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Vacuum Filtration Equipment

1-, 3-, 6-branch Combisart® Manifold

Type of vacuum filtration system

Biosart®100 Monitor

Type of funnel

Suction Flask 1- | 2-Liters

Type of suction flask

Electrical Membrane Pump

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INSTALLATION & OPERATIONAL QUALIFICATION DOCUMENTS

Vacuum Filtration Equipment

1-, 3-, 6-branch Combisart® Manifold

Type of vacuum filtration system

Biosart®100 Monitor

Type of funnel

Suction Flask 1- | 2-Liters

Type of suction flask

Electrical Membrane Pump

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INSTALLATION QUALIFICATION DOCUMENT

Vacuum Filtration Equipment

1-, 3-, 6-branch Combisart® Manifold

Type of vacuum filtration system

Biosart®100 Monitor

Type of funnel

Suction Flask 1- | 2-Liters

Type of suction flask

Electrical Membrane Pump



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Biosart® 100 Monitors

IQ Protocol

Installation Qualification Content

CLIENT INFORMATION		
Client name:		
Type of vacuum filtration	n system:	Manifold Combisart® System
No. of filter stations:		(1, 3 or 6)
Type of funnel:		Biosart [®] 100 Monitor
1x Biosart [®] 100 Monitors	Model no.	and Lot no.:
1x Combisart [®] Manifold * x Combisart [®] Single	Base	and Serial no.:
1x Vacuum Pump	Model no.	and Serial no.:
1x Vacuum Hose	Model no.:	
* x Biosart [®] Adapter	Model no.:	
1x Suction Flask	Model no.:	
1x Silicone Stopper	Model no.:	
1x Tube Connector	Model no.:	
*) for each filter station one single base and o	ne adapter should be	available
Choice one out of two w	ater traps (p	olease delete where inapplicable)
☐ 1x Vacusart [®]	Model no.	and Lot no.:
☐ 1x Woulff's bottle	Model no.:	
Operator Signature:		Date:
COMPANY:		
Witness Signature:		Date:
COMPANY.		



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Biosart® 100 Monitors

IQ Protocol

Installation Qualification Content

CONTENT OF INSTALLATION QUALIFICATION

- 1. Document Inspection
- 2. Physical Inspection
 - 2. A. Delivery Control
 - 2. B. Physical Aspects
 - 2. C. Power Management

Operator Signature:	Date:
COMPANY:	
Witness Signature:	Date:
COMPANY:	



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IQ Protocol

Installation Qualification 1. Document Inspection

1. DOCUMENTS PROVIDED WITH THE VACUUM FILTRATION FOLIPMENT

EQUIPMENT			
Purpose: To ensure that all standard docume	ntation has bee	n supp	lied.
A) User manual for Combisart [®] system including adapters and accessories:	Yes □	No	
B) User manual for vacuum pump:	Yes □	No	
	5.		
Operator Signature:	Date:		
COMPANY:			
Witness Signature:	Date:		
COMPANY.			



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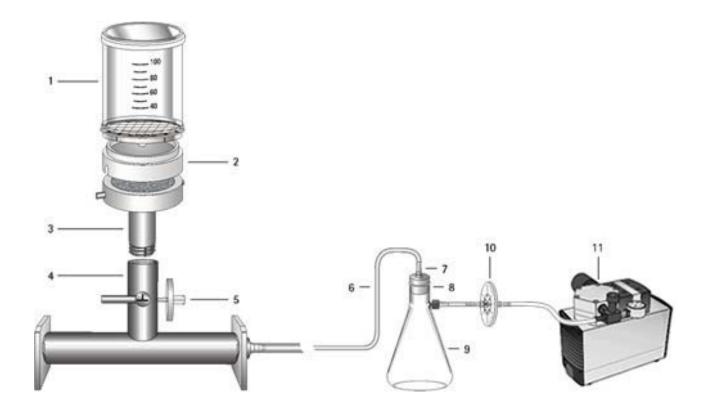
Biosart® 100 Monitors IQ Protocol

Installation Qualification 2. Physical Inspection

2. A- DELIVERY CONTROL

Purpose: To ensure that all standard components have been supplied.

