Clinical Guideline

IMPELLA CP WITH SMART-ASSIST: MECHANICAL CIRCULATORY SUPPORT DEVICE

SETTING Bristol site – Cardiac Cath labs, GICU (A600), CICU (C604), Cardiac theatres.

FOR STAFF All staff

PATIENTS Adult patients requiring mechanical circulatory support during high-risk primary percutaneous coronary intervention (PPCI), or for cardiogenic shock.

SECTION 1 – OVERVIEW, INDICATIONS, CONTRAINDICATIONS

Device Overview

Impella catheters are a family of intravascular micro axial blood pumps that act as temporary ventricular assist devices for the left ventricle (LV), creating flow rates of up to 5.5L/min, depending on the device. The Impella catheter sits across the aortic valve and via an intracorporal pump motor draws blood from the left ventricle (inlet) into the aortic root or ascending aorta (outlet) resulting in left ventricular unloading, reduction in left ventricular work and increase in cardiac power output.

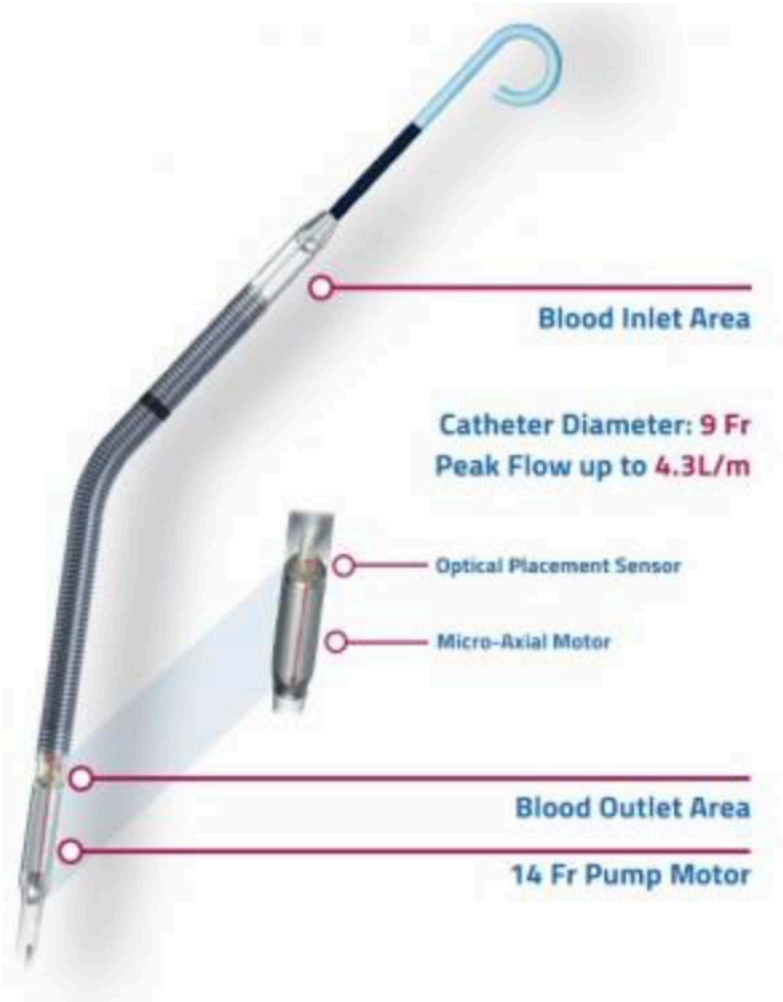


Figure 1: Impella CP with SmartAssist

There are different Impella catheters, however the percutaneously inserted CP catheter, with SmartAssist technology, is the only catheter currently available at the BHI and can deliver flow rates up to 4.3L/min.

The Impella device improves cardiac power output, thereby facilitating organ perfusion in low cardiac output states. It also unloads the left ventricle, with reductions in LV volumes, wall stress and stroke work.

It is approved for use in patients with poor LV function in 2 circumstances:

1.) High risk PCI (constituting complex coronary anatomy and clinically high-risk patients)

2.) Cardiogenic shock due to severe decompensated LV failure (post cardiotomy, post AMI, acute myocarditis, peripartum cardiomyopathy, and other forms of cardiomyopathy with shock that have failed conventional treatment).

The Impella performance is independent of cardiac rhythm (i.e. different from intra-aortic balloon pump), but highly dependent on the LV preload and afterload. In addition, the native cardiac output and pulsatility may be further reduced post Impella insertion (unloading of the native LV) therefore the total cardiac output of the patient may be lower than the sum of native CO pre Impella + Impella flow.

Indications for use

1. To provide **organ perfusion in cases of potentially reversible cardiogenic shock (SCAI grading C or above)* due to left ventricular failure**, regardless of aetiology, in patients who are not maintaining adequate organ perfusion despite optimal conventional management.
See appendix 2 for local "Impella in Shock candidacy assessment"

2. To **prevent cardiogenic shock during high-risk revascularisation procedures** (elective or urgent), usually characterised by two or more of the following:

a.) LVEF<40%
b.) high coronary jeopardy score
c.) increased procedural complexity
d.) potentially long ischaemic times
e.) coexistence of structural cardiac pathology

3. In patients on veno-arterial extracorporeal membrane oxygenation (VA-ECMO) with evidence of LV distension or pulmonary oedema, despite optimal medical management. The aim of the Impella in this setting is to reduce LV distension – reducing the flow to the minimum sufficient level capable of achieving unloading.**

* See the guidelines Cardiogenic Shock Team and Management of Cardiogenic and Mixed shock on Critical Care for further details on cardiogenic shock definition and management.
** VA-ECMO is currently not available at the BHI, however Impella is an accepted tool in this setting and has been included in this SOP in anticipation that it may be required for this purpose in the future.

Contraindications

Absolute Contraindications

1. Moderate to severe aortic stenosis with a valve area of less than 0.6cm2/m2
2. Mechanical aortic valve
3. Mural thrombus in the left ventricle
4. Haematological disorder causing fragility of red blood cells or active haemolysis
5. Significant right ventricular (RV) failure:
   - Raised JVP, peripheral oedema, enlarged tender liver, ascites.
   - Significant RV dysfunction (TAPSE <17mm, raised pulmonary artery pressures) and dilated RV on transthoracic echocardiography.
   - Biochemical markers of liver and renal dysfunction.
6. Cardiac tamponade
7. LV rupture
8. Presence of an atrial or ventricular septal defect
9. Evidence of infective endocarditis

Relative contraindications

1. Any condition precluding anticoagulation
2. Severe peripheral vascular disease that would preclude Impella insertion, or likely cause an ischaemic distal limb.
3. Moderate to severe aortic regurgitation

SECTION 2 – EQUIPMENT

The Impella CP consists of the following components:

Disposables

- *Purge cassette*:
  Integrated infusion pump and pressure transmitter - delivers rinsing fluid through the catheter to prevent blood from entering the Impella motor

- *Introducer Kit*:
  14F peel away introducer and dilator, 8, 10 and 12Fr dilators, 0.035 guidewire.

- *Impella catheter and accessories*:
  Impella CP with SmartAssist catheter, white connector cable, 0.018 placement guidewire (Figure 2).

