TERUMO BLOOD AND CELL TECHNOLOGIES

# Spectra Optia™ Apheresis System Versions 12.1 and v12.1.1 (consolidated) Software Update Training Presentation

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TS-OPTI-02868

TRAINING

# Disclaimer

**Intended Use**[1]
The Spectra Optia Apheresis System, a blood component separator, may be used to perform the following therapeutic apheresis, cell collection, and cell processing procedures*:

- Therapeutic plasma exchange
- Therapeutic plasma exchange with a secondary plasma device
- Red blood cell exchange, depletion, and depletion/exchange
- Mononuclear cell collection from the peripheral blood
- Granulocyte collection from the peripheral blood
- White blood cell depletion
- Platelet depletion*
- Processing of harvested bone marrow

**Contraindications for Use**

- Leukocytapheresis is contraindicated in AML FAB M3 (APL) because of the accompanying disseminated intravascular coagulation. (Vahdat L, et al.,"Early mortality and the retinoic acid syndrome in acute promyelocytic leukemia: impact of leukocytosis, low-dose chemotherapy, PMN/RAR-alpha is o form and CD13 expression in patients treated with all-trans retinoic acid." *Blood* 1994; 84: 3843-3849. Daver, et al., "Clinical characteristics and outcomes in patients with acute promyelocytic leukaemia and hyperleucocytosis." *British Journal of Haematology* 2015, 168, 646-653.)
- Other contraindications for the use of the Spectra Optia system are limited to those associated with the infusion of solutions and replacement fluids as required by the apheresis procedure, and those associated with all types of automated apheresis systems.

**Possible adverse events of apheresis procedures include:**

- Anxiety, headache, light-headedness, digital and/or facial paresthesia, fever, chills, hematoma, hyperventilation, nausea and vomiting, syncope(fainting), urticaria, hypotension, allergic reactions, infection, hemolysis, thrombosis in patient and device, hypocalcemia, hypokalemia, thrombocytopenia, hypoalbuminemia, anemia, coagulopathy, fatigue, hypomagnesemia, hypogammaglobulinemia, adverse tissue reaction, device failure/disposable failure, air embolism, blood loss/anemia, electrical shock hazard, fluid imbalance, inadequate separation of blood components.

**Reactions to Blood Products Transfused During Procedures**

- Reactions to transfused blood products can include fever, circulatory overload, shock, allergic reactions, alloimmunization, transfusion-related acute lung injury (TRALI), and graft-versus-host disease (GVHD), as well as transmission of infectious diseases and bacteria. (Sources: *Circular of Information for the Use of Human Blood and Blood Components*, AABB, et al, ed., April 2006; *Guide to the Preparation, Use And Quality Assurance of Blood Components*, 10th Edition, Council of Europe Publishing; Toy P et al.,"Transfusion-Related Acute Lung Injury: Incidence and Risk Factors." *Blood* 2012; 119: 1757-1767).

**Restricted to prescription use only:**

- Operators must be familiar with the system's operating instructions.
- Procedures must be performed by qualified medical personnel.

*Procedure availability varies by country.




[1]Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual. August 2023. Part no. 10000001322;1-4.

TERUMO BLOOD AND CELL TECHNOLOGIES

# Software Upgrade Features

- Usability Enhancements
- Report enhancements
- Data Connectivity
- New Alarms and Alarm Changes
- Data Management Features

# Usability Enhancements

# Usability Enhancements

## Improvements

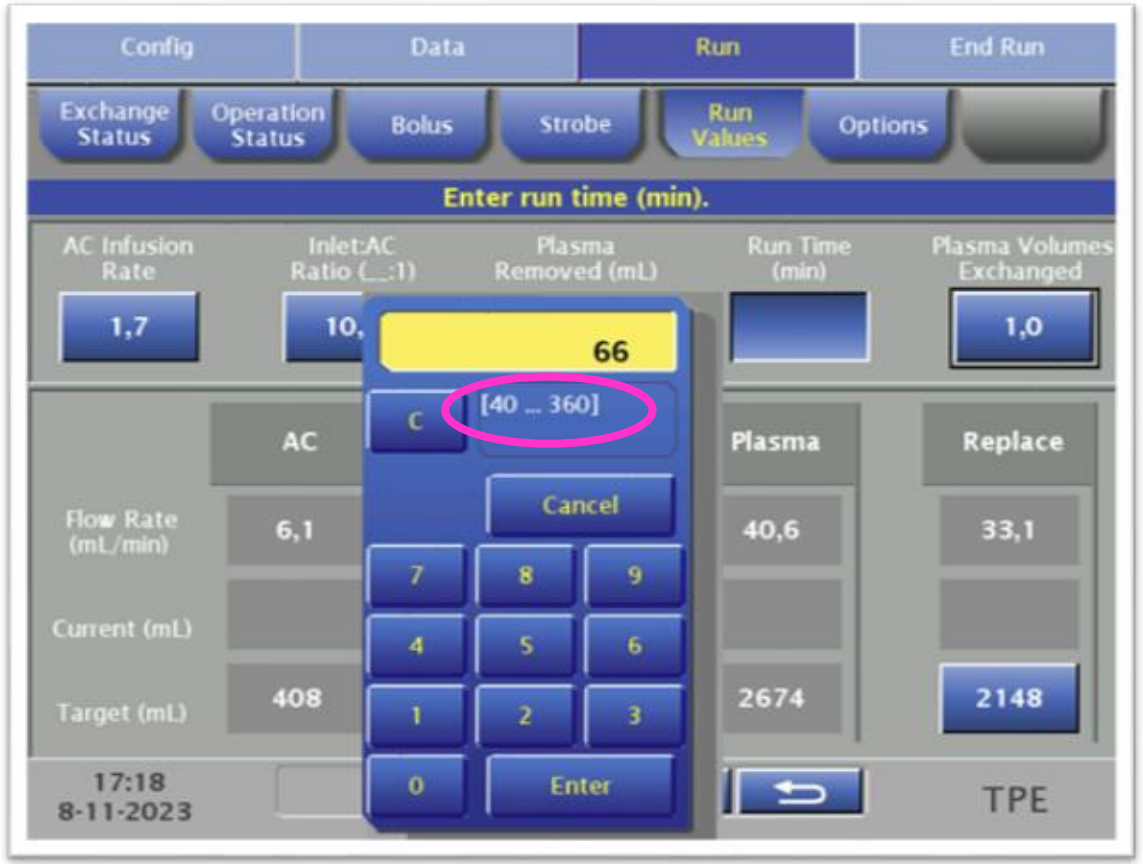
- Improved alarm mitigation and reduce watchdog alarms and screen freezing.
- Prevention of product loss during memory failures with valves closing at the critical point.
- Enhanced protocols, alarms, and instructions.

## New features

- Exchange procedures are capped at 360 instead of 480 minutes.
- New features include patient ID and procedure ID.
- Splash screen shows the new logo.

# Exchange Procedure Run Time and Splash Screen Logo

Exchange procedures run time capped at 360 min



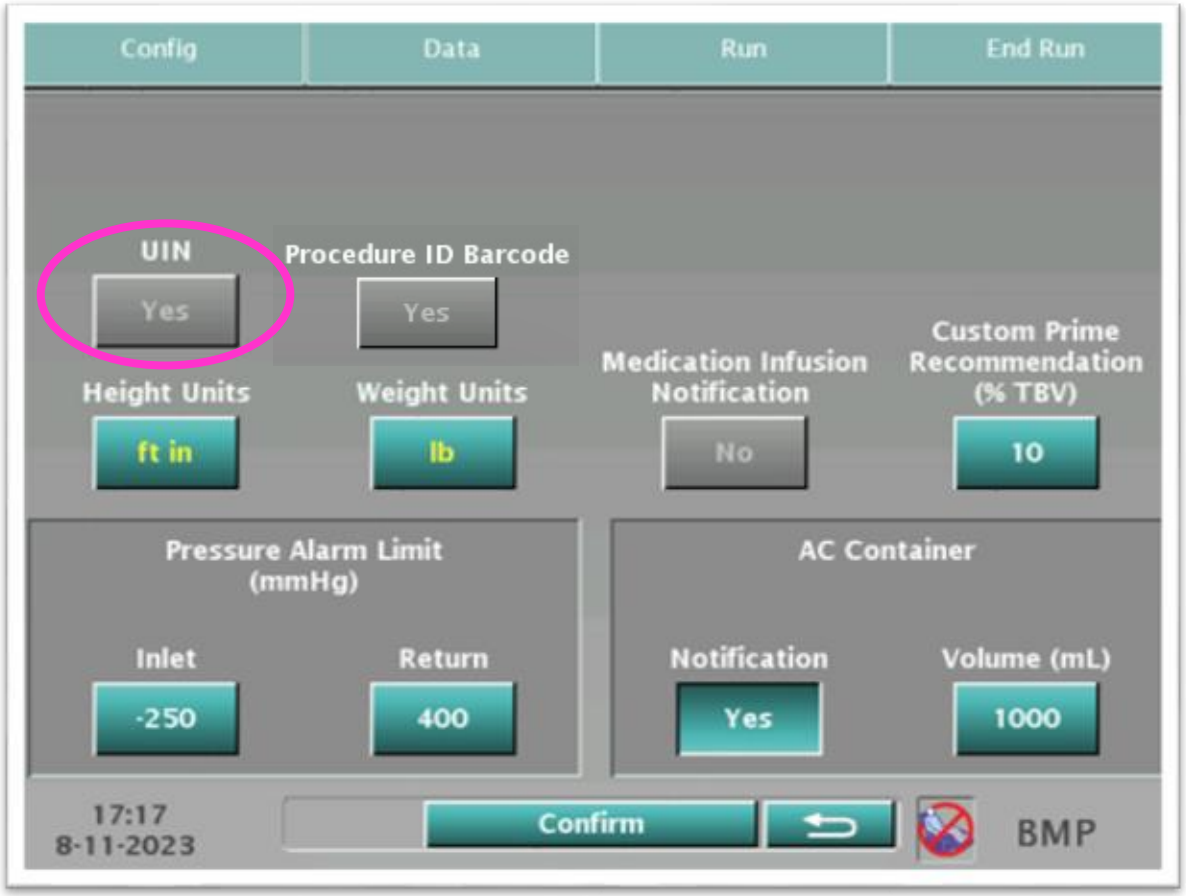

New splash screen with new logo

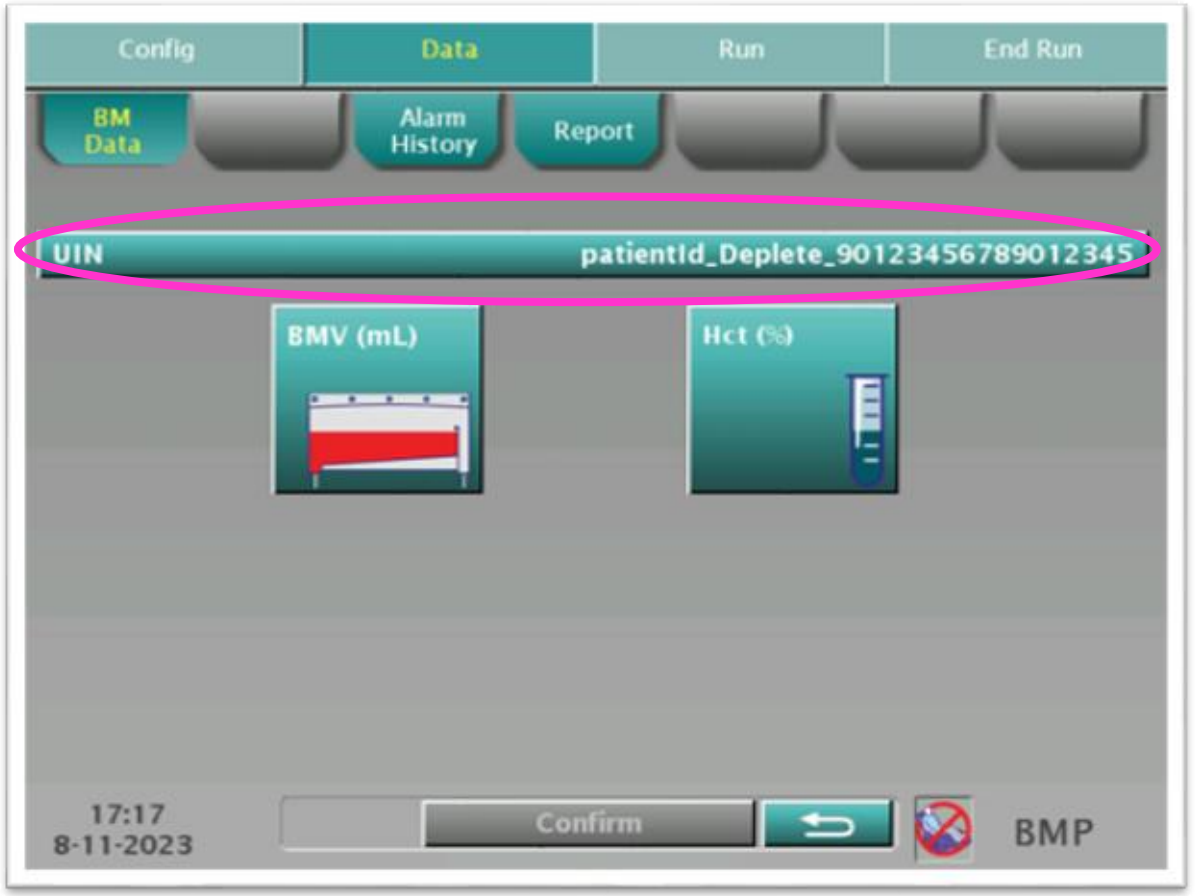



[2]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);21.

# New Unique Identifier Number[3] (UIN) for BMP procedures

BMP procedure




BMP: bone marrow processing

[3]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);5.

