Continuous Monitoring and Assessment of Vascular Blood Flow

FloPatch FP120

Joe Eibl (PhD): Co-Founder, Chief Executive Officer

- PhD - Physiology
- Postdoc - Bioengineering
- 10+ Patents
- 60+ Peer-reviewed publications

ICD-10 Coordination and Maintenance Committee Meeting
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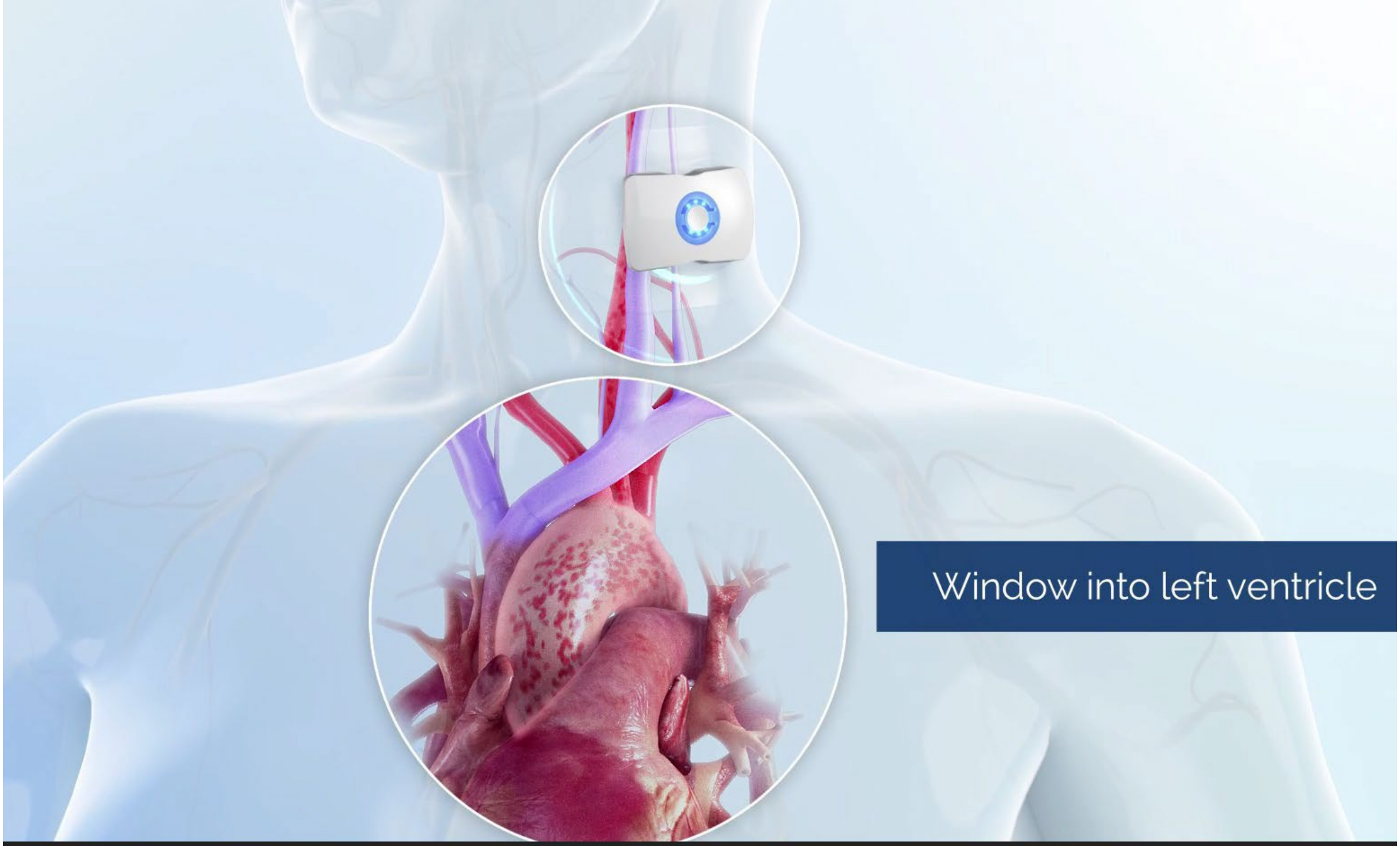
PRIMARY CLINICAL QUESTION

- FloPatch FP120 is the only commercially available technology which can perform real-time simultaneous assessment of venous and arterial Doppler across an intervention (>100 cardiac cycles) due to the technological advancement
- Both patients and clinicians can greatly benefit from these assessments to inform precision IV fluid administration and prevent over-resuscitation. This is achieved through flow-guided fluid prescription, which essentially means administering IV fluids only when there is a demonstrable beneficial response in the patient. This response is measured by changes in cardiac output or stroke volume surrogates, ensuring that fluid administration is both effective and necessary for the patient's condition.

