for completion.

[0194] In the networked compounding environment that the order entry process manager **84** makes possible, when it is time to compound, the compounding clinician at the compounding station logs into the compounding control manager **72** and selects the AUTO PGM touch button **234** on the main screen **202** generated by the compounding control manager **72** (see FIG. **9**B). This opens a queue selection screen **236** (FIG. **9**P), which displays a list of preprogrammed schedule queues that have been established by the previously described order entry and processing steps, as controlled by the order entry process manager **84**. The operator selects the desired queue (based upon the present compounding shift—e.g., morning or afternoon) and presses the ENTER touch button on the queue selection screen **236**. The compounding control manager **72** holds the order queue list it receives from the order entry process manager **84** in memory, and the main screen **202** (see FIG. **9**Q) thereafter allows the operator to view the current order queue list in the window **238**. In this arrangement, the operator selects the order from the programmed order queue list **238** on the main screen **202**, and then, as prompted by the compounding control manager **72**, proceeds to connect the final solution container **14** to the manifold **36**, perform the source solution and final solution verifications, perform the flushing sequences (if necessary), and starts compounding in the manner previously described.

[0195] As previously described, the use of bar code data in the verification function of the compounding control manager **72** necessitates that the labeling (FIG. **12**) that is generated by the order entry process manager **84** must be available to and used by the compounding clinician in order to operate the compounding device and complete the compounding order. This integrates the submission, authorization, and printing functions of the order entry process manager **84** with the control functions of the compounding control manager **72**.

[0196] The compounding control manager **72** communicates with the order entry process manager **84** when the compounding process has been completed, the COMPOUNDED icon **480** on the Order Entry window is colored or highlighted accordingly.

[0197] The order entry process manager **84** can provide other functions that can be accessed through the PRESCRIPTION ORDERS menu box. For example, as shown in FIG. **11**A, a Schedules component can be included that allows the operator to view and alter the scheduling of compounding orders by shifts.

[0198] On the home screen shown in FIG. **11**A, the operator can, with a mouse click, select other functional modules of the order entry process manager **84**. If, for example, the operator seeks to view the inventory of base components maintained by the compounding facility, the operator mouse-clicks on the Base Components function of the SOURCE SOLUTIONS menu box **402**, which opens the BASE COMPONENTS MAIN PAGE **482** shown on FIG. **11**H(**1**). This window provides access to the features of the Base Solutions Data Base Component **428** of the order entry process manager **84**, the functional units of which are shown schematically in FIG. **10**D.

[0199] When selected, the BASE COMPONENTS MAIN PAGE **482** (FIG. **11**H(**1**)) permits the operator to select a base component maintained in the existing facility inventory, or to add a base component to the inventory. Selection of a base component opens a scrollable Base Component Inventory Page **484** pertaining to the selected component, as shown in FIGS. **11**H(**2**) and **11**H(**3**). The Base Component Inventory Page **484** allows entry and retention by the order entry process manager **84** of pertinent information pertaining to the selected base component—e.g., its name; family type (Amino Acid, Dextrose, Fat Emulsion, etc.); concentration; specific gravity; cost per 100 mL; the choice of the pump rotor assembly of the compounding device to convey the component; NDC lot number; expiration date; electrolyte content, nutritional content, and other information.

[0200] Similarly, if the operator seeks to access the inventory of additive solutions maintained by the compounding facility, the operator mouse-clicks on the Additive Solutions function of the SOURCE SOLUTIONS menu box **402**, which opens the ADDITIVE SOLUTIONS MAIN PAGE **486** shown on FIG. **11**I(**1**). This window provides access to the features of the Additive Solutions Data Base Component **430** of the order entry process manager **84**, the functional units of which are shown schematically in FIG. **10**E.

[0201] When selected, the ADDITIVE SOLUTIONS MAIN PAGE **486** (FIG. **11**I(**1**)) permits the operator to select an additive solution maintained in the existing facility inventory, or to add an additive solution to the inventory. Selection of an additive solution opens a scrollable Additive Solution Inventory Page **486** pertaining to the selected additive solution, as shown in FIGS. **11**I(**2**) and **11**I(**3**). The Additive Solution Inventory Page **486** allows entry and retention by the order entry process manager **84** of pertinent information pertaining to the selected additive solution—e.g., its solution type; its patient type; concentration; specific gravity; cost per mL; the choice of the pump rotor assembly of the compounding device to convey the component; NDC lot number; expiration date; electrolyte content; and other information.

[0202] The Base Solutions Data Base Component **428** and the Additive Solutions Data Base Component **430** of the order entry process manager **84** store pertinent information, for cross-reference by the other functional modules of the order entry process manager **84**. For example, the Formula Library **426** draws upon information stored in the Base Solutions Data Base **428** and the Additive Solutions Data Base **430** to fill out the default information in the formula templates. Thus, library solutions can be restricted by patient type. As another example, the nutritional information derived by the order entry process manager **84** contained in the printed labeling (label **472** in FIG. **12**) is drawn from information stored in the Base Solutions Data Base **428**. Administration reports (to be described later) derive inventory, use, and cost management information based upon information stored in the Base Solutions Data Base **428** and the Additive Solutions Data Base **430**.

[0203] From the home page shown in FIG. **11**A, the operator can, with a mouse click, select to access the report module **404**. The operator can select among a list of report selections contained in the REPORTS menu box **404**. The reports module **404** provides an operator the capability of tracking compounding activities and generating various administrative reports relating to these activities. The nature and format of the reports can, of course, vary according to the particular requirements of the compounding facility. The reports module **404** can generate reports that, for example, (i) list the compounding orders entered during a prescribed reporting period (arranged, e.g., by patient, date, time, entry operator, and the like); or (ii) list the compounding orders that were compounded during a prescribed reporting period (arranged, e.g., by compounding device number, date, time, compounding clinician, patient, final container number, time elapsed, and the like); or (iii) list source solution usage in liters during a prescribed reporting period arranged, e.g., by solution type, day, month, cost, and/or lot numbers, and the like; or (iv) list customer billing records for completed compounded containers, including, e.g., costs per mL of compounded fluid by solution type, flat rates costs by container or solution type, labor costs by machine compounding hours, flat labor costs, or a combination of any of these; or (v) list a log of operators accessing the order entry processing manager, arranged, e.g., by date, time, operator name, and event. Any or all of these reports can be generated by the reports module **404** of the order entry process manager **84** according to preformatted templates, or by customized or relational field searches of data bases maintained by the order entry process manager **84**. The reports module **404** desirably includes the capability of formatting the reports for printing in hard copy format, or offloading the reports in electronic file format, e.g., in PDF file format.

[0204] From the home page shown in FIG. **11**A, the operator can, with a mouse click, select to access the administration module **406**. The operator can select among a list of administration options contained in the ADMINISTRATION menu box **406**. The administration module aids the operator, who is in this instance typically the compounding activity administrator or supervisor, in the performance of various administration tasks in support of the compounding activity.

[0205] The nature of the administrative functions supported by the administration module **406** can, of course, vary according to the particular requirements of the compounding facility. The administration module **406**, for example, can allow the administrator to add, delete or modify the schedule of shifts during which compounding takes place—which, in turn, becomes viewable (box **460**) in the Order Entry web page (FIG. **11**E(**4**)), for selection by the authorizing pharmacist during the order authorization process. The administration module **406**, as another example, can allow the administrator to add, delete or modify the inventory list of compounding devices maintained by the compounding facility—which information, in turn, becomes available for use in the compounding reports generated by the reports module **404**. The administration module **406**, as another example, can allow the administrator to add, delete or modify the categories of patient types (e.g., standard adult; standard neonate; standard pediatric) accounted for by the compounding facility—which, in turn, can be linked to the patient information data base and can also be linked to the formula template data base **426** maintained by the order entry process manager **84** (i.e., a standard adult formula template can be linked to a standard adult patient type, to facilitate the compound order entry process). The administration module **406**, as another example, can allow the administrator to add, delete or modify the list of operators by name or by operator groups (e.g., administrative staff, pharmacy staff, pharmacy technician, supervisor) that are permitted access to the order entry process manager **84**, as well as assign passwords and access rights particular to each operator and each operator group. In this respect, operator's rights and restrictions can be tailored

for that operator individually, and not as part of an overall group (e.g., as a technician or a pharmacist). Groups can also be prohibited or allowed access to certain patient types (e.g., Dr. Brown cannot see information pertaining to Dr. Smith's patients).