Set Up of a manifold filtration system with a 1-|2-liter suction flask



Operator Signature:	Date:
COMPANY:	
Witness Signature:	Date:
COMPANY:	



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Biosart® 100 Monitors

IQ Protocol

Installation Qualification 2. Physical Inspection

2. A- DELIVERY CONTROL

Purpose: To ensure that all standard components have been supplied.

 A.[1] Biosart® 100 Monitors 1. Packing carton: 2. Packaging foil: 3. Carton stickers: 4. User manual: 5. Certificate: 6. Biosart® Monitors: 7. Plugs: 	Yes No Ses Ses No Ses Ses No Ses Ses No Ses Ses Ses No Ses Ses Ses Ses Ses Ses Ses Se
8. PE adapter:	Yes No
A.[2] Adapter(s) for Biosart [®] 100, units 1. Biosart [®] 100 Adapter: 2. PE-bag: 3. Sticker on PE-bag:	Yes No Yes No No No No No No No No No N
 A.[3] Combisart[®] Single Base(s), units	Yes No Yes No Yes No Yes No Yes No Yes
Operator Signature:	Date:
COMPANY:	
Witness Signature:	Date:
COMPANY:	



IQ | OQ Documentation

Biosart® 100 Monitors

IQ Protocol

Installation Qualification 2. Physical Inspection

2. A- DELIVERY CONTROL

Purpose: To ensure that all standard components have been supplied.

 A.[4] Combisart® Manifold A.[5] Minisart® SRP Venting Filter 1. Packing carton: 2. Foam inserts: 3. Carton stickers: 4. User manual: 5. Combisart® Individual Base: 6. Minisart® SRP venting filter: 	Yes	No 🗆 No 🗆 No 🗆
A.[6] Tube Connector		
1. Tube connector: 2. PE-bag: 3. Sticker on PE-bag:	Yes □ Yes □ Yes □	No 🗖
A.[7] Vacuum Hose		
Vacuum hose tubing:	Yes 🗖	No 🗆
A.[8] Silicone Stopper1. Silicone stopper:2. PE-bag:3. Sticker on PE-bag:	Yes Yes Yes	No 🗖
Operator Signature:	Date:	
COMPANY:		
Witness Signature:	Date:	
COMPANY		



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Biosart® 100 Monitors

IQ Protocol

Installation Qualification 2. Physical Inspection

2. A- DELIVERY CONTROL	
Purpose: To ensure that all standard component	s have been supplied.
A.[9] Choice one out of two Suction Flasks (ple	ase delete where inapplicable)
 2-Liters Suction Flask Vacuum Bottle 1. Packing carton: 2. Foam inserts: 3. Carton stickers: 4. Suction Flask Vacuum Bottle: 5. Hose nipple: 	Yes No Yes
 1-Liter Suction Flask Vacuum Bottle 4. Packing carton: 5. Foam inserts: 6. Carton stickers: 7. Suction Flask Vacuum Bottle: 	Yes No Yes No Yes No Yes No Yes No Yes No Yes
Operator Signature:	Date:
Witness Signature:	Date:
COMPANY:	



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Biosart® 100 Monitors

IQ Protocol

Installation Qualification 2. Physical Inspection

2. A- DELIVERY CONTROL

Purpose: To ensure that all standard compo	onents have been supplied.
A.[10] Choice one out of two Water Traps	(please delete where inapplicable)
 Vacusart® 1. Packaging carton: 2. Carton stickers: 3. PE-bag: 4. Sticker on PE-bag: 5. Vacusart® Filter Unit: 	Yes
 Woulff's Bottle 1. Packing carton: 2. Foam inserts: 3. Carton stickers: 4. Woulff's Bottle: 5. Glass tube, long: 6. Glass tube, short: 7. Glass tube with tap: 8. Caps: 	Yes
Operator Signature:	Date:
COMPANY: Witness Signature:	

COMPANY: ____



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Biosart® 100 Monitors

IQ Protocol

Installation Qualification 2. Physical Inspection

2	Δ_	DEI	IVE	PV	CON	NTROL	
Z - 1	~ -	D = L	_I V 🗀	n I	w	$\mathbf{A} \mathbf{I} \mathbf{D} \mathbf{C} \mathbf{L}$	_

