

Benefits of integrating plasmapheresis devices with donation center software

IPFA/EBA, March 16th, 2022

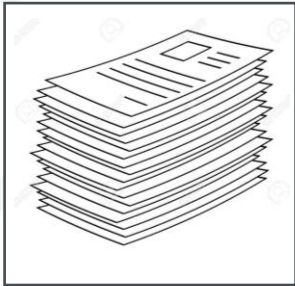
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HAEMONETICS®

Regulatory requirements necessitate high level of documentation and process control in Blood Centers and Plasma Centers.

Paperwork



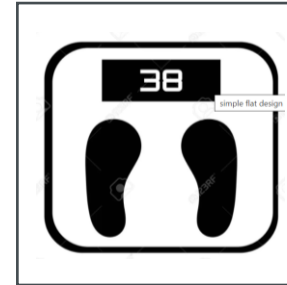
- General donor information
- Donor questionnaire
- Information for donors regarding infectious risks
- Consent forms



- SOPs
- Quality documentation



- Certificates
- Invoices
- Delivery notes



- Weight
- Size
- BMI
- General donor info



- Haematocrit
- Haemoglobin

Current state in many centers

- Mostly paper based
- Manual entry and transfer of data
- Manual control mechanisms (e.g. two person rule)
- Manual documentation mechanisms/no time stamps
- Partly supported by barcode scanners and/or handhelds

Non-digitalized, manual processes carry risks, even with best controls in place

Examples

- Consumables from lots that are blocked or not released are used
- SOP not followed: e.g. consumables on the device longer than SOP allows, skin disinfection waiting time not followed
- Donation # and donor ID are not matched
- Incorrect volume target is entered into the device
- Procedural data captured incorrectly and/or incompletely “by hand”
- Entry mistake when manually transferring procedure data into BECS
- Allocation of samples to donation not correct
- Unauthorized operator fulfils certain activities
- Process steps happen without documented sign off of authorized person (2nd person)
- Mistakes when archiving the paper documents around a donation procedure

**Compliance
&
Safety risks**

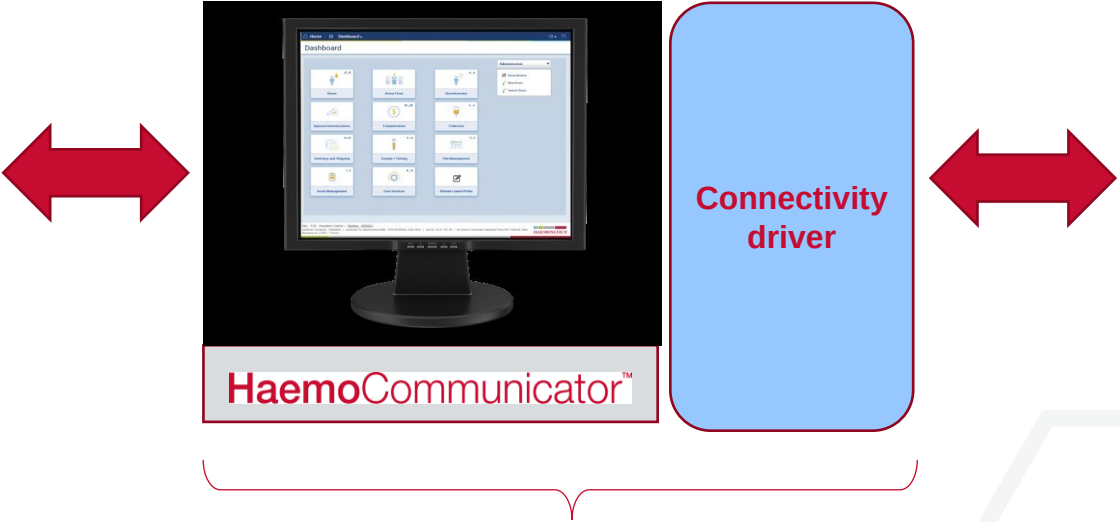
Fully integrated, bi-directional connectivity



Scanner

Middleware

- installed on server
- no data storage
- real time



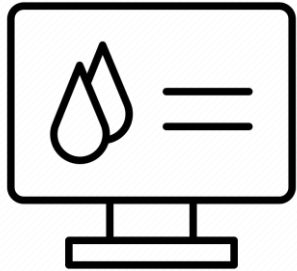
“Connectivity Package”