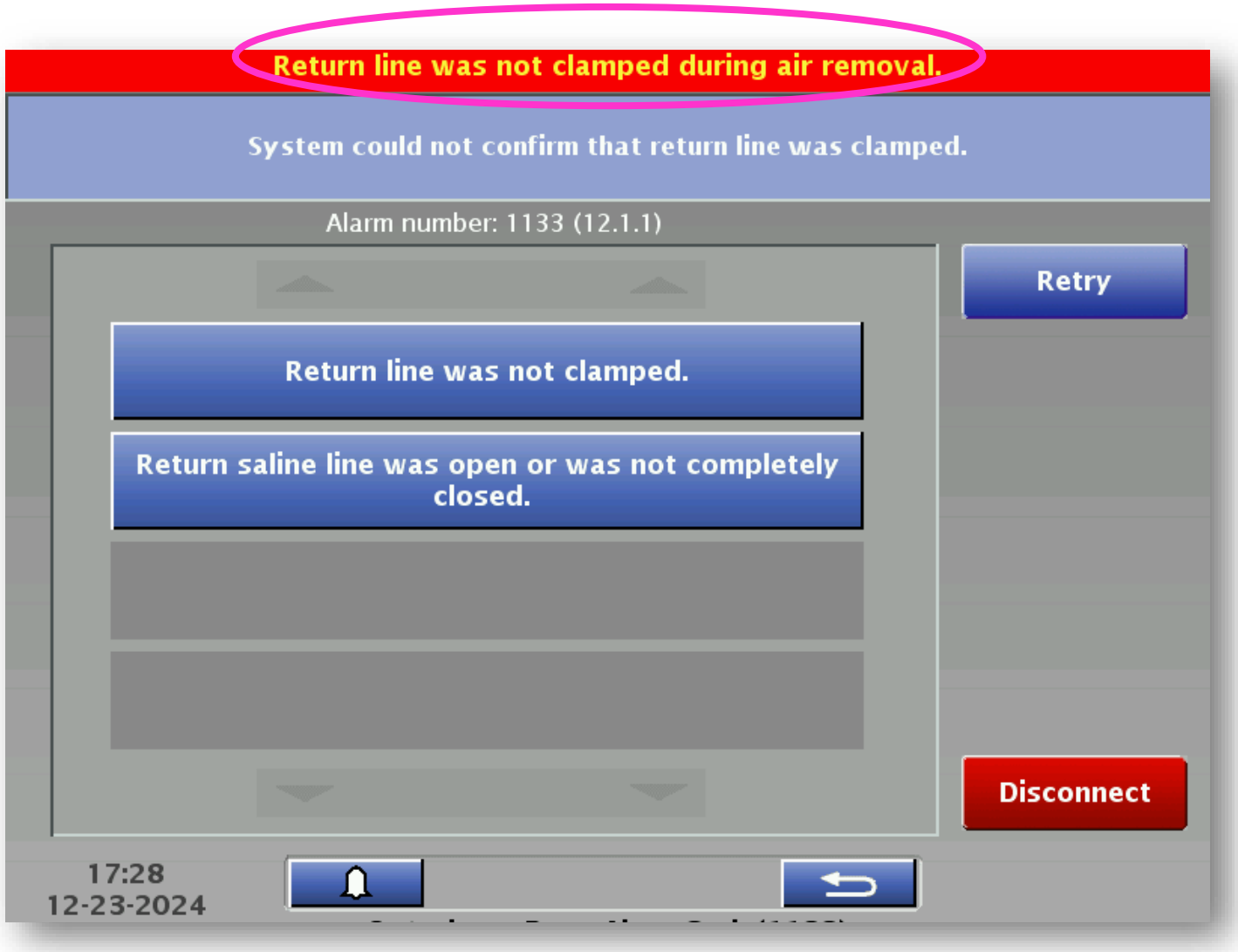
# Other enhancements in Protocols, Alarms and Instructions[4]

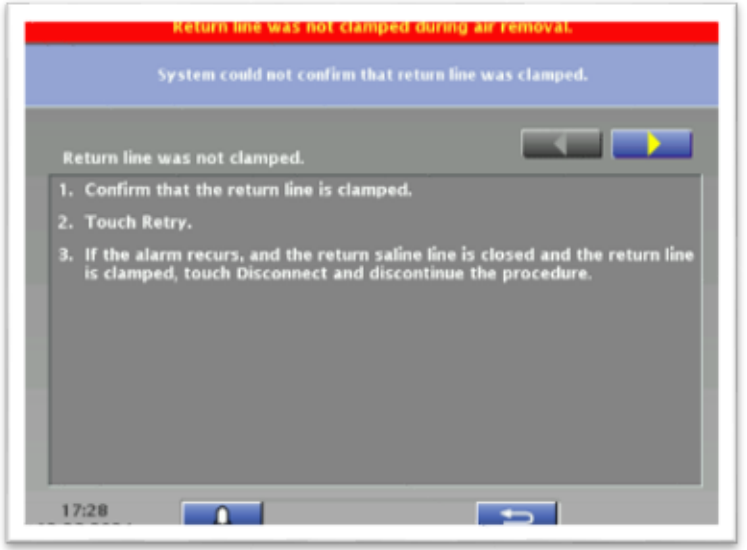
- In exchange procedures, when changing to single needle during a procedure, the pumps will automatically pause.
- Instructions are simplified for “Bolus volume caused fluid balance to exceed limits” alarm.
- The RBCX fluid data screen is enhanced with dimming of the unavailable RBCX protocol variants.
- During RBCX, the Disable RBC detector button has been removed for “Cells were detected in plasma line from centrifuge” alarm with addition of two new alarm causes to the initial alarm screen.
- Instructions are improved for the alarm “Hypervolemic condition was possible” for CMNC, PMN, WBCD, PLTD, and MNC protocols.
- Instructions are improved for “Hypovolemic condition was possible” alarm.
- Instructions are revised for “Packing factor exceeded recommended limits” to display the correct packing factor rather than 0.0.
- Possible causes are revised for “Low level reservoir sensor detected excess fluid” alarm.
- The Collection Preference window will display the trend graph after disabling AIM but not display the green diamonds during cell collection procedures.

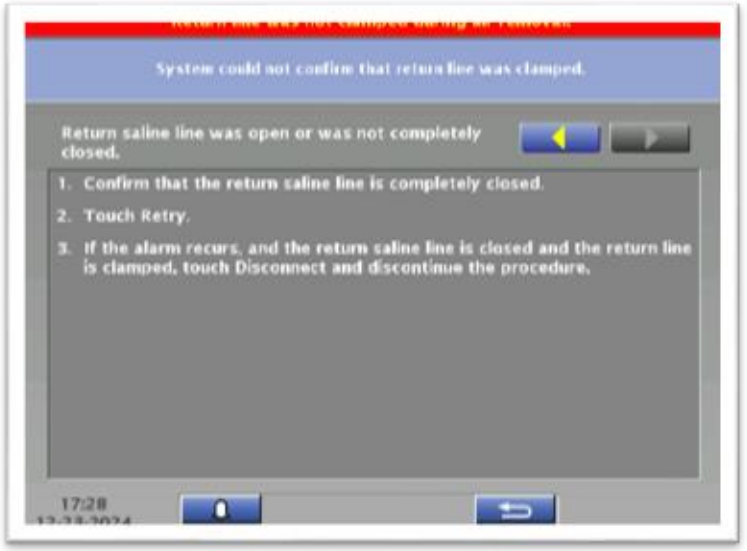
[4]Spectra Optia Apheresis System Software Updates v12.1, TS-OPTI-02165 (2024); 21-27.