2. A- DELIVERY CONTROL			
Purpose: To ensure that all standard components	s have been	suppli	ed.
 A.[11] Vacuum Pump 1. Packing carton: 2. Foam inserts: 3. Carton stickers: 4. CE-conformity statement: 5. User manual: 6. Vacuum pump: 	Yes	No No No No	
Operator Signature:	Date:		
COMPANY:			
Witness Signature:	Date:		
COMPANY:			



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Biosart® 100 Monitors IQ Protocol

Installation Qualification 2. Physical Inspection

2. B- PHYSICAL ASPECTS				
Purpose: To ensure that the equipment is supplied	ed intege	er and	d und	amaged
A) General appearance (no visible damage):	Yes I		No	
B) Type plate Serial numbers attached:	Yes [No	
C) CE – approval plate attached:	Yes [No	
D) Line cord installed:	Yes [No	
Operator Signature:	Date:_			
COMPANY:				

Witness Signature:_____

COMPANY:

Date:_____



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IQ Protocol

Installation Qualification 2. Physical Inspection

2. C- VERIFICATION OF POWER MANAGEMENT

Purpose: To ensure that all electrical devices are suitable for the locally provided power supply.

C.1. Voltage Supply			
Voltage locallyV			
Suitability to local Voltage:	Yes □	No I	
C.2. Frequency Supply			
Frequency locally Hz			
Suitability to local Frequency:	Yes □	No I	
Operator Signature:	Date:		
COMPANY:			
Witness Signature:	Date:		
COMPANY:			



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Biosart® 100 Monitors

IQ Protocol

Installation Qualification Summary

PROTOCOL OF INSTALLATION QUALIFICATION

	The following installation qualification protocols hade been completed satisfactorily.						
	Document Inspection						
	Physical Inspection						
Oper	ator Signature:	Date:					
СОМ	PANY:						
Witne	Witness Signature: Date:						
COM	COMPANY:						

IQ | OQ Documentation

OPERATIONAL QUALIFICATION DOCUMENT

Vacuum Filtration Equipment

1-, 3-, 6-branch Combisart® Manifold

Type of vacuum filtration system

Biosart®100 Monitor

Type of funnel

Suction Flask 1- | 2-Liters

Type of suction flask

Electrical Membrane Pump



IQ | OQ Documentation

Biosart® 100 Monitors

OQ Protocol

Operational Qualification Content

CLIENT INFORMATION	
Client name:	
Type of vacuum filtration system: No. of filter stations: Type of funnel:	Manifold Combisart [®] System (1, 3 or 6) Biosart [®] 100 Monitor
Serial Lot numbers of the equipme	ent
Biosart® 100 Monitor Lot no.:	
Combisart® Manifold Serial no.:	
Vacuum Pump Serial no.:	
Vacusart® Lot no.:(please delete where inapplicable)	
CONTENT OF OPERATIONAL QUAI	IFICATION
I. Assembly of the System II. Start-Up and Functional Tests A. Combisart® tap positions and the B. Start-up the system C. Verification of the Combisart® tap III. Test Filtration	
Operator Signature:	Date:
COMPANY:	
Witness Signature:	Date:
COMPANY:	



IQ | OQ Documentation

Biosart® 100 Monitors

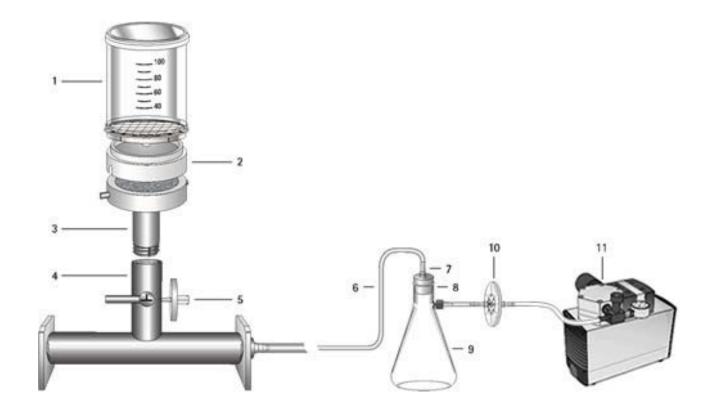
OQ Protocol

Operational Qualification I. Assembly

I. ASSEMBLYOF ALL SYSTEM COMPONENTS

Purpose: To ensure that all supplied components are connected correctly

Set Up of a manifold filtration system with a 1-|2-liter suction flask



Operator Signature:	Date:
COMPANY:	
Witness Signature:	Date:
COMPANY:	



