



OMNI[®] Training Record

Acute Blood Purification System

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Name:





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1. INTRODUCTION

Training should begin with the trainer identifying, with the trainee, the various components of the machine which are listed under the section "General External Overview" on Page 5.

The following pages of the document refer to the various aspects of the machine e.g. screen content, preparation, treatment steps, troubleshooting.

2. COMPETENCY STATEMENT

This form is to be completed during your assessment. The assessment is designed to establish that self-competence has been achieved within the clinical practice.

The aim of this workbook is to aid the participant in demonstrating a practical knowledge and appropriate clinical use of the OMNI system.

Trainer name: Date of training:

Trainer signature:

Trainee name: Date of training:

Trainee signature:

Hospital: Unit/Ward:

If you have any queries, please contact one of your key trainers or your B. Braun representative.

3. GENERAL EXTERNAL OVERVIEW

GENERAL EXTERNAL OVERVIEW	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Machine Overview				
Be able to understand where the different parts of the hardware are situated				
Front Left View				
STOP key				
Status indicator light				
Touch screen				
Syringe pump				
IV pole				
Centre load cell				
Citrate load cell				
Left load cell				
Arterial pressure sensor connector (AP)				
Pre-filter pressure sensor connector (FP)				
Venous pressure sensor connector (VP)				
Citrate pump				
Blood pump				
Blood side door				
Blood side disposable kit locks				
Level detectors for arterial and venous chambers				
Venous tube clamp				
Left-side tube holder				
Front handle				
Side handle				
Right View				
Barcode scanner				
Right load cell (dialysate or substitution pre)				
Effluent pressure sensor connector (EP)				
Solution pressure sensor connector (SP)				
Substitution fluid pump				
Dialysate pump				
Effluent pump				
Fluid side door				
Fluid side disposable kit locks				
Solution chamber level detector				
3-Way clamp				
Blood leak detector				
Right-side tube holder				

3. GENERAL EXTERNAL OVERVIEW

GENERAL EXTERNAL OVERVIEW	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Rear View				
Standby switch				
Mains inlet				
Potential equalisation bolt				
Battery charge indicator LED				
Data port				
Staff call port				
Warmer door				
Warmer door latch				
Fans				
User Interface				
Be able to understand the different parts of the user interface				
Static Elements on the Touch Screen				
Date and time				
Patient id				
Current therapy				
Current operating mode				
Clean icon				
Audio pause icon				
Reset alarm icon				
Levels icon				
Bags icon				
Patient care icon				
Heparin bolus icon				
Heparin icon				
Calcium icon (in citrate mode)				
Citrate icon (in citrate mode)				
Therapy icon				
Blood pump icon				
Battery status				
Syringe status				
Current blood flow				
Status and output temperature of warmer				
Status of the blood leak detector				
Current transmembrane pressure (TMP)				
Current venous pressure (VP)				
Current pre-filter pressure (FP)				
Current arterial pressure				

3. GENERAL EXTERNAL OVERVIEW

GENERAL EXTERNAL OVERVIEW	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Onscreen numeric keypad and keyboard				
Screensaver (wait 2 minutes for screensaver to appear)				
Menu bar				
Preparation				
Be able to operate step-by-step through all the tasks required for the preparation of a therapy.				
Main				
Locate the fluid volumes and flow rates administered to and discharged from the patient. This can be monitored in the course of a therapy				
Parameters				
Select the correct icons which allow the monitoring and setting of operating parameters during therapy. (Patient ID, flow rates, anticoagulation, renal dose)				
History				
Locate all relevant therapy information with the four sub screens: volumes screen/graph screen/event log screen/report screen				
Functions				
Go through all activities needed to complete typically recurring tasks. End therapy/therapy or dilution change, temporary disconnect patient/syringe change/air removal or blood leak detector				
Service				
Open the Service menu. It is not necessary for the normal operation of the machine but used for system diagnosis by trained personnel. Detailed information is available in the OMNI Service Manual				

4. CONSUMABLES

CONSUMABLES	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
OMNISETS - The operator should be able to understand the differences between the OMNISET surfaces related to patient body weight				
OMNISET 0.8 sq = 152 ml priming volume				
OMNISET 1.2 sq = 171 ml priming volume				
OMNISET 1.6 sq = 192 ml priming volume				
Be able to unpack and handle the OMNISET properly as explained in preparation phases. The operator shall also be able to dispose the OMNISET as specified in the Instructions for Use				
Solutions - The operator should be able to understand the differences between the available bags				
Duosol (0/2/4K) = for all therapies using heparin or no anticoagulation				
HD Calcium-Free = for therapy using citrate anticoagulation only				
Citrasol = for therapy using citrate anticoagulation only				
Others Consumables - The operator should be able to understand the differences and function of other accessories				
OMNIBag = for all therapies. 7 litre bag for single use only				
Syringe = to be used either for heparin or calcium infusion				
Priming/saline bag = for priming phase (800 ml needed) or for recirculation and/or end of treatment				
Manual clamps = can be used for emergency issues or troubleshooting purposes				