# New Alarms and Alarm Changes

# New updated alarm #1133[5]

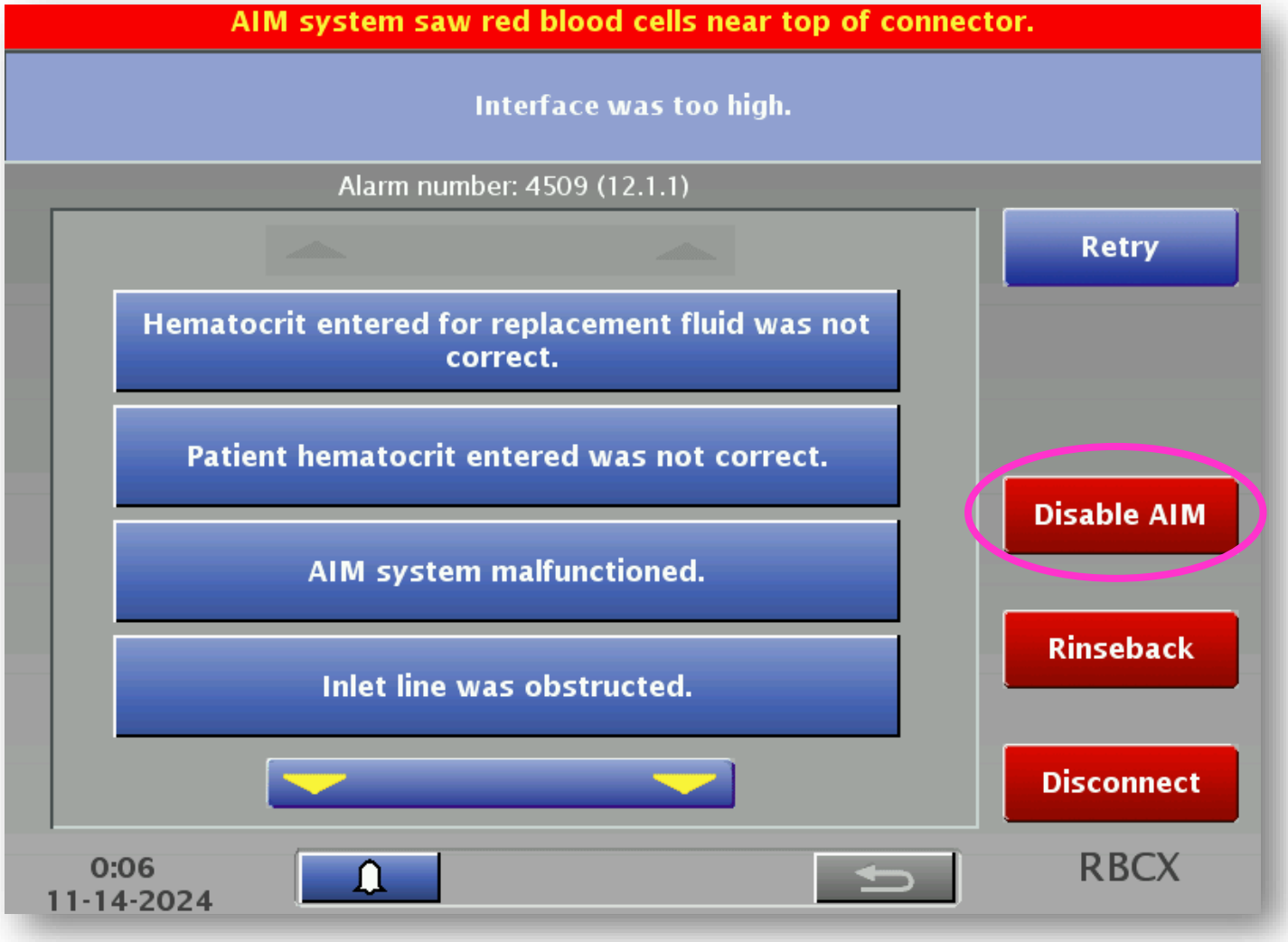


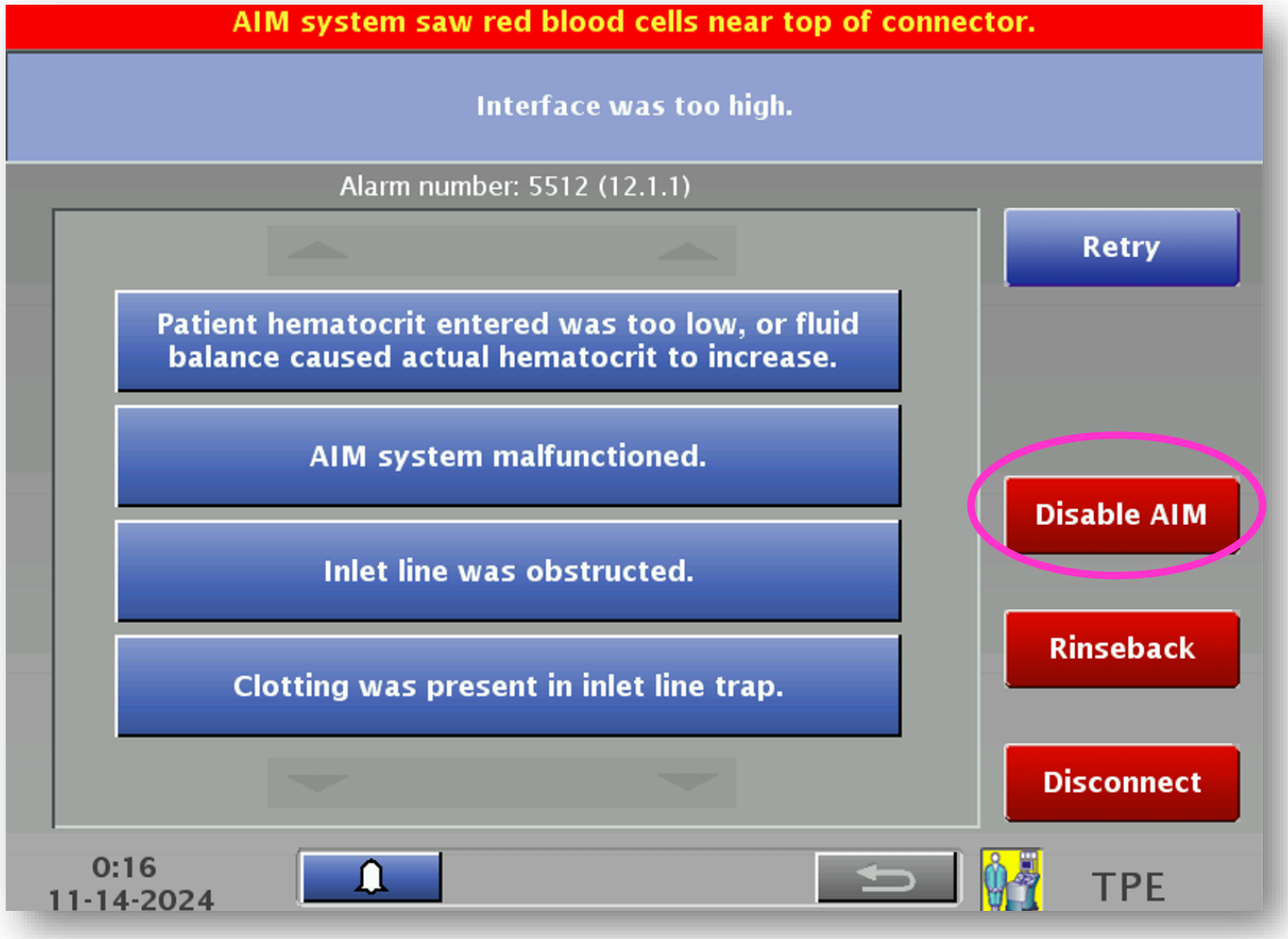

[5]TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025); 23

# New Disable AIM alarm update[6]



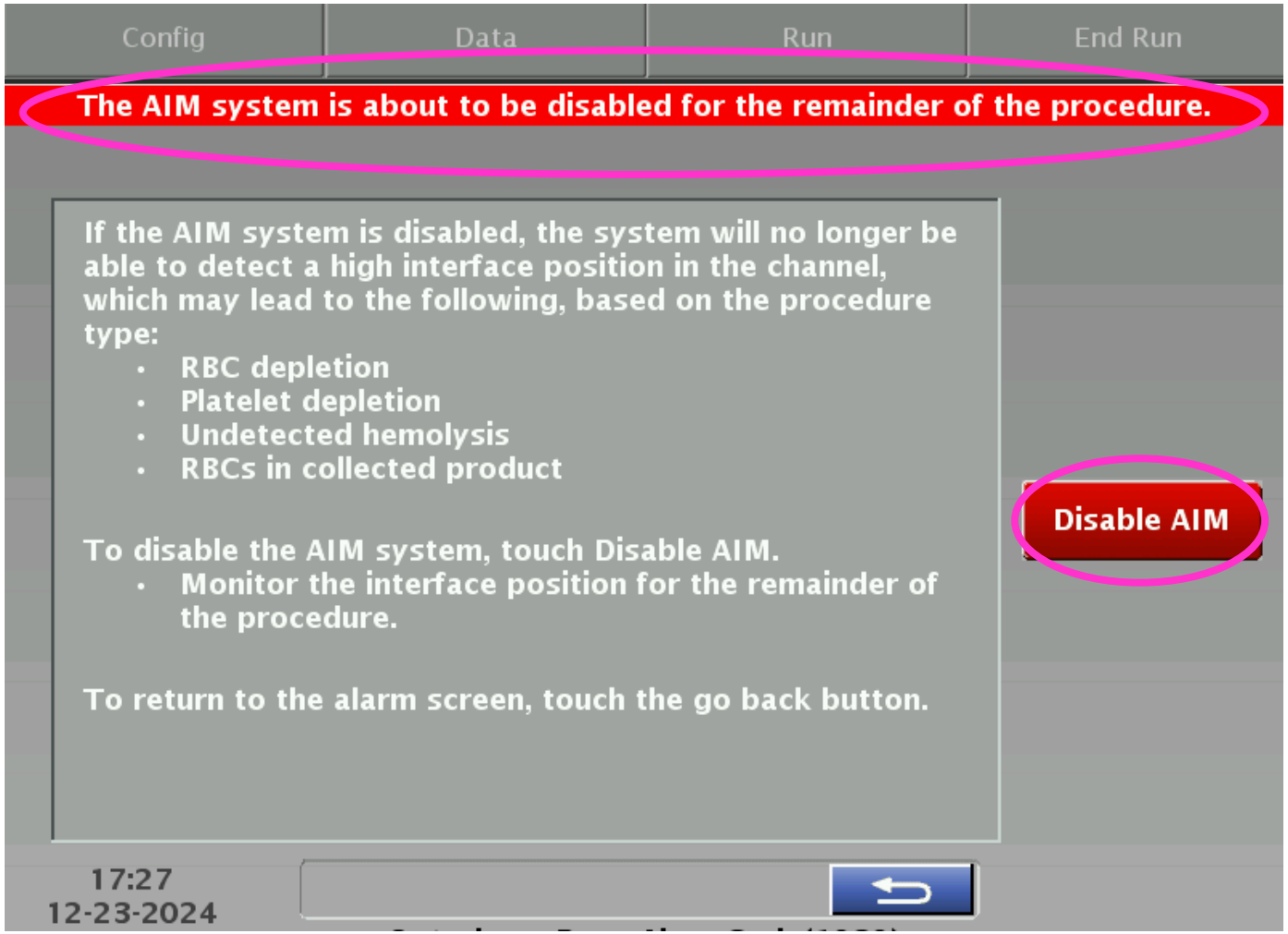

[6]TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025); 24

# New Disable AIM alarm update[6]



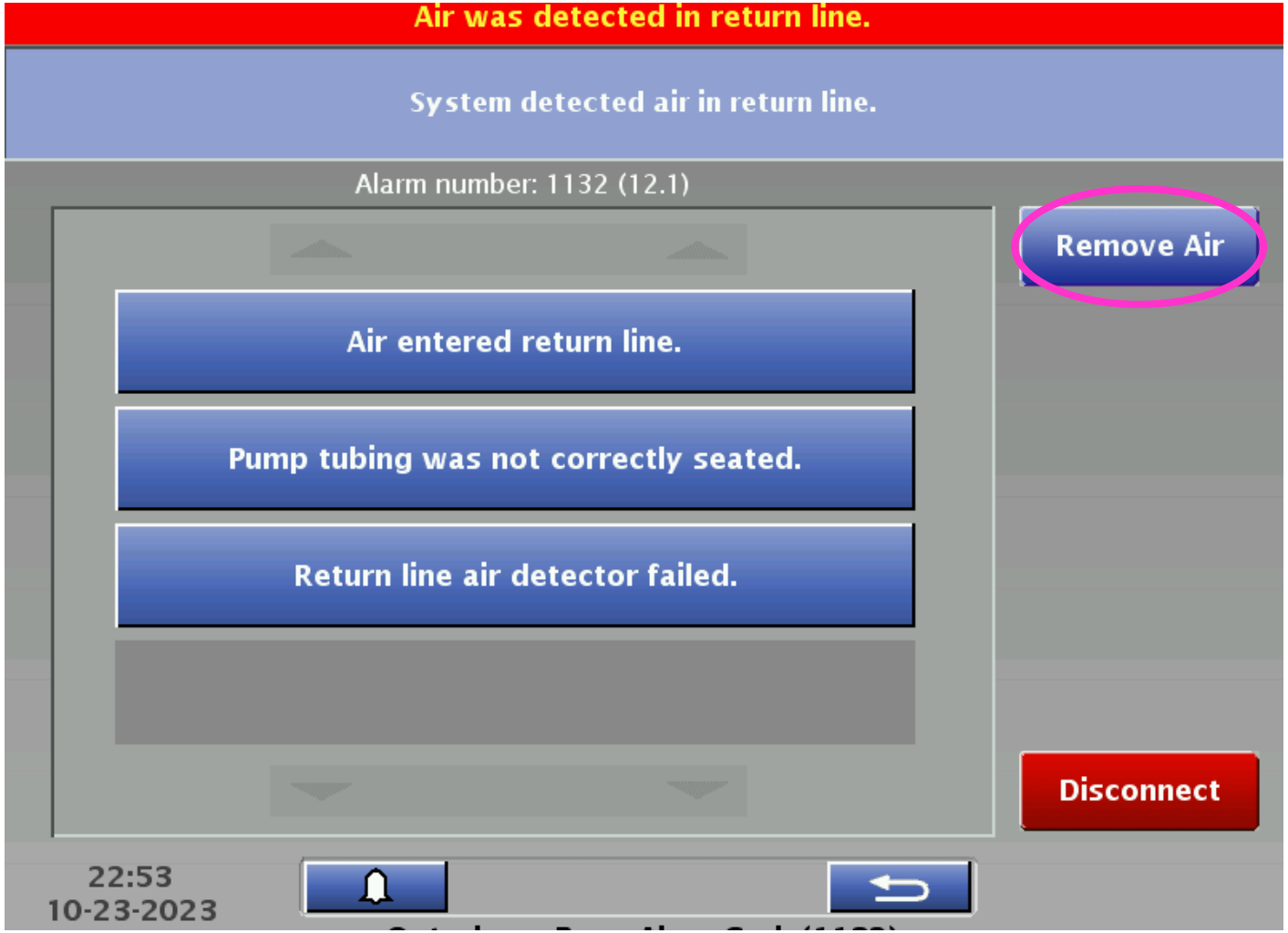

[6]TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025); 24

# New Disable AIM alarm prompt update[7]




[7]TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025); 26

# New Return line air detector (RLAD) alarm[8] can be triggered during custom prime

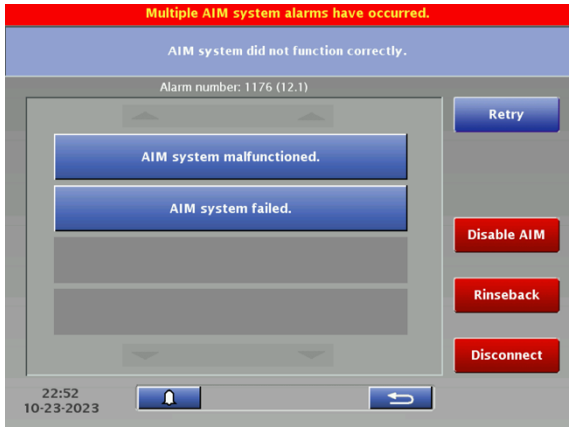


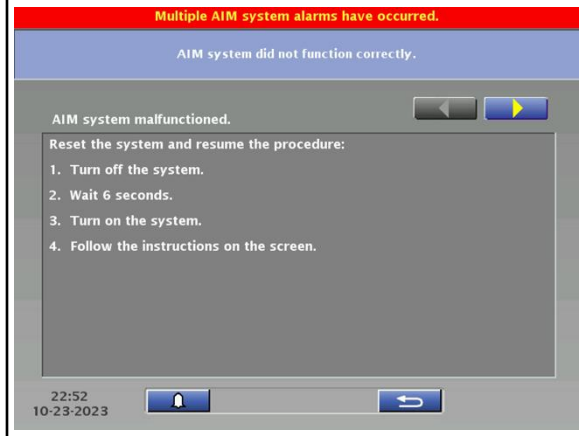

[8]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12(2025);1

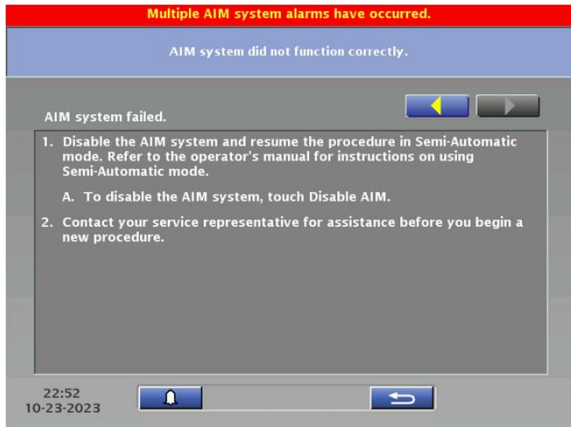
# New Alarms[9]

All procedures

- New alarm: 1176 “Multiple AIM system alarms have occurred”



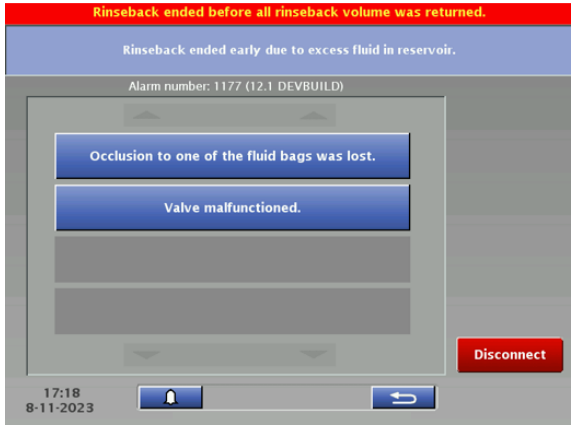
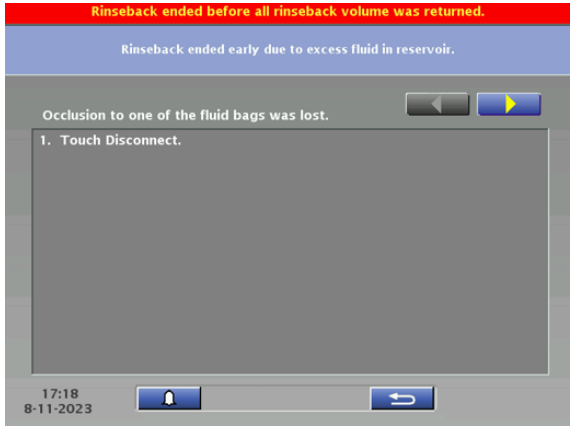
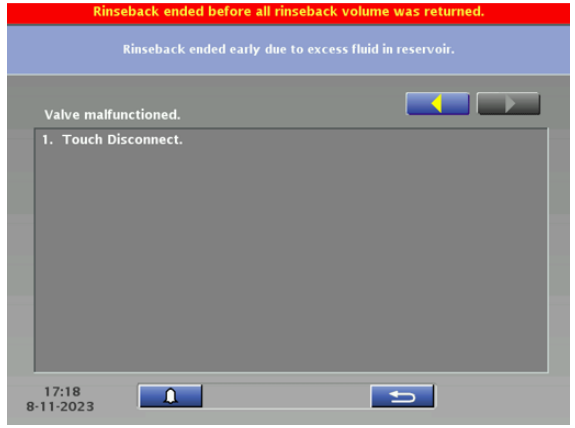
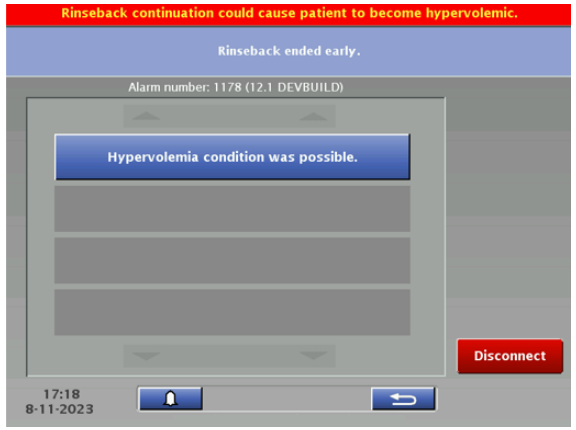
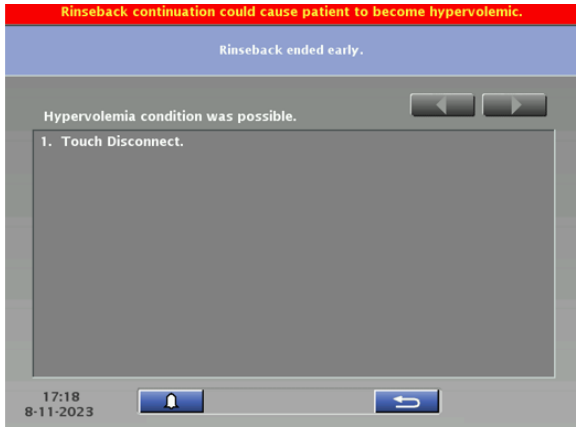




[9]Software Release Notes for Spectra Optia v12.1 (2024); 2

# New Alarms[10]

## All procedures

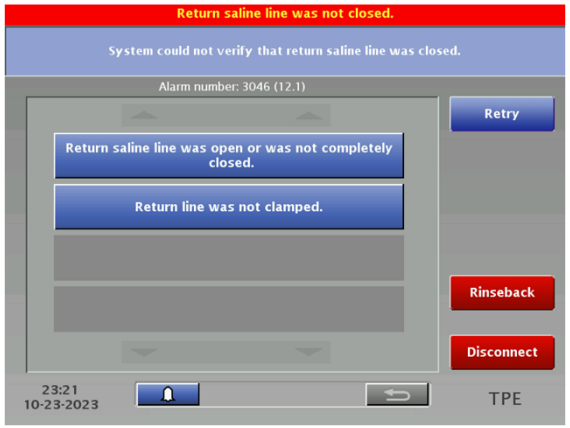
| | | | |
|---|---|---|---|
| ▪ Alarm 1177 “Rinseback ended before all rinseback volume was returned” |  |  |  |
| ▪ Alarm 1178 “Rinseback continuation could cause patient to become hypervolemic” |  |  | |

[10]Software Release Notes for Spectra Optia v12.1 (2024);7

# New Alarms[11]

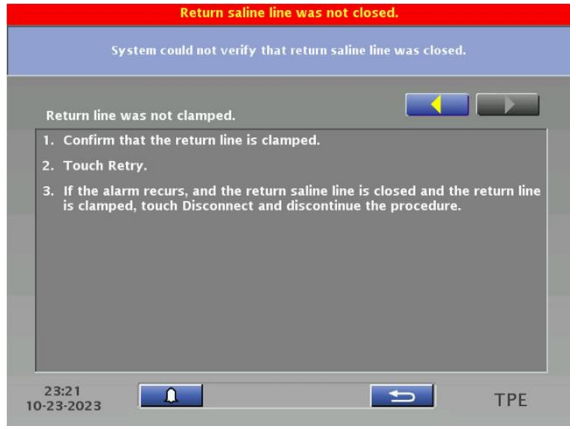
## Exchange procedures

- The system will check to ensure the return line saline clamp is closed at these occurrences:
  - After the final confirmation of closing the saline lines at the beginning of the run
  - After conversion to single needle





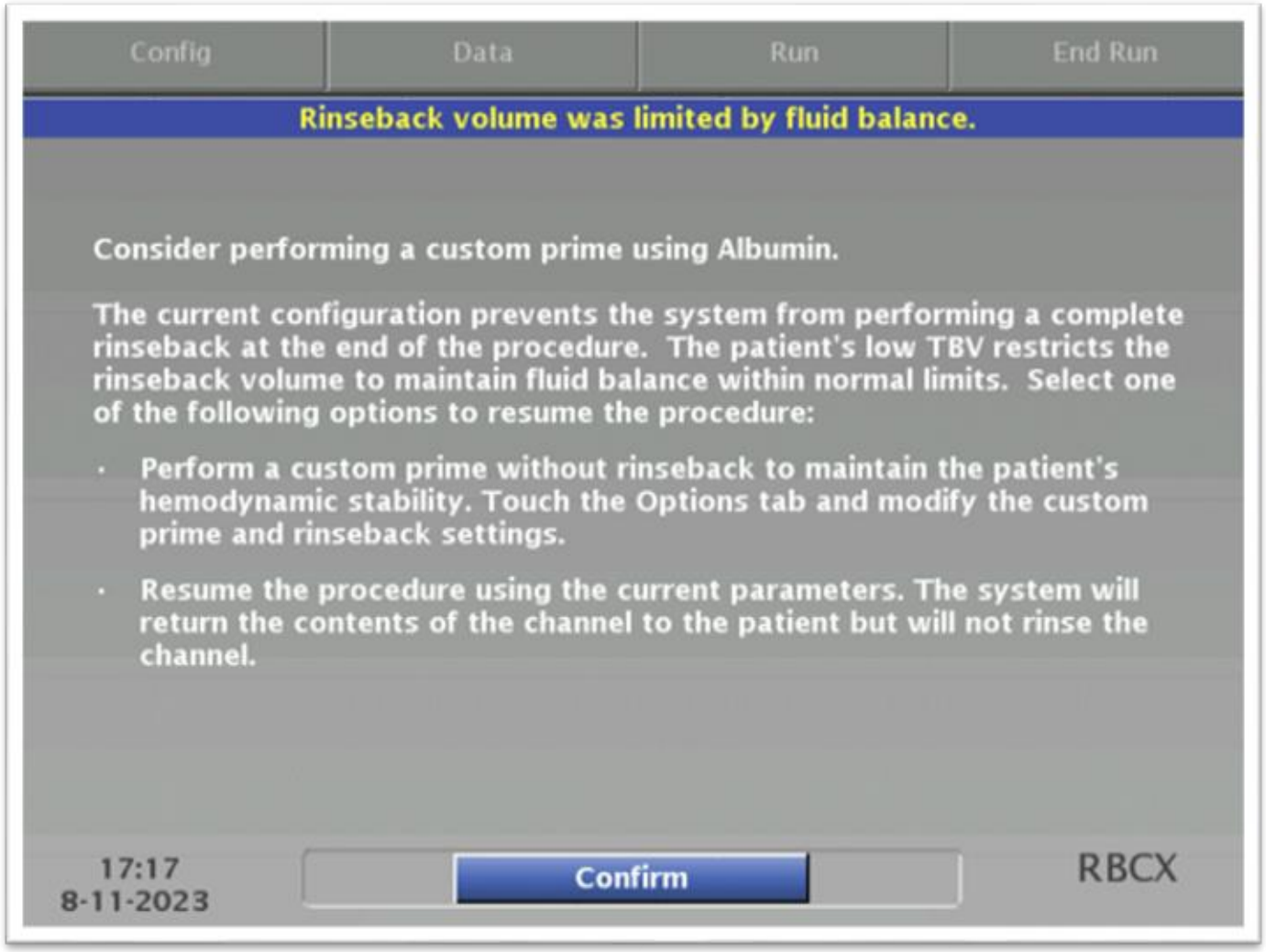





[11]Software Release Notes for Spectra Optia v12.1 (2024);9

# New Prompt for Custom Prime[11]

RBCX rinseback volume is limited by fluid balance




[11]Software Release Notes for Spectra Optia v12.1(2024);9

# Report Enhancements

# Additions to Summary Report[12,13]

All procedures

- Additional alarms are included for start-up, disposable loading, saline prime, and custom prime.
- Packing factor changes will be captured in summary report.
- When in semi-automatic mode, run value changes will be recorded.
- Added AIM disabled messages.

[12] Spectra Optia Apheresis System Operator's Manual (2025);15:6-8
[13] TS-OPTI-02165 Spectra Optia Apheresis System Version 12.1 Software Updates (2024);39-41

# Additions to Summary Report[12,13] *(cont'd)*

All procedures

- RBCX reports caution status for out-of-target HCT and minimum HCT ranges.
  - This fix ensures these caution statuses are reported in end-of-run reports and proper real-time messaging
- Total blood volume (TBV) processed was missing in reports, but that has been added.
- Report had an incorrect remove bag volume, but that is corrected.

[12] Spectra Optia Apheresis System Operator's Manual (2025);15:6-8
[13] TS-OPTI-02165 Spectra Optia Apheresis System Version 12.1 Software Updates (2024);39-41

# Additions to Summary Report[12,13] *(cont'd)*

MNC procedures

- For MNC only, the fluid balance failed prior to this upgrade to account for the final chamber volume collected.
  - This ensures that the final volume is reported on both summary screens and the report accurately.

[12] Spectra Optia Apheresis System Operator's Manual (2025);15:6-8
[13] TS-OPTI-02165 Spectra Optia Apheresis System Version 12.1 Software Updates (2024);39-41

# Additions to Summary Report *(cont'd)*

## RBCX Procedures

Spectra Optia Apheresis System: 1P00836 06-16-2023 RBCX
Software version: 12.1 Time: 02:44 - 03:00
Male 180 cm 60 kg TBV: 4675 mL
Hct: 50% Single-needle option: Yes
Patient ID: 12345abcde67890ghij

| Run Values | Initial | Final |
|---|---|---|
| Replaced: Exchange | RBC 45% Hct | RBC 45% Hct |
| Fluid Balance (mL) | 100 | 128 |
| Fluid Balance (%) | 102 | 103 |
| Blood Removed (mL) | 504 | 301 |
| Run Time (min) | 20 | 10 |
| FCR (%) | 92 | 95 |
| Target Hct (%) | 47 | 49 |
| Replaced (mL): Exchange | 420 | 257 |
| AC (mL) | 63 | 32 |
| Inlet (mL) | 815 | 459 |
| Remove Bag (mL) | 533 | 320 (AC 19) |
| Replacement Used (mL) | 420 | 257 |

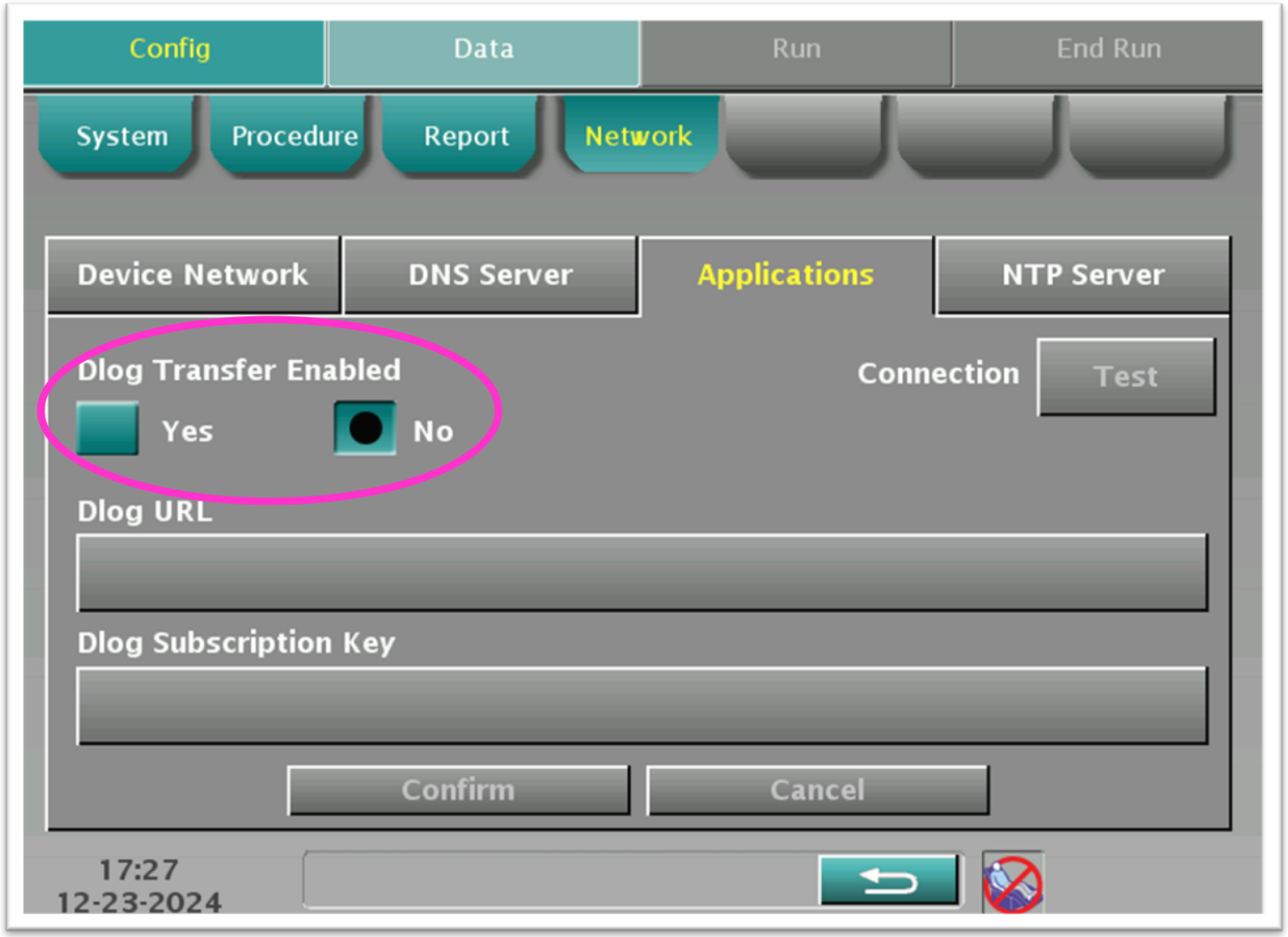
| Fluid Balance (mL) | |
|---|---|
| AC | 32 |
| Remove Bag | -320 |
| Replacement Used | 257 |
| Tubing Set | -33 |
| Rinseback | 178 |
| Subtotal | 128 |
| Bolus | 0 |
| Additional Fluid | |
| Total Fluid Balance | |

AC to patient: 24 mL

Notes:

Operator:

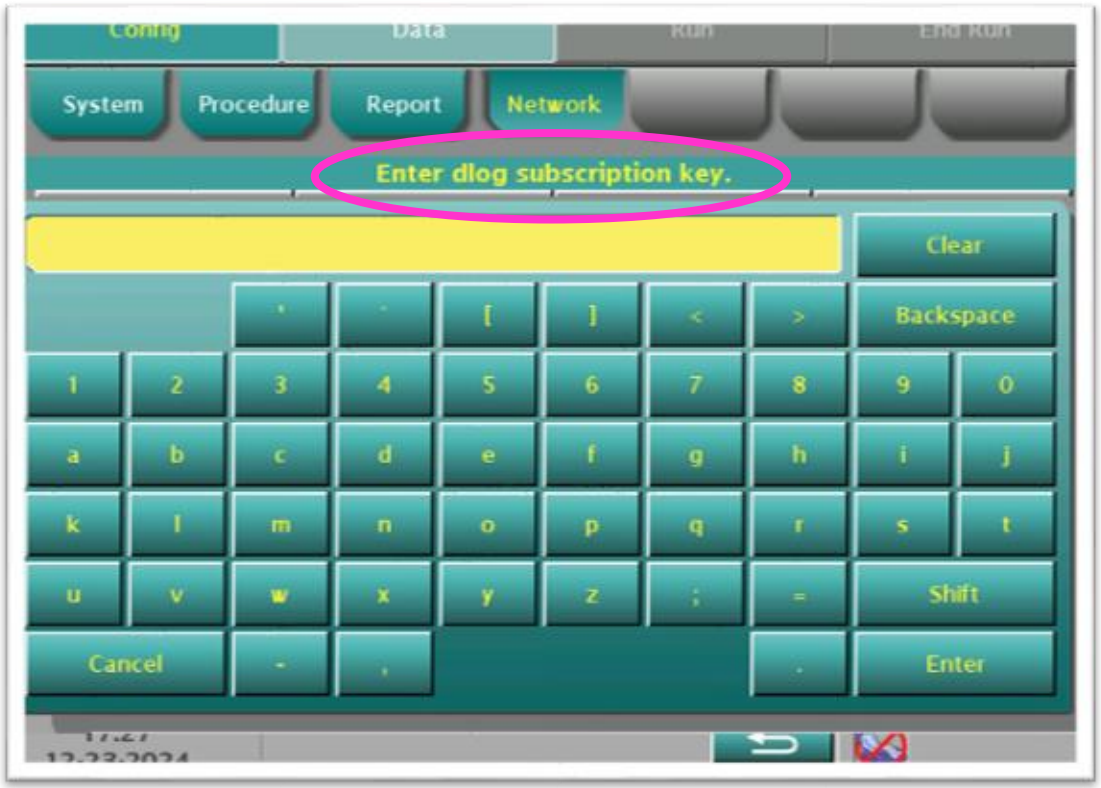
# New Dlog Transfer[14,15] feature




[14]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025);1-14
[15] Ref-03545 Template for Detailed Design Document (2025);11

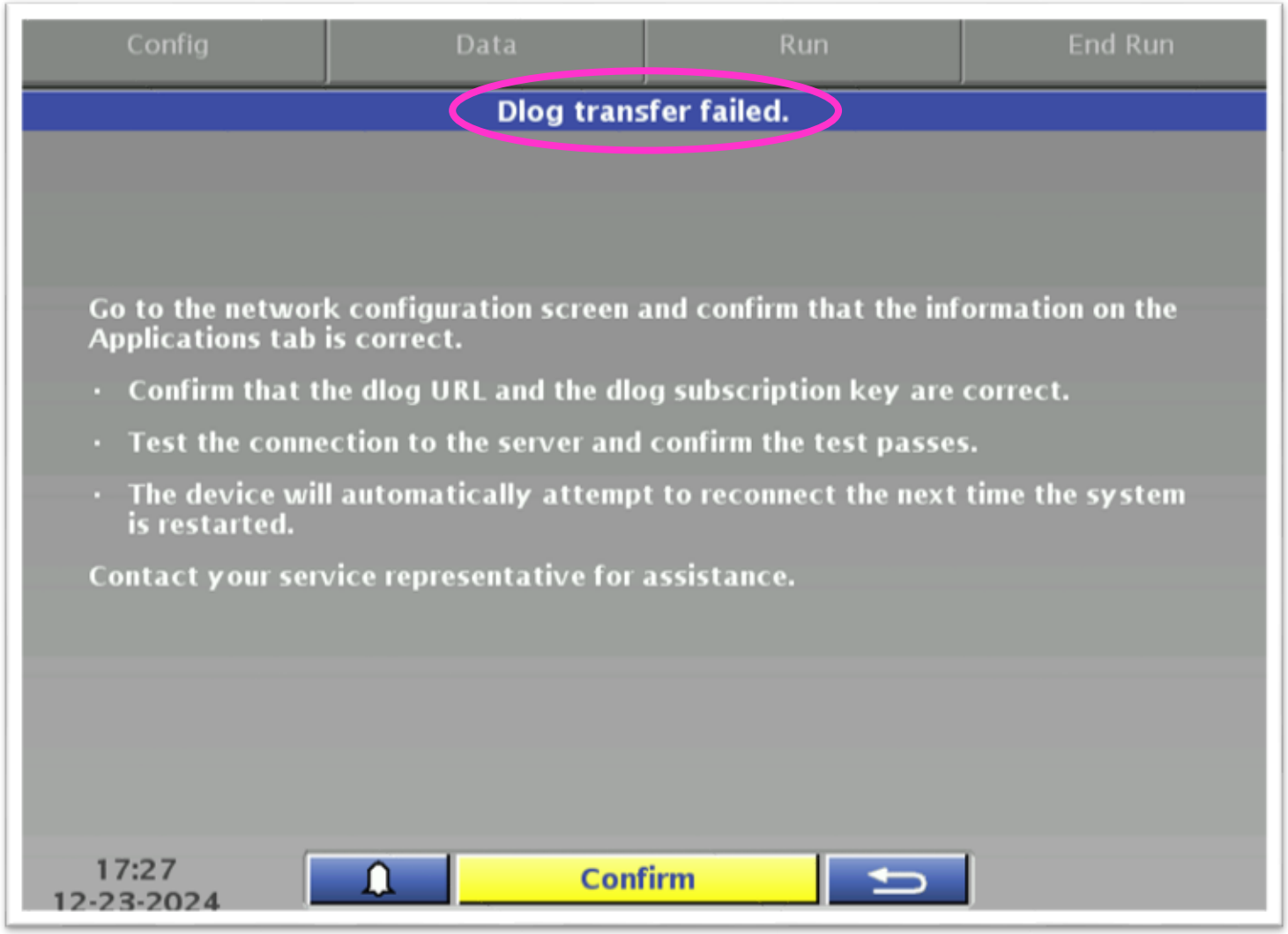
# New Dlog URL[14] and subscription key



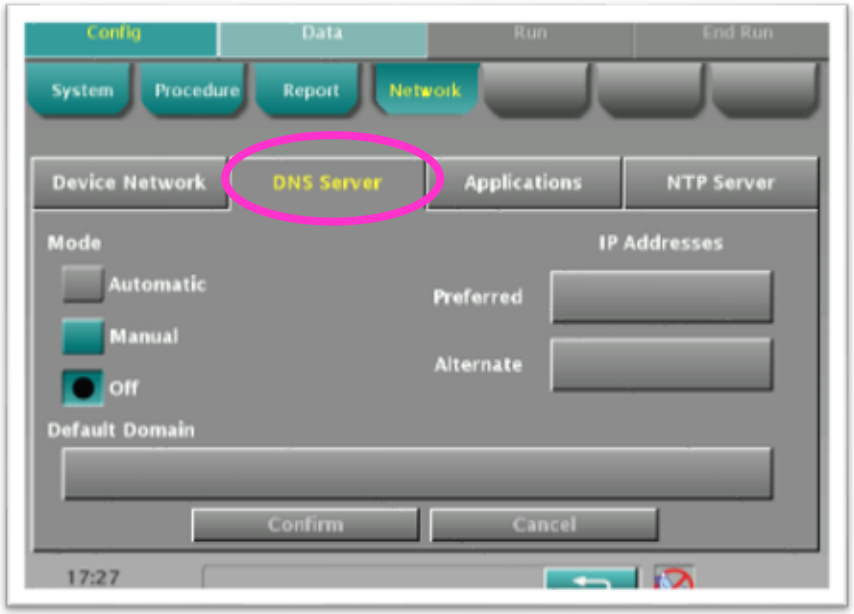

[14]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025); 1-14

# New Dlog Transfer Failed[16] notification




[16]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025);1-16

# New Tab for DNS[17] server







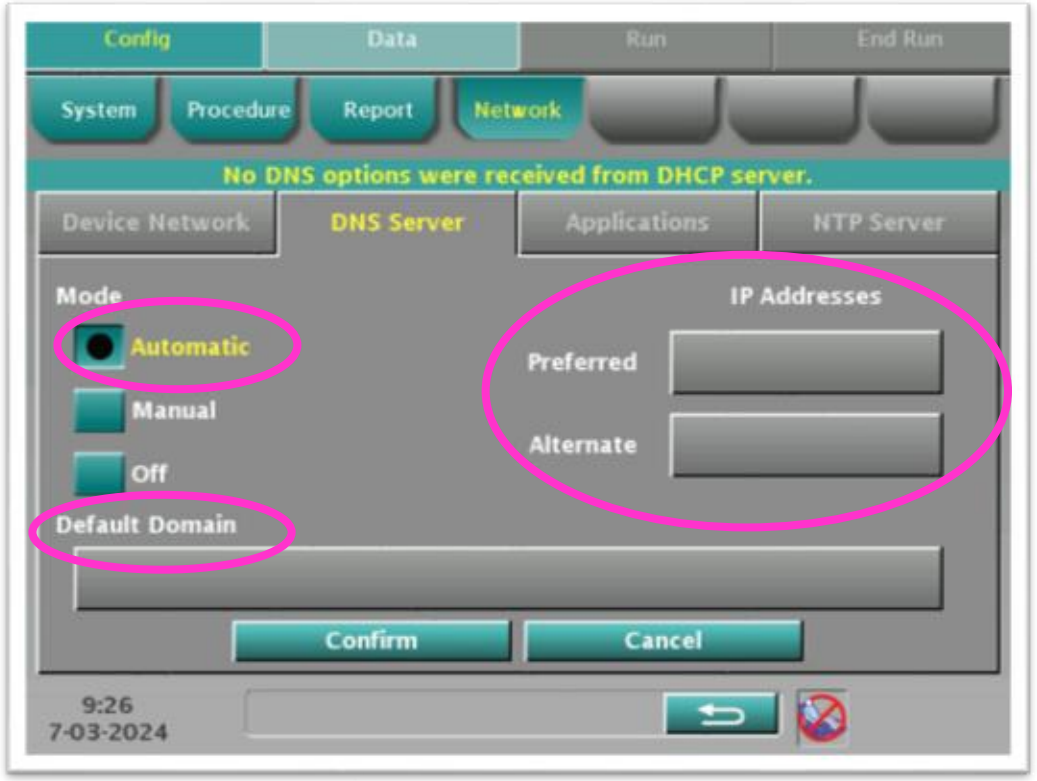



DNS: domain name system

[17]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025);1-4

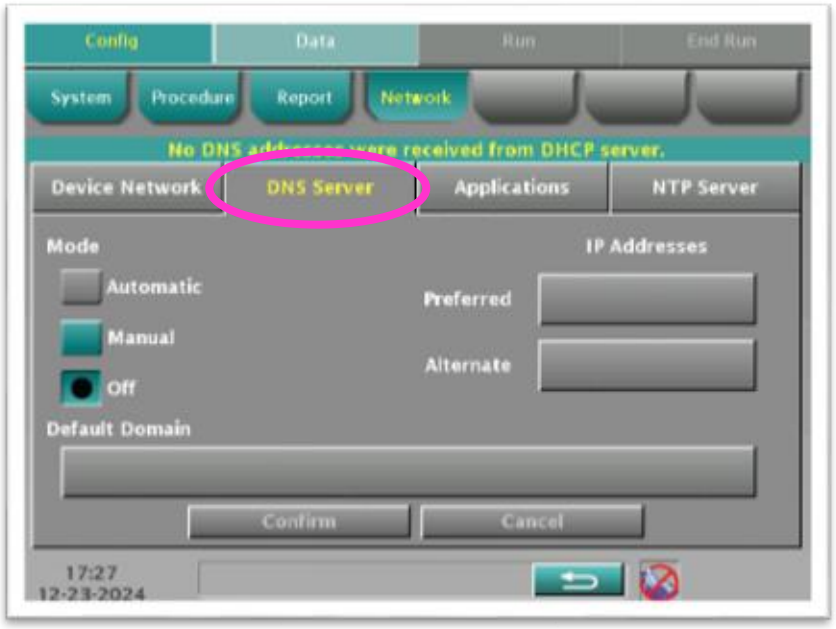
# New Automatic mode[18] for DNS server

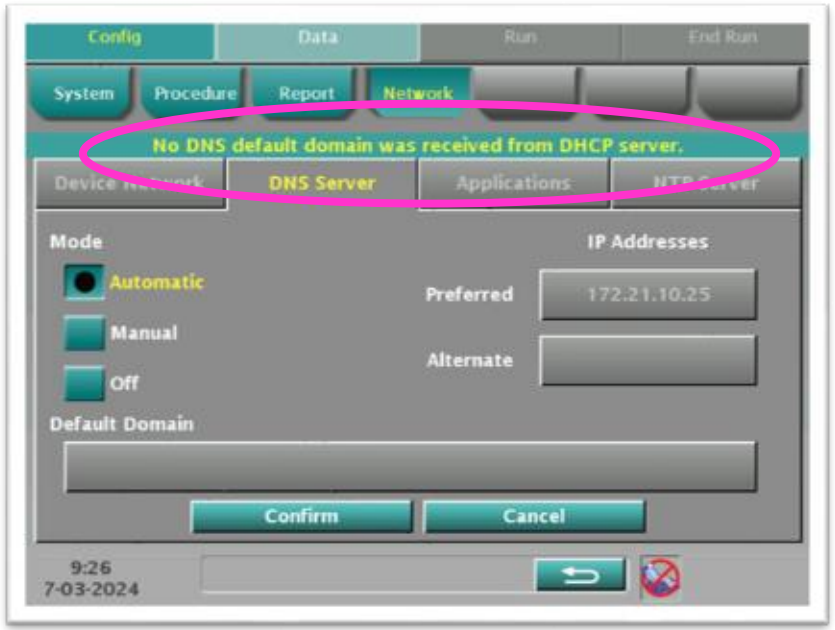


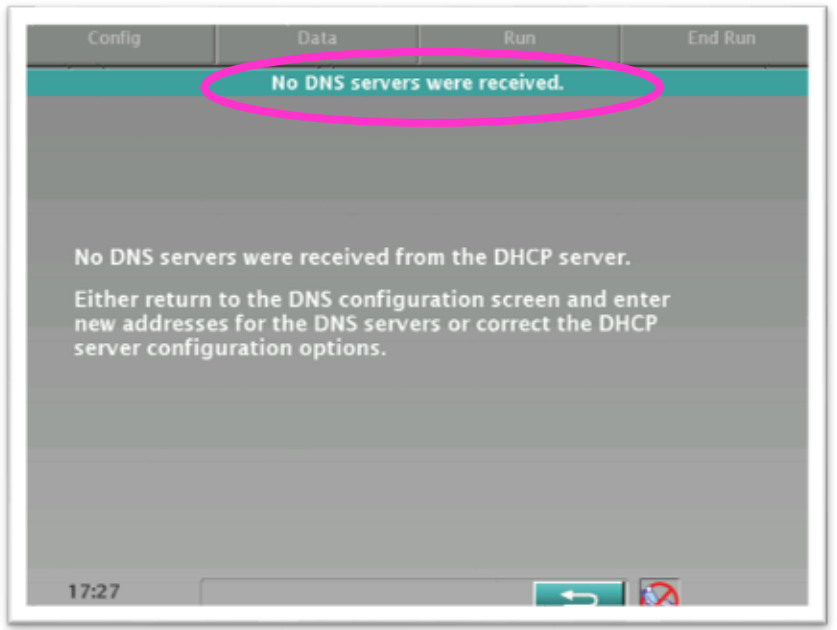




[18]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025);4-5

# New DHCP[18] server notifications



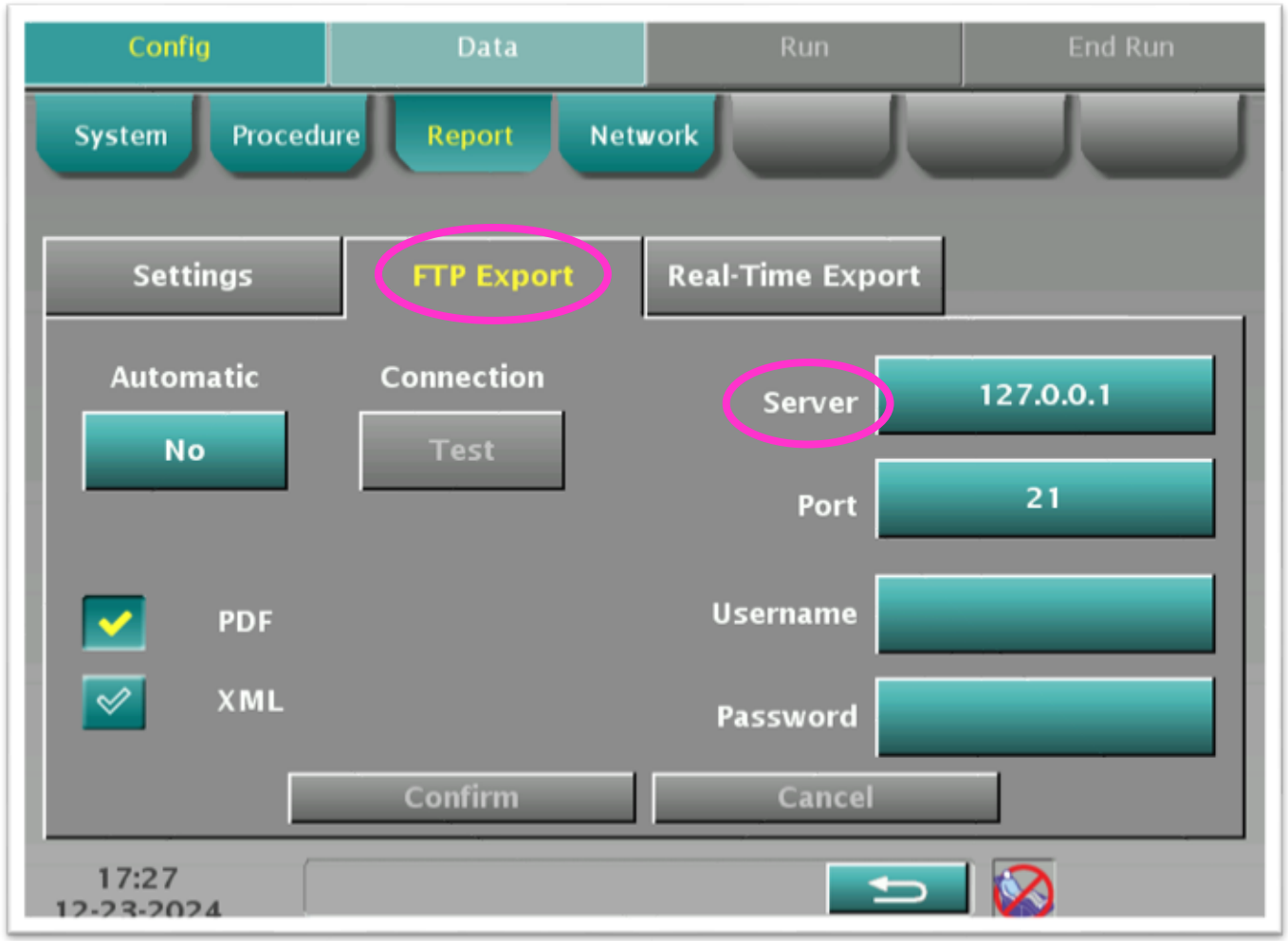




DHCP: dynamic host configuration protocol

[18]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025); 4-5

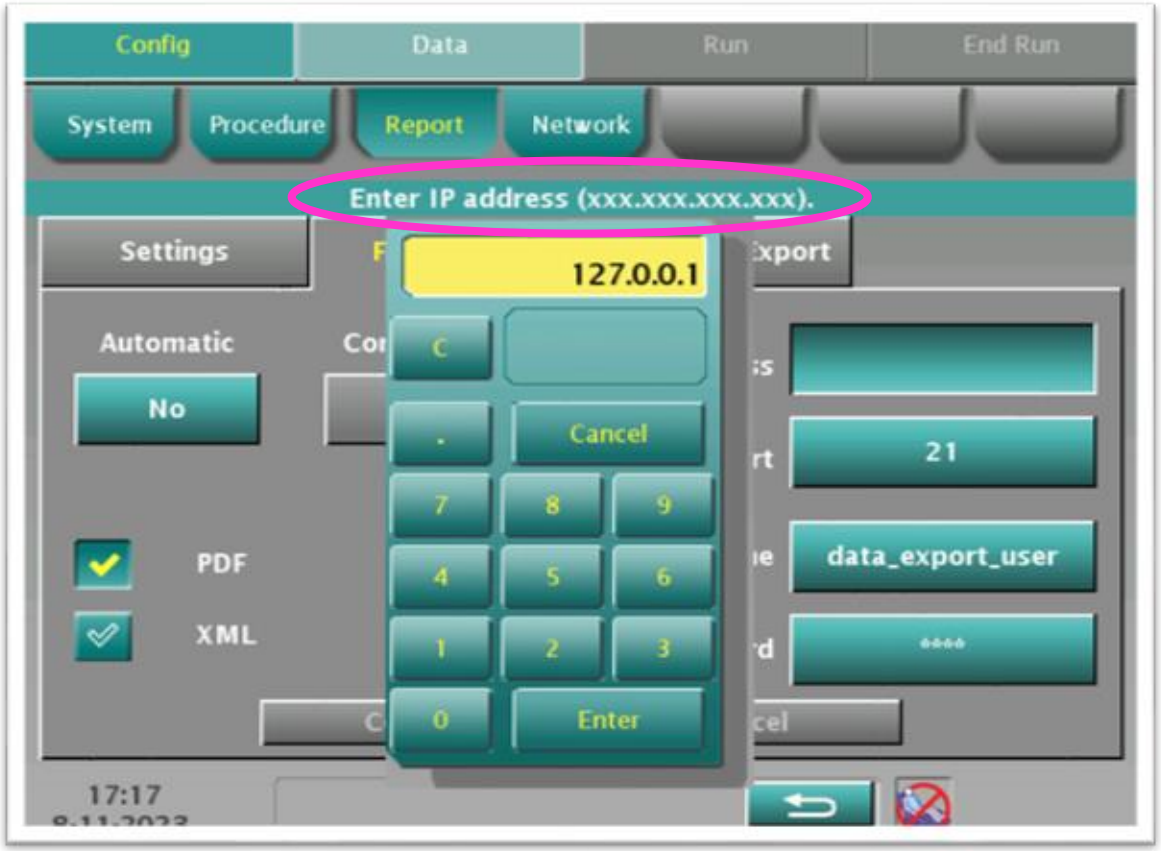
# New FTP[19] screen update

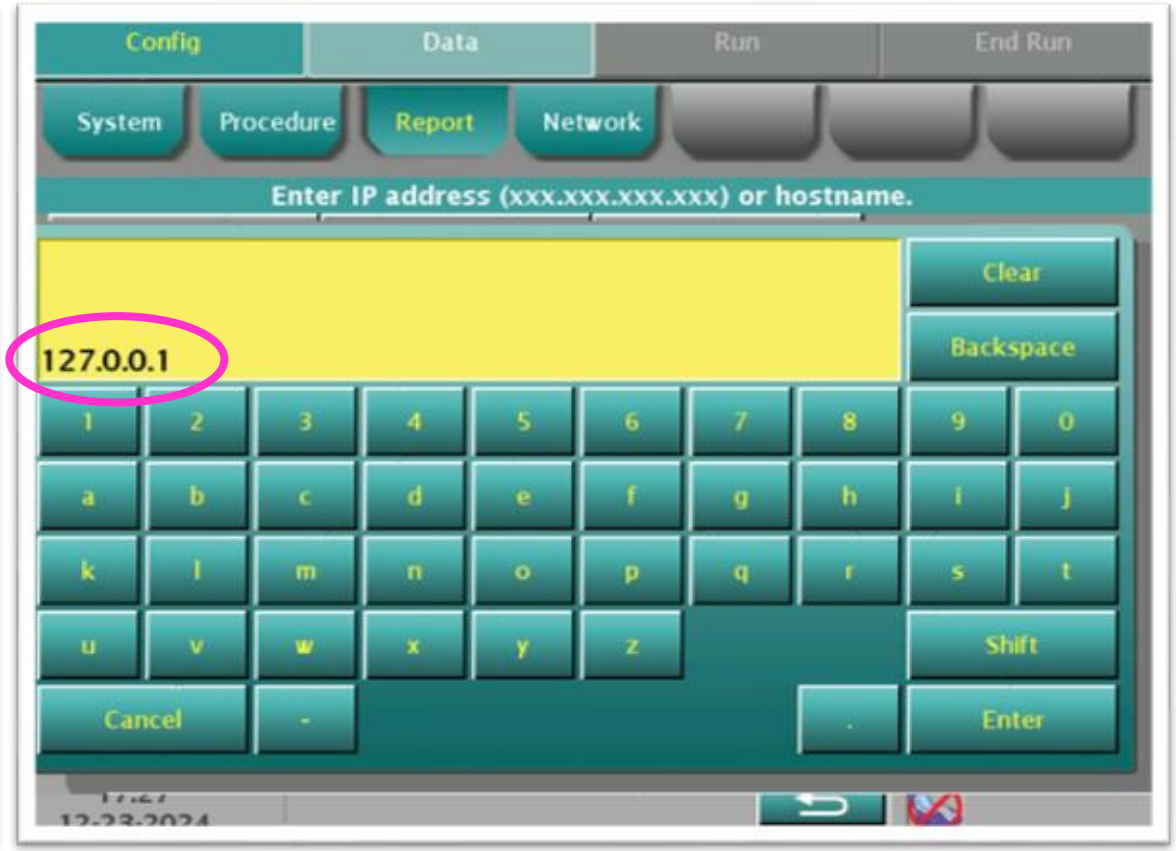