IQ | OQ Documentation

Biosart® 100 Monitors **OQ Protocol**

Operational Qualification I. Assembly

I. ASSEMBLYOF ALL SYSTEM COMPONENTS

Purpose:	To ensure that all supplied components	are c	connec	cted c	orrectly		
Remark: In the following section the assembly of the Combisart [®] System described in detail. If your Combisart [®] System has more than filter station, please make sure that you follow the instructions every filter station.							
the Com single ba right let Tighten	ne Combisart [®] single base [3] into the threbisart [®] manifold [4], turning the Combisactes [3] until the two pins are positioned effection of the threaded nut using a 24-mm open-erest (spanner).	art [®] either	f				
Firm fit o	of the Combisart [®] single base	Yes		No			
All Com	oisart [®] single bases fit	Yes		No			
base [3]	e flat silicone gasket into the Combisart [®] , and place the stainless steel filter supposilicone gasket.	_					
Gasket a	and frit are positioned	Yes		No			
All gaskets	and frits are positioned	Yes		No			
Operator S	Signature:	Date	:				
COMPAN	/ :						
Witness Si	gnature:	Date	:				

COMPANY: ____



IQ | OQ Documentation

Biosart® 100 Monitors **OQ Protocol**

Operational Qualification I. Assembly

I. ASSEMBLY OF ALL SYSTEM COMPONENTS

urpose: To ensure that all supplied components are connected correctly							
3. Place the Biosart [®] 100 adapter [2] onto the Combisart [®] single base [3]							
All Biosart® 100 adapters are placed	Yes □	No					
Firm fit of all components	Yes □	No					
4. Insert the air filter [5] into the venting hole							
Venting hole closed with Minisart® SRP	Yes □	No					
All venting holes closed with Minisart® SRP	Yes 🗖	No					
5. Insert the tube connector [7] into the silicone stopper [8] and insert the stopper into the opening of the suction flask [9].							
Firm fit of the stopper and the tube connector	Yes □	No					
Operator Signature:	Date:						
COMPANY:							
Witness Signature:	Date:						



IQ | OQ Documentation

Biosart® 100 Monitors

OQ Protocol

Operational Qualification I. Assembly

I. ASSEMBLY OF ALL SYSTEM COMPONENTS

1. /	I. ASSEMBET OF ALL STSTEM COMITONEINTS						
Pι	urpose: To ensure that all supplied components are connected correctly						
6.	_	he hose nipple on the outlet of the sk [9] (not necessary for 1-Liter fla					
	Firm fit of t	he hose nipple	Yes		No		
7.	Cutting the	vacuum hose [6] in half					
	Vacuum ho	ose cut	Yes		No		
8.	hose [6] or	one end of one half of the vacuum on the tube connector [7] and the of hose nipple of the Combisart [®] I].					
	Hose seat	ed tight at both ends	Yes		No		
9.	Cutting the	remaining vacuum hose [6] in ha	ılf				
	Hose cut		Yes		No		
Oþ	perator Sigr	nature:	Date):			_
C	OMPANY:						_
Wi	itness Signa	ature:	Date	e:			_
\sim							



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Biosart® 100 Monitors

OQ Protocol

Operational Qualification I. Assembly

I ASSEMBLY OF ALL SYSTEM COMPONENTS

I. ASSLIVII	BET OF ALL STSTEM COMM CHEMT	3						
Purpose:	Purpose: To ensure that all supplied components are connected correctly							
hose [6 [9] and the wa	ng one end of one half of the vacuum of on the hose nipple of the suction flast the other end on the inlet-hose nipple ter trap [10]. The inlet of the Woulff's sthe long glass tube.							
Hose s	eated tight at both ends	Yes □	No					
end on (short of the oth	ng the remaining vacuum hose [6] with the <u>outlet</u> -hose nipple of the water tra glass tube of the Woulff's bottle) and w er end on the hose nipple <u>providing va</u> vacuum pump [11].	p [10] vith						
All hos	e connections tight	Yes □	No					
12. Conne	cting the line cord							
Firm co	onnection of the cable	Yes □	No					
Operator S	Signature:	Date:						
COMPAN'	Y:							
Witness S	ignature:	Date:						