THE SOLUTION

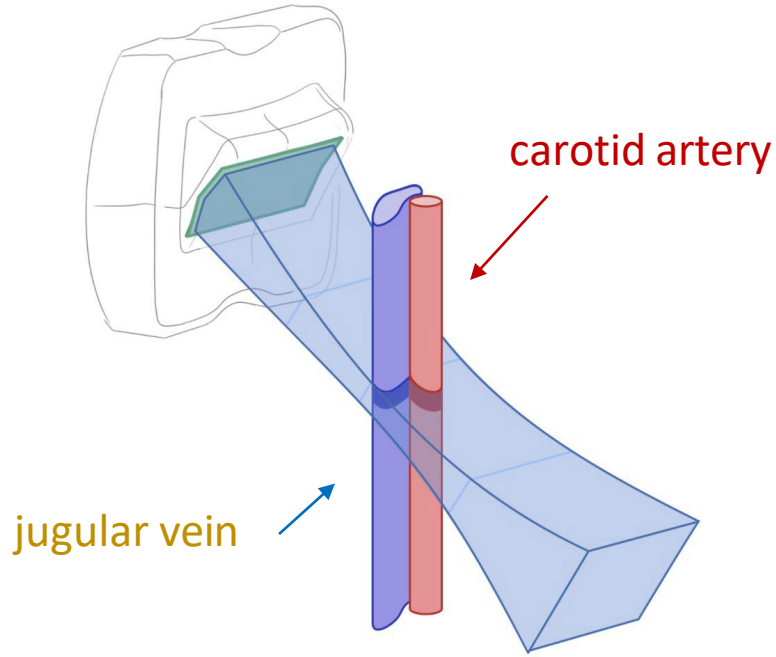
WEARABLE ULTRASOUND GUIDING IV FLUID RESUSCITATION

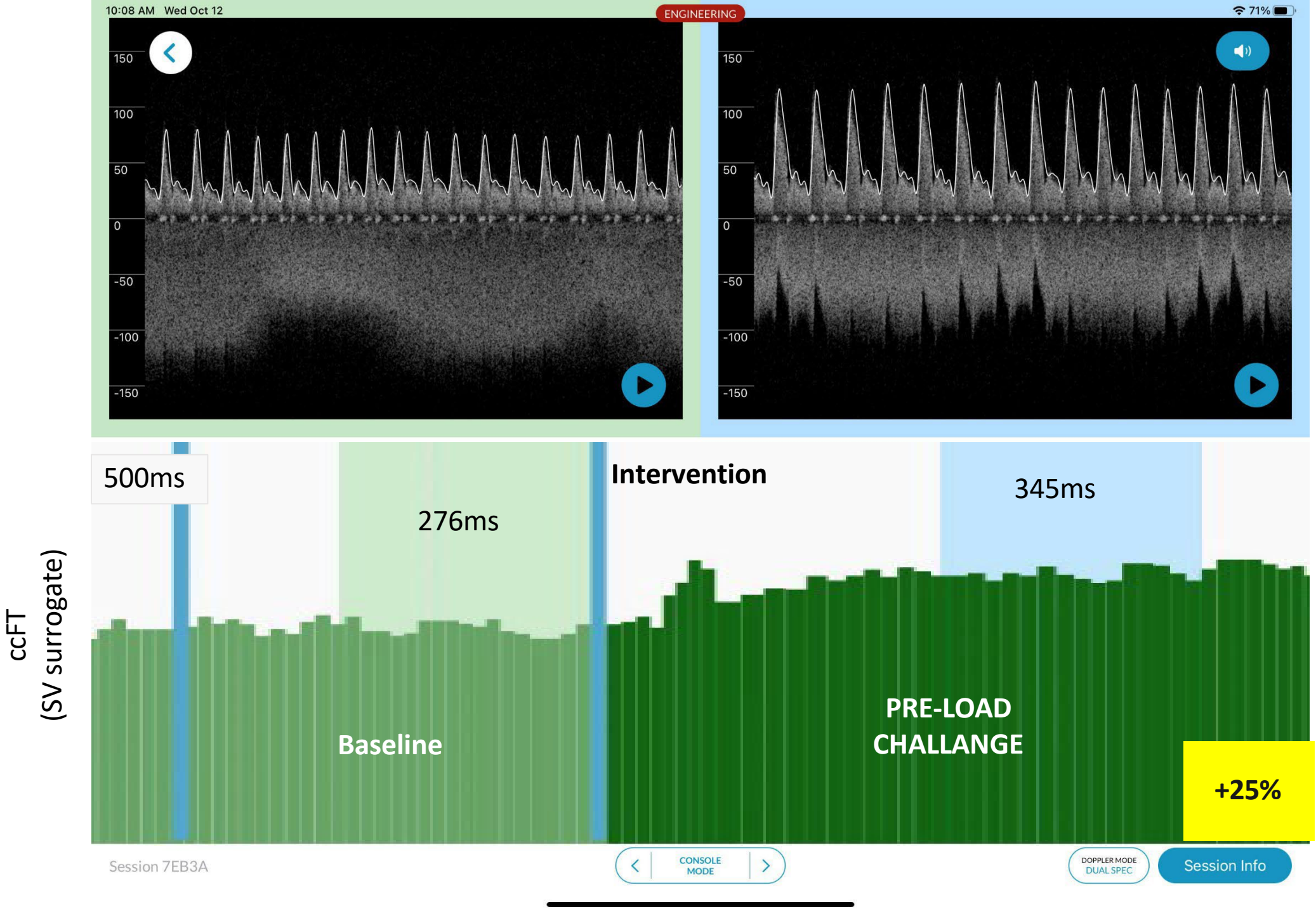

Window into left ventricle

INNOVATIVE TECHNOLOGY

WEARABLE ULTRASOUND

Tandem venous/arterial Doppler provides a real-time view of right and left heart to guide resuscitation including sepsis, hemorrhage, and CPR




10:08 AM Wed Oct 12
ENGINEERING
71%
150
100
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0
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-100
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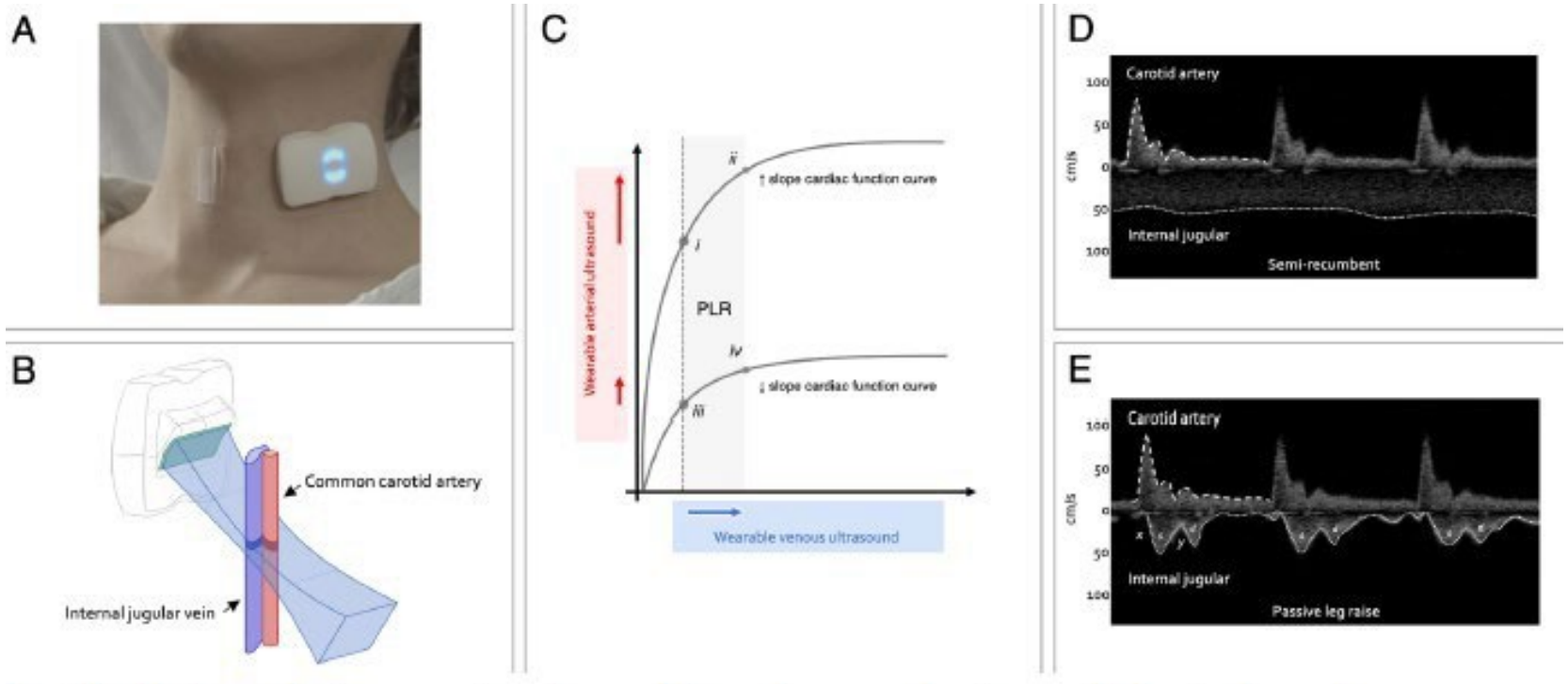
ccFT
(SV surrogate)
500ms
276ms
Intervention
345ms
Baseline
PRE-LOAD
CHALLANGE
+25%
Session 7EB3A
CONSOLE
MODE
DOPPLER MODE
DUAL SPEC
Session Info