FTP: file transfer protocol

[19]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025);1-11

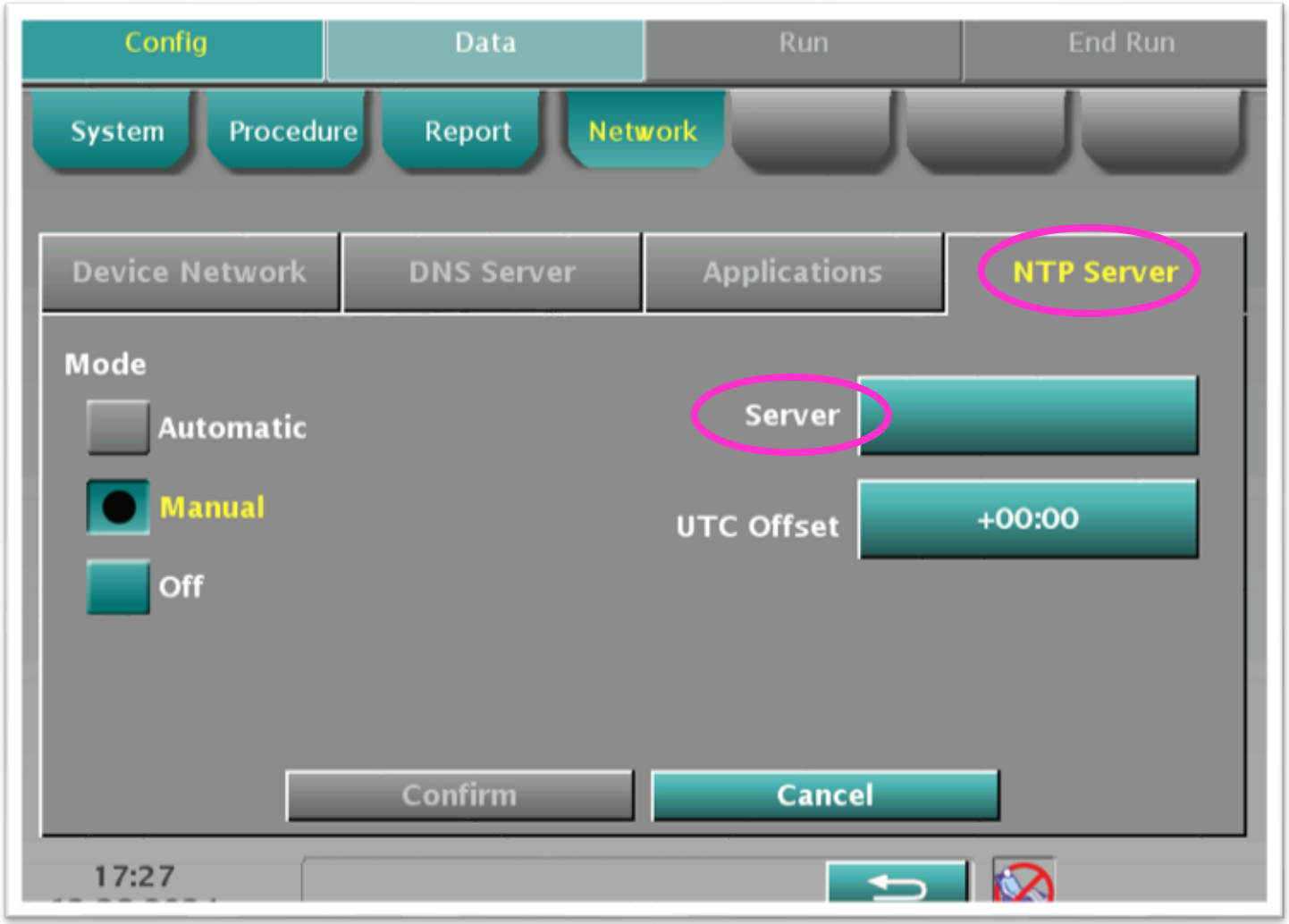
# New Option to enter IP address[19] or hostname




[19]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025);1-11

# New NTP[20] screen update



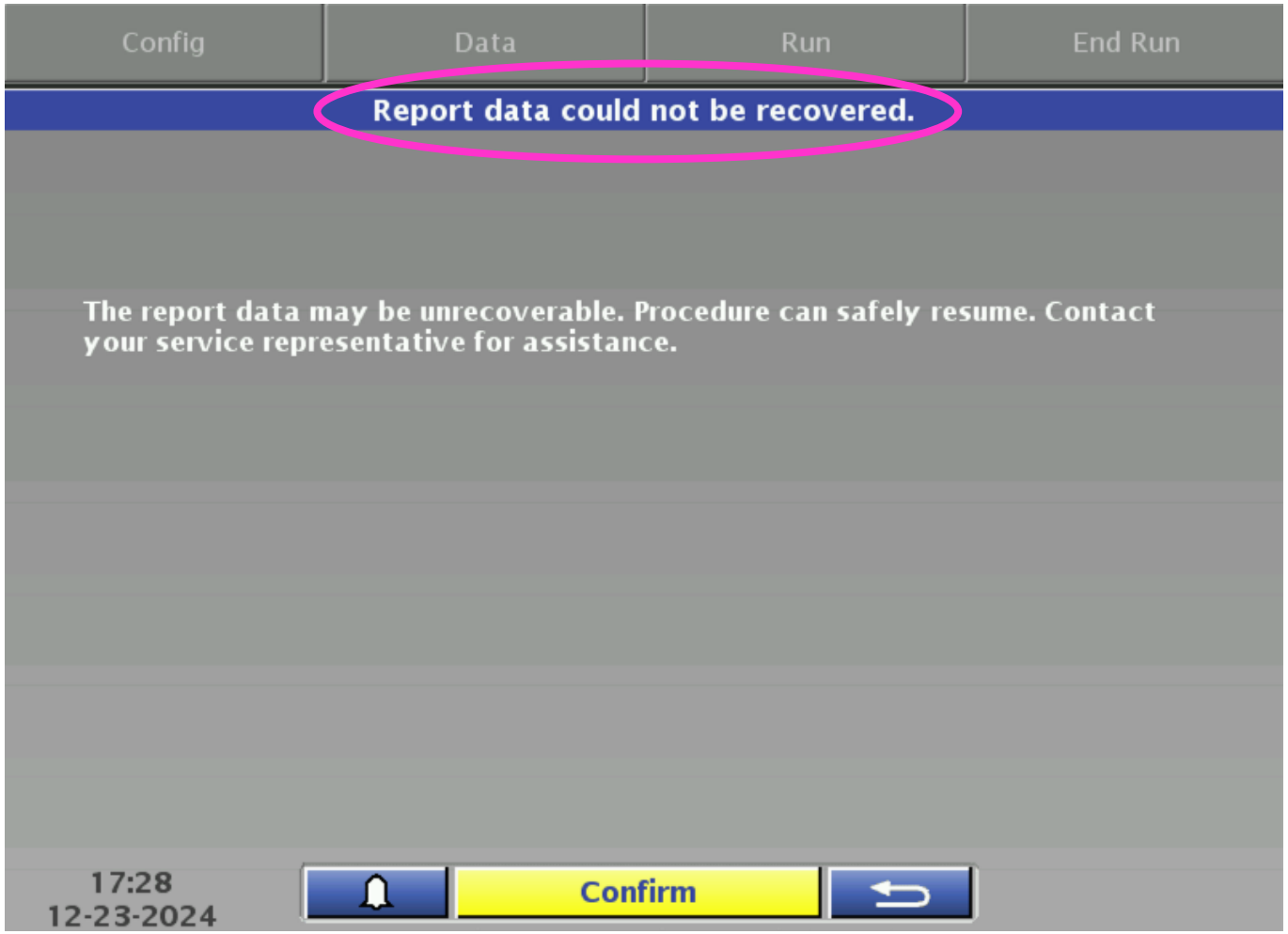

- On the network time protocol (NTP) Server screen, select **Automatic** from "**Mode**: Automatic/Manual/Off".

**Note**: When NTP Server is set to Automatic, this indicates that the system will automatically synchronize its clock with an NTP server.

NTP: network time protocol

[20]Spectra Optia Apheresis System Version 12, System Administration and Data Export Guide (2025);1-6

# New End of Run (EOR) report notification[16]

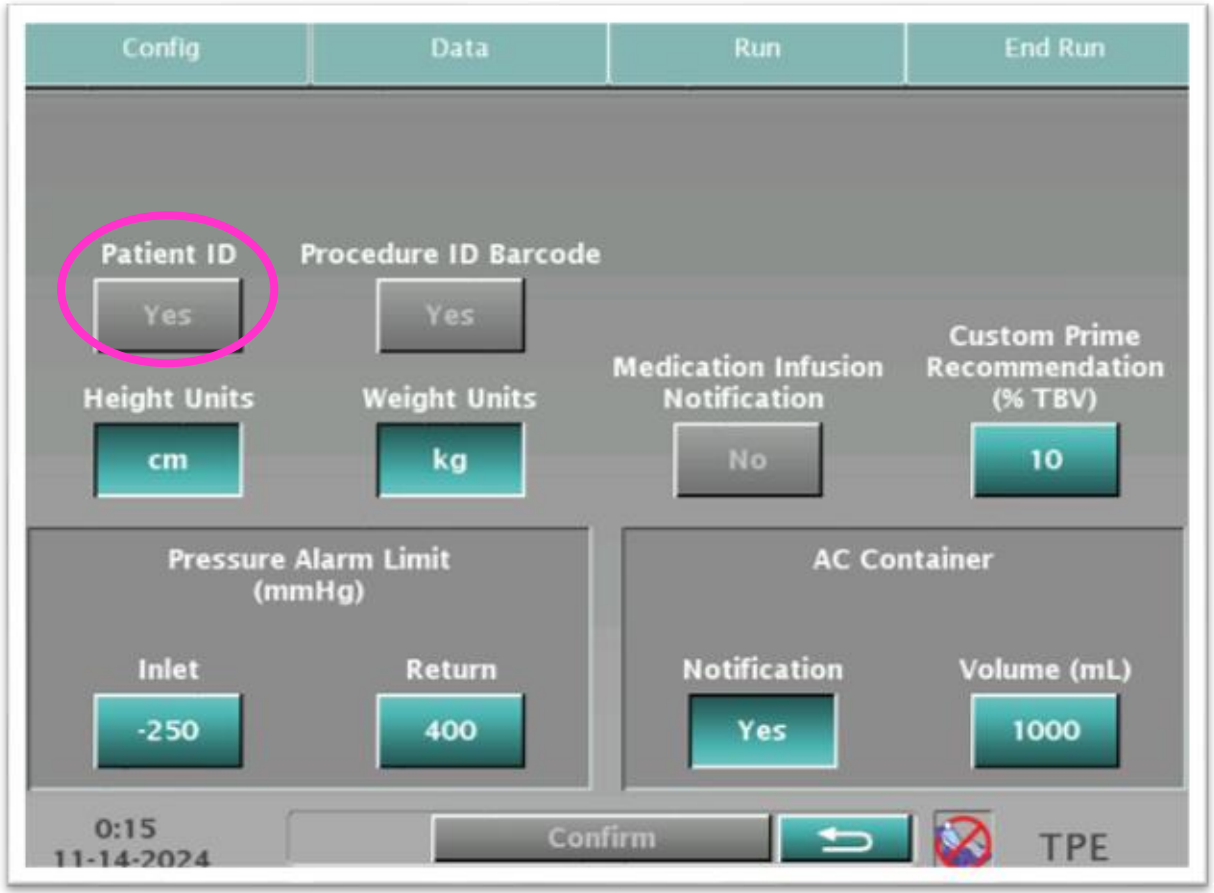



[16]TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025); 21

# Data Management

# New Patient ID[21]

(if data management is enabled in configuration)