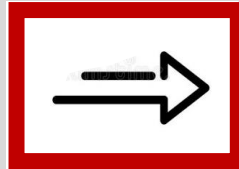
No barcode readers or handhelds required

BECS to NexSys PCS®:

All relevant data is sent to the device



BECS



- Donor Picture
- Name
- Date of birth
- Donor ID
- Plasma Target
- Allergic events
- Adverse events
- Weight & Height
- Collection history
- Hematocrit
- First time donor
-

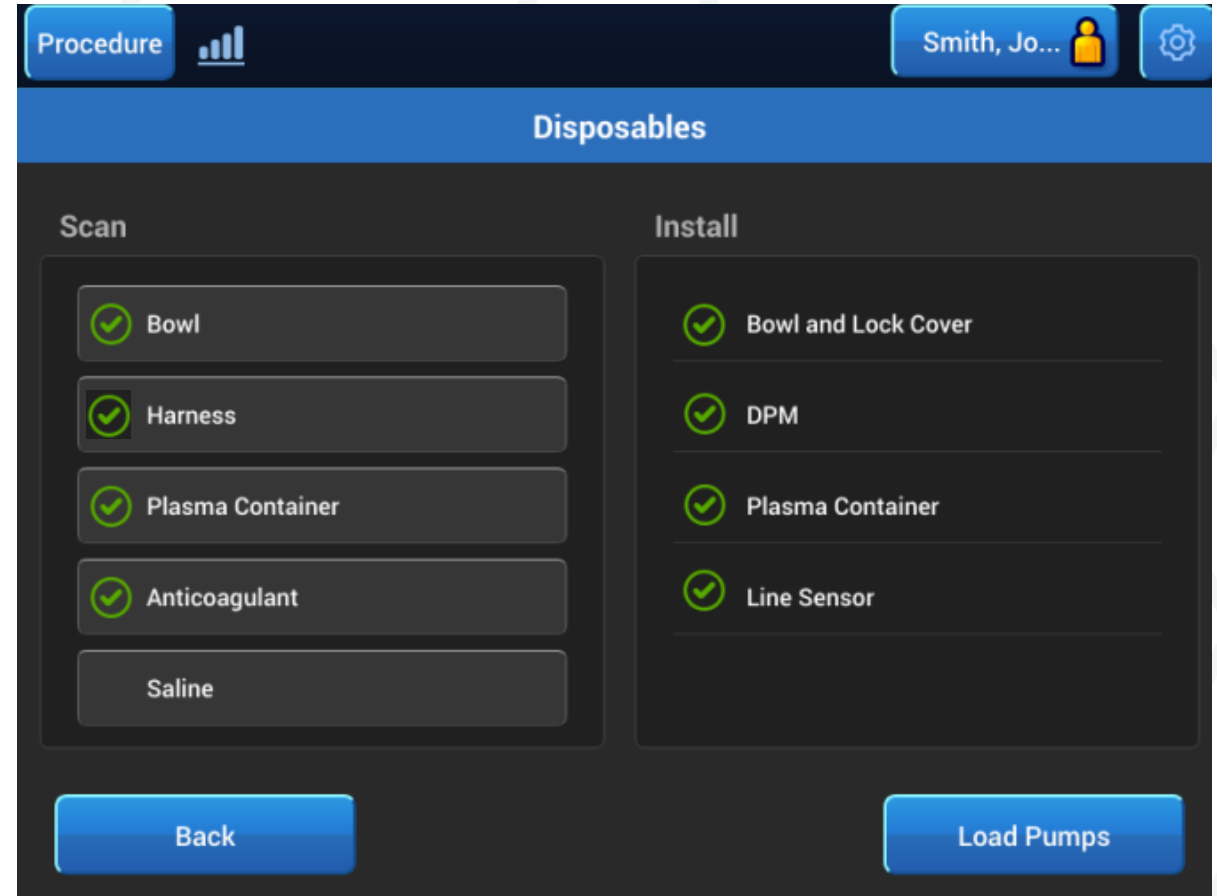
Procedure

Smith, Jo...

Plasma Target	Samples	Donor ID	
750 ml	0 / 3	00004012	
Hematocrit	Height	Weight	
45 %	71 in	186 lb	
Government ID			
012345			
Blood Pressure	Protein	Collection #	
80/120	10.0	235402	
Exceptions			
10/02/2019 Allergic Eve...			
History			
Lifetime 3			
Collected	Time	Date	
1: 750 ml	43	10/02/2019	
2: 880 ml	40	09/10/2019	
Iodine			
Right Arm Preferred			

Donation set-up: Automatic control of lot numbers and operator ID between device (scanner) and BECS

- (1) Registration of the operator setting the device up.
- (2) Scanning of the bar codes of all consumables
- (3) Validation and confirmation of consumable lot numbers 
- (4) Finalizing installation with checks on every step (DPM, Line Sensor, Cover Lock) 



Procedure  Smith, Jo...  

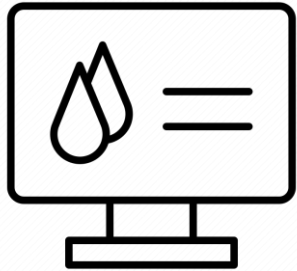
Disposables

Scan	Install
 Bowl	 Bowl and Lock Cover
 Harness	 DPM
 Plasma Container	 Plasma Container
 Anticoagulant	 Line Sensor
Saline	

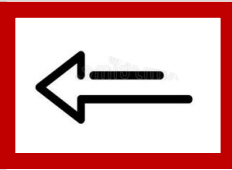
 

NexSys PCS® to BECS:

Procedure data is transmitted to BECS after donation.



BECS



- Actual Plasma
- Plasma Target
- Total collected product
- Date & Time of collection
- Collection number
- RBC loss
- Adverse Events
- Citrate & Saline used
-

Procedure History

2019/06/12 10:51

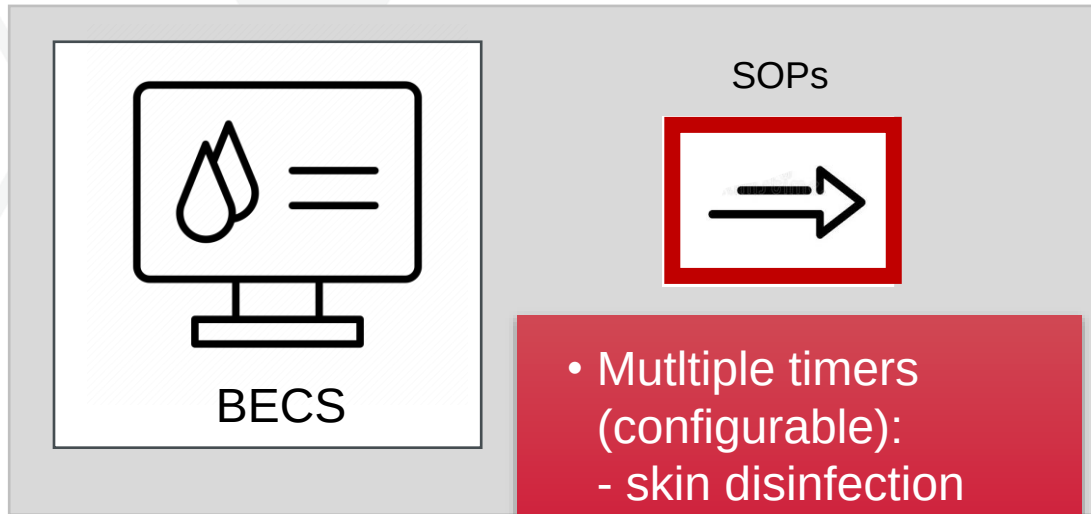
Collection Number	654136
Plasma Target	750 ml
Donor Hematocrit	40 %
Actual Plasma	750 ml
Total Collected Product	750 ml
RBC Loss	>200