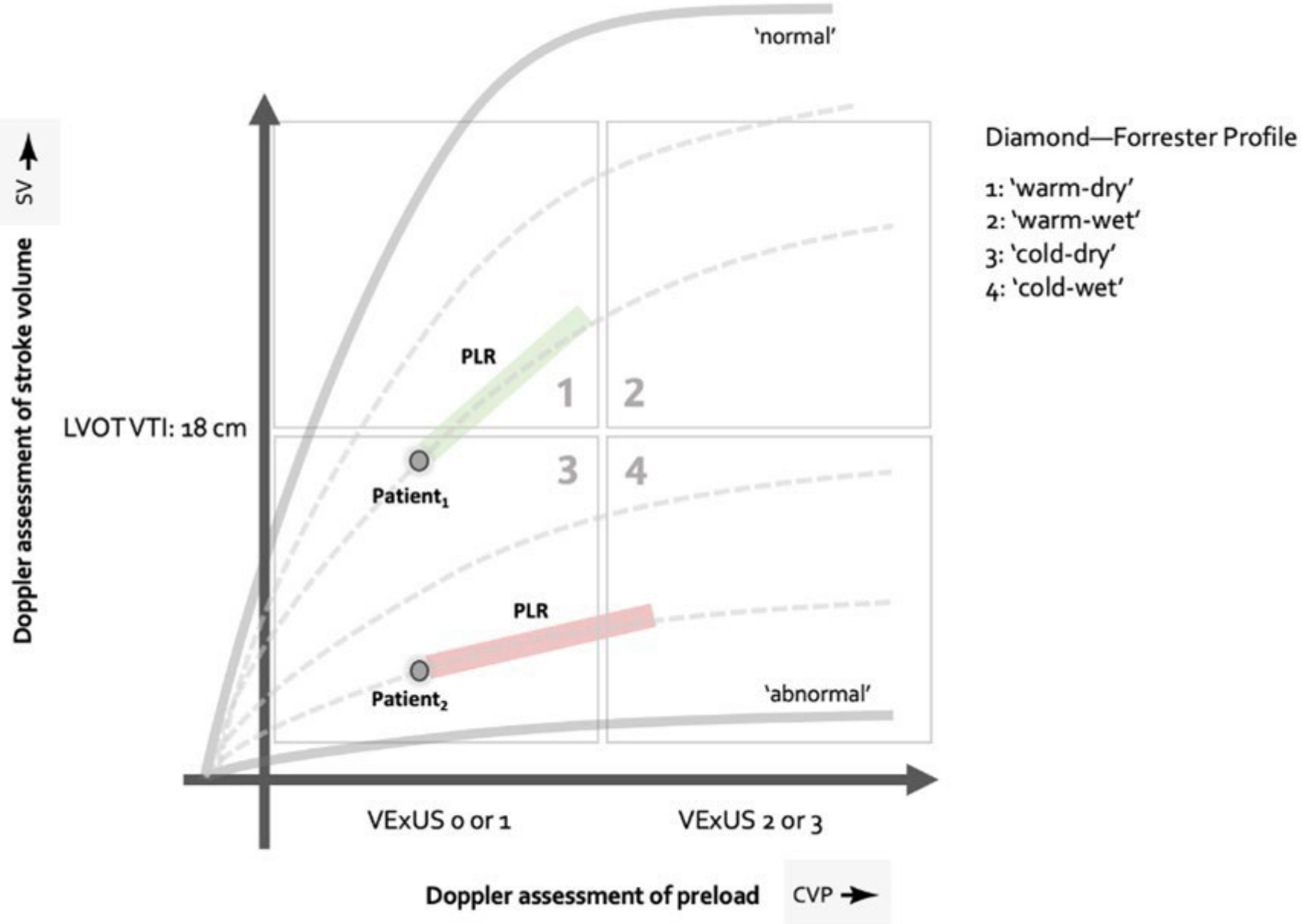
Kenny et al. Critical Care (2022) 26:329
https://doi.org/10.1186/s13054-022-04206-7

Critical Care

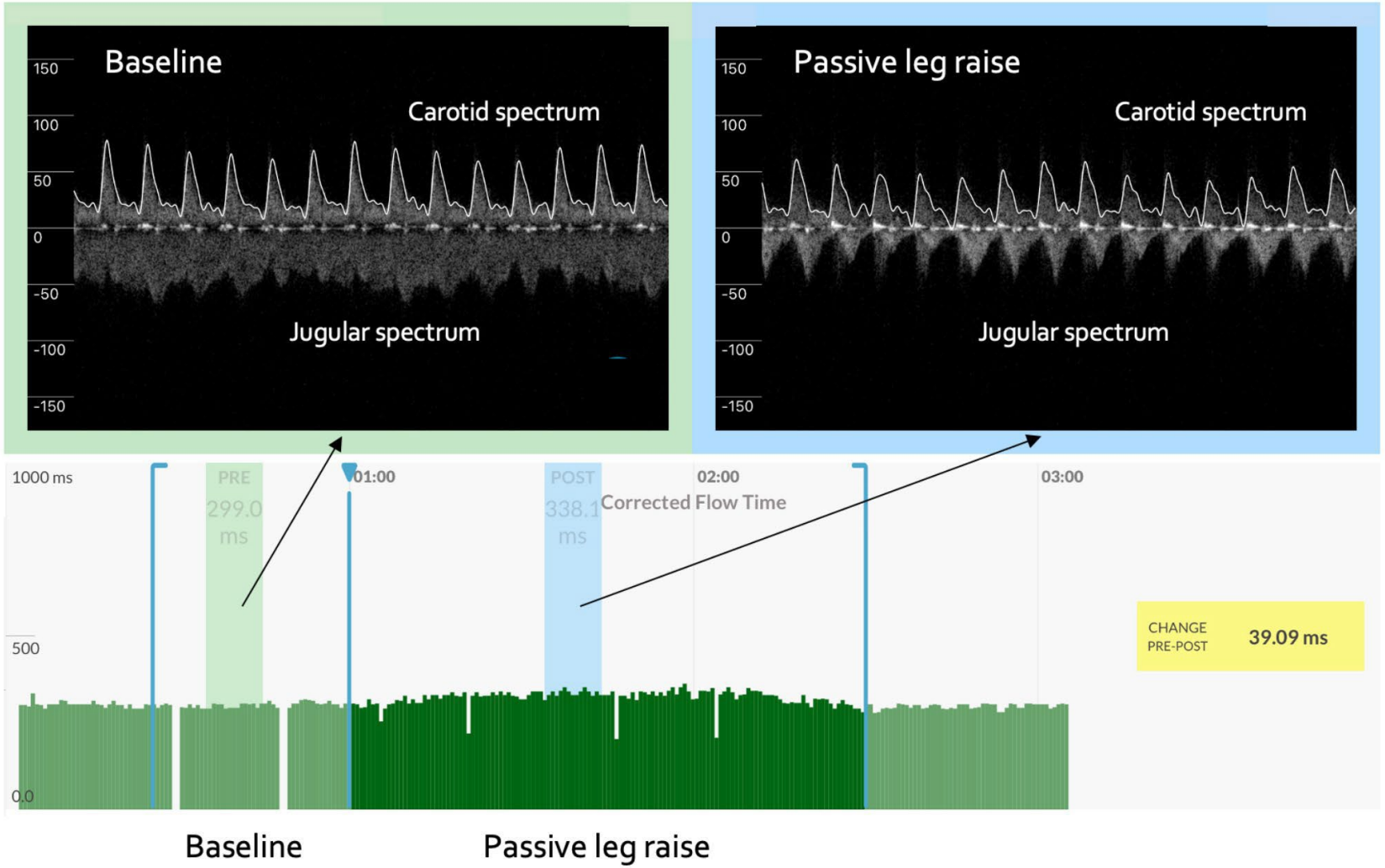
COMMENT Open Access

Wearable ultrasound and provocative hemodynamics: a view of the future



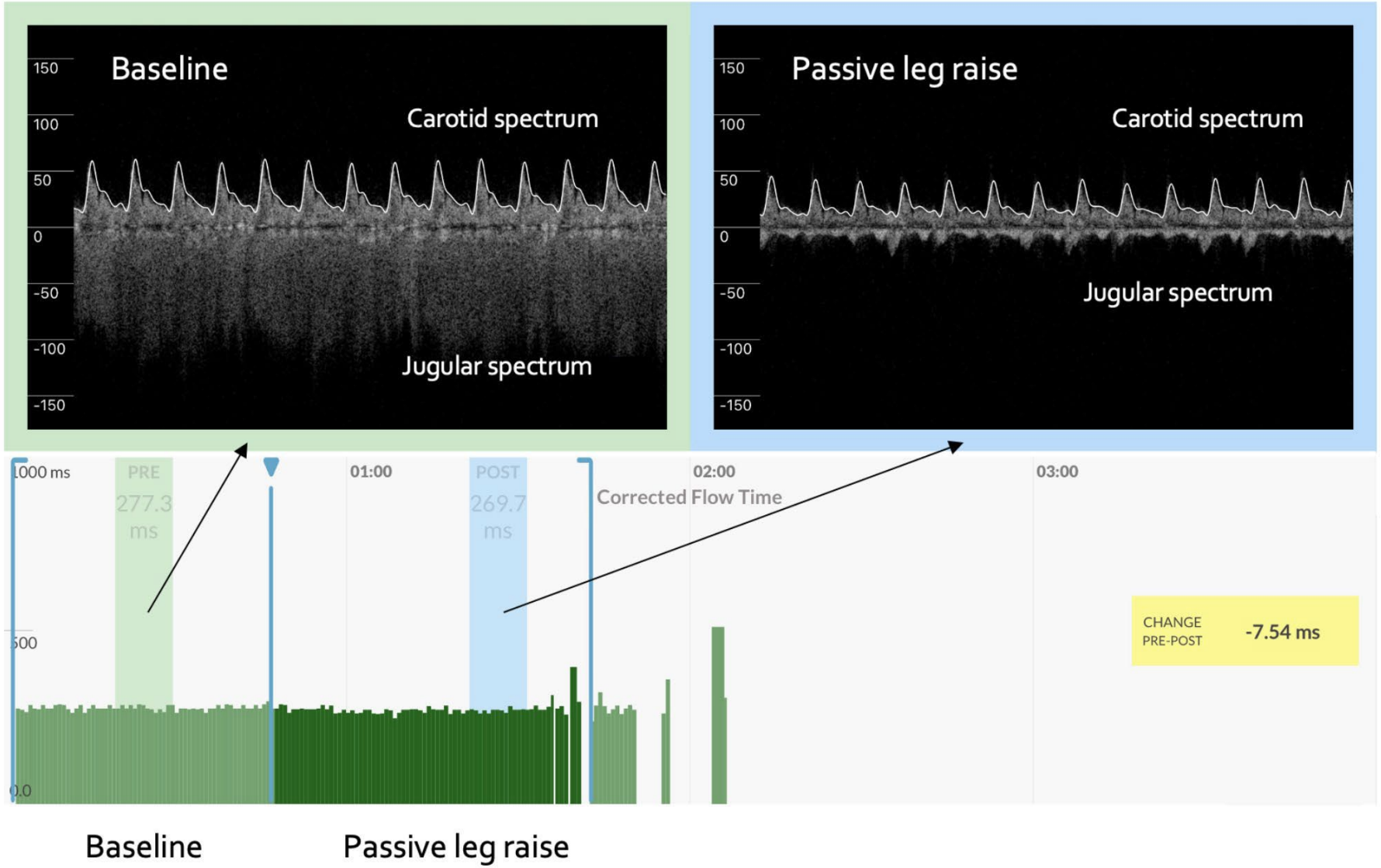

'normal'
SV
Doppler assessment of stroke volume
LVOT VTI: 18 cm
PLR
1
2
3
4
Patient1
PLR
Patient2
'abnormal'
VExUS 0 or 1
VExUS 2 or 3
Doppler assessment of preload
CVP
Diamond—Forrester Profile
1: 'warm-dry'
2: 'warm-wet'
3: 'cold-dry'
4: 'cold-wet'

Example 1 - Increased slope of the cardiac function curve



Increased slope of the cardiac function curve. In an example of a "normal" or "expected" result, the **venous** waveform progresses from being high velocity, low amplitude, and non-pulsatile to being lower velocity, higher amplitude, and pulsatile in character. The pulsatile venous waveform can be marked by a monophasic signal, as seen here. Concomitantly, the arterial Doppler waveform shows an increase in the ccFT from baseline, suggesting that the increase in the cardiac preload is met by a rising cardiac output. These responses, taken together, indicate a "cardiac function" curve with a steep slope. The y-axis on the spectrum represents the velocity in centimeters per second. The positive velocity is toward the brain (e.g., the carotid artery), while the negative velocity is toward the heart (e.g., the jugular velocity). The x-axis on the spectrum is time.

Example 2 - Flattened slope of the cardiac function curve