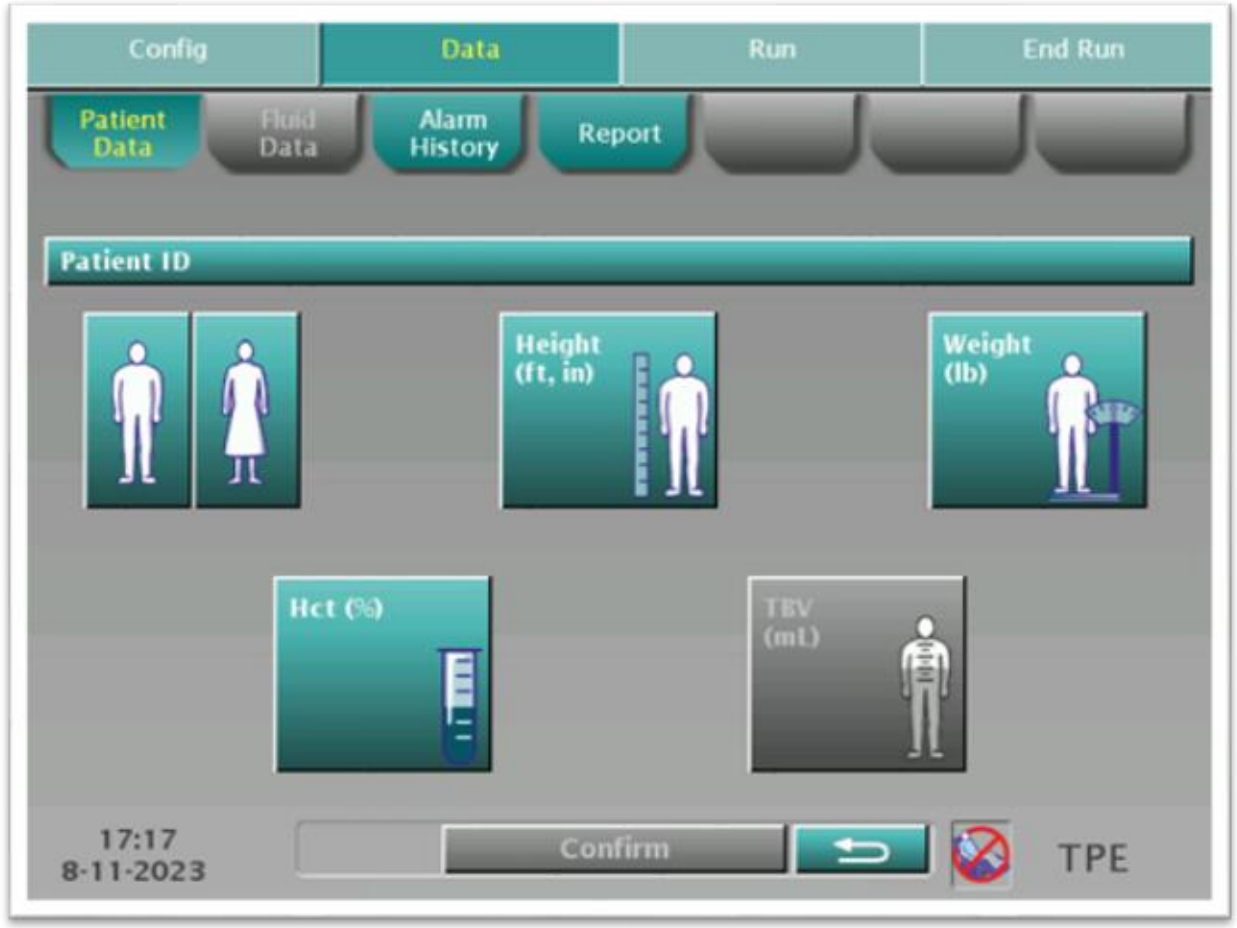



- To access the patient ID, **enable Patient ID** in the **Configuration** screen to Yes.

Note: If patient ID is configured to “Yes”, the operator will not be able to confirm the patient data until they enter an ID.

[21]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);5.

# Patient ID

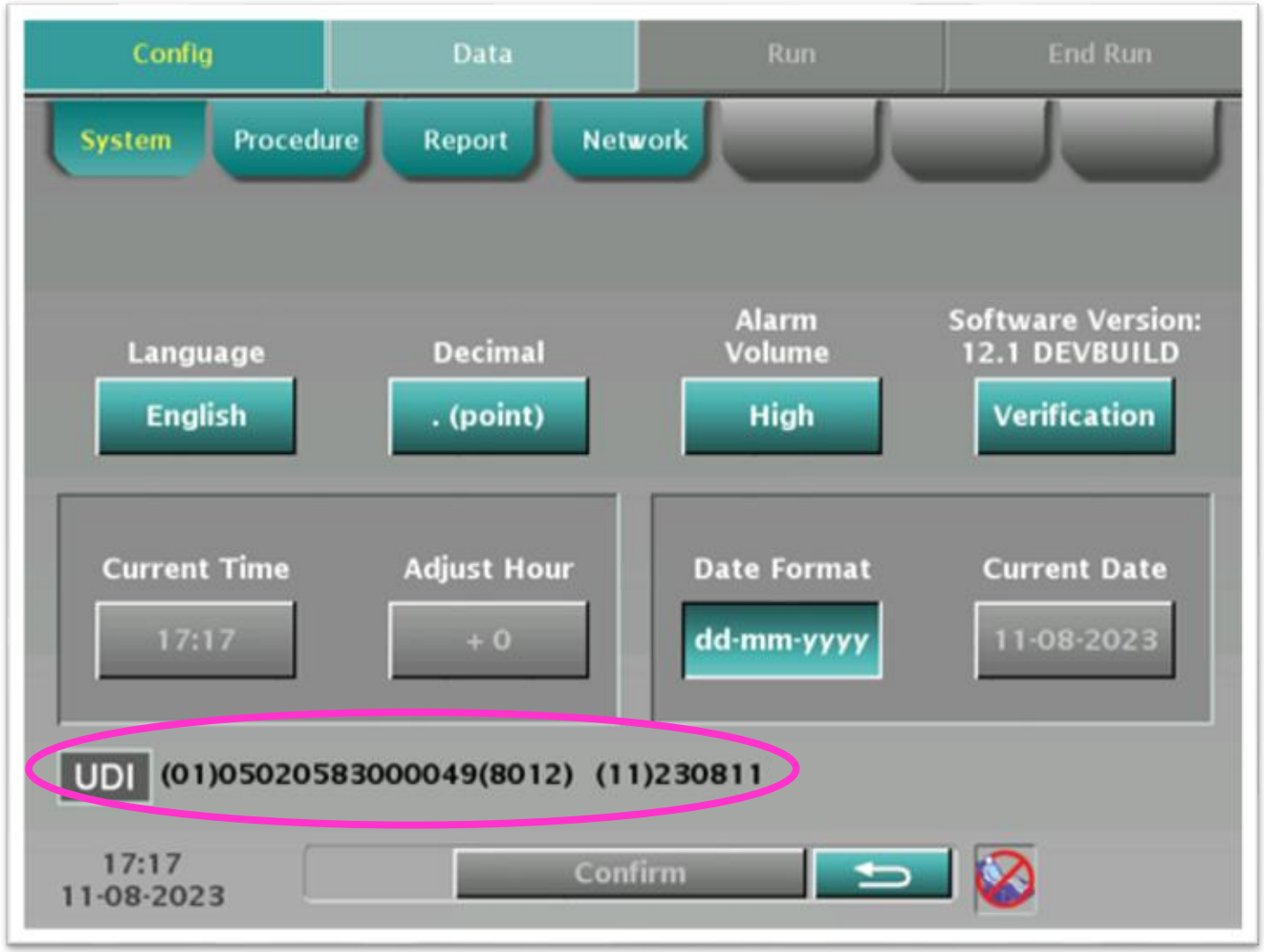



- Patient data screen with patient ID displayed.

**Note:** The patient ID or UIN feature is available only if Data Management has been enabled in Configuration.

# New Unique Device Identifier (UDI)[22]

All procedures – new UDI number format

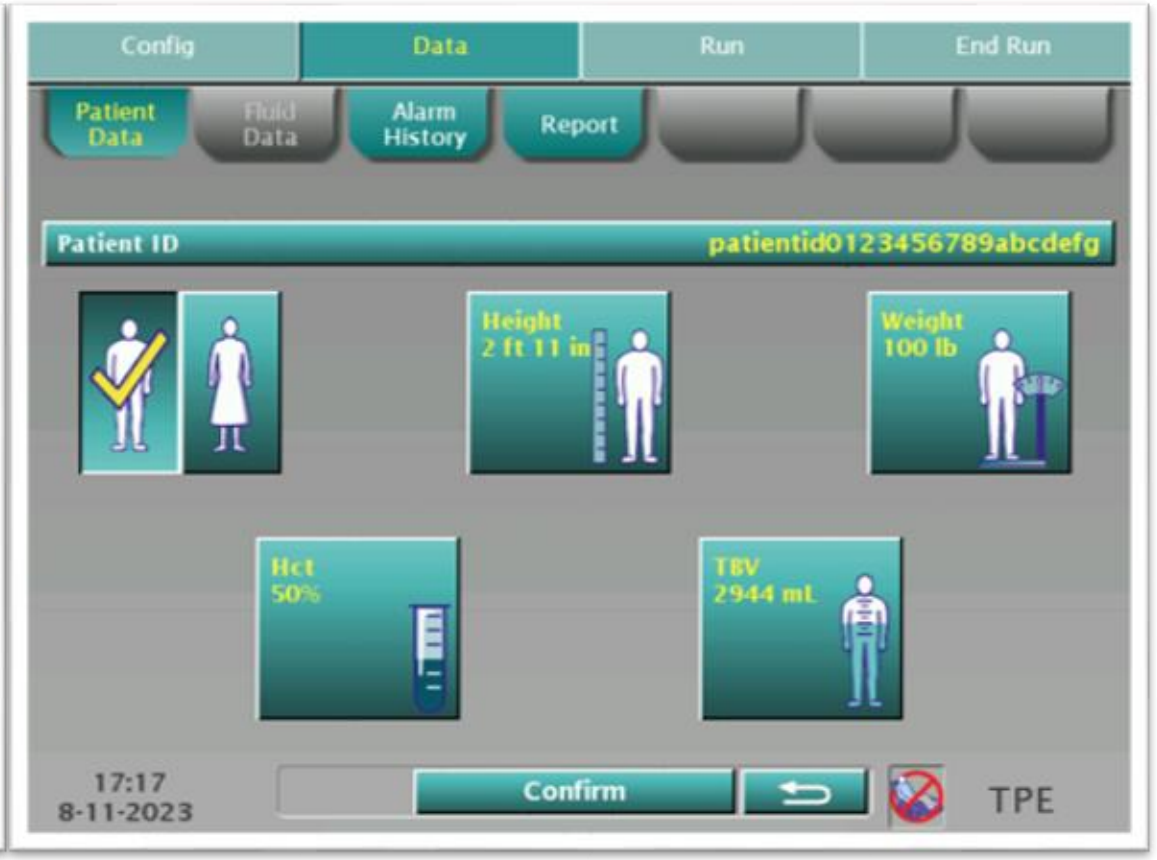



[22]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025); 25.