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Biosart® 100 Monitors

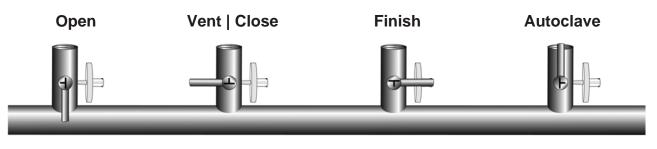
OQ Protocol

Operational Qualification II. Start-Up and Functional Test

II. A- COMBISART® TAP POSITIONS AND THEIR FUNCTIONS

Purpose: To ensure that the Combisart® tap is used correctly. So the vacuum below the membrane filter is released sterilely.

Tap Position:



6 o'clock 9 o'clock 3 o'clock 12 o'clock

Function:

Function:			
For Filtration	After Filtration	After the Filtration Run	For Autoclaving
The full vacuum draws the sample through the membrane filter. The venting filter is "off-line."	The vacuum between the tap and membrane filter is released under sterile conditions. Secondary contamination of the bottom of the filter is ruled out entirely.	The residual vacuum between the pump and valve is released via the sterilizing grade filter.	For reliable sterilization, the steam flows freely through all openings.
Operator Signature:		Date:	
COMPANY:			
Witness Signature:_		Date: _	
COMPANY:			



IQ | OQ Documentation

Biosart® 100 Monitors **OQ Protocol**

Operational Qualification II. Start-Up and Functional Test

II. B- START-UP THE SYSTEM

Purpose: To ensure that the Combisart® System is working correctly.

B.1. Start-Up the system

Turning each of the Combisart® taps to position "Vent | Close" (9 o'clock) S

and switching the vacuum pump on. If a Woulff's bottle is used, making sure the tap is closed. Place Biosart [®] 100 Monitor(s) [1] on top of the Biosart [®] 100 Adapter(s) [2].						
1. Pump running, audible noise	Yes □	No				
2. Vacuum is build up in the system	Yes □	No				
3. Biosart® 100 Monitor(s) are installed	Yes □	No				
Operator Signature:	Date:					
COMPANY:						
Witness Signature: Date:						
COMPANY:						



IQ | OQ Documentation

Biosart® 100 Monitors

OQ Protocol

Operational Qualification II. Start-Up and Functional Test

II. C- VERIFICATION OF THE COMBISART® TAP

Purpose: To ensure that the Combisart® tap is working and used correctly. So the vacuum below the membrane filter is released sterilely.

Remark: In the following section the test of the functionality of the

Combisart[®] 3-way-taps is described. If your Combisart[®] System has more than one filter station, please make sure that you follow the instructions for every Combisart[®] tap separately, while the

other taps are closed (9 o'clock position).

C.1. Functionality Combisart® Tap Position "Open"

Place a Biosart[®] 100 Monitor [1] on top of the Biosart[®] 100 Adapter [2] and fill the Monitor with 100 ml tap water. Turn the Combisart[®] tap to position "Open" (6 o'clock)

1. Water is drawn through the Biosart [®] 100 Monitor	Yes □	No E
 No vacuum occurs on the venting filter Minisart[®] SRP 	Yes □	No E
3. All Combisart® taps were tested	Yes □	No 🗖
Operator Signature:	Date:	
COMPANY:		
Witness Signature:	Date:	
COMPANY:		



IQ | OQ Documentation

Biosart® 100 Monitors

OQ Protocol

Operational Qualification II. Start-Up and Functional Test

II. C- VERIFICATION OF THE COMBISART® TAP

Purpose: To ensure that the Combisart[®] tap is working and used correctly. So the vacuum below the membrane filter is released sterilely.