[0206] An example of how physicians can be added is described with reference to FIGS. **20**A and **20**B. Within administration module **406** is a selection Individual Physicians **407**, which upon selection provides screen **2000** (FIG. **20**A) to the user including physician list **2002**. If a physician needs to be added to the list, the operator selects link **2002** which brings up physician information screen **2006** (FIG. **20**B). The Physician Information screen **2006** includes certain information concerning the physician which desirably includes for example, Login ID; A facility pull down to limit the facilities in which this physician has privileges; Name; Title; Address; Office Telephone Number; Mobil Telephone; Pager Number; Facsimile Number; email address; additional contact information; Federal Physician ID; and after hours service number. The Physician Information screen **2006** also includes two buttons **2007**, **2008**. When selected, the "Update" Button **2007** takes the information on the screen and saves it into the Physician database. When selected, the Cancel Button will abort the present screen and return to the previous screen without updating the Physician database.

[0207] On the home page shown in FIG. **11**A, selection among the options provided by the navigation module **408** of the order entry process manager **84** can provide a short cut to the operator's home page, a help function, a general data base search function outside of the order entry, report, or administration functions, and/or a user log-out function. Selective use of operator access rights allows for patient record privacy in compliance with governmental HIPAA regulations.

[0208] As can be by now be appreciated, the order entry process manager **84** and browser software provide a physician or compounding order facility the capability to electronically transfer compounding requirements to a compounding facility via direct wire, network, or internet based systems. The order entry process manager **84** and browser software provides a compounding facility the capability to electronically enter compounding requirements on site or to receive electronically generated customer compounding requirements from remote sites. The order entry process manager **84** and browser software provide a compounding facility the capability to queue multiple customer compounding requirements into an efficient compounding and delivery schedule. The order entry process manager **84** and browser software provide a compounding facility the capability to generate container labels, including bar codes, as well as control the actual compounding process. The order entry process manager **84** and browser software provides a compounding facility the capability to automatically generate customer billing and inventory control for completed compounded containers. Billing options can include costs per mL of compounded fluid by solution type, flat rates costs by bag or solution type, labor costs by machine compounding hours, flat labor costs, or a combination of any of these.

[0209] A Daily Checklist which is derived from screen **500** (FIG. **11**J(**1**)-**11**J(**2**)) is desirably displayed upon log on of the operator at the control panel. Items on the checklist may be added or rearranged as necessary or desired. It is desirable that all active items be displayed. If an item is indicated as being complete, the date/time and ID of the operator will be entered into the log. Required items must be completed before compounding is allowed to occur.

[0210] As shown in FIG. **18**A, upon selecting the Infusion Pump line item **495** of the Inventory Configuration module **490** of the order entry process manager **84** a list **496** of available infusion pumps is displayed. The infusion pump is the device that is used to deliver the final solution prepared by the compounder to the patient. Through this screen, any one of the available infusion pumps may be selected for use as the means to deliver the final solution to the patient. Once an infusion pump is selected, ramp-up and ramp-down profiles we be made available to the operator via drop-down lists for loading into appropriate text fields. This is useful in configuring how the infusion pump is to deliver the final solution to the patient, so as not to start the delivery of the nutrients too quickly (ramp up) nor to abruptly discontinue feeding toward the end of the final solution container (ramp down). The bar coding on the final solution container provides information and/or instructions to the infusion pump regarding the selected flow rate and/or ramp up/ramp down times. Manual entries will also be allowed. If the operator needs to add a new infusion pump to the inventory (primarily because the patient has a different infusion pump already installed at their bedside or home) this may be accomplished by selecting "Add a New Infusion Pump" selection **497**, whereupon screen **498** (FIG. **18**B) is presented to the operator. As shown in FIG. **18**B, the operator has the capability to enter a description for the infusion pump as well as certain particulars about the new pump. If the operator decides to save the information into the inventory, he selects "Update," otherwise, the operator can delete the record to start over again, cancel to exit this screen without changing the inventory configuration.

[0211] With respect to interfacing compounding system **10** to other information systems, such as hospital or home care pharmacy systems, the inventors have determined that electronic handshaking and protocols necessary to carry out this interface are complicated, add additional cost, and may be counter to the desires of the hospital to maintain autonomy of their systems. Thus, a further embodiment of the present invention provides an interface that is less complex and does not rely on handshaking protocols to transfer compounding information to compounding system **10**.

[0212] Referring now to FIG. **22**, a block diagram of hospital or home care pharmacy system **2200** is illustrated. As shown in FIG. **22**, system **2200** comprises input devices, such as keyboard **2202** and mouse **2204**, processor **2206** (shown for example as contained within display device **2208**), and printer **2214**. In one non limiting example, system **2200** may be centrally located on a patient floor. In another non limiting example, system **2200** may be part of a hand held computing device, such as a PDA and may include or be detachably coupled to a small printer via either direct wiring (USB, fire wire interface, etc.) or via well-known wireless communication link.

[0213] Referring again to FIG. **22**, when a physician determines the needs of a patient, the physician may enter or have entered into system **2200** a desired compound defining solution types and respective volumes. The desired compound is displayed to the physician via display **2208** where, upon verification for accuracy, a printout of the required compound is output from printer **2214** as paper or label **2216**. Although a standard printed page may be useable to carry out the present invention, it may be desirable to use label material as will become evident below.

[0214] In one exemplary embodiment, indicia in the form of a barcode may be imprinted as part of label **2216**. It is contemplated that various fields of the barcode will indicate certain characteristics of the desired compound. All necessary information to prepare a desired compound is included within the barcode, including desired solutions and respective volumes, patient ID (not absolutely necessary but highly desirable in order to prevent administering the compound to the wrong patient), order number, and compound bag ID number. An example of Barcode fields is listed below:

[0215] 1. "O"=Barcode Identifier Code (upper case letter 'O').

[0216] 2. Order Control Flags (see notes below)

[0217] 3. Patient ID, maximum of 12 characters (see notes below)

[0218] 4. Order ID, maximum of 30 characters (see notes below)

[0219] 5. Bag ID, maximum of 12 characters (see notes below)

[0220] 6. Station #1 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0221] 7. Station #1 Solution Name, blank to skip station programming

[0222] 8. Station #2 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0223] 9. Station #2 Solution Name, blank to skip station programming

[0224] 10. Station #3 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0225] 11. Station #3 Solution Name, blank to skip station programming

[0226] 12. Station #4 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0227] 13. Station #4 Solution Name, blank to skip station programming

[0228] 14. Station #5 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0229] 15. Station #5 Solution Name, blank to skip station programming

[0230] 16. Station #6 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0231] 17. Station #6 Solution Name, blank to skip station programming

[0232] 18. Station #7 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0233] 19. Station #7 Solution Name, blank to skip station programming

[0234] 20. Station #8 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0235] 21. Station #8 Solution Name, blank to skip station programming

[0236] 22. Station #9 Volume: value can be 0, 5.0 to 99.9, or 100 to 5000 mL

[0237] 23. Station #9 Solution Name, blank to skip station programming

[0238] Exemplary barcode content for a non-limiting example of a TPN order is listed below and an exemplary barcodes **2300** is illustrated in FIG. **23**A.

[0239] O,L,111-11-1111,RX12345-Abc,0001,250, FreAmine 15%,180,

[0240] Dextrose 50%,55.5,Hyperlyte CR,,,,,,,,,,450,Sterile Water

[0241] It is also contemplated that other types of labels may be implemented to carry out the present invention, such as RFID tags. In such an implementation, the RFID tag includes the information outlined above and may be accessed using conventional RFID activation systems. Such systems transmit and RF signal to the RFID tag in order to activate the tag, which in turn transmits its information to a local receiver, normally incorporated within the RFID activation system.

[0242] Barcode Explanation:

[0243] Although the following is directed to bar coded embodiments, it is equally applicable to an RFID implementation.

[0244] The entire barcode should desirably be one line (do not include carriage returns within the line, but a carriage return should be present at the end of the line).

[0245] The first 2 fields identify the barcode and specify a (L)ocked order. Since the order is "locked", it is prevented from being modified by the pharmacy technician and can only be compounded as originally ordered.

[0246] The Patient ID is '111-11-1111'.