5. TREATMENT

TREATMENT	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Select Treatment Mode				
Select the treatment mode to start preparation. The other option available is Treatment History				
Prepare Disposable (kit)				
Select the correct disposable kit type according to the prescription				
Set up Disposables: Check Barcode				
Check the OMNI disposable kit by scanning the barcode of the package with the device				
Set up Disposables: Select Therapy Mode and Anticoagulation Type				
Select from the therapy modalities supported by the device				
Set up Disposables: Install kit				
Be able to unpack kit from its packaging				
Be able to load the disposable kit onto the front plate by locating it on the front kit holder pins				
Be able to close the kit wings onto the blood and fluid side manifolds				
Be able to open the warmer door, load the warmer bag and close the warmer door				
Be able to connect all the pressure connectors to the proper system pressure transducers				
If the Disposable Kit is properly loaded, the operator should be able to start the automatic disposable kit loading via the user interface to thread the pump segments into the pumps				
Be able to differentiate the lines of the disposable kit (fluid lines, pressure lines) by their colour				

5. TREATMENT

TREATMENT	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Set up Disposables: Install Anticoagulant				
In case of citrate/calcium anticoagulation the operator should be able to insert the calcium line into the calcium air detector				
Be able to connect the calcium line to the syringe				
Be able to open the clamp on the calcium line				
Be able to use the same concentration as displayed on the device for Calcium solution				
Be able to set the correct syringe filling volume				
Be able to load the citrate bag on the top load cell				
Be able to use the same concentration as displayed on the device for Citrate solution				
Be able to connect the Citrate line to the bag				
Be able to open the clamp on the citrate line				
In case of heparin anticoagulation the operator should be able to insert the heparin syringe into the syringe holder				
Be able to connect the heparin line to the heparin syringe. It is important to distinguish the heparin line to the calcium line. When using heparin the clamps on the calcium lines should be properly closed				
Enter Parameters - Start Treatment – Connect Patient				
Be able to enter parameters, connect arterial and venous line to patient (or priming bag during training)				

5. TREATMENT

TREATMENT	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Start Blood Pump – Start Treatment				
Adjust/Stop Blood Pump				
Be able to adjust and stop blood flow during therapy and understand the automatic blood flow regulation during patient care mode or pressure changes				
Intervention: Screensaver				
Be able to read the values from the screensaver				
Intervention: Change Bag (Citrate)				
Recognised when the system detected the empty Citrate bag				
Be able to close the clamps on the citrate bag and the line and disconnect them				
Be able to hang a new bag on the same load cell				
Be able to connect the bag with the line				
Be able to open the clamps				
Checked that the new bag has the same concentration as the old bag				
Intervention: Change Bag				
The operator shall be able to initiate bag change procedure				
Be able to close the clamps on the bag(s) and/or the lines and disconnect them				
Be able to hang a new bag on the same load cell				
Be able to connect the bag with the line				
Be able to open the clamps				
Intervention: Changing Syringe (Calcium)				
Be able to initiate Calcium syringe change				
Be able to close the clamps on the line and disconnect from the syringe				
Be able to load a new syringe				
Be able to connect the syringe with the line				
Be able to open the clamps				
Be able to set and confirm the syringe parameters				
Be able to check the Calcium concentration and change to a new Calcium syringe with the same concentration as indicated on the screen				

5. TREATMENT

TREATMENT	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Check Treatment History				
Be able to check the most important therapy parameters for reporting				
Recover from Power Fail				
Be able to continue therapy after a power fail recovery or start a new therapy				
End of therapy – Disconnect Arterial Line (disconnecting patient)				
Be able to prepare a saline bag on the IV pole				
Be able to clamp and disconnect the arterial line from the patient				
Be able to return blood to the patient				
End of Therapy – Unload kit				
Be able to unload the kit from the front of the machine				
Be able to unload the syringe from the device				
Be able to dispose of kit safely				

6. TROUBLESHOOTING

TROUBLESHOOTING	✓	SIGNATURES		DATE
		TRAINEE	TRAINER	
Alarm Handling and Special Alarms				
Dealing with Alarms				
Be able to check the most important alarms and learn how to mute and solve issues using the user interface				
Understand the significance of the Green, Amber and Red signal on the top of the machine				
Discontinue Treatment Quickly				
Be able to quit an alarm and go through all key steps to discontinue treatment and return blood to patient (when possible)				
Alarm Priorities				
Be able to understand most important alarms and the reasons of: <ul style="list-style-type: none"> ■ Long stop of blood pump ■ Long stop of fluid side pumps ■ Long stop of anticoagulation pump 				
Most Frequent Alarms				
Low venous pressure				
High arterial pressure				
Low arterial pressure				
High transmembrane pressure				
High pre-filter pressure				
High effluent pressure				
Low solution pressure				
Blood leak alarms during therapy				
Removing air from venous line				
Anticoagulation/syring alarm				
Bag movement alarms				
Stop Key				
Be able to press the STOP key in order to immediately stop therapy				

7. CONSENT

I certify that I am competent using the OMNI system and I am aware of the support material available to me. I accept that I am accountable for my actions.

Print Name:

Signature:

Date:

