

Adult Valved Peripherally Inserted Central Catheters (PICCs) Placement and Management Policy

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Document	Ref No
References:	
Guidelines on the Insertion and Management of Central Venous Access Devices in Adults – Bishop et al 2007	
The Microintroducer technique for Peripherally Inserted Central Catheter Placement – Sansivero 2000	
Improved Care and Reduced costs for Patients Requiring Peripherally Inserted Central Catheters: the role of the Bedside Ultrasound and a Dedicated Team – Robinson et al 2005	
Hamilton et al 2009 ESPEN Guidelines on Parenteral Nutritional Control Venous Catheters	
Guidelines on the Insertion and Management of Central Venous Access Devices in Adults – Bishop et al 2007	
DH, 2001 “Guidelines for the preventing infections associated	

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with the insertion and maintenance of central venous catheters". In <i>Journal of hospital infection</i> , 47 (supplement), S47-S67. (I)	
Nice Institute for Clinical Excellence - Technology Appraisal Guidance – No 49. Sept 2002 Guidance on the use of ultrasound locating devices for placing central venous catheters	
Pratt RJ, Pellowe CM, Wilson JA, Loveday HP, Harper PJ, Jones SR, et al. epic2: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. <i>J Hosp Infect</i> 2007 Feb; 65 Suppl 1:S1-64.	
O'Grady NP, Alexander M, Burns LA, Dellinger EP, Garland J, Heard SO, et al. Guidelines for the Prevention of Intravascular Catheter-related Infections. <i>Clin Infect Dis</i> 2011 Apr 1.	
Gillies D, O'Riordan L, Carr D, Frost J, Gunning R, O'Brien I. Gauze and tape and transparent polyurethane dressings for central venous catheters. <i>Cochrane Database Syst Rev</i> 2010;(4):CD003827.	
Assadian O. Skin antiseptic in reducing the risk of central venous catheter-related infections. <i>Critical Care Medicine</i> 2004 Mar;32(3):887-8.	
Adams D, Elliot TS. Skin antiseptics used prior to intravascular catheter insertion. [Review] [27 refs]. <i>British Journal of Nursing</i> 2007 Mar 8;16(5):278-80.	
Raad II, Hohn DC, Gilbreath BJ, Suleiman N, Hill LA, Brusco PA. (1994) Prevention of central venous catheter-related infections by using maximal sterile barrier precautions during insertion. <i>Infection Control Hospital Epidemiology</i> , 15:231-38.	
Ruesch S, et al. Complications of central venous catheters: Internal jugular versus subclavian access - A systematic review. <i>Crit Care Med</i> 2002; 30:454-460.	
Royal College of Nursing: Standards for Infusion Therapy. June 2010	
Emmerson et al (1996). The Second National Prevalence Survey of Infection in Hospital: an overview of the results. <i>Journal of Hospital Infection</i> : 32 175-90	
Jackson A. (1998). Infection Control a battle in vein infusion phlebitis. <i>Nursing Times</i> : 94 (4) 68-71 (III)	
DH. High Impact Intervention: Central venous catheter care bundle. 2011. http://hcai.dh.gov.uk/whatdoido/high-impact-interventions .	
EPIC 2	
Tanner J. Surgical hand antisepsis: the evidence. <i>J Perioper Pract</i> 2008 Aug;18(8):330-4, 339.	
Kent and Medway Cancer Network Vascular Access Guidelines	
Quality Commission Essential Standards of Quality & Safety	
Nursing & Midwifery Council Code of Professional Conduct 2008	
GMC: Good Medical Practice 2006	
ANTT © Rowley 2006	
The Microintroducer Technique for Peripherally Inserted Central Catheter Placement – Sansivero 2000	

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Improvement Care and Reduced Costs for Patients Requiring Peripherally Inserted Central Catheters: The Role of the Bedside Ultrasound and a Dedicated Team – Robinson et al 2005	
Hamilton et al 2009 ESPEN Guidelines on Parenteral Nutrition Control Venous Catheters	
Guidelines for the Insertion and Management of Central Venous Access Devices in Adults – Bishop et al 2007	
Trust Associated Documents:	
Isolation Policy for Patients	POLCGR37
Mattress Policy	POLCGR38
Arrangements for the Control of an Outbreak of Infection in Medway NHS Trust	POLCGR39
Policy for the Management of Viral Gastroenteritis due to Norovirus	POLCGR40
Policy for the Management of Suspected or Confirmed Tuberculosis (including MDR TB)	POLCGR41
Management of MRSA (Meticillin Resistant Staphylococcus aureus)	POLCGR42
Guidelines for the Management of Clostridium <i>difficile</i>	POLCGR43
Control of Infestations: Scabies, Head Lice, Pubic Lice, Body Lice	POLCGR44
Varicella Zoster Virus (VZV) Chickenpox and Shingles	POLCGR45
Viral haemorrhagic Fever (VHF)	POLCGR46
Policy for Investigating Hospital-Acquired Legionellosis	POLCGR47
Guidelines for Laundry	POLCGR50
Hand Hygiene Guidelines	POLCGR51
Cleaning/Disinfection Policy	POLCGR52
Guidelines for the Management of Transmissible Spongiform Encephalopathy (TSE) including Creutzfeldt-Jakob Disease (CJD)	POLCGR53
Policy for the Prevention of Blood Borne Viruses	POLCGR54
Preventing Infections Associated with Indwelling Urinary Catheters	GUCPCM011
Meningococcal Meningitis/Septicaemia	POLCGR060
Control of Glycopeptide Resistant Enterococci (GRE)	POLCGR66
Policy for the Management of Risks Associated with Infection Prevention & Control	POLCGR067
Control of Multi-Resistant Gram Negative Bacilli	POLCGR068
Blood Culture Policy	POLCGR-069
Principles of Asepsis and Aseptic Non Touch Technique (ANTT)	POLCGR070
Policy for the Prevention of Infections Associated with Vascular Access Devices	POLCCPM026
Guidelines for the Prevention of Infections Associated with Peripheral Venous Catheters	GUCPCM007
Adult Valved Peripherally Inserted Central Catheters (PICCs) Placement and Management Policy	POLCPCM075
Guidelines for Flexi-seal	GUCGR017
Infection Control in the Built Environment	POLCGR088
Environmental Policies and Infection Prevention and Control	POLCGR091

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Peripherally Inserted Central Catheters Policy	POLCPCM054
Peripherally Inserted Central Catheters CVAD Integrated Care Pathway	OTCPCM017

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21 EQUALITY IMPACT ASSESSMENT TOOL – APPENDIX 1..... 35

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To be read in conjunction with any policies listed in Trust Associated Documents.

1 INTRODUCTION

1.1 The aims of these guidelines are:

- 1.1.1 To provide comprehensive guidance in the application and management of valved PICCs in adult patients
- 1.1.2 To support and encourage the use of PICCs as an alternative to traditional central vascular access devices.

2 DEFINITION AND EVIDENCE BACKGROUND

- 2.1 The Peripherally Inserted Central Catheter (PICC) is a central vascular access device (CVAD) which is placed via the antecubital fossa or the upper aspect of the arm using either the basilic or cephalic vein, the tip of the catheter must lie in the lower third of the superior vena cava. PICCs are usually manufactured from silicone or polyurethane, measure 50-60cm (which can be shortened to suit the size of the patient) and range in diameter from 2 to 6 French. PICCs can be open-ended or valved and management of the catheter is different in both cases, these guidelines will focus on the management of valved catheters. Using correct management techniques the catheter can remain in situ for many months.
- 2.2 PICCs are rapidly becoming an acceptable alternative to traditional central venous catheters and tunnelled catheters, with advantages of patient comfort, reduced insertion complications, reduced associated infection risks and ease of placement. PICCs have the potential to provide continuous venous access for patients throughout the duration of the treatment episode, thus avoiding delays in both recovery and discharge from hospital. Where possible, patients should be considered and assessed for PICC suitability at the earliest opportunity when optimum peripheral vein integrity is available. PICCs are also suitable for outpatient and home intravenous therapy services.
- 2.3 The Sherlock 3CG* Tip Location and Confirmation System (TLS/TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The Sherlock 3CG* TLS/TCS provides real-time tracking of the catheter and tip location information by using the patient's cardiac electrical activity. Sherlock 3CG* TLS/TCS is indicated for use as an alternative method to chest x-ray and fluoroscopy for PICC tip placement confirmation in adult patients. Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to PICC insertion, the use of an additional method is required to confirm catheter tip location ie Chest X-Ray

See [Appendix 1](#) and [Appendix 2](#)

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3 RECOMMENDATIONS FOR PRACTICE

- 3.1 Referral for PICC placement can be by any healthcare professional that has recognised the need.
- 3.2 Patient assessed by PICC placer for suitability of PICC placement, with consideration for patients' physical status and intravenous therapy requirements.
- 3.3 Consent of consultant, or SpR in the consultant's absence or the PICC placer.
- 3.4 Informed written consent obtained from patient – Medway NHS Foundation Trust
- 3.5 Suitable time for PICC placement agreed with placer, patient and clinical department.
- 3.6 All PICCs to be inserted under ultrasound guidance using microintroducer technique, without exception.
- 3.7 Fluoroscopic guidance must be used to establish tip of PICC in Superior Vena Cava during insertion (preferably lower third) before PICC is used.
- 3.8 Full documentation of procedure in patient medical records and Saving Lives.
- 3.9 All documentation must be completed following insertion: this should include both internal and external length of PICC.
- 3.10 Educational information for patient or family where appropriate.