Exceptions

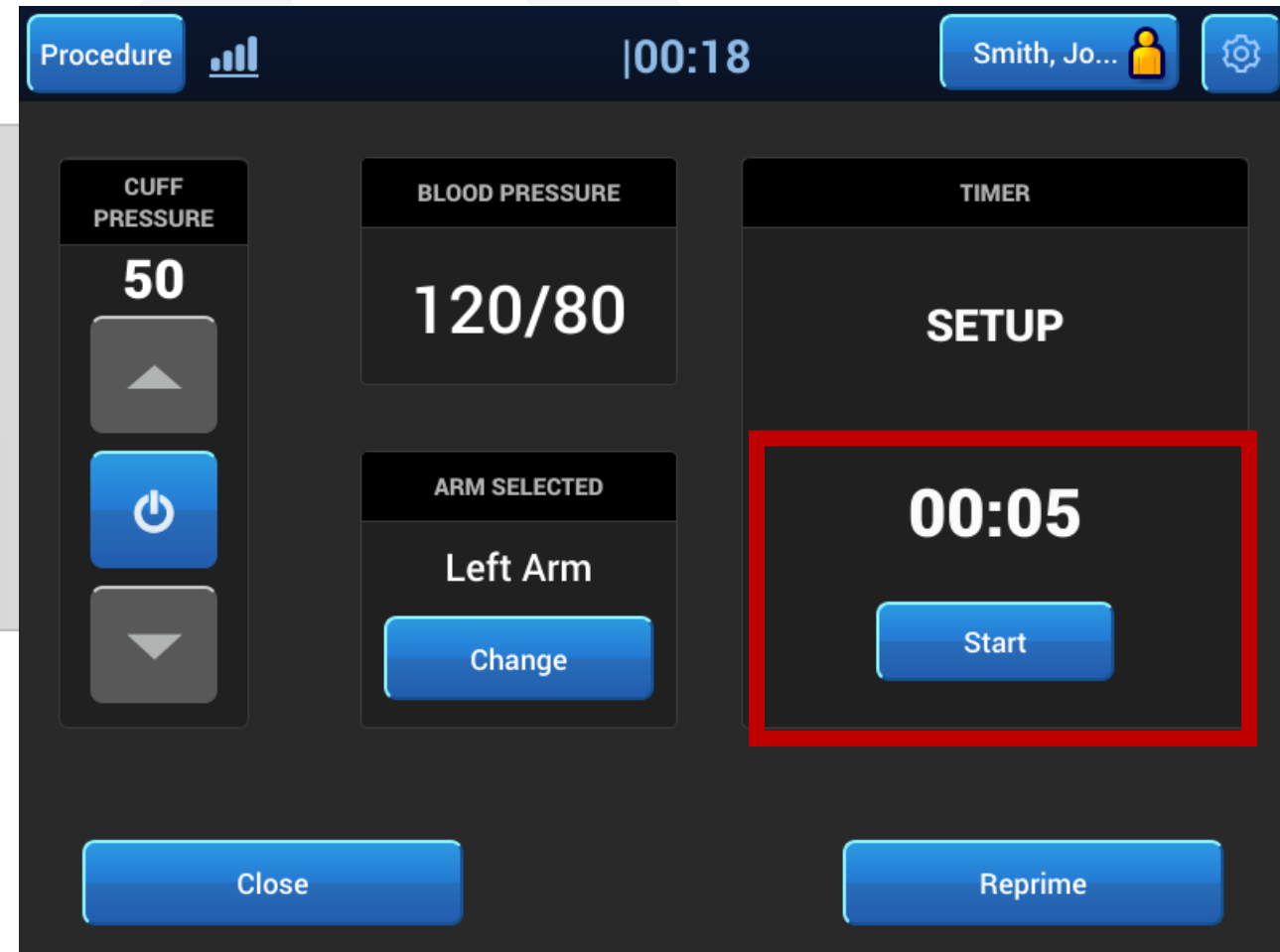
- ! Hypotensive Event : Prefaint, No LOC (Minor)
- ! Other Event
- ! Citrate Reaction Event : Moderate

Close

SOP's can be directly programmed into the devices settings



- Multiple timers (configurable):
 - skin disinfection
 - phlebotomy
 - consumable
 - etc.
- Levels of operator authorization
- Adverse events
-



Cornerstones of integration projects

Set up

- Hardware:
 - No additional IT hardware required but “Golden” device recommended
- Project team:
 - Customer IT team
 - Customer donation management team
 - Provider of center software (BECS)
 - Haemonetics Software Implementation team
- Regular meetings
- In-depth workshops including several functions of blood bank (e.g. medical, quality)

3 – 12 months

Project steps (example)

- Haemonetics provides IT/BECS team with driver specs to define interface
- IT/BECS team develops interface
- Customer defines scope:
 - which data?
 - center process steps / optimization?
 - highly configurable!
- “Sandbox” trial
- Amendments / corrections
- Pilot center
- Validation
- Go live!

Benefits of integrating plasmapheresis devices with BECS



Donor safety

- Improved control of identity
- Reduction of manual entry errors (e.g. target volume)
- Display of special donor conditions (allergies, side effects etc.)
- Reduced likelihood of complications (e.g. citrate tracking)



Donor satisfaction

- Less time in center
- Lean & modern process
- Less paperwork, more digital steps
- Transparency of process steps and donation status
- Higher return rate



Compliance

- Forced adherence to SOPs, GMP standards
- Avoid manual entry and documentation errors
- Transparency: Full record of all process steps (e.g. operators, disposable lots, error messages, time stamps, Adverse Events)
- Automated archiving



Efficiency

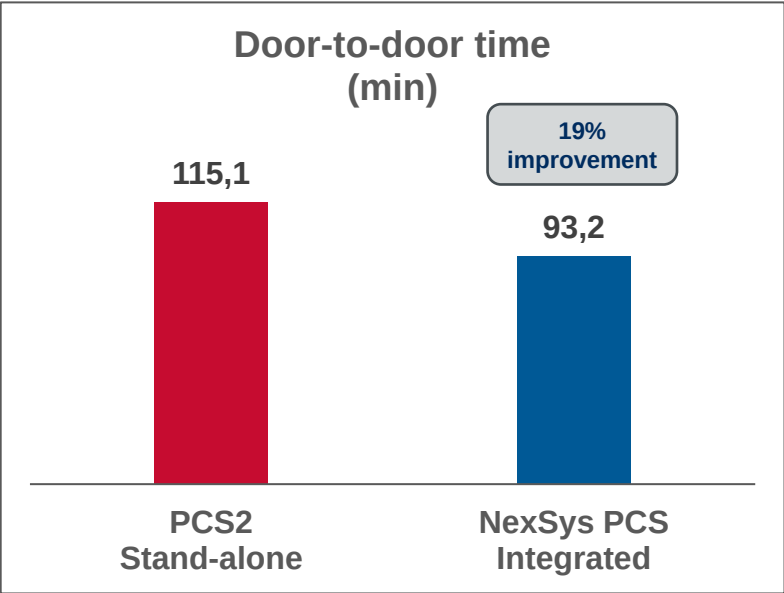
- Faster process & reduction of manual process steps reduces time of staff
- More time for donors, increased capacity
- Significantly reduced time for documentation and archiving after donation
- Increased transparency of center operations allows better management

Case study NexSys PCS® integration 2017/2018: Results show reduced door-to-door time and reduction in overdraws & documentation errors

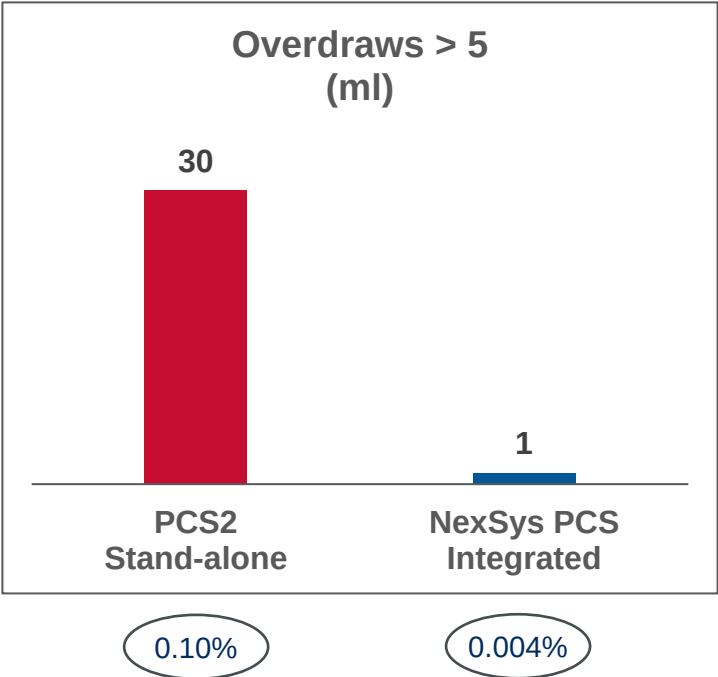
- United States, one customer, one center
- Before: PCS2, not connected, Oct 24, 2017 - Jan 21 2018, 30.192 donations
- After: NexSys PCS, fully integrated, Jun 24, 2018 – Sep 18, 2018, 28.442 donations