C.2. Functionality Combisart® Tap Position "Vent | Close"

Turn the Combisart® tap to position "Vent | Close" (9 o'clock). Refill the Biosart® 100 Monitor with tap water.

 Vacuum occurs on the venting filter Minisart[®] SRP No water is drawn through the Biosart[®] 100 Monitor All Combisart[®] taps were tested 	Y			No No No	0
C.3. Functionality Combisart [®] Tap Position "Fin	ish"				
The Biosart [®] 100 Monitor is filled with tap water. Tu to position "Finish" (3 o'clock)	rn the (Com	bisart	® tap	
 Vacuum occurs on the venting filter Minisart[®] SRP No water is drawn through the Biosart[®] 100 Monitor The vacuum of the system is released All Combisart[®] taps were tested 	Y Y			No No No No	
Operator Signature:	Date:_				_
COMPANY:					_
Witness Signature:	Date:_				_
COMPANY:					



IQ | OQ Documentation

Biosart® 100 Monitors

OQ Protocol

Operational Qualification II. Start-Up and Functional Test

	_	_			_	<u></u>
2	C-	VFRIFIC	ΔΤΙΩΝ	OF THE	COMBISA	ΙΡΤΨ ΤΔΡ

Purpose: To ensure that the Combisart® tap is working and used correctly. So the vacuum below the membrane filter is released sterilely.

C.4. Functionality Combisart® Tap Position "Autoclave"

The Biosart® 100 Monitor is filled with tap water. position "Autoclave" (12 o'clock)	Turn the Com	bisar	rt [®] tap	to
 Water is drawn through the Biosart[®] 100 Monitor Vacuum occurs on the venting filter 	Yes		No	
Minisart [®] SRP	Yes		No	
3. All Combisart® taps were tested	Yes		No	
Operator Signature:	Date:			
COMPANY:				
Witness Signature:	Date:			
COMPANY:				



IQ | OQ Documentation

Biosart® 100 Monitors **OQ Protocol**

Operational Qualification III. Test Filtration

III. VERIFICATION OF THE FUNCTION – TEST	T FILTRATI	ION	l		
Purpose: To ensure that the Combisart® Syste	em is workin	ng c	orrec	tly.	
1. Placing Biosart® 100 Monitor(s) [1] on top of Adapters [2] and turning the Combisart® tap(s o'clock). Switching on the vacuum pump [9] (t must be closed).) to position	า "V	ent	Close	•
1. Pump running, audible noise	Ye	es		No	
2. Vacuum is build up in the system	Ye	es		No	
2. Filling the Biosart® 100 Monitor with 100 ml of Combisart® tap to position "Open" (6 o'clock)	f tap water a	and	l turni	ng the)
1. Filling procedure functioning	Ye	es		No	
2. Emptying procedure functioning	Ye	es		No	
3. <u>All</u> Combisart [®] taps were tested	Ye	es		No	
Operator Signature:	Date:				_
COMPANY:					_
Witness Signature:	Date:				
COMPANY:					



IQ | OQ Documentation

OQ Protocol

Operational Qualification III. Test Filtration

III. VERIFICATION OF THE FUNCTION – TEST F	ILTRATI	ON	l		
Purpose: To ensure that the Combisart® System	is workin	ıg c	orrec	tly.	
3. After the filtration turning the Combisart® tap to p (9 o'clock). The vacuum between the tap and Bio released under sterile conditions by the Minisart®	osart [®] 10				
 Vacuum occurs on the venting filter Minisart[®] SRP for a short moment 	Ye	es		No	
2. Noiseless removing of the Biosart® 100 Moni	tor Ye	es		No	
3. All Combisart® taps were tested	Ye	es		No	
Operator Signature:	Date:				_
COMPANY:					_
Witness Signature:	Date:				_
COMPANY:					



IQ | OQ Documentation

OQ Protocol

Operational Qualification Summary

PROTOCOL OF OPERATIONAL QUALIFICATION

The following operational qualification protocols had been completed satisfactorily.			
	Assembly		
	Start-Up and Functional Tests		
	Test Filtration		
Oper	ator Signature:	Date:	
COM	PANY:		
Witne	ess Signature:	Date:	
COM	PANY:		