4 Qualifications for PICC Insertion using Sherlock 3CG:

- 4.1 A registered nurse who has demonstrated competency in PICC Placement and have completed the online education course on Sherlock 3CG and advanced PICC Placement Techniques may insert the Sherlock3CG Solo PICC.
- 4.2 A clinician's order is needed for PICC insertion
- 4.3 PICCs are commonly inserted in the basilic, brachial and cephalic veins above the antecubital area in the upper arm. Care and maintenance shall be performed by persons knowledgeable of the risks involved and qualified in the procedures.
- 4.4 The recommended tip location for PICCs is in the distal SVC or cavoatrial junction.
- 4.5 Sherlock 3CG provides tip tracking and confirmation when proper procedure is followed. Where the changes to be P wave are not clear or where the patient has a condition that precludes using tip confirmation then a chest x ray should be carried out to verify PICC tip location.

5 Sherlock 3CG* Stylet Warnings

- 5.1 Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end combined with kinking and excessive forces, may result in vessel damage, stylet damage, difficult removal, stylet separation, potential embolism and risk of patient injury.

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- 5.2 Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-wave is difficult. For example, when:
- P-wave is not present
 - P-wave is not identifiable
 - P-wave is intermittent
- 5.3 These conditions may be a result of heart rhythm abnormalities, atrial fibrillation, atrial flutter, severe tachycardia or presence of cardiac rhythm devices. In these cases, rely on magnetic navigation and external measurement for tip positioning and use chest x-ray or fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.
- 5.4 Do not rely on ECG signal detection for catheter tip positioning when there are no observable changes in the P-wave. In these cases, rely on magnetic navigation and external measurement for tip positioning and use chest x-ray or fluoroscopy to confirm catheter tip location, as indicated by organizational guidelines and clinical judgment.
- 5.5 Place skin electrodes carefully at locations indicated in the Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms that are not described in the Instructions for use. In such a case, rely on magnetic navigation and external measurement for tip positioning and use chest x-ray or fluoroscopy to confirm catheter tip location, as indicated by the organizational guidelines and clinical judgment.
- 5.6 Monitor catheter tip placement during insertion procedure and verify catheter tip location placement using organisational guidelines.

6 Sherlock 3CG* Stylet Precautions

- 6.1 Failure to verify catheter placement may result in serious trauma or fatal complications.
- 6.2 Placement of larger catheters at or below the antecubital fossa may result in an increased incidence of phlebitis. Placement of PICC above the antecubital fossa is recommended.
- 6.3 Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- 6.4 The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.
- 6.5 The magnetic detector identifies the relative position of the stylet tip. Ensure that the stylet tip remains inside and within 1 cm from the end of the catheter tip. Failure to do so could result in degraded magnetic navigation.
- 6.6 Never use excessive force to remove the stylet as it may damage the device.
- 6.7 Ensure the Sherlock 3CG remote control is not discarded.

7 Sherlock 3CG Warnings

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- 7.1 The Sherlock 3CG should only be operated by qualified medical personnel.
- 7.2 Do not power the Sherlock 3CG in the presence of flammable anesthetic gases. Explosion may result.
- 7.3 Do not attempt to sterilize the Sensor. Damage to the equipment may occur.
- 7.4 The following actions void the warranty of the Sherlock 3CG and may result in injury or equipment damage.
 - Opening or servicing the Sherlock 3CG by anyone other than Bard Access Systems' authorised service personnel.
 - Removing system labels by anyone other than by Bard Access Systems' authorised service personnel.
 - Connecting the Sensor to any unauthorized system or accessory.
- 7.5 If the Sherlock 3CG is visibly damaged, discontinue use immediately. Use of the damaged system may result in injury or equipment damage.
- 7.6 Do not submerge the Sensor in liquid or allow fluid to enter the connectors. Damage to the equipment may occur.
- 7.7 Sherlock 3CG is not intended to diagnose or treat disease.
- 7.8 Only Bard Access Systems' authorised service personnel should attempt to service this equipment. The Sherlock 3CG static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.
- 7.9 Do not place and/or use the Sherlock 3CG in the presence of strong magnetic fields such as Magnetic Resonance Imaging (MRI) devices. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Consult the MRI manufacturer for more information.
- 7.10 The Sherlock 3CG must only be charged with the Sherlock 3CG Medical Grade Power Supply.
- 7.11 Do not remove Sherlock 3CG enclosures. To avoid electrical shock, use only the power cord supplied with the system, connect only to properly grounded wall outlets. Only Bard Access qualified personnel should service the system.
- 7.12 Ensure all connecting cables and connections are electrically insulated and do not come into contact with other electrical cables or metal surfaces.
- 7.13 Do not pull the cables to disconnect from the system. Pulling the cable may damage the cable or cable connection.
- 7.14 Excessive twisting or bending of the Sensor cable may cause system failure.
- 7.15 Use only Bard Access System' cleaning and disinfection procedures. Failure to do so may damage the device.
- 7.16 Do not use excessive force when connecting or disconnecting the Fin assembly to or from the sensor or equipment damage may occur.