[0247] The Order ID is 'RX12345-Abc'.

[0248] The Bag ID is '0001'.

[0249] Station **1** will be programmed for 250 mL of FreAmine 15%.

[0250] Station **2** will be programmed for 180 mL of Dextrose 50%.

[0251] Station **3** will be programmed for 55.5 mL of Hyperlyte CR.

[0252] Stations **4** through **8** will not be changed.

[0253] Station **9** will be programmed for 450 mL of Sterile Water.

[0254] Exemplary barcode content for a non-limiting example of a Library Formula or Quick Setup is listed below and an exemplary two dimensional barcode **2300** is illustrated in FIG. **23**B.

[0255] Barcode Content:

[0256] O,,,,,0,FreAmine 15%,0,Dextrose 50%,0,Hyperlyte CR,0, Trophamine 10%,0,FreAmine HBC 6.9%,0, Dex 5%/0.2% NaCl,0, Liposyn 30%,0, Tham 0.3 Molar Sol,0, Sterile Water

[0257] Barcode Explanation:

[0258] The entire barcode should desirably be one line (do not include carriage returns).

[0259] The first field identifies the barcode.

[0260] The order is allowed to be manually adjusted after loading. No Patient ID is specified.

[0261] No Order ID is specified (so it will be automatically recorded as 'Manual ###').

[0262] No Bag ID is specified.

[0263] Station **1** will be programmed for FreAmine 15%.

[0264] Station **2** will be programmed for Dextrose 50%.

[0265] Station **3** will be programmed for Hyperlyte CR.

[0266] Station **4** will be programmed for Trophamine 10%.

[0267] Station **5** will be programmed for FreAmine HBC 6.9%.

[0268] Station **6** will be programmed for Dex 5%/0.2% NaCl.

[0269] Station **7** will be programmed for Liposyn 30%.

[0270] Station **8** will be programmed for Tham 0.3 Molar Sol.

[0271] Station **9** will be programmed for Sterile Water.

[0272] All station volumes will be reset to zero.

[0273] Alternately, the code may contain all pertinent information such as solution name and volume information, but may lack information with respect to specific stations into

which the source solution is to be placed. In this example, the Compounder would determine any new or already existing source solution placements with those contained in the bar coded prescription order.

[0274] After the barcode label is printed, it is physically transferred to location where the compounder, such as compounding system **10**, is located. Referring again to FIG. **1**, barcode label **2216** may desirably be attached to a final solution container **14** intended to contain the desired compound. By attaching the barcode label to the solution container before compounding begins, errors may be minimized. Next, the barcode label **2216** of final solution container **14** is scanned into system **10** using barcode scanner **82**. As discussed above with respect to the compounding system **10** embodiments, the system will direct the operator to install the correct source solutions to the appropriate stations before allowing compounding to begin. Once compounding is complete, system **10** may optionally produce another barcode label, such as that illustrated in FIG. **24**, in which a compounding summary **2400** is contained. As shown in FIG. **24**, a non-limiting example of compounding summary **2400** includes Order ID **2402**, Operator information **2404**, Start Time **2406**, Job Time **2408**, Job Status **2410**, and details of the solution **2412**. Additionally result barcode **2414** is included which contains all information necessary to verify that the solution in container **14** is as intended.

[0275] Used in conjunction with the Order barcode **2300**, the Result barcode **2414** provides another way to move information reliably. As mentioned above, result barcode **2414** is printed on the compounding summary page, in any desired location. Result barcode **2414** contains basically the same information as the compounding summary header, which includes the compounding order identification, compounding date and time, and the compounding result code.

[0276] Examples of Result barcode fields are as follows:

[0277] 1. "R"=Barcode Identifier Code.

[0278] 2. Result Code: (C)ompleted, (A)borted, (F)ailed (see notes below).

[0279] 3. Patient ID, maximum of 12 characters.

[0280] 4. Order ID, maximum of 30 characters.

[0281] 5. Bag ID, maximum of 12 characters.

[0282] 6. Compounding Date, "mm/dd/yyyy" format.

[0283] 7. Compounding Time, "hh:mm" format (24 hour).

Note—The result code for a compounding operation can be one of the following:

[0284] "C"—Completed successfully.