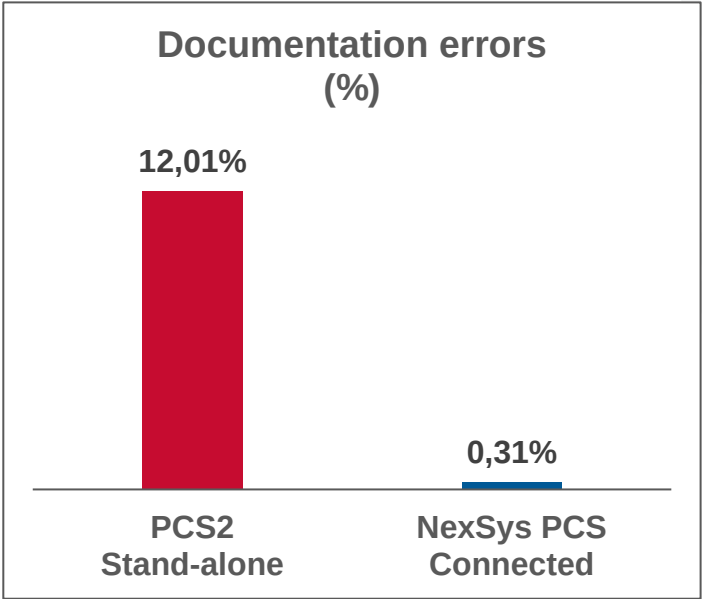
Higher efficiency



... fewer overdraws ...



... less documentation errors

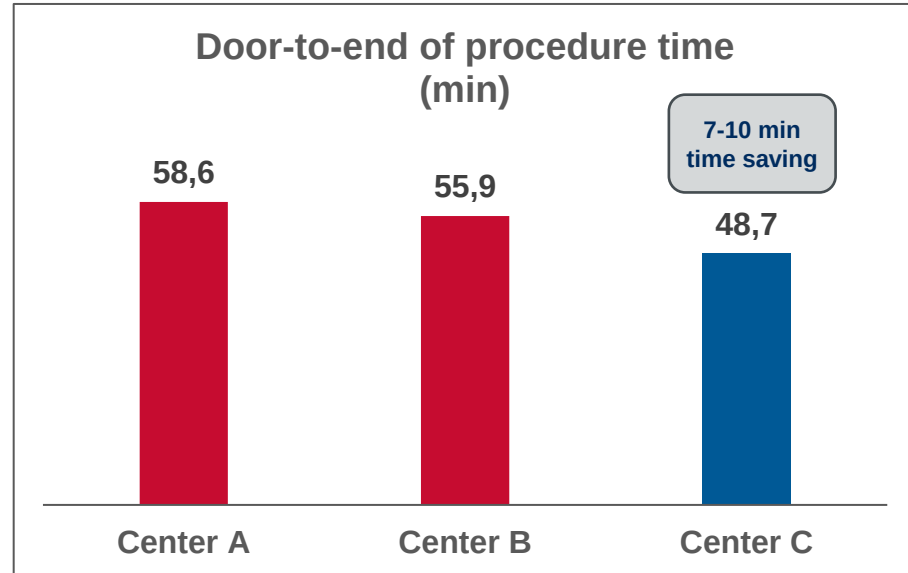


Case study 2021/2022: Initial results show that project with fully integrated NexSys PCS® decreased process time and reduced overdrews