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- 7.17 When the Sensor is not in use, store in the holster, roll stand basket or other secure location to avoid damage.

8 PICC PLACEMENT

- 8.1 Prior to beginning the procedure, examine the package carefully before opening to confirm integrity and ensure expiration date has not been passed. Do not use expired kits or packages that appear damaged.

- 8.2 Prepare electronic systems following instructions provided (i.e. Site~Rite 5* ultrasound system, Sherlock 3CG)

8.3 Position Patient and Perform Ultrasound Pre-scan

- Position the arm abducted at 90* angle for catheter placement.
- Apply tourniquet above the anticipated insertion site.
- Perform ultrasound pre-scan.
- Select a vein based on patient assessment and pre-scan.
- Note the maximum vessel depth at catheter insertion site as displayed on ultrasound.
- Accurately mark planned insertion site on patient's arm.
- Release tourniquet.

8.4 Determine External Measurement

- For central placement, the recommended tip location is the lower 1/3 of the SVC, close to the cavoatrial junction.
- When possible, ensure patient has both shoulders on the bed without rotation during measurement procedure.
- To prevent inaccuracy, measure directly on patient's skin avoiding clothing, bedding, dressings, ECG electrodes and other medical or personal equipment.
- **NOTE:** External measurements can never exactly duplicate the internal venous anatomy.
- Measure path from the planned insertion site (or ACF is trimming catheter after accessing the vessel) using the following external landmarks:
 - Insertion site to axillary crease
 - Axillary crease to right clavicular head. Measure to the RIGHT clavicular head for both left and right-sided placements.
 - Right clavicular head to right sternal border of the third intercostals space.
 - **NOTE:** The first intercostal space may be difficult to palpate due to its proximity to the clavicle.
 - In cases where target vessel depth is significant, maximum vessel depth may be added to measured path to determine final external measurement.

8.5 Prepare Sensor

- Attach fin assembly to Sensor and place sensor in holder.
- Position Sensor on patient's chest with the top of Sensor above the sternal notch and centered on the sternum.

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- Prepare and attach external ECG electrodes to the lead wires. Ensure electrode locations are oil-free and completely dry.
- Remove backing and press firmly onto skin at the specified locations:
 - Place BLACK electrode lead wire on patient's right shoulder
 - Place RED electrode lead wire on lower left side inferior to the umbilicus and laterally along the mid-axillary line. CAUTION: Placement of red lead wire outside of this region may result in reduced ECG performance.
- **WARNING:** Place skin electrode lead wires carefully at locations indicated above and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms. In such a case, use chest radiograph or fluoroscopy to confirm catheter tip location, as indicated by organisations guidelines and clinical judgment.

8.6 Evaluate baseline ECG:

- Input patient identification details
- Review external waveform then calibrate magnetic tracking system
- Verify that P-wave is present, identifiable and consistent on the main screen.
- If no persistent or regular P-wave is identified, continue with procedure using Sherlock magnetic tracking and external measurements followed by tip confirmation via chest radiograph or fluoroscopy.
- Adjust ECG scale as needed to ensure that entire ECG waveforms are visible in the ECG window throughout the insertion procedure.

8.7 Prepare insertion site and sterile field.

- Apply tourniquet above intended insertion site to distend vessel.
- Set up sterile field and drapes according to catheter Instructions for Use (IFU).
- Don sterile gown and sterile gloves.
- Place the remote control in the remote control holder. Cover the probe and cable with the sterile probe cover.

8.8 Access Vein

- Using ultrasound, locate vessel.
- Identify the vessel depth and using the appropriate needle guide Perform micro puncture to access vein.
- Secure guidewire and advance dilator.

8.9 Prepare catheter:

- Pre-flush all lumens of the catheter with sterile normal saline to wet hydrophilic stylet. Follow catheter instructions for Use (IFU).
- Trim catheter to length (this may be done after accessing the vessel)
 - To ensure adequate catheter length to reach maximum p-wave amplitude, it is recommended that 5 cm be added to this measurement. Catheter length should be based on clinician measurement technique and experience
 - Loosen the T-lock connector/stylet assembly

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- Retract the entire T-lock connector/stylet assembly as one unit until the stylet is well behind the catheter cut location. Do not entirely remove the stylet from the catheter
- Using a sterile scalpel or scissors, carefully cut the catheter
- Inspect cut surface to ensure there is no loose material
- Re-advance the T-lock connector/stylet assembly locking the connector to the catheter hub. Ensure stylet tip is intact
- Gently retract the stylet through the locked T-lock connector until the stylet tip is contained inside the catheter
- Prior to insertion, ensure that the stylet tip is contained inside and within the catheter but not more than 1 cm from the trimmed end of the catheter

8.10 Catheter Insertion

- Attach catheter stylet to fin assembly.
 - Palpate the Fin Assembly through the drape.
 - Form and pinch the drape around the Fin Assembly to conform the drape to the Fin Assembly.
 - Place the stylet connector on the bottom end of the Fin Assembly and slide connector forward until it is fully seated.
 - Lay catheter on sterile field.
- Uncoil catheter stylet lead.
- Remove guidewire and dilator from microintroducer.
- Place 3cm of catheter into the dilator
- Calibrate Sherlock magnetic tracking system immediately prior to advancing catheter insertion
- Insert catheter until magnetic tracking icon appears or approximately 10cm and STOP inserting catheter.
- Attach saline-filled syringe. Flush catheter with saline and await intravascular waveform to stabilize.
- Verify that P-wave on the intravascular ECG waveform is present, identifiable and consistent on the main screen of the Sherlock 3CG.

8.11 Catheter TIP Guidance and Positioning:

- Insert catheter until the magnetic navigation shows stylet icon moving consistently downward.
- Continue to slowly advance catheter until the catheter is inserted to the external measurement determined prior to insertion.
- Press the FREEZE button on Sherlock 3CG. This will save the current waveform on the right side reference screen for later comparison.
- SLOWLY adjust catheter tip position until maximum P-wave amplitude is reached. Compare main screen waveform to reference screen waveform while closely monitoring for negative P-wave deflection.
- **Warning:** Do not rely on ECG signal detection for catheter tip positioning when there are no observable changes in the P-wave. In this case, rely on magnetic navigation and external measurement for tip positioning and use chest radiograph or fluoroscopy to confirm catheter tip location as indicated by organisational guidelines and clinical judgment.

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- **NOTE:** The P-wave may continue to increase in amplitude when initial negative deflection is noted. In this case, adjust catheter tip position to maximum P-wave amplitude with no negative deflection.
- Advance or retract catheter from maximum P-wave to place tip in desired location as per organizational protocol. Note catheter exit site marking and document on Sherlock 3CG screen.
- To record waveforms at final catheter tip position, press FREEZE button on Sherlock 3CG. Press the “print to file” button to save image. This will save baseline and final waveforms for documentation in medical record.

8.12 Procedure Completion:

- Remove stylet / T-Lock assembly
 - Hold the front portion of the Fin Assembly to stabilize the Fin Assembly and Sensor. Disconnect the stylet lead from the Fin Assembly by pulling the connector toward the bottom of the Sensor.
 - Follow catheter Instructions for Use to remove the Stylet/T-Lock assembly from the catheter.
- Aspirate and flush PICC.
- Secure catheter following the unit policy and confirm that exit site marking is accurate.
- Locate and secure remote control.
- Apply sterile dressing according to institutional protocol.
- Remove drapes, external electrodes, and sensor.
 - Remove and discard drapes according to policy.
 - Remove external ECG electrodes and Sensor from patient.
 - Loosen the cinch ring on the sensor holder and take out the Sensor with Fin Assembly.
 - Remove fin assembly.
 - Remove remote control from remote control holder.
 - Dispose of sensor holder, remote control holder and fin assembly according to institutional protocol.
 - **CAUTION: Ensure remote control is not discarded.**
 - Verify tip placement prior to releasing catheter for use.

8.13 REFERENCES:

- BARD Access Systems Site~Rite* 5 Ultrasound System Instructions for Use
- BARD Access Systems PICC Placement Instructions for Use with Sherlock 3CG*

9 PICC MANAGEMENT

9.1 Accessing PICC Line

Basic equipment to access line steps 1-9, 24-28
 Cleaned dressing trolley with orange bag attached
 Sterile basic procedure pack
 Plastic apron
 Sterile gloves of the correct size
 2% Chlorhexidine 70% Isopropyl alcohol

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PLUS

Take blood sample and flush valved PICC steps 10-14

2 x 10ml leur slip syringe

Blue needles x 2

10mls 0.9% Sodium Chloride

The required sample bottles

A needle free adaptor and hub if being used OR extra 10ml or larger syringe and blood transfer device

Either needle-free access device (bung) if needs changing (refer to manufacturers' recommendation)

Or single use bung if line is only accessed once a week

Flush valved PICC only steps 15-18

2 x 10ml leur slip syringe

10mls 0.9% Sodium Chloride

Needle-free access device

Either needle-free access device (bung) if needs changing (refer to manufacturers' recommendation)

Or single use bung if line is only accessed once a week

Dressing change of a valved PICC steps 19-23

Transparent semi-permeable occlusive dressing (e.g. IV3000)

Statlock dressing (if needed)

Steri strips (if needed)

9.2 Accessing Catheter

PROCEDURE	RATIONALE
1. Check patient identity	Ensure correct patient.
2. Explain the procedure to the patient giving the opportunity for questioning.	To ensure patients' understanding and obtain informed consent.
3. Establish appropriate positioning, ensuring that there is adequate lighting and ventilation	Ensuring comfort and safety for patient and nurse.
4. If necessary, carefully lift the edge of the dressing without removing it or exposing the exit site	To allow access to the bung.
5. Decontaminate hands using: <ul style="list-style-type: none"> • alcohol hand rub for visibly clean hands • otherwise wash hands with liquid soap followed by the use of alcohol rub 	To minimise the risk of cross infection.
6. At all times when the dressing is being removed the PICC must be supported at the exit site.	To minimise the risk of inappropriate migration.

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7. Observe external measurements of PICC (exit to proximal end of white hub)	The PICC length should be measured and checked against documented length to ensure that it has not migrated.
8. Open out sterile pack. Open all required sterile equipment onto pack with a drop technique	To maintain asepsis.
9. Decontaminate hands with alcohol rub and apply well fitting sterile gloves.	To minimise risk of infection and maintain asepsis.
10. Place sterile sheet under end of line.	To maintain asepsis.

And/or if taking blood and flushing

PROCEDURE	RATIONALE
11. Draw up 2 x 10mls 0.9% sterile saline solution into 2 x 10ml syringe without handling ampoule	
12. Holding line with a wipe (2% Chlorhexidine 70% Isopropyl alcohol). <ul style="list-style-type: none"> • Remove single use bung or needle free access device (if it has been in situ for more than one week). • Clean end of line with 2% Chlorhexidine in 70% Isopropyl alcohol wipe for 30 seconds and allow to dry. Or • Clean needle free access device with 2% Chlorhexidine 70% Isopropyl alcohol wipe for 30 seconds and allow to dry. 	To maintain asepsis.
13. Insert empty syringe into end of line or needle free access device and gently aspirate, allowing a few seconds for valve to open. Withdraw 5mls blood and discard.	To ensure catheter patency.
14. Withdraw the amount of blood required using either: <ul style="list-style-type: none"> • a blue vacutainer adapter and required bottles; or • a syringe of the correct volume for the blood to be transferred into the correct bottles 	To obtain the correct volume of blood.
15. Flush with 10mls normal 0.9% Sodium Chloride using a push pause technique. Before the last 1-2mls goes in, start to remove the syringe while still pushing in the saline.	To remove blood from the line. To ensure positive pressure is maintained in the line and prevent backflow into the line.

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Or if flushing only

PROCEDURE	RATIONALE
16. Draw up 10mls 0.9% Sodium Chloride solution into 10ml syringe without handling ampoule.	
17. Holding line with sterile gauze, Either <ul style="list-style-type: none"> • Remove single use bung or needle free access device (if it has been in situ for more than one week) • Clean end of line with 2% Chlorhexidine 70% Isopropyl alcohol wipe for 30 seconds and allow to dry Or <ul style="list-style-type: none"> • Clean needle free access device with 2% Chlorhexidine 70% Isopropyl alcohol wipe for 30 seconds and allow to dry. 	To optimise asepsis.
18. Insert syringe with 0.9% Sodium Chloride into needle free access device and flush then aspirate, allowing a few seconds for valve to open. Withdraw 2mls blood and discard.	To ensure catheter patency
19. Flush with 10mls normal saline 0.9% using a push pause technique. Before the last 1-2mls is inserted, start to remove the syringe while still pushing in the saline.	To remove blood from the line. To ensure positive pressure is maintained in the line and prevent backflow into the line

And/or if changing dressing

PROCEDURE	RATIONALE
20. Remove transparent semi-permeable dressing to uncover exit site, making sure the dressing is removed from the bottom upwards. Remove dressings according to manufacturer's instruction, always supporting the PICC at the exit site whilst doing so.	To ensure PICC does not inappropriately migrate.
21. Statlock securing should be changed weekly unless clinically indicated sooner.	To optimise exit site management.
22. Clean exit site using 3ml Chlorhexidine 70% Isopropyl alcohol with a back, forth, up and down technique working from the centre outwards.	To minimise contamination of exit site.
23. Allow to dry for 30 seconds	To minimise the risk of contamination and destroy skin flora.
24. Apply statlock if necessary and new transparent semi-permeable dressing,	To provide complete occlusion and prevent movement of the line during

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ensuring the exit and the whole of the line is covered.	further interventions.
---	------------------------

Finally

PROCEDURE	RATIONALE
25. Remove gloves and decontaminate hands.	To reduce the risk of infection
26. Dispose of sharps and other waste correctly.	To prevent needle-stick injury and comply with Trust policy
27. Document date and time of procedure in the nursing notes.	Maintain accountability