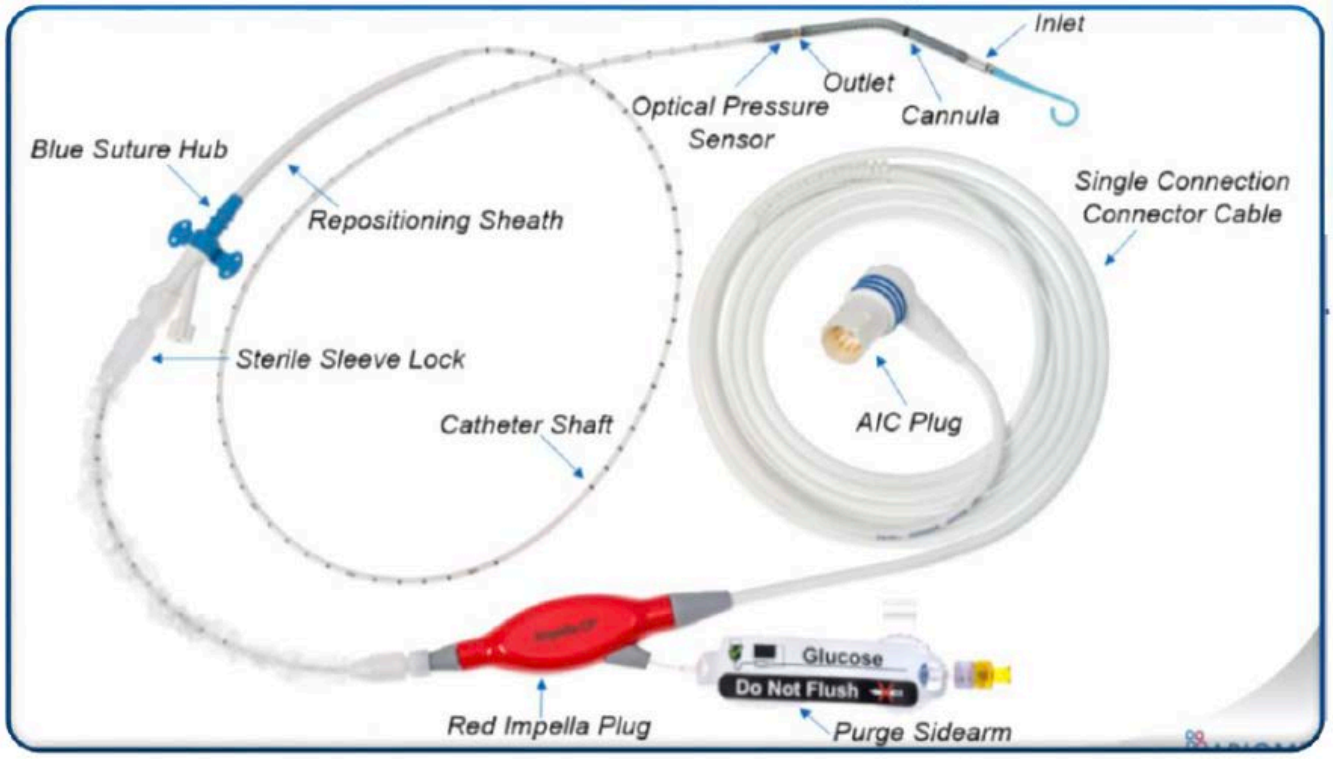


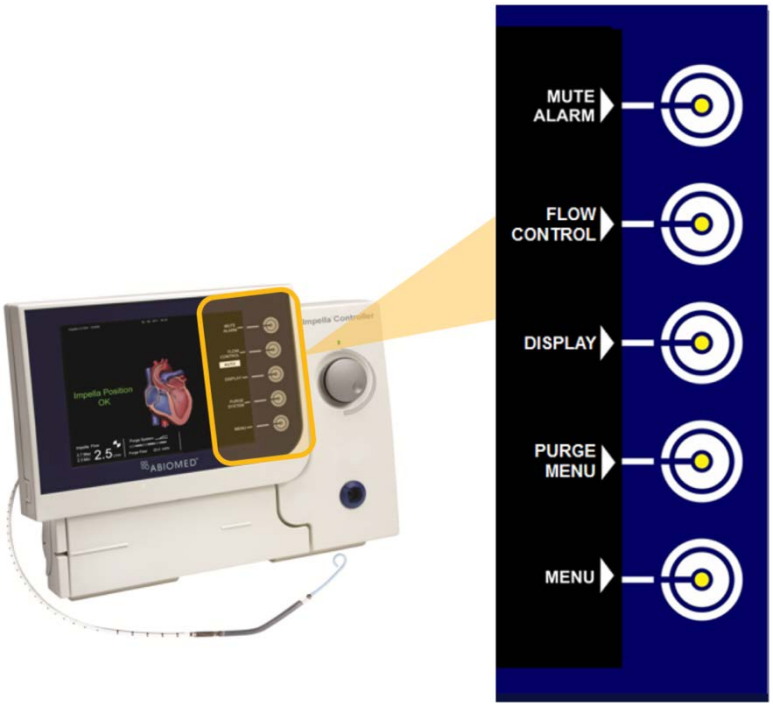
Figure 2: Impella CP with SmartAssist Catheter

Automated Impella Controller (AIC)

The Automated Impella controller (AIC) is the primary user control interface for the Impella catheters (Figure 3). It has automated alarms, controls performance and provides information on catheter position. The controller allows priming, detection of air entrainment and de-airing. It also has an automatic purge system, which adjusts purge pressure to allow constant flow through the device to prevent thrombosis of the micro-axial pump.

Figure 3: Impella Console

Key AIC functions – Soft Buttons:



- **Mute alarm**: silences or clears alarms, for 2mins

- **Flow control**: 0.5 to 4.3L/min via P1-9 levels or AUTO (Figure 4)

- **Display:** opens a menu to select different display screens and change time

- **Purge Menu**: opens purge menu for selecting various purge procedures

- **Menu**: settings, alarm history, data recording, start repositioning guide, case start

The Impella CP with SmartAssist will normally be run on "AUTO" mode, where the desired P-level is set by the clinical team, but then the AIC may adjust the P-level to derive the best flow rate without suction events or pressure alarms. However, it can also be placed in manual mode and the P-level selected by the clinician will be maintained – but there is an increased risk of suction alarms. Manual mode is useful if you are evaluating the effect of changes in preload and afterload on the Impella flow rates – and is required during cardiac arrest and catheter re-positioning as the device must be reduced to P2 until ROSC is achieved.

P-level		*Flow Rate (L/min)	Revolutions Per Minute (rpm)
P-0	Impella CP with SmartAssist Catheter motor is stopped	0.0	0
P-1	Flow rate increases as the P-level increases	0.0 – 0.9	23,000
P-2		1.1 – 2.1	31,000
P-3		1.6 - 2.3	33,000
P-4		2.0 – 2.5	35,000
P-5		2.3 – 2.7	37,000
P-6		2.5 – 2.9	39,000
P-7		2.9 – 3.3	42,000
P-8		3.1 – 3.4	44,000
P-9**		3.3 – 3.7	46,000

Figure 4: P (Performance) levels and likely flow rates with correct position and loading conditions

Placement Screen

The screen displays 3 waveforms (Figure 5), as long as the device is set to P4 or above. At P1-P3, the white LV placement signal waveform will not be displayed:

UPPER BOX: Placement Signal Waveforms

1.) Aortic placement signal waveform – RED waveform

- A display of pressure being measured (via an optical pressure monitor) from close to the outlet area of the cannula
- This should look like a typical arterial line trace, with a normal arterial diastolic pressure.

2.) LV placement signal waveform – WHITE waveform

- A display of a derived pressure (NOT being measured) which estimates to the LV pressures.
- This should look like a typical LV pressure waveform - with a much lower diastolic, but approximately same systolic, pressure as the Aortic placement signal waveform.

LOWER BOX:

3.) Motor Current Waveform – GREEN waveform

- Motor current is a measure of the energy intake of the Impella catheter motor. The energy intake varies with motor speed and the pressure difference between the inlet and outlet areas of the cannula. When the catheter is positioned correctly, the motor current is pulsatile, due to the differing pressure between the inlet and outlet areas throughout the cardiac cycle.

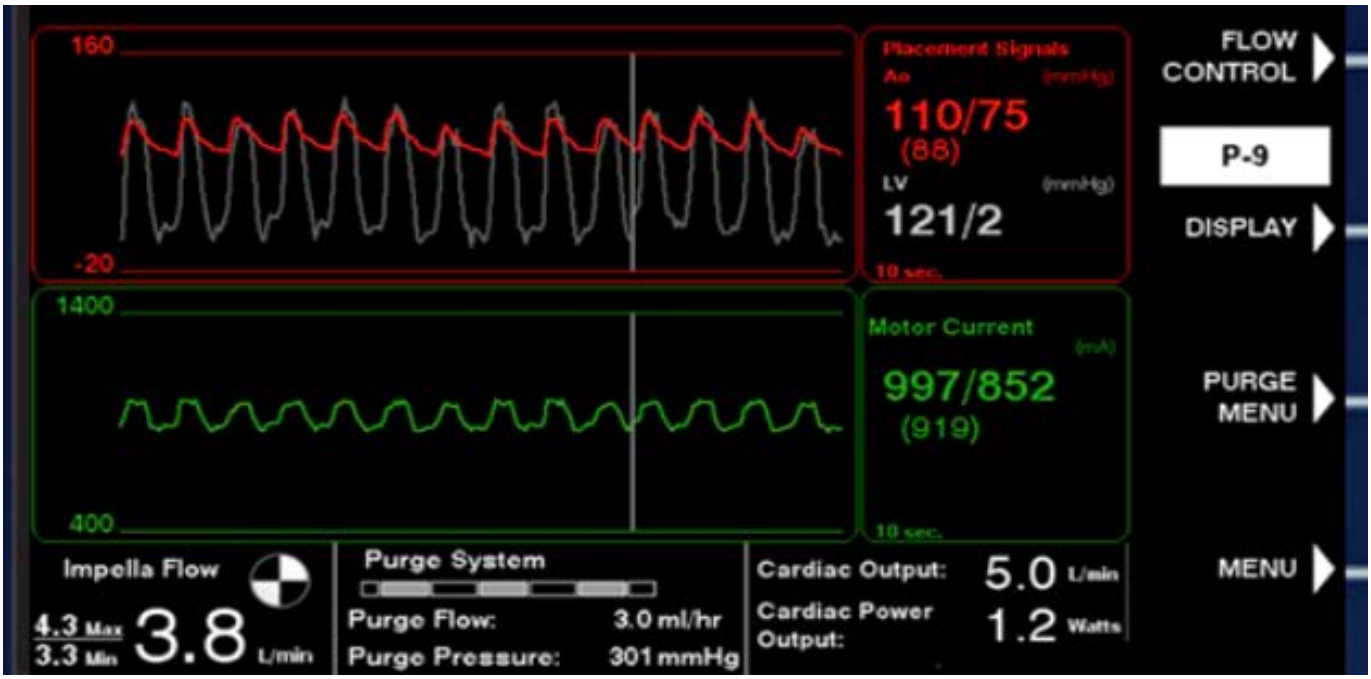
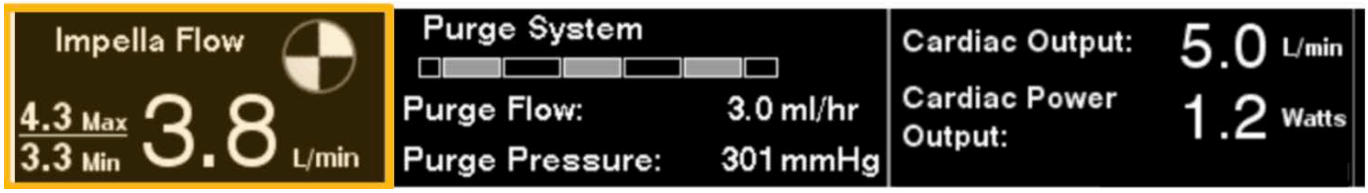


Figure 5: Waveforms on the placement screen

Using a combination of these waveforms, the catheter position can be checked and pressure / cardiac output data can be estimated. The AIC will automatically detect if the waveforms indicate catheter misplacement – and an alarm will sound to alert staff to the need to adjust the Impella catheter position (see section 7 for Common Alarms).

AIC Common Screen Additional elements

The bottom of the AIC screen contains 3 sections:



1.) Impella Flow:

- The large number is the ***average*** flow being achieved from the Impella catheter over the last 10 seconds, at the current P value setting.
- There is also a minimum and maximum flow, which is the highest and lowest flows achieved at the current P value during the same period as the average is calculated.
- This is NOT the exact current Impella flow

2.) Purge system:

- A moving bar shows the purge system is working
- As the AIC automatically adjusts the purge flow to achieve a purge pressure of 300-1100mmHg – the pressure and flow will be different hour to hour, and needs to be recorded in the patients notes.

3.) Cardiac Output (CO) / Cardiac Power Output (CPO):

- If calibrated, this box will provide estimated values of CO and CPO, using an aortic waveform detection algorithm, similar to the PiCCO CCO technology.
- Initial calibration requires values from a separate invasive thermodilution technique (Pulmonary Artery Catheter or PiCCO study) to be inputted. Non-invasive techniques and echocardiography are not valid.
- Re-calibration is required every 24hrs. Once the Impella is in-situ, only a PAC study will give a true estimate of the cardiac output – PiCCO is not accurate.

SECTION 3 – INSERTION

All insertions of Impella catheters are to be performed in the cardiac catheter lab or cardiac theatres by a trained consultant Interventional Cardiologist or Cardiac Surgeon.

Pre-Insertion Considerations:

1.) All patients planned electively for an Impella (either as an inpatient or an outpatient) should be assessed for a history of peripheral vascular disease (PVD). If there is a history of PVD or a history of claudication, CT aortic/iliac/femoral angiogram should be acquired prior to planned device insertion to assess patency of peripheral vessels. This will then allow planning for the appropriate approach to the insertion which may be femoral, subclavian or axillary - the latter two via either a percutaneous or surgical approach.

2.) All patients should have the following blood tests prior to the procedure: full blood count, coagulation screen, renal biochemistry and two sets of group and save.

3.) Baseline echo to ensure there is no significant aortic valve disease or LV thrombus.

4.) If the patient is not a current inpatient, the patient should be admitted to a cardiac ward/CCU the day before the procedure.

5.) Strong consideration needs to be given to having anaesthetic support planned and available from the start of the case, given the high probability of deteriorating cardiogenic shock. Anaesthesia support should be requested via:

- Elective / Semi-Elective case: Cardiac Anaesthesia group, via the CICU consultant.
- Emergency case: General Anaesthesia group (Bleep 3036), or Cardiogenic Shock Team (CST) activation via 2222 if the patient meets the calling criteria.

6.) If the Impella is explanted successfully at the end of the procedure and there are no signs of shock (see Appendix 1 – BHI Ventricular Support Algorithm) the patient should be nursed on CCU, utilising the high-risk bundle.

7.) If the Impella is being inserted for cardiogenic shock, or it is likely to remain in situ after a high-risk PCI, GICU (A600) should be given as much notice as possible, as this is where the patient will be sent post procedure. GICU Consultant referral phone – 27139.

8.) Place a urinary catheter prior to Impella insertion if the device is likely to remain in situ.

Insertion:

1.) Femoral artery access is the standard. Ultrasound guidance is essential.

2.) Femoral angiogram required prior to insertion to ensure no significant PVD that would preclude insertion of a large sheath.

3.) Catheter preparation (Figure 6):

- Prepare the purge solution. There are 2 options – the former is preferred:

  A.) 500mls of dextrose 5% with 12.5mls of 8.4% sodium bicarbonate injected into it.

  B.) 500mls of dextrose 5% with 25IU of heparin per ml (12,500iu of heparin in 500ml bag).

- Using a sterile technique, open Impella kit onto sterile field. Scrubbed assistant hands the purge cassette and spike to physiologist, retaining the luer end.

- If there is a Y-connector on the luer end of the purge kit, remove it.

- Physiologist spikes the purge solution bag and inserts purge cassette into AIC, as indicated on screen

- Auto setup will start. Follow on screen commands

- Insert the white cable into the AIC when instructed

- When prompted, sterile person connects luer of purge cassette to purge sidearm of the Impella catheter

- Scrubbed assistant squeezes white clamp when indicated on AIC, to prime the pump.

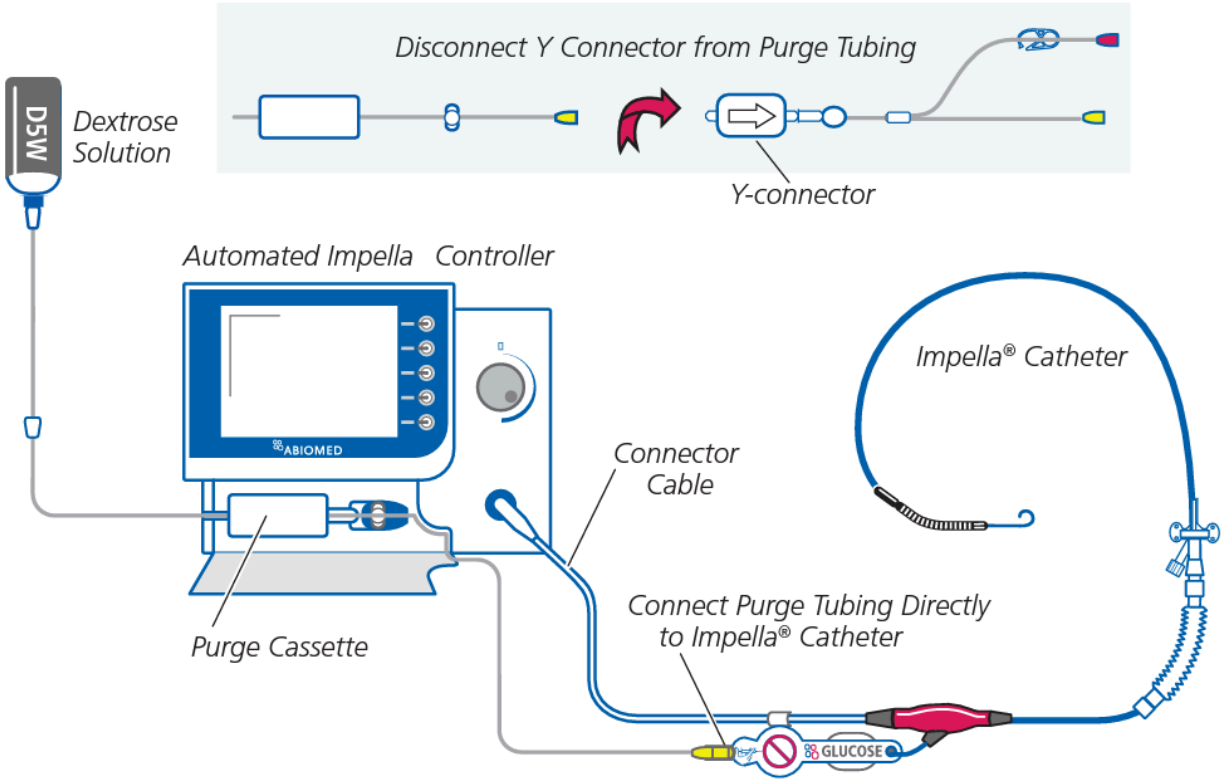


Figure 6: Impella CP with SmartAssist catheter preparation

4.) Insert 14Fr sheath via Seldinger technique (may require pre-dilation with smaller dilators provided) and administer heparin bolus before Impella device is inserted (70 units per kg, to achieve an activated clotting time (ACT) of >250 seconds at the time of dilator removal and Impella insertion). Note if device being used at the time of PCI only, a vascular closure device should be deployed prior to Impella insertion. If there is a likelihood of the device remaining in post procedure no closure device should be used.

5.) Remove stiff 0.035 guide wire used to insert sheath. Insert an AL-1 or multi-purpose catheter or pigtail catheter over a standard 0.035 guide wire into the LV using fluoroscopy, remove the guide wire and insert the 0.018 guide wire into the LV via the catheter. Remove diagnostic catheter.

6.) Load Impella catheter on the placement guidewire through the lumen in the temporary red plastic tube as indicated. Once loaded, advance into the LV using fluoroscopy. In emergent situations, the Impella can be inserted directly into the LV, without the need for a 0.018 guide wire.

7.) Ensure the pigtail and inlet are in the LV, and the outlet in the aorta.

8.) Start Impella after guidewire removed. AUTO will be the starting setting.

9.) Ensure any slack is removed from the catheter.

10.) Check motor current and pressure signals are adequate. Document position after insertion both at catheter shaft and using fluoroscopy. A well-positioned Impella catheter is one that is stable and does not migrate, produces unobstructed flow, the outflow is well above aortic valve and the device free from the anterior leaflet of the mitral valve.

11.) To reduce the risk of ischaemic limb complications, the peel-away 14F sheath can be removed and swapped to the repositioning sheath. The decision about exchanging the 14F sheath to the repositioning sheath is at the discretion of the operator. We would advise keeping the 14F sheath in if the device is only planned to be in for the procedure (and a vascular closure device is used) or for a short period afterwards (or if there may be a need to upgrade to ECMO), given the risks of bleeding with the repositioning sheath and need for vessel access for the closure devices.

12.) If a decision is made to swap to repositioning sheath this can be done as follows:

- Place pressure above sheath on femoral artery.
- Remove 14F sheath completely out of the groin before peeling.
- Peel away the 14F sheath and advance the tapered repositioning sheath (which comes preloaded on the catheter).
- Attach and securely tighten Tuohy Borst adapter, suture wings to skin.

13.) After procedure, secure catheter with sutures and tegaderm and document the position of the device at the sheath entry point. To reduce bleeding from the Impella sheath entry point when using the repositioning sheath, gauze can be placed underneath the repositioning sheath to apply a larger angle from the skin. A femstop device can also be applied with light pressure over the exit site.

14.) A screening echocardiogram should be performed prior to leaving the cath lab to document device position in the LV.

15.) If there is ongoing haemodynamic instability and/or a need for prolonged support, the insertion of an arterial line +/- CVC should be performed prior to transfer to ICU. If inserting a CVC, this would ideally be in the left internal jugular vein, to avoid vessels needed for potential PAC and ECMO cannula insertion.

16.) Pre-transfer to ICU, the purge fluid should be changed to the bicarbonate solution, if the heparin solution has been used in the cath lab (500mls of dextrose 5% with 12.5mls of 8.4% sodium bicarbonate injected into it).

For further education on insertion, visit the Abiomed website:

https://www.heartrecovery.com/education/education-library/qsv-impella-cp-with-smartassist-setup-procedure

SECTION 4 - STAFFING

Physicians

The Impella clinical service is led by the Interventional Cardiology Consultants, with input from the ICU/ ECMO consultant when used for shock.

The interventional cardiology consultants provide:

- Assessment of and decisions regarding all patients referred for Impella at the BHI
- Insertion and optimal placement
- Daily review of all Impella patients (by CCU consultant or interventional consultant)
- Medical reference for ICU staff
- Involvement in all key decision-making (e.g. weaning, withdrawal of therapy, bleeding management)
- Supervision of trainees

The on-call cardiology SpR (Ext #6527) is on site 24 hours a day for immediate assistance and advice. They can provide assistance with echocardiography out of hours for positioning and make small adjustments with echo guidance if required.

Nursing Cover

On ICU, patients with an Impella in-situ will be considered Level 3, with a 1:1 nursing ratio.

The nurse in charge (NIC) or deputy nurse in charge (DNIC) will have primary responsibility for the nursing management of the Impella – and must have completed training on the device.

Ideally the bedside nurse would also have completed training on the Impella, but if they have not then assistance should be sought from the NIC / DNIC if there are concerns with the Impella device or management principles.