# Patient ID or UIN Data Entry Screen

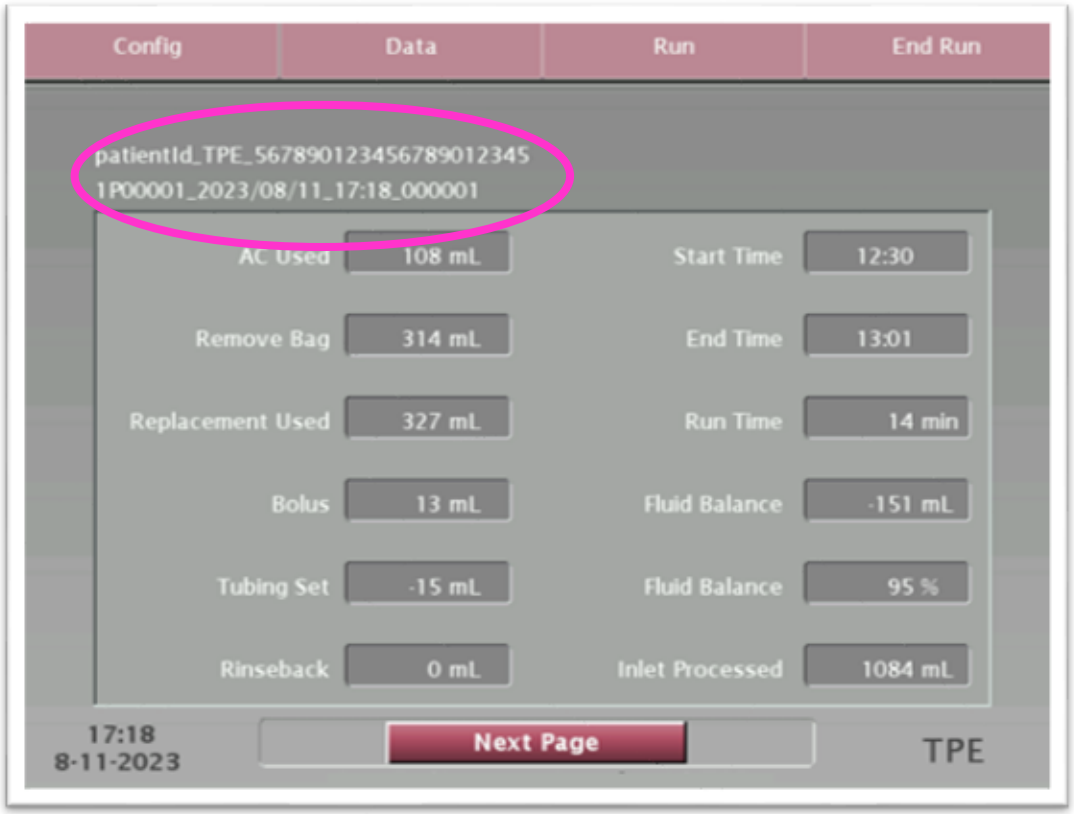
All procedures

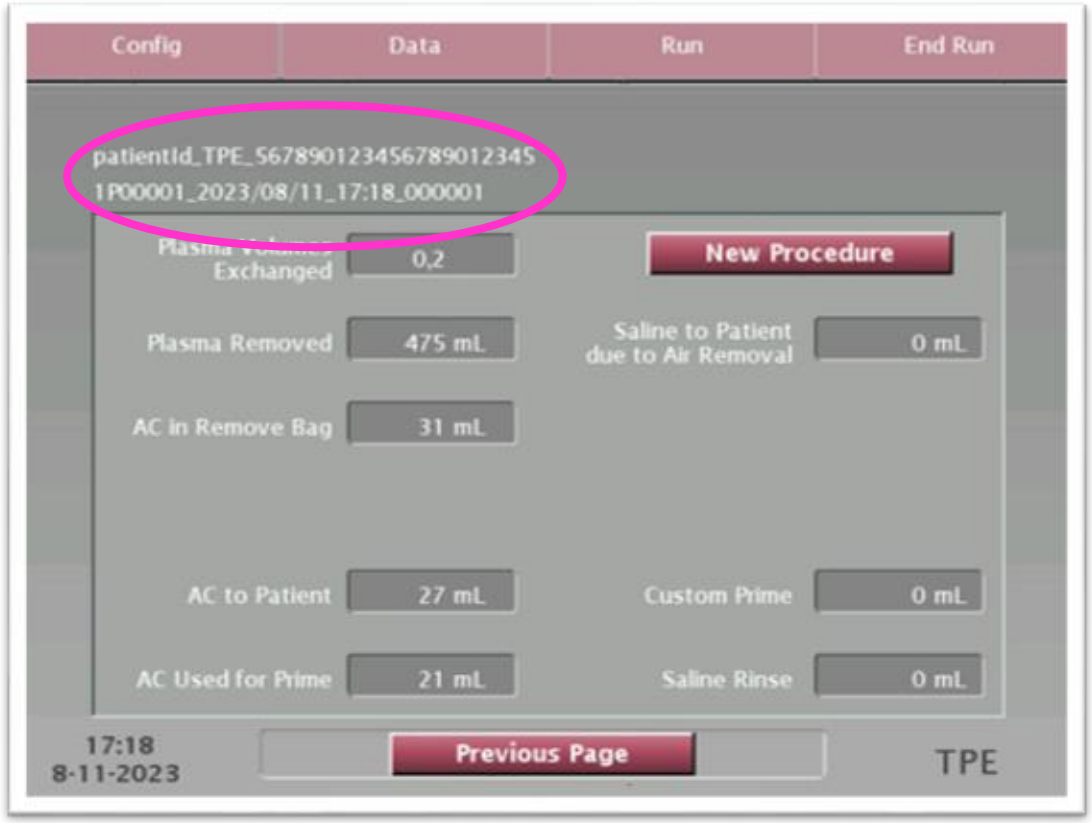


# New Procedure Summary Report[23]
(with patient ID/UIN info)

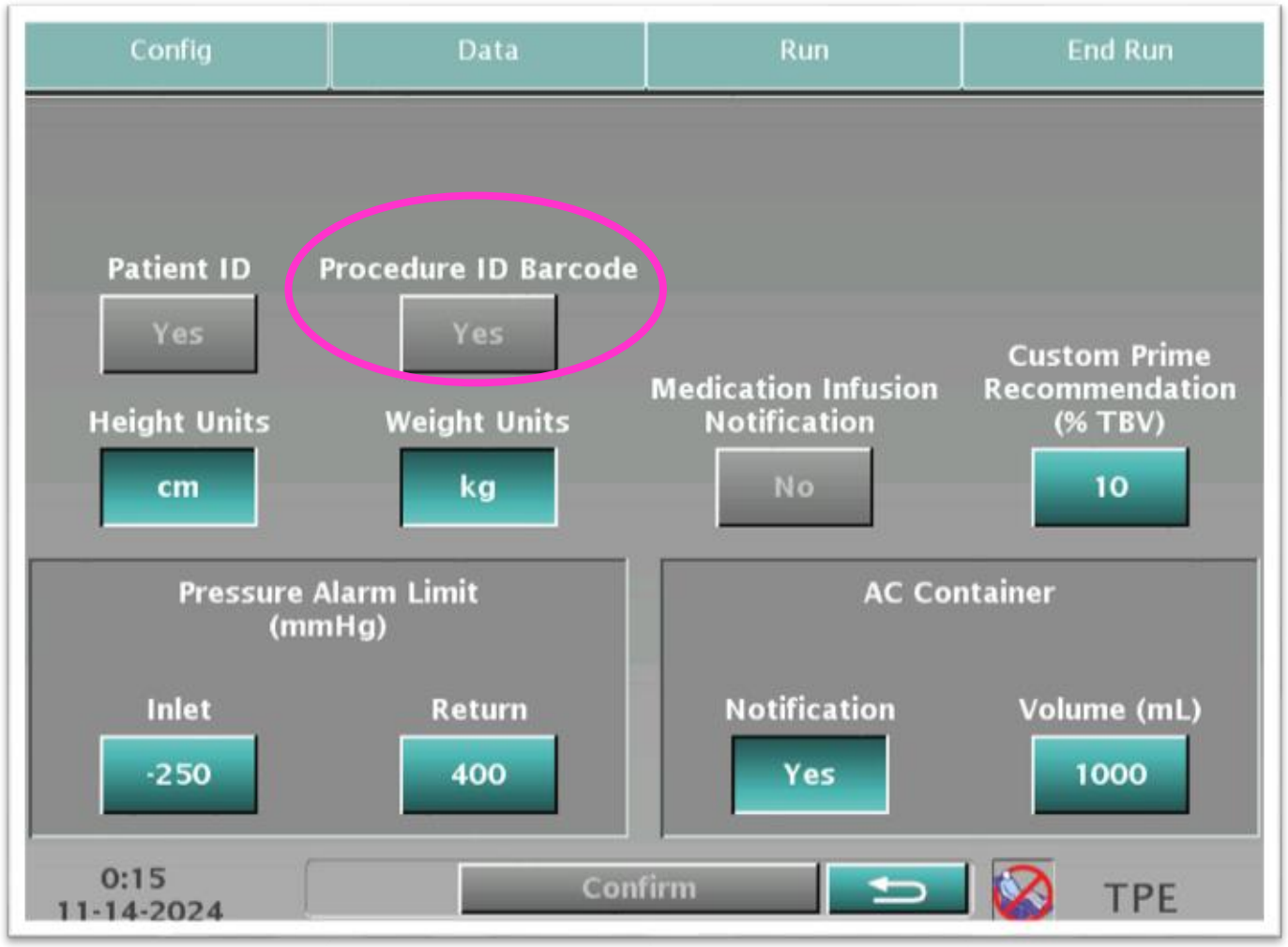
All procedures




[23]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);20.

# New Procedure ID[21]




[21]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);5.

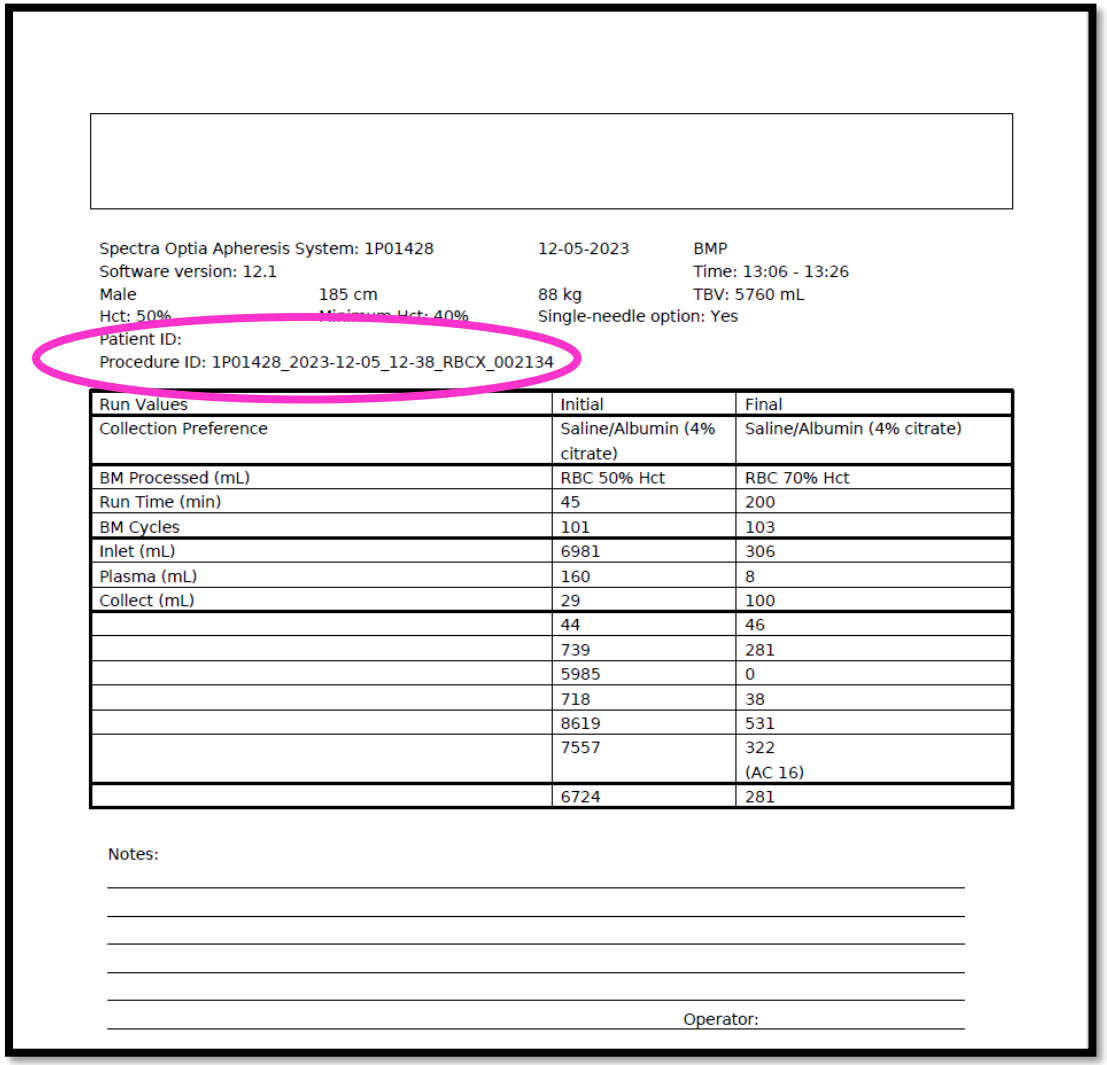
# New Barcode tab displays Procedure ID QR code[24]




[24]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);18.

# New updated PDF reports[24]

(if data management is enabled)



Spectra Optia Apheresis System: 1P01428 12-05-2023 BMP
Software version: 12.1 Time: 13:06 - 13:26
Male 185 cm 88 kg TBV: 5760 mL
Hct: 50% Minimum Hct: 40% Single-needle option: Yes
Patient ID:
Procedure ID: 1P01428_2023-12-05_12-38_RBCX_002134

| Run Values | Initial | Final |
|---|---|---|
| Collection Preference | Saline/Albumin (4% citrate) | Saline/Albumin (4% citrate) |
| BM Processed (mL) | RBC 50% Hct | RBC 70% Hct |
| Run Time (min) | 45 | 200 |
| BM Cycles | 101 | 103 |
| Inlet (mL) | 6981 | 306 |
| Plasma (mL) | 160 | 8 |
| Collect (mL) | 29 | 100 |
| | 44 | 46 |
| | 739 | 281 |
| | 5985 | 0 |
| | 718 | 38 |
| | 8619 | 531 |
| | 7557 | 322 (AC 16) |
| | 6724 | 281 |

Notes:

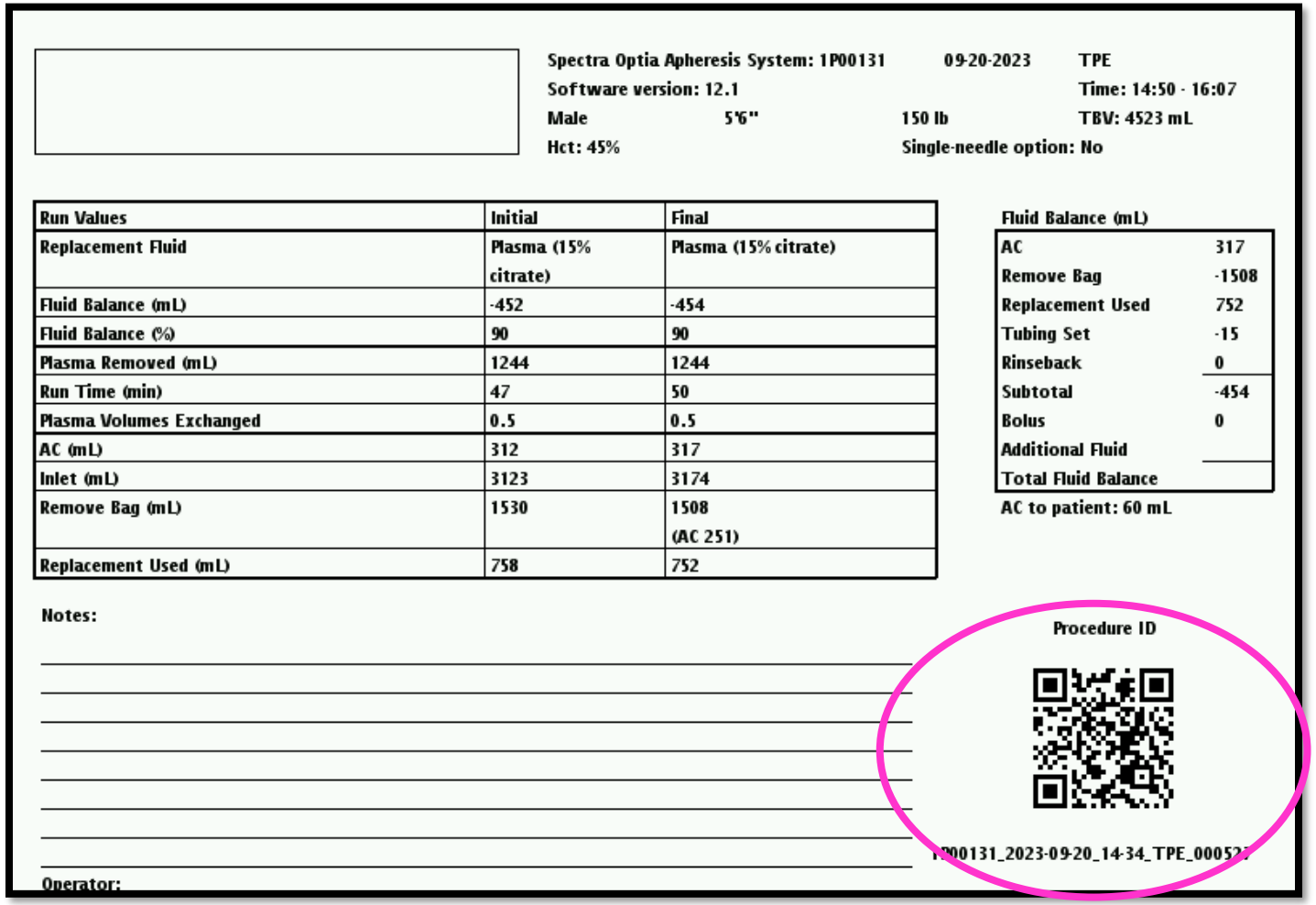
Operator:

The reports (if data management is enabled) will have both patient ID and procedure ID details.

[24]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);18.

# New updated on-screen reports[24]

(if data management is enabled)



Spectra Optia Apheresis System: 1P00131 09-20-2023 TPE
Software version: 12.1 Time: 14:50 - 16:07
Male 5'6" 150 lb TBV: 4523 mL
Hct: 45% Single-needle option: No

| Run Values | Initial | Final |
|---|---|---|
| Replacement Fluid | Plasma (15% citrate) | Plasma (15% citrate) |
| Fluid Balance (mL) | -452 | -454 |
| Fluid Balance (%) | 90 | 90 |
| Plasma Removed (mL) | 1244 | 1244 |
| Run Time (min) | 47 | 50 |
| Plasma Volumes Exchanged | 0.5 | 0.5 |
| AC (mL) | 312 | 317 |
| Inlet (mL) | 3123 | 3174 |
| Remove Bag (mL) | 1530 | 1508 (AC 251) |
| Replacement Used (mL) | 758 | 752 |

Fluid Balance (mL)

| | |
|---|---|
| AC | 317 |
| Remove Bag | -1508 |
| Replacement Used | 752 |
| Tubing Set | -15 |
| Rinseback | 0 |
| Subtotal | -454 |
| Bolus | 0 |
| Additional Fluid | |
| Total Fluid Balance | |

AC to patient: 60 mL

Notes:

Procedure ID

1P00131_2023-09-20_14-34_TPE_000521

Operator:

The on-screen reports will show the procedure ID QR code as well as showing the procedure ID in plain text.

[24]Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12 (2025);18.

# Thank You

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# Reference List


1. Terumo BCT, Inc. Spectra Optia Apheresis System Operator’s Manual. August 2023. Part no. 10000001322.1-4
2. Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12. 2025. Part no. 1000072672. 21
3. Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12. 2025 Part no. 1000072672.5
4. Terumo BCT, Inc. Spectra Optia Apheresis System Software Updates Version 12.1 Presentation. 2024. Part no. TS-OPTI-02165. 21-27
5. TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025);23
6. TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025);24
7. TS-OPTI-02770 Spectra Optia Apheresis System v12.1.1 Software Updates (2025);26
8. Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12. 2025 Part no. 1000072672.1
9. Software Release Notes for Spectra Optia v12.1(2024);2
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11. Software Release Notes for Spectra Optia v12.1(2024);9
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13. TS-OPTI-02165 Spectra Optia Apheresis System v12.1 Software Updates(2024);39-41
14. Terumo BCT, Inc. Spectra Optia Apheresis Version 12 System Administration and Data Export Guide. 2025. Part no.1000072576.1-14
15. Ref-03545 Template for Detailed Design Document (2025);11
16. Terumo BCT, Inc. Spectra Optia Apheresis Version 12 System Administration and Data Export Guide. 2025. Part no.1000072576.1-16
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18. Terumo BCT, Inc. Spectra Optia Apheresis Version 12 System Administration and Data Export Guide. 2025. Part no.1000072576.4-5
19. Terumo BCT, Inc. Spectra Optia Apheresis Version 12 System Administration and Data Export Guide. 2025. Part no.1000072576.1-11
20. Terumo BCT, Inc. Spectra Optia Apheresis Version 12 System Administration and Data Export Guide. 2025. Part no.1000072576.1-6
21. Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12. 2025 Part no. 1000072672. 5
22. Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12. 2025 Part no. 1000072672.25
23. Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12. 2025 Part no. 1000072672.20
24. Terumo BCT, Inc. Spectra Optia Apheresis System Operator's Manual Addendum for Software Version 12. 2025 Part no. 1000072672.18