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10 TROUBLESHOOTING TIPS FOR MANAGEMENT OF PICC LINES

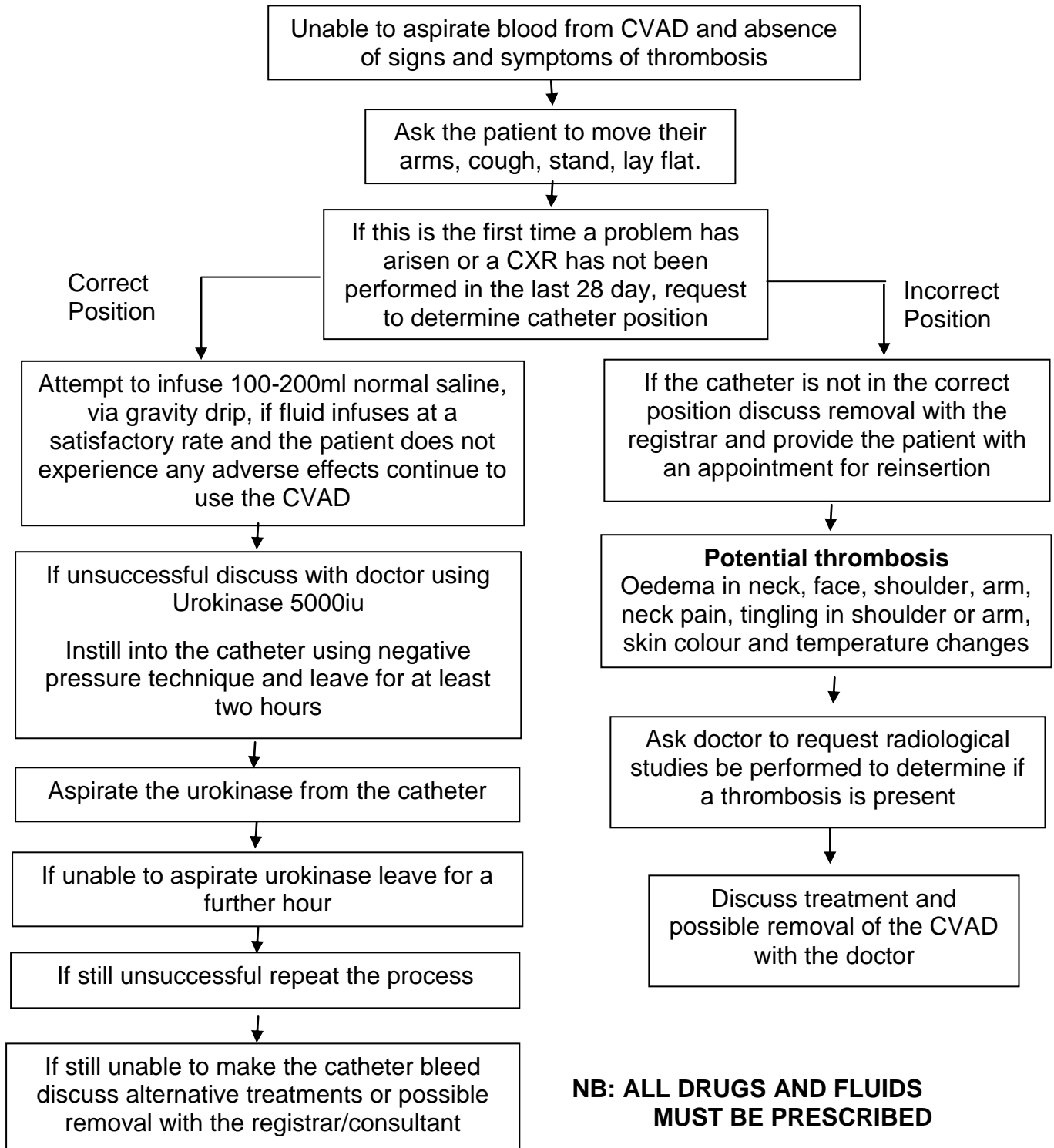
Nursing assessment	Nursing intervention
Accidental catheter removal	Apply pressure dressing at the insertion site for at least 5 minutes, elevate limb and notify clinician.
Increased External length of PICC. Possible partial removal of PICC	External length should be documented in notes and checked at each access. Measure the catheter length to determine if measurements coincide with catheter insertion measurements.
Fluid leak at insertion site	May be related to a hole or tear in the catheter or a loose connection between catheter and connection tubing. Check connections using sterile technique. Never use scissors to remove tape or dressing. If leak persists refer to the Interventional Radiology team.
Mechanical phlebitis; Generalised inflammation / swelling of arm above insertion site	Related to sensitivity of PICC insertion. Elevate extremity, apply warm compress 3 times daily for 72 hours. Consult with doctor for prescription of anti-inflammatory drugs. Review and consider catheter removal if not resolved within 3 days.
Pain, redness, drainage at insertion site	May be related to movement of the PICC, skin irritation or infection. Reposition the catheter hub, check statlock applied correctly, swab site, apply sterile dressing. Monitor skin irritation or infection and check cultures results. Consult with doctor for antibiotics. Follow Trust guidelines re management of infection. Review in 3 days or if symptoms worsen.
Pain in arm, ear, shoulder	May be due to thrombosis of the superior vena cava, misplacement of the PICC in the internal jugular vein or internal PICC leak. Check if able to aspirate blood. Follow flow chart (appendix 4). May require to be re x-rayed or venogram performed to determine if DVT or PICC migration.
Pump occlusion alarm	Assess for kink in IV tubing or in PICC at dressing site and for occlusion in catheter. If unable to aspirate blood from line follow the flow char.(Appendix 4)
Unable to aspirate blood from PICC	See flow chart below in section 8
"Stuck catheter" (on removal)	Catheter will appear to be firmly held within the vessel - potential causes are vasospasm, vasoconstriction and thrombophlebitis. Remove the PICC/PIC dressing, apply moderate tension on the catheter with tape below the insertion site and apply a sterile dressing. Apply warm compresses and attempt catheter removal in 8, 12 and 24 hours.