Cardiac Physiologists

Assistance with insertions, removals and patient transfers will be provided during weekday hours by the cardiac physiologists. They can be contacted through the cardiac catheter laboratory.

Out of hours support will be provided by the interventional cardiac physiologist, through switchboard or the cardiology SpR on call.

Further Trouble-shooting

Please contact, in this order:

a.) The on-call cardiology registrar – Ext: #6527
b.) The cardiac physiologist (via switchboard if out of hours, or in the cath labs if in-hours)
c.) The Interventional Cardiology consultant (via switchboard).
d.) The Abiomed helpline - 001-800-422-8666 - 24 hours a day

SECTION 5 – MANAGEMENT OF PATIENTS ON IMPELLA IN ICU

ICU check-in from the catheter laboratory

1.) Ensure spare purge cassette is brought with the patient.

2.) A trans-thoracic echocardiogram is required to check position following transfer. See Appendix 2 for details – most importantly the edge of the distal stainless steel bead, where the inlet is, should be 3.5cm from the aortic valve annulus. TTE should be performed by:

- ICU physician competent in TTE: At anytime
- Cardiology SpR (Ext #6527): 1700-0900 weekdays and all weekend
- Echocardiographer: 0900-1700 Monday-Friday

3.) Document position of Impella (in cm) at the sheath hub using the graduations on the catheter shaft after transfer of patient from trolley to bed.

4.) Ensure adequate preload (PCWP >10 if available, no suction alarms on Impella)

5.) Check and document colour of the limb distal to the Impella insertion point, peripheral pulses manually and with Doppler.

6.) At 4 hours post ICU admission, perform a TEG, to determine the TEG-ACT. If the TEG-ACT is >160, continue to perform TEGs every 4 hours until it is <160.

7.) Once TEG-ACT is 160 or lower, start a heparin infusion (without bolus) as per the ECMO guidelines (target Anti-Xa 0.3-0.5).

8.) Check and document colour of urine looking for presence of haemolysis.

9.) If patient is moving, leg immobilisation with a knee brace should be strongly considered.

Ongoing Care

All patients with an Impella in-situ require:

- Standard critical care monitoring including:
  - Central arterial line (a PiCCO is NOT required and will not function correctly).
  - CVC
  - Strong consideration should be given to inserting a Pulmonary artery catheter, ideally with continuous cardiac output capabilities.
- Daily screening echocardiography to assess Impella position and LV function.
- Daily ICU bloods including LDH, plasma free haemoglobin and fibrinogen levels.
- Daily review by the ECMO consultant

- Anticoagulation with unfractionated heparin infusion, as per the ECMO guidelines.
  - Target Anti-Xa of 0.3-0.5.
  - Anti-Xa levels should be sent at a minimum of every 6 hours.

- Access site management- regular assessment of access site for bleeding /sheath position.

- Knee immobilser where required – the leg with the Impella in-situ must stay straight at the knee, although the patient may be flexed at the hip to a maximum of 30 degrees.

Specific Nursing Management

- Hourly monitoring and documentation of Impella flow rates, purge pressure, purge fluid rate and placement signal from the AIC screen.
  - Add the CIS "Impella" row group on Phillips ICCA.

- Hourly assessment of limb, monitoring of pedal pulses manually and with doppler.

- Hourly assessment of access site for haematoma and bleeding.

- 4-Hourly monitoring of Impella position on catheter shaft.

- Impella position should also be checked using the AIC waveform screen after each re-positioning of patient.

- Do not raise the head of the bed to higher than a 30-degree angle.

- To prevent the purge tubing from kinking, do not allow the red Impella plug to hang freely from the catheter and do not bend the catheter near the red Impella plug.

- Safety checks at the start of each shift:
  - Impella console plugged into mains and the UPS plug
  - Backup console available in cath lab
  - Impella cart in secure place and brake is engaged
  - Ensure Tuohy-Borst adapter is tight and secure

Key tips:

- Suction alarms and position alarms indicate less ideal support and may be a precursor for haemolysis. In the event of suspected haemolysis (plasma free Hb >0.5) - reduce Impella flow rate and assess for position of the Impella catheter.

- In the event of major bleeding complications, it is likely that heparin will need to be discontinued. Given the device's position in the LV there is a high risk of thrombus formation with subsequent embolic phenomena and device failure. A decision to discontinue heparin and device removal should be made by the treating cardiologist and intensive care consultant in combination.

- If a patient requires ongoing Impella support but is not tolerating lying flat/agitated/confused there should be a low threshold for providing sedation and invasive ventilation to facilitate the optimal Impella device function.

- In the event of cardiac arrest, Impella support should continue, but flow rates should be reduced down to P2. Following return of spontaneous circulation position of the Impella should be checked with echo and if adequate position is confirmed, the P level can be returned to the previous support level. Defibrillation is safe during Impella support.

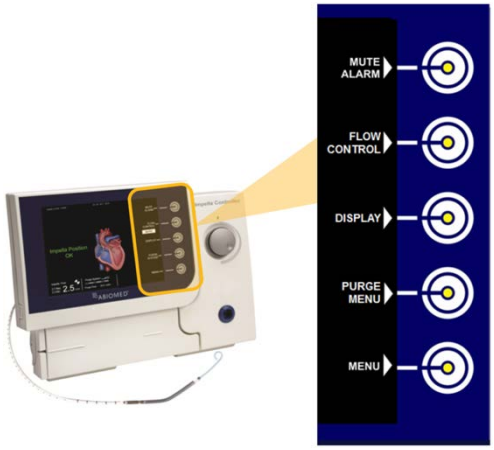
Changing the purge fluid:

ICU nurses are expected to change the purge fluid. If required, changing the purge cassette is the responsibility of the cath lab physiologist team.

1.) ***Prepare a new bag of purge solution.***

Standard is:
500mls 5% glucose
+
12.5mls 8.4% sodium bicarbonate

2.) ***Select "Purge Menu" using soft buttons***



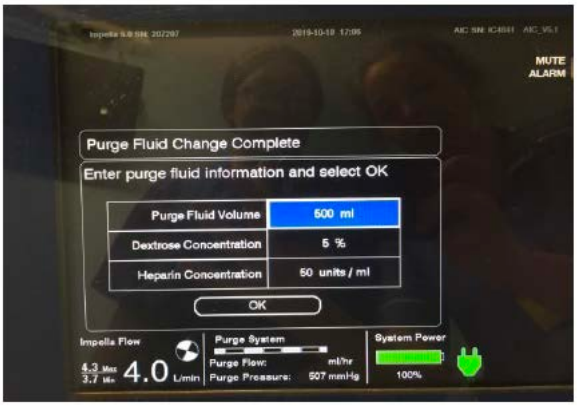
3.) Select "Change purge fluid" using dial

4.) Select "OK" to bolus purge fluid using dial

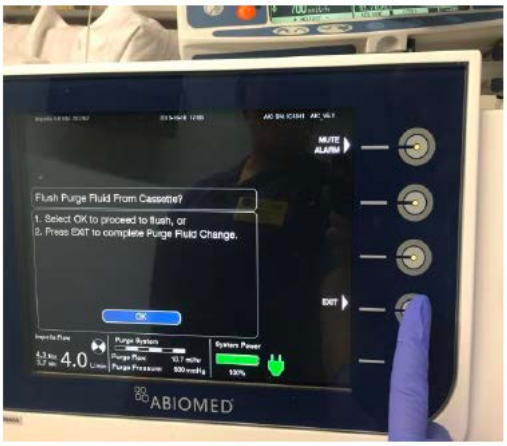
5.) Change purge fluid

6.) Select "OK" to confirm bag change using dial.

7.) Ensure purge fluid information is correct. Select OK to confirm using dial. If bag concentration changes, enter the appropriate concentration



8.) Press "EXIT" to complete purge fluid change



SECTION 6 – ESCALATION

ALL patients having an Impella device inserted, regardless of indication, should:

a.) ***Have a ReSPECT form completed***, documenting their escalation status

b.) ***Be appropriate for escalation to ICU level of care***:
- There may be limits placed on the escalation of organ supports (both type and duration), but all patients should be eligible for admission for the basic level of ICU care (vasoactive medications and NIV/HFNC).
- If there is concern about whether this level of escalation is appropriate (i.e. due to significant co-morbidities, frailty, advancing age, poor physiological reserve etc) then the patient should be discussed with the GICU Consultant BEFORE the case is started / Impella inserted.

c.) Have a ***clearly documented plan for Mechanical Circulatory Support escalation,*** should the Impella not improve the shocked state. See below re options for escalation. This plan should include:
- Whether escalation is appropriate
- What physiological variables would be considered to constitute "failure"
- The persons involved in these discussions

IMPELLA INSERTED FOR CARDIOGENIC SHOCK

Despite the Impella device, cardiogenic shock may not improve or continue to worsen. In these instances, it should be confirmed that the device is performing optimally. Position should be checked and the device P level, as well as patient pre- and afterload optimised, Conventional management should also be optimised (see Management of Cardiogenic and Mixed shock on Critical Care). If despite this the shock state does not improve, it may be due to:

1.) Right Heart (RH) Failure

Impella CP Smart-Assist only provides left sided heart support. Right heart failure can lead to issues with the Impella such as reduced output and suction alarms. The patient may have clinical signs of right heart failure (elevated filling pressures, signs of liver failure, elevated pulmonary pressures) or evidence on echo. Conventional right heart failure therapies (inodilators, nitric oxide, invasive ventilation optimisation etc.) should be tried in the first instance to try to improve the RH function.

2.) Inadequate LV support

The Impella CP with SmartAssist device may not be able to provide the required total cardiac output to reverse shock. This is more likely if there is low intrinsic cardiac output, or if the Impella device can only be run on a low P setting. This will be noted by the ongoing abnormality of standard shock indices, despite optimal Impella function and conventional management.

In these instances, escalation to a different mechanical circulatory support (MCS) system is required.

The only potential option currently available in the BHI is VA-ECMO. However, combined RP and CP Impella devices, termed “Bi-Pella” (for biventricular support) or escalation to the Impella 5.5 (for improved LV support) may also be considered. Appropriateness for destination therapy should also be considered. The decision about whether the patient is suitable for escalation to other mechanical support devices should be discussed PRIOR to the Impella insertion and should locally include:

1.) Interventional Cardiologist
2.) GICU / CICU Consultant
3.) Bristol ECMO Consultant

If the patient is considered locally to potentially be appropriate for escalation – the BRISTOL ECMO consultant should liaise with the Brompton (RBH) ECMO consultant and the Harefield hospital ICU / transplant teams (via the ECMO network). If required, a SHOCK call with members from all hospitals will be set up.

The aim of a SHOCK call is to produce an individualised patient plan for optimal conventional management – as well as when and how MCS would be escalated, and to which device. It should also consider the best location for the patient to be cared in. Any patient requiring escalation of MCS from Impella will need transfer to a different centre for ongoing care, either before or after MCS device escalation.

SECTION 7 – WEANING AND REMOVAL

Progress should be re-evaluated several times per day.

In those patients with improving haemodynamics and markers of end organ perfusion, the Impella can be weaned. Ideally inotropic support should be weaned prior to weaning the Impella flow, but does not need to be completely stopped.

Weaning Instructions:

1.) Reduce P-level by 2 level increments over time intervals as haemodynamics and cardiac function allow. *NOTE: Below P4, the white LV placement signal waveform will disappear – this is normal and does not indicate Impella catheter malposition*

2.) Reassessment after each P-level reduction is vital, including performing:

- Mixed venous and arterial blood gases at least 30 minutes after each reduction.
- Cardiac output studies – observe the PAC-CCO, or perform thermodilution injection on intermittent PAC at 30 minutes post P-level reduction
- Utilise the trends screen on the AIC to see the correlation between P-level support and MAP / LVEDP / CO (Figure 9)

3.) Evidence of weaning failure is shown by any of:
- Arterial lactate >2mmol/L
- ScvO2 (venous saturation) <60%
- Cardiac Index < 2.2 L/min
- A rise in pulmonary artery pressures (PCWP or PADP >18mmHg is concerning)
- A combination of rise in LVEDP, fall in MAP and fall in native CO on the AIC screen.

If weaning failure is evident - increase the support back to the previous level.

If the wean is tolerated, do not reduce to less than P2 until the catheter is ready to be removed.

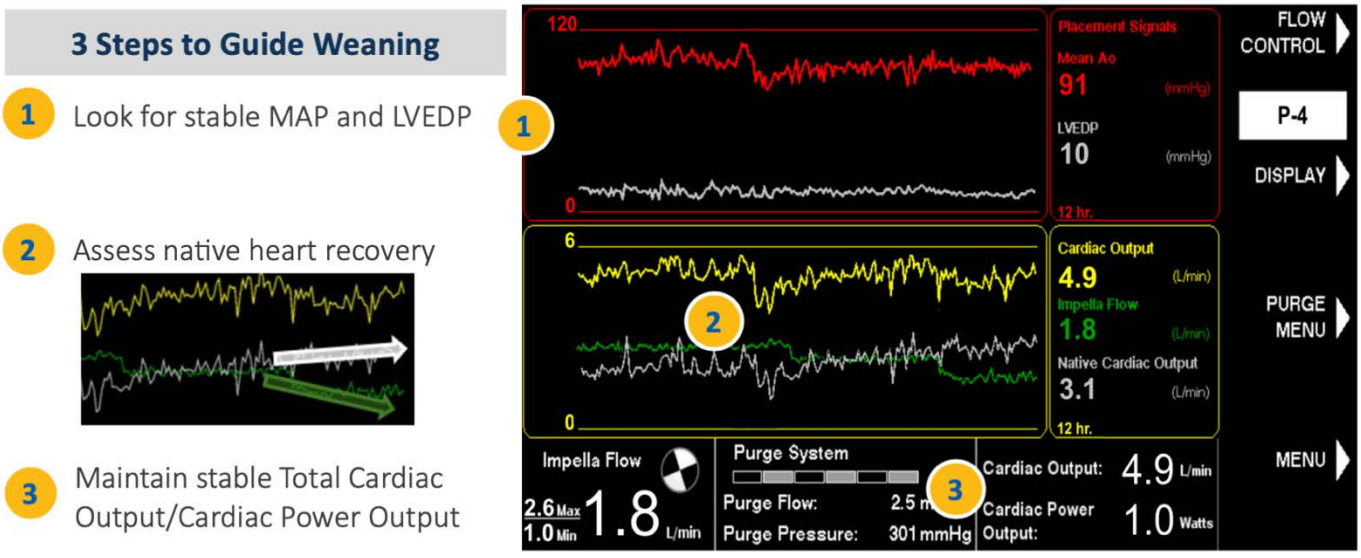


Figure 9 – Weaning utilising metrics from the AIC trends screen

Removal Instructions:

The decision to remove the device and the process to follow should be guided by the interventional cardiology consultant. A senior medic from either the cardiology or ICU team should be primarily in charge of removing the device and should not leave the patient's bedside until haemostasis has been confirmed.

1.) When the decision to remove the device is made, reduce the P-level to P1 and pull the Impella catheter back across the aortic valve.

2.) In the cath lab (with the introducer sheath still in situ):

- With the 14F introducer sheath in place switch the Impella off and remove the catheter through the introducer.
- Stop the heparin, and monitor the ACT. Once below 150s remove the 14F sheath.
- Groin management depends on use of closure devices and hospital protocol.

In ICU (with the repositioning sheath):

- Stop the heparin and perform a TEG at 2hrs.
- Wait until the TEG-ACT is <150s – continue to repeat the TEG 2 hourly until this is the case.
- At this stage switch Impella off and remove both the catheter and repositioning sheath together.
- Apply manual pressure initially for 15 minutes, followed by a femstop.

If there are any concerns regarding haemostasis, the vascular team on call (based at NBT) should be contacted for assistance in removal.

Weaning during VA-ECMO

ECMO, interventional and imaging cardiology consultants together will make the decision about weaning of both the ECMO and Impella device flows. This is related to assessment of native contractility/output, LV size, reduction in pulmonary congestion and overall haemodynamics. It a complex balance, with individual assessment required at multiple time points.

The Impella should be removed in theatres with primary vascular repair of the vessel for all patients on ECMO – and with the heparin anti-coagulation still running.

SECTION 8 – COMPLICATIONS AND COMMON ALARMS

If an alarm sounds, in the first instance it is the bedside nurse, NIC/DNIC and ICU medical staff responsibility to review the AIC and follow the instructions to address the problem.

If the Impella AIC continues to alarm, despite following the console screen tips, the cardiology team will need to be contacted in this order:

a.) The on-call cardiology registrar – Ext: #6527
b.) The cardiac physiologist (via switchboard if out of hours, or in the cath labs if in-hours)
c.) The Interventional Cardiology consultant (via switchboard).
d.) The Abiomed helpline - 001-800-422-8666 - 24 hours a day

The AIC continuously monitors the catheter based on placement signals and motor current. There are three alarm levels, white (advisory), yellow (serious), and red (critical).

Purge Alarms

Purge pressure must always be greater than systolic blood pressure. The purge system delivers rinsing fluid to the Impella pump motor and prevents blood from entering it. The purge fluid usually consists of a 500ml 5% dextrose bag with either 12.5mls 8.4% sodium bicarbonate/500mls, or 25 units per ml of heparin. The purge flow is usually 2-30ml/hr with a pressure of 300-1100mmHg.

Purge pressure low (red alarm):

If purge pressure <300mmHg and flow greater than 30ml/hr, alarm will trigger.

1.) Check for leaks and or loose connections along the whole of the purge cassette and line, including making sure the yellow luer lock is connected and secure to the purge sidearm.
2.) Consider changing the purge fluid to a higher dextrose concentration (dextrose 10-20%) (through “Purge menu” soft key select “Change purge fluid”).
3.) If despite changing the purge fluid the alarm continues for 20 minutes, change the purge cassette.
4.) If continued alarm despite above, need to consider changing the Impella catheter

Purge flow low or purge system blocked (red alarm):

1.) Check for kinks in tubing.
2.) Ensure Tuohy Borst on the repositioning sheath is not too tight.
3.) Monitor motor current for any upward trends.
4.) Consider replacing Impella catheter.

Purge System Open alarm:

May occur if purge pressure is less than 100mmHg.

1.) Inspect purge system for leaks.
2.) If no leaks, replace purge cassette.
3.) If alarm continues, will need to consider replacing the Impella catheter.

High Purge Pressure with Purge Flow Low alarm

This occurs if the purge pressure exceeds 1100mmHg.

1.) Inspect the purge system for any kinks in the tubing.
2.) If pressure remains high decrease the concentration of the dextrose in the purge fluid.
3.) Motor current should be monitored. If dampening of signal or persistent alarms, the Impella catheter should be replaced.

Purge System Blocked Alarm

1. Check Purge System tubing and Impella catheter for kinks.
2. Decrease the concentration of dextrose in purge fluid
3. Replace the purge cassette.

Position Alarms

Good Impella position is key in preventing complications and maximizing device function. If there is an incorrect position as described below, this may be accompanied by haemolysis.

Incorrect positions are often picked up automatically by the AIC, utilising the placement and motor current waveforms. Even if an alarm has not been activated – reviewing the waveforms can tell you if the catheter position may be incorrect. It is important to review the waveforms after each patient position change.

Impella Position in Ventricle (red alarm):

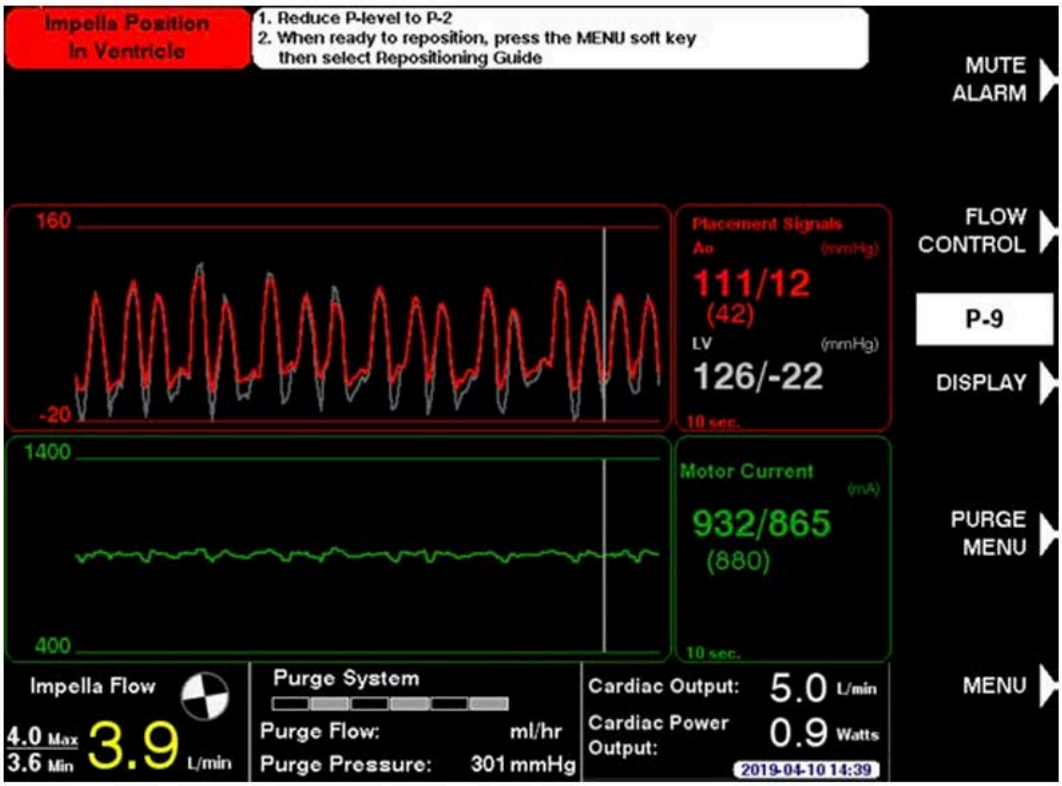


Figure 10 – Waveforms seen in ventricular placement of the Impella Catheter

- Inflow, outflow and open pressure lumen are all in LV.
- Therefore, the aortic and LV placement signals will be almost identical with a LOW diastolic pressure (both will look like an LV trace)
- The motor current waveform is flattened and less pulsatile

1.) Contact Cardiology SpR on call for catheter re-positioning.
2.) Minor adjustments can be performed on ICU. Before re-positioning P level needs to be reduced to P-2. Repositioning can be done with:
   a.) Echo guidance (See Appendix 2)
   b.) The AIC Repositioning guide – Select "MENU" softkey and then select "Repositioning guide" and follow the instructions on the screen.
3.) If unsuccessful the patient should be brought back to the cath lab for re-positioning under fluoroscopic guidance.
4.) The interventional cardiology consultant on call must be informed any time an Impella needs to be repositioned.

Impella Position in Aorta (red alarm):

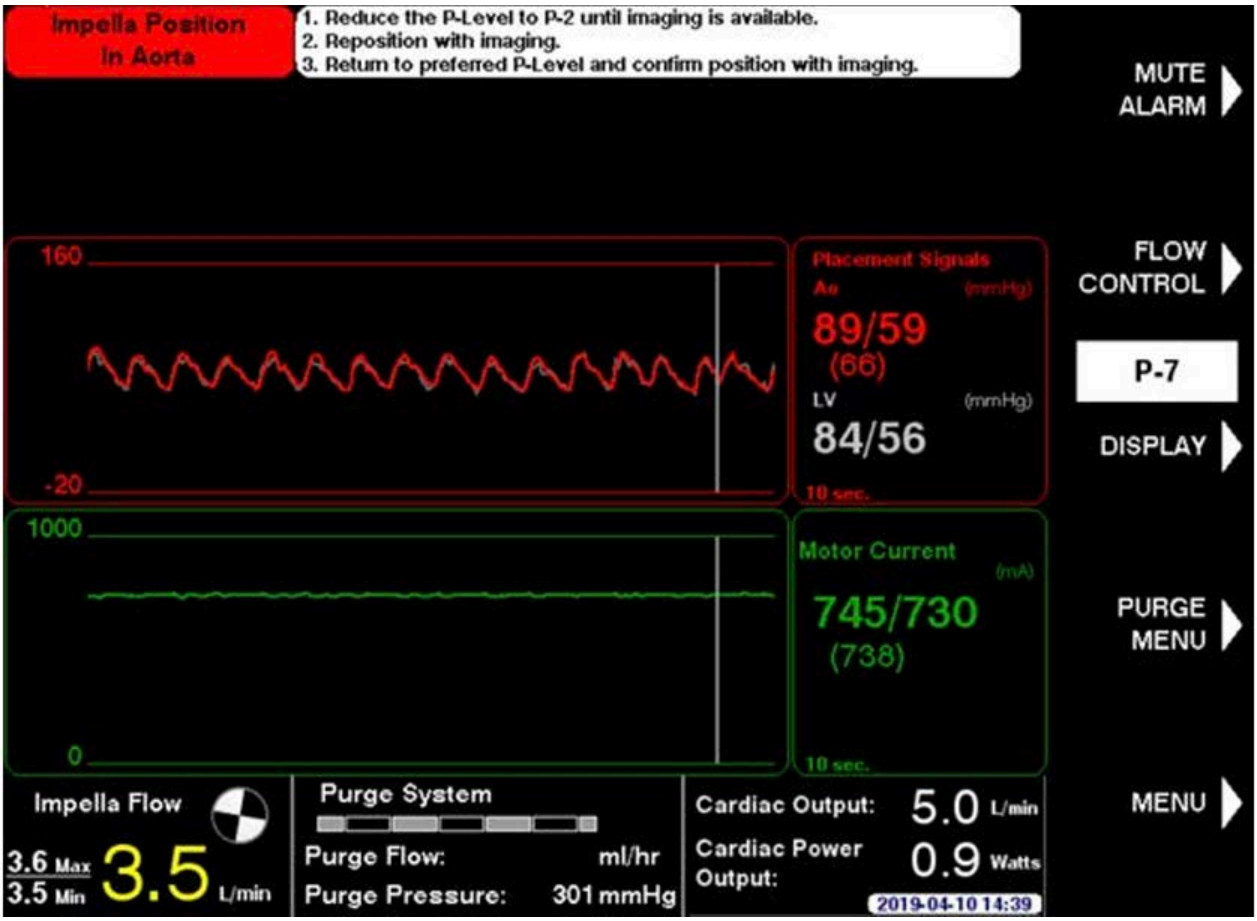


Figure 11 – Waveforms seen in aortic placement of the Impella Catheter

- Inflow, outflow and open pressure lumen are all in aorta.
- Therefore, the aortic and LV placement signals will be almost identical with a HIGH diastolic pressure (both will look like an arterial line trace)
- The motor current waveform is flattened and less pulsatile
- The position of the pigtail could either be still in the ventricle, or also in the aorta

1.) Reduce the P level to P-2.
2.) Contact Cardiology SpR on call for echocardiogram to determine catheter position.
3.) If the pigtail is:

a.) ***IN THE AORTA*** – the patient will need to return to the cath labs for re-insertion of the Impella catheter into the ventricle over a stiff wire.

b.) ***IN THE VENTRICLE*** – Impella repositioning can be performed under echocardiographic guidance on the ICU in the first instance (see Appendix 2). If this is unsuccessful the patient should return to the cath labs for fluoroscopic guided repositioning.

4.) The interventional cardiology consultant on call must be informed any time an Impella needs to be repositioned.

Impella Position Unknown (red alarm)

Caused by low native heart pulsatility.

- The placement waveform signals (either aortic or LV) pulse pressure is narrowed to <20mmHg.
- The motor current remains pulsatile but dampened.

Management: Reassess patients LV contractility and Impella position with echocardiography.

Placement Signal Low (red alarm)

If the inflow and outflow areas are in the LV (i.e. the Impella device is too deep in the LV), but the open pressure area remains in the aortic root close to the aortic valve, the waveforms will show:

- Correct aortic and LV placement signals
- A dampened and less pulsatile motor current waveform.

Management: Echocardiographic confirmation of the Impella position – with manipulation as per “Impella position in ventricle” alarm.

Flow/Suction Alarms

Suction may occur if the blood volume is inadequate for the Impella catheter. Suction limits the amount of support that the Impella Catheter can provide to the patient and results in a decrease in arterial pressure and cardiac output. It can also lead to haemolysis. These alarms can also occur when the patient is developing right heart failure.

If the AIC detects suction while running in AUTO mode, it automatically reduces the motor speed to a lower flow rate to resolve the suction and displays an ‘Impella Flow Reduced’ advisory alarm. If the suction is cleared, the controller will return to the flow rate of the desired setting. If suction is still detected at lowest motor speed the AIC will display the ‘suction’ alarm. In the manual configuration, any suction will require adjustment of the P-level by the clinical team.

General Management Steps:

1.) Reduce P-level by 1 or 2 steps.
2.) Assess patient's volume status and trial a small fluid bolus (250mls crystalloid)
3.) Check Impella position with echocardiography and reposition if needed.
4.) Review RV function by assessing CVP/PAPs and via echo – and instigate RV failure treatments as required.
5.) Once resolved, return P-level to pre alarm settings.

If the AIC detects suction or low flows at start up:

1.) If clot entrainment is suspected, the Impella catheter will need to be removed and have the inflow, cannula and outflow gently flushed looking for thrombus.
2.) Check ACT above 250.
3.) Before re insertion, test the Impella catheter in a basin of clean sterile water.
4.) Exclude LV thrombus prior to re-insertion of the Impella catheter using echocardiography.

Haemolysis

Clinical signs include red or dark brown urine, jaundice and renal failure.
Results in raised bilirubin and LDH and these should be tested for.
Check plasma free haemoglobin - clinically significant haemolysis defined as a plasma free Hb >0.5g/L.

Treatment:

- Rule out non-device related causes
- Check volume status/preload.
- Check Impella position
- If haemolysis persists despite above measures, device removal will need to be considered.

Heparin Induced Thrombocytopenia (HIT)

Once this is diagnosed, the purge fluid MUST be changed to the sodium bicarbonate containing bag if the heparin containing bag is being used.

All other management should be as per the UHBW clinical guideline on HIT – including changing the peripheral anticoagulation to a direct thrombin inhibitor such as argatroban.

SECTION 9 – TRAINING

Initial training and the maintenance of professional skills are essential. A training record will be held by:

- Each member of staff
- Lead interventional cardiologist for percutaneous mechanical circulatory support (cath lab and cardiology staff).
- CICU / GICU PEF teams (ICU nursing staff)
- Lead ECMO nurse specialist (ECMO nurse specialists)
- Chief Perfusionist (Perfusionists)
- Lead consultant intensivist for cardiogenic shock (CICU/GICU medical staff /ACCPs).

Nursing

Initial training:

1.) Abiomed Online Training Course:
   a.) Access the Abiomed Academy: (https://abiomedloop.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=221000308)
   b.) Complete the "***Impella CP with SmartAssist Patient Management - online training programme***".
   c.) Complete the “quiz” at the end and send the certificate to the respective PEF team (CICU/GICU) or the Lead ENS.
2.) In-person training session with Abiomed rep

Ongoing training:

- Online training courses via Abiomed Academy (https://abiomedloop.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=221000308)
- Lectures at BHI / BRI
- Repeat in-person training with Abiomed reps as required to maintain individual competence

Physicians / ACCPs / Perfusion:

Initial training:

1.) Abiomed Online Training Course:
   a.) Access the Abiomed Academy: (https://abiomedloop.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=221000308)
   b.) Complete the "***Impella CP with SmartAssist Patient Management - online training programme***".
   c.) Complete the “quiz” at the end and send the certificate to:
      - For ICU: Matt Govier (matthew.govier@UHBW.nhs.uk)
      - For Cardiology: Julian Strange (julian.strange@UHBW.nhs.uk)
      - For Perfusion: Will Lansdowne (William.lansdowne@UHBW.nhs.uk)

2.) In-person training session with Abiomed rep

Ongoing training:

- Online training courses via Abiomed Academy (https://abiomedloop.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=221000308)
- Lectures at BHI/BRI
- Repeat in-person training with Abiomed reps as required to maintain individual competence

Cardiology SpR:

Initial training:

1.) Training session delivered by Abiomed reps at annual SpR induction.
2.) Abiomed Online Training Course:
    a.) Access the Abiomed Academy: (https://abiomedloop.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=221000308)
    b.) Complete the "***Impella CP with SmartAssist Patient Management - online training programme***".
    c.) Complete the "quiz" at the end and send the certificate to Julian Strange (julian.strange@UHBW.nhs.uk)
3.) In-person training session with Abiomed rep
4.) Attendance at cases where possible in the cath lab

Ongoing training:

- Online training courses via Abiomed Academy (https://abiomedloop.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=221000308)
- Lectures at BHI/BRI
- Repeat in-person training with Abiomed reps as required to maintain individual competence

Other

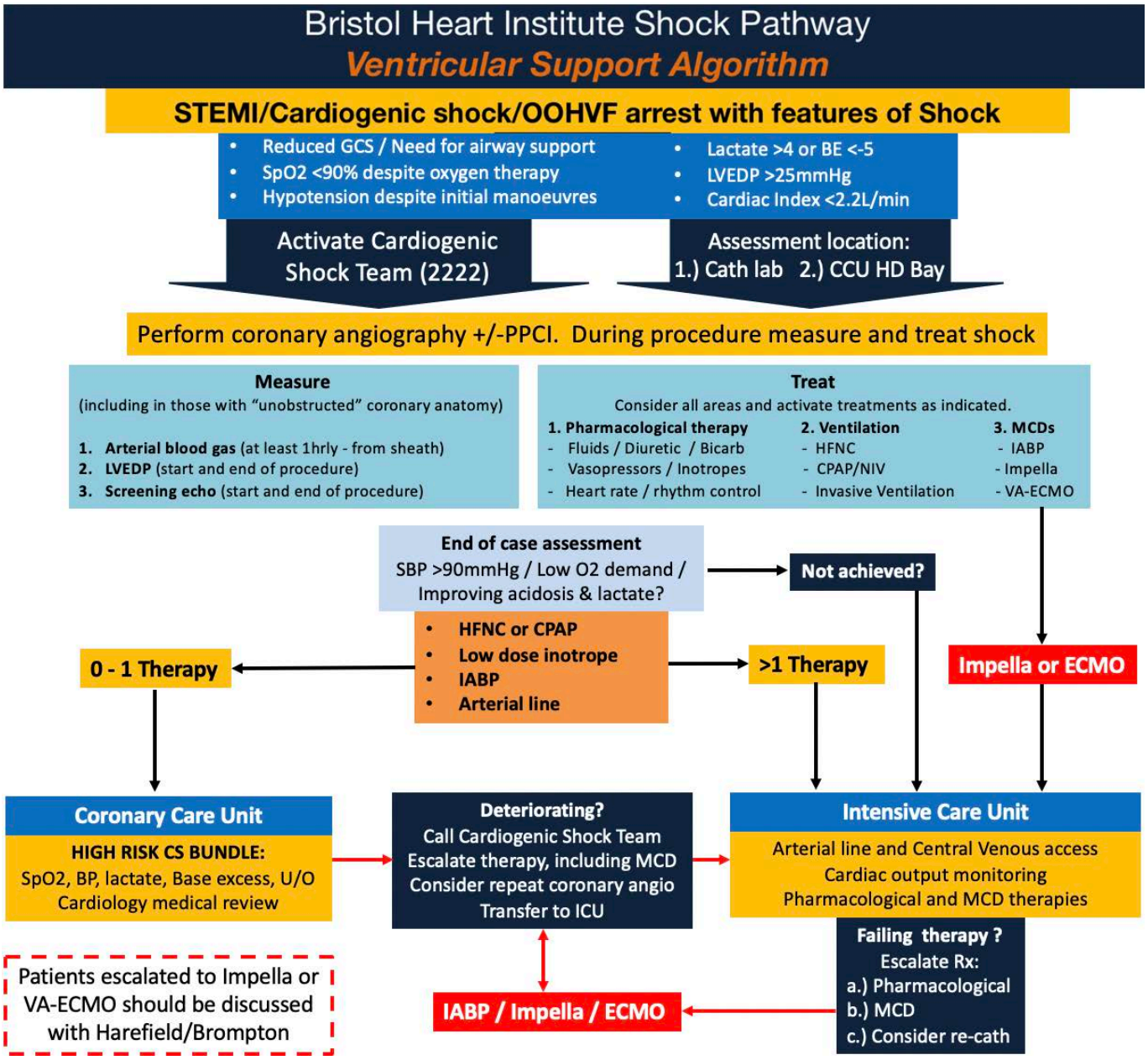
There is an Abiomed Impella app available to download from the App store, which provides information on set up, insertion, management and troubleshooting.

Abiomed support

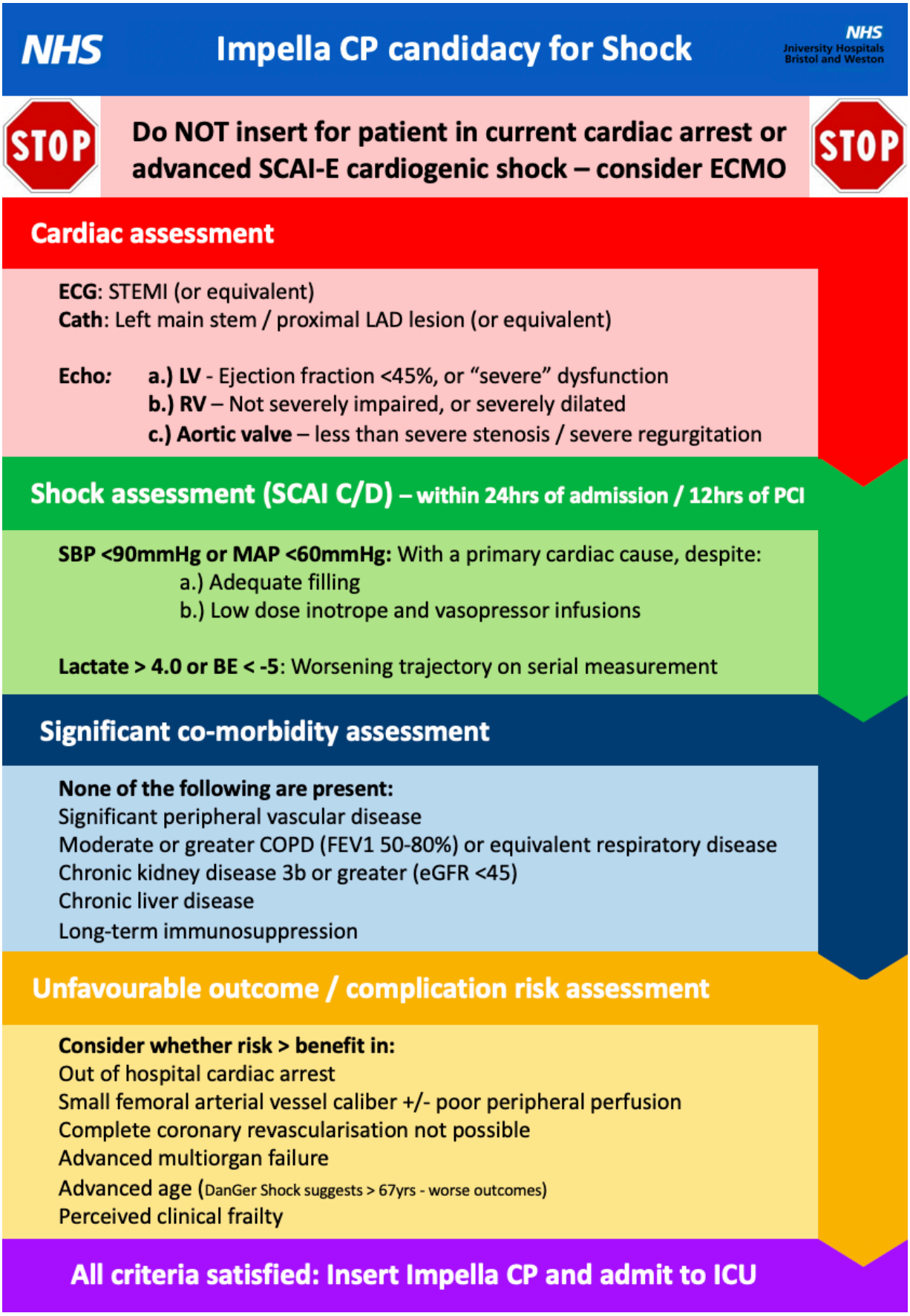
If external support is required the UK rep for Abiomed can be contacted in hours from 9am to 5pm Monday to Friday (through the catheter laboratory physiologists).

An Abiomed clinical specialist can also be contacted on their support line on 001-800-422-8666 24 hours a day. The Cardiology SpR/cardiac physiologist must be contacted prior to the Abiomed specialist. If the company needs to be called, this should be undertaken by the cardiac physiologist.

Appendix 1: BHI Ventricular Support Algorithm



Appendix 2 : UHBW Impella CP candidacy for shock assessment



Appendix 3 : Echocardiography and repositioning guidance

Re-position (to be performed by on call cardiology SpR or interventional cardiologist) with echo guidance. The interventional cardiology consultant on call must be informed any time there is a catheter reposition.

Please follow the steps below:

1.) Push catheter into LV until the aortic pressure waveform becomes an LV pressure waveform (low or zero diastolic pressure)

2.) Pull back (1cm at a time using catheter graduations at sheath hub) until aortic placement develops a diastolic pressure consistent with an aortic pressure trace.

3.) Pull back an additional 4cm. Note position of catheter by recording cm reading at sheath hub.

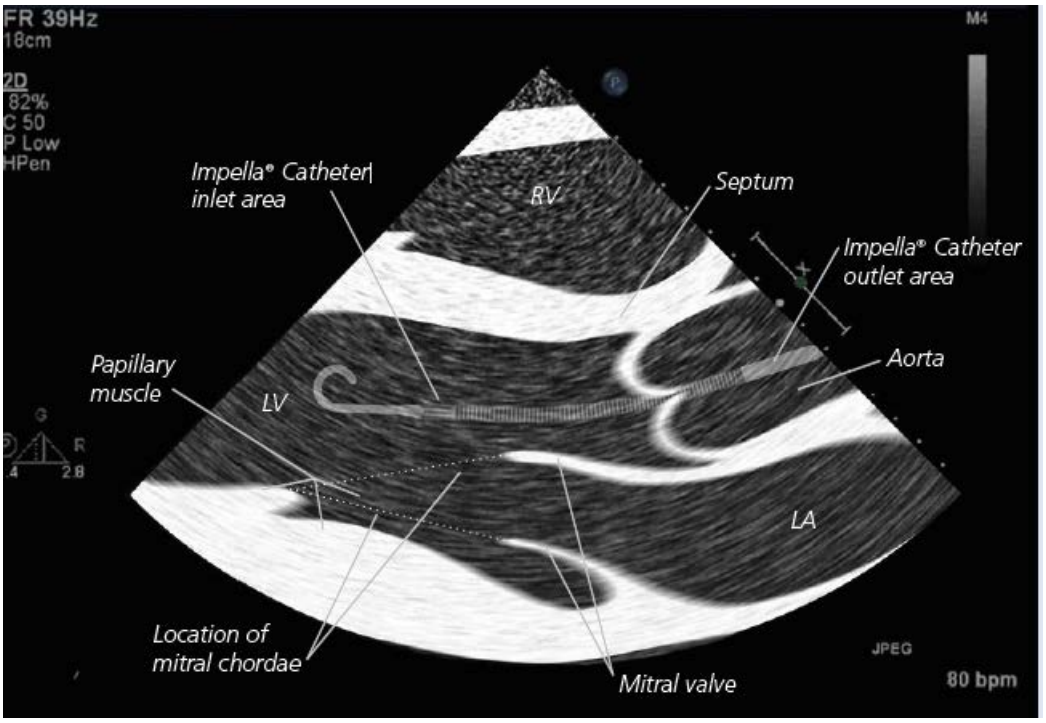
4.) Fix catheter position by tightening Tuohy Borst valve.

5.) Employ measures to limit motion.

6.) Re-echo to confirm position. With echo, visualise LV in the parasternal long axis view. Measure pump inlet to valve annulus (aiming 3.5cm).

7.) Before securing the Tuohy, remove all slack until you visualise the Impella just about to move backwards.

8.) Lock the Tuohy Borst valve.



Echo Tips on position of the Impella catheter

- Best view is parasternal long axis on TTE
- Inlet should be 3.5cm from aortic annulus for correct position.
- Colour Doppler can be added over the aortic valve, and if in correct position a dense mosaic pattern of turbulence will appear above the aortic valve area near the outlet area of the catheter. If the mosaic appearance is just below the AV, this may mean the catheter is too deep into the LV.

If unsuccessful, transfer to the catheter laboratory for re-positioning under fluoroscopy should be arranged.

Appendix 3 : Distal perfusion cannula

If the Impella catheter is likely to remain in-situ for >6 hours and there is a concern about femoral vessel size, or distal limb perfusion, strong consideration should be given to inserting a distal perfusion cannula into the ipsilateral superficial femoral artery (SFA) under USS guidance.

The distal perfusion cannula can either be a specific 6-8Fr distal perfusion cannula (these can be acquired from the perfusion department) or a small (5-6Fr) caliber sheath.

To achieve passive arterial flow down the distal perfusion cannula, it can either be attached to:

a.) The side port of the Impella catheter repositioning sheath (Figure 12), or;

b.) A further small sheath can be inserted into the contralateral common femoral artery and then the 2 sheaths connected. Connection of the 2 sheaths will require a specific male-to-male luer connector – this can be sourced from cardiac theatres, but ensure it is available prior to undertaking this technique (Figure 13).

The distal perfusion cannula should be aspirated every 4-6 hours, to prevent thrombosis occurring. This is performed by aspirating 2-5mls off the 3 way tap, from both the afferent and efferent limbs. The distal perfusion catheter should NOT be flushed (risk of distal emboli).

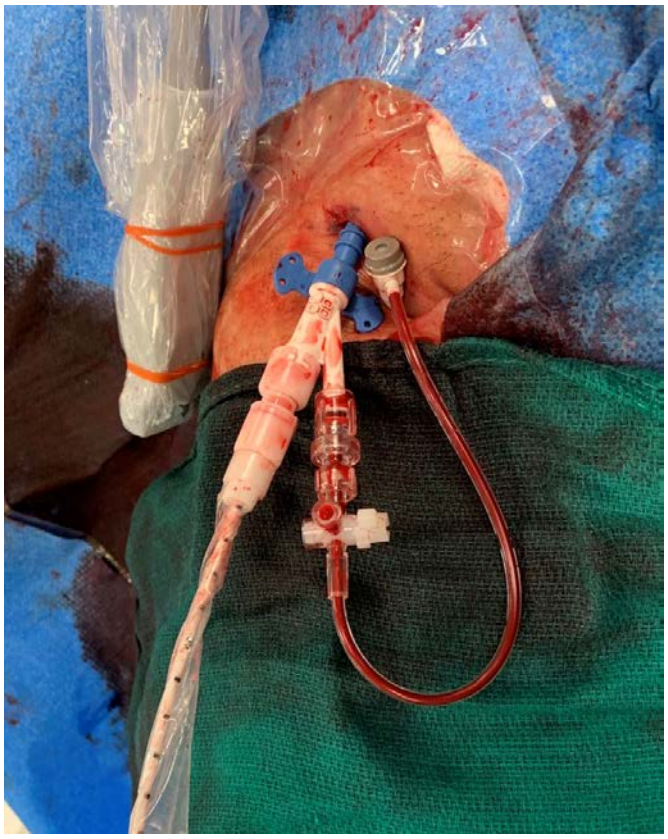


Figure 12: Connection of distal perfusion cannula to the side port of the Impella repositioning sheath.

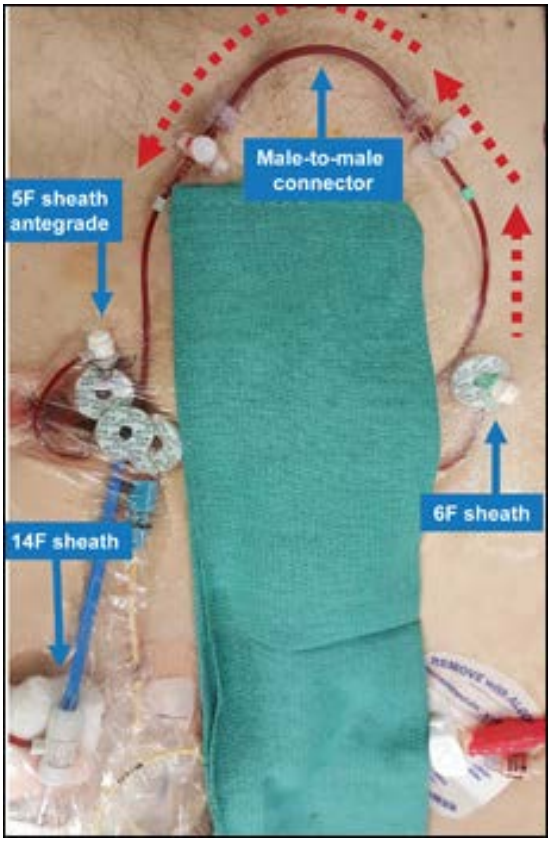


Figure 13: Connection for contralateral to ipsilateral sheath technique for distal perfusion cannula.

Table A

REFERENCES	Impella CP with SmartAssist manual: https://www.fda.gov/media/140767/download (accessed 11/10/23) Abiomed Academy – Impella CP with SmartAssist Patient Management - online training programme https://abiomedloop.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=221000308 (accessed 11/10/23)
RELATED DOCUMENTS AND PAGES	Management of cardiogenic and mixed shock on critical care – DMS and ICU SharePoint Cardiogenic Shock Team – DMS and ICU SharePoint Heparin anticoagulation for patients receiving VV-ECMO – DMS and ICU SharePoint
AUTHORISING BODY	Critical Care Executive Cardiology Management Meeting
SAFETY	This is a complex and invasive device – please see main document (Section 8) for a list of common potential complications.
QUERIES AND CONTACT	In an emergency – please contact, in this order: a.) The on-call cardiology registrar – Ext: #6527 b.) The cardiac physiologist (via switchboard if out of hours, or in the cath labs if in-hours) c.) The Interventional Cardiology consultant (via switchboard). d.) The Abiomed helpline - 001-800-422-8666 - 24 hours a day If not an emergency - email Dr Matt Govier (matthew.govier@uhbw.nhs.uk) for ICU related queries and Dr Julian Strange (julian.strange@uhbw.nhs.uk) for cardiology related queries.
AUDIT REQUIREMNTS	This will be provided by the Audit lead for Cardiology through regular auditing of Impella use at BHI. This will also be performed on a national level through the BCIS database.

Document Change Control

Date of Version	Version Number	Lead for Revisions	Type of Revision	Description of Revision
Dec 23	3	M Govier	Minor	Update from previous BHI version (out of date) to encompass use on ICU, as well as changes to priming fluid, heparin and patient management principles.
Nov 24	3.1	M Govier	Minor	Inclusion of local “candidacy for shock assessment” post DanGer shock trial and further local experience.
March 25	3.2	M Govier	Minor	Change to local “candidacy for shock assessment” after clinical events