Flattened slope of the cardiac function curve. An "abnormal" response during a preload challenge is marked by a venous Doppler waveform that evolves as above but with an arterial response that reveals no significant change or even a decrease in the ccFT as compared to baseline, as seen here. This constellation of venous and arterial findings implies a flat or, potentially, impaired cardiac function curve with increased preload.

Where would the drug/device/technology/service or procedure be documented in the medical record for individuals (E.g. medical coders) to identify?

- Example, Sepsis Care Pathway – The device would be prescribed as part of the sepsis order set and document as part of completing that order set.
- In the order set prior to or during fluid resuscitation perform dynamic assessment and capture the output of the assessment
  - Initial dynamic assessment results are recorded in a field
  - Subsequent dynamic assessment results are recorded if hypotension persists, or additional volume is being considered
- Assessment value thresholds are defined by the hospital department

What are the different naming conventions for the drug/device/technology/service or procedure?

- Dynamic blood flow assessment
- Fluid responsiveness
- Fluid Tolerance
- Dynamic Change in stroke volume surrogate

If the technology is a device or implant, is only one device/implant routinely inserted or can multiple devices/implants be utilized?

- A single-patient use device, non-invasive over major peripheral vessels
- Many dynamic assessments can be performed (typically over the course of 0-48 hours)