[0285] "A"—Aborted by operator.

[0286] "F"—Failed due to unrecoverable delivery error.

[0287] Verification of the solution in container **14** is simply conducted by scanning barcode label **2414** and comparing the information contained therein with the information in the system based on either the memory of the initially scanned barcode label **2300** or the patient record. In one exemplary embodiment, result barcode **2414** may be scanned into compounding system **10** for comparison with the information contained in barcode label **2300**. Alternatively, and/or additionally, result barcode **2414** may be scanned by personnel before administering the compound to the patient using scanner **2210** of system **2200** (see. FIG. **22**). If an error is detected in the comparison, the operator is alerted so that corrective measures can be taken, such as recreating the compound or conducting self-test of the systems. If the comparison is successful the operator may be notified as well.

[0288] Although examples discussed above may relate to a bar code system, the invention is not so limited in that, as identified above, RFID tags may be used as a means to convey compounding information to the compounder and compound solution information from the compounder system back to the ordering system of other check point to verify compliance.

[0289] Features of the invention are set forth in the following claims.

[0290] Although the invention is illustrated and described herein with reference to specific embodiments, the invention is not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the invention.

What is claimed:

1. A method for use with a data entry system for providing input data to a pharmaceutical compounding device having an associated plurality of source solutions, the method comprising the steps of:

a) generating a first label comprising first indicia defining an allocation of said plurality of source solutions;

b) providing said first label directly to said pharmaceutical compounding device;

c) reading said first indicia from said first label with said pharmaceutical compounding device; and

d) generating a pharmaceutical compound with said pharmaceutical compounding device based on said first indicia input into said pharmaceutical compounding device.

2. The method according to claim **1**, wherein said first indicia further compromises information relating to a patient for which the pharmaceutical compound is intended.

3. The method according to claim **1**, wherein said first indicia comprises a bar code.

4. The method according to claim **1**, wherein said first indicia comprises a two dimensional bar code.

5. The method according to claim **1**, wherein said first label is an electronic label.

6. The method according to claim **5**, wherein said electronic label is a Radio Frequency Identification label.

7. The method according to claim **6**, wherein the providing step (b) comprises the steps of:

activating said electronic label with an RF signal; and

transmitting said indicia responsive to said RF signal.

8. The method according to claim **1**, wherein said data entry system generates said first label.

9. The method according to claim **1**, wherein at least one of the first indicia or second indicia includes information for instructing an infusion pump regarding delivery of the generated pharmaceutical compound to a patient.

10. The method according to claim **1**, wherein the first indicia includes information for instructing an operator of the pharmaceutical compounding device at which pumping stations to install respective ones of said plurality of source solutions.

11. The method according to claim **10**, further comprising the steps of:

scanning a bar code of said installed plurality of source solutions;

scanning a bar code of respective ones of transfer tubing coupled to said plurality of source solutions and said pump station;

comparing the scanned information of the installed plurality of source solutions and transfer tubing with an expected configuration; and

either permitting the operator to commence compounding if the comparison is valid or preventing the operator from compounding if the comparison is invalid.

12. The method according to claim **1**, wherein Step d) comprises the steps of:

d1) pumping a first portion of at least one of the source solutions at a first flow rate with a first pump element until a predetermined threshold of the source solution is reached, and

d2) pumping a remaining portion of the at least one source solution at a second flow rate with the first pump element until a target volume of the source solution is reached, the second flow rate being less than the first flow rate.

13. The method according to claim **1**, further comprising the step of generating a second label comprising second indicia indicative of at least said pharmaceutical compound as generated by said pharmaceutical compounding device.

14. The method according to claim **1**, wherein the pharmaceutical compound is a TPN compound.

15. A method for use with a data entry system for providing input data to a pharmaceutical compounding device having an associated plurality of source solutions, the method comprising the steps of:

a) generating a first label comprising first indicia defining an allocation of said plurality of source solutions conforming to a predetermined configuration;

b) providing said first indicia to said pharmaceutical compounding device as an input;

c) reading said first indicia from said first label with said pharmaceutical compounding device; and

d) generating a pharmaceutical compound based on said indicia input into said pharmaceutical compounding device by pumping at least two separate sources of a first type of source solution simultaneously into a designated receptacle.

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