- Germany, one customer, three centers, analysis of 12 months (Mar 2021 to Feb 2022)
- Center A, PCS2, non-integrated, 38.543 donations
- Center B, PCS2, non-integrated, 34.855 donations
- Center C, NexSys PCS, fully integrated, 29.785 donations



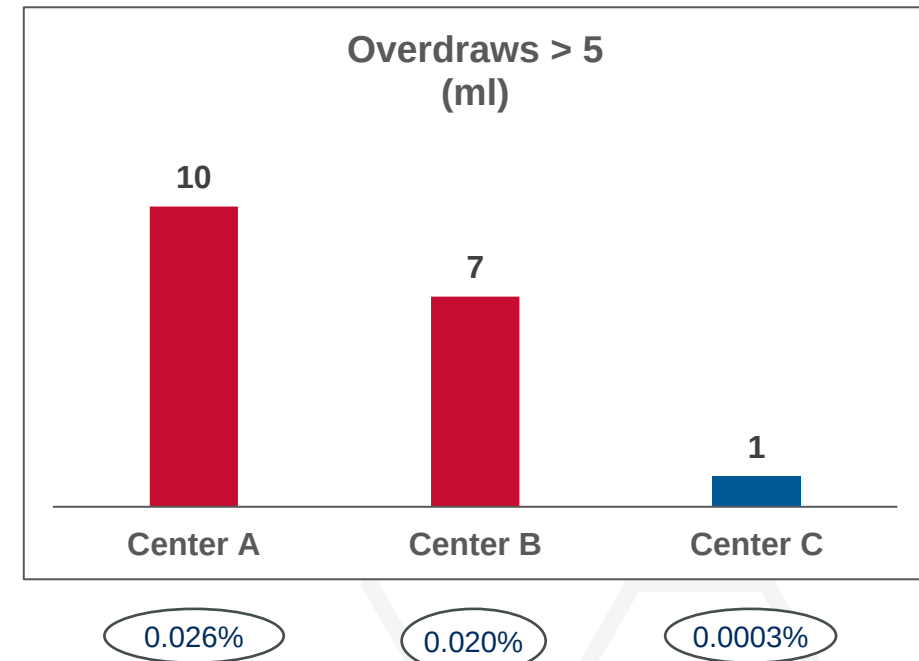
Higher efficiency



PCS2, non-integrated

NexSys PCS
fully integrated

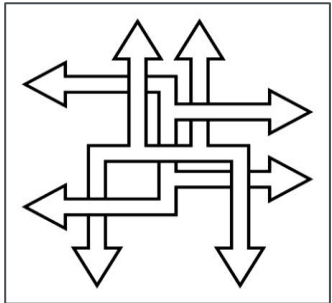
... with fewer overdrews



Lessons learned from connectivity projects



- **Implementing Connectivity is a joint effort**
 - Software provider and device manufacturer cannot do it alone
 - Implementation is customized and depends on many factors
 - Significant input and contribution of collection center is required



- **Do not “electrify” your current processes**
 - Integration offers many ways to do things differently and streamline processes
 - Use the potential, question your current state and optimize your processes when integrating



- **Integration projects have shown great benefits**
 - Very positive feedback from centers and donors
 - Smooth reliable workflows, improved safety profile
 - Time savings allow for more donations and to better serve donors
 - Reduced burden of documentation & better compliance

What will the future bring?



Connecting through cloud opens new opportunities



Fleet management

- Remote diagnosis of devices to minimize downtime
- “Wireless” Software updates and upgrades
- Control of settings plus standardization

Center management

- Performance transparency and visualization
- Within individual center and between centers (or clusters)
- KPIs and benchmarking

Executive Summary

- Regulatory requirements necessitate high level of documentation and process control in blood centers and plasma centers.
- Today many processes in blood and plasma centers are based on paperwork and manual entry, sometimes supported with handheld devices.
- This leads to the possibility of mistakes and significant amount of “non”- productive time, control mechanisms, documentation and archiving.
- Technology of devices and software has evolved in the past years so that it is possible to create fully integrated, completely paperless donor floors.
- This creates significant benefits in terms of donor safety, donor satisfaction, ease and quality of documentation/archiving, and center efficiency.

Thank you!