- Typical dynamic assessment is 3-5 minutes
- Check for fluid responsiveness before giving fluids during resuscitation
- Precision fluid management (check early and often)

If the technology involves a device or implant, is the device considered permanent?

- Temporary, non-invasive
- Can be left adhered to patient or removed and reapplied for future assessments

If the procedure involves vessels or specific body parts, is it beneficial or necessary to identify a range of the specific site? (E.g. 2-3 vertebrae, 4+ vessels or stents, etc.)

- Major peripheral vessels preferred, for example:
  - Common Carotid Artery / Internal Jugular Vein
  - Brachial Artery / Brachial Vein
  - Femoral Artery / Femoral Vein

Important to place the device over both the artery and vein for the simultaneous blood flow assessment

Is the procedure/technology performed in conjunction with another procedure/technology or is it considered a standalone procedure/technology?

- The Technology is standalone
- Clinically, the technology provides the best insights during a dynamic assessment, pre-load challenge (i.e., Passive Leg Raise, fluid challenge, etc.), or other clinically meaningful hemodynamic change (i.e., falling stroke volume from internal bleed)

Have there been any associated complications/sequela/adverse events? If yes, how many and what did they consist of? (E.g. dislodgement, failure, loosening, etc.)

- No complications or adverse events to report

Thank you

Q & A