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11 CENTRAL VENOUS CATHETER ACTION FLOW CHART

Central Venous Catheter Action Flow Chart

Problem: Unable to aspirate blood from CVAD



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12 CLEARING AN OCCLUSION LINE USING A ‘NEGATIVE PRESSURE’ PROCEDURE

This should only be attempted after consultation with a doctor/experienced practitioner, having followed the flowchart in Appendix 4. Competency in this management is required.

Equipment

Step One

- Cleaned dressing trolley with orange bag attached
- Sterile basic procedure pack
- Plastic apron
- Sterile gloves of the correct size
- 2% Chlorhexidine 70% Isopropyl alcohol wipe
- 2 x 10ml leur lock syringes
- 5000iu Urokinase in 1ml (**PRESCRIBED**)
- Three way tap
- 2 x single use bungs

Step Two

- Cleaned dressing trolley with orange bag attached
- Sterile basic procedure pack
- Plastic apron
- Sterile gloves of the correct size
- 2% Chlorhexidine 70% Isopropyl alcohol wipe
- 2 x 10ml leur lock syringes
- 10ml 0.9% normal Saline for Injection
- Transparent semi-permeable occlusive dressing (e.g. IV3000)
- Statlock dressing (if needed)
- Steristrips (if needed)
- Tubifast or light bandage (optional)

STEP ONE

PROCEDURE	RATIONALE
1. Check patient identity.	To ensure correct patient identity.
2. Explain the procedure to the patient providing an opportunity for questioning.	To ensure patients’ understanding and obtain informed consent.
3. Establish appropriate positioning, ensuring that there is adequate lighting and ventilation.	Ensuring comfort and safety for patient and nurse.
4. If necessary, carefully lift the edge of the dressing without removing it or exposing the exit site	To optimise access to the bung.
5. Observe external measurement of PICC (exit to distal end of grey hub)	The PICC length should be measured and checked against documented length to

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PROCEDURE	RATIONALE
	ensure that it has not migrated.
6. Using Aseptic Non Touch Technique (ANTT) prepare trolley.	To maintain asepsis.
7. Decontaminate hands with alcohol rub and apply well fitting sterile gloves	To optimise infection control precautions.
8. Place sterile sheet under end of line.	To maintain asepsis.
9. Draw up 1ml Urokinase 5000iu solution into 1 x 10ml syringe without handling ampoule	
10. Holding line with sterile gauze, remove bung and clean end of line with Chlorhexidine 2% in 70% alcohol for 30 seconds and allow to dry	To maintain asepsis.
11. Attach the 3-way tap	
12. Connect the empty syringe to one port of the 3-way tap and to the other port, the syringe containing the Urokinase	
13. Turn the tap so that it is closed to the Urokinase filled syringe (Figure 1) and draw back on the empty syringe	Creates negative pressure within the catheter.
14. While maintaining this pressure, turn the tap so that it is open to the heparin filled syringe and closed to the vacuumed empty syringe (Figure 2)	The negative pressure will draw the Urokinase into the catheter.
15. Leave 3-way tap on line and place sterile bung on each connection. Leave Urokinase in site for two hours	To allow the anticoagulant to take effect.

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Figure 1: Tap open to empty syringe



In Figure 1 the Urokinase filled syringe is on the left, and the empty syringe, on the right, is drawn back to create a vacuum. **Please note the syringe in picture shows 5ml liquid, 1ml only is needed for PICC lines.**

Figure 2: Turning tap to open Urokinase filled syringe



In figure 2 the Urokinase filled syringe is on the left, and the empty syringe on the right. **Please note the syringe in picture shows 5ml liquid, 1ml only is needed for PICC lines.**

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STEP TWO

Follow procedure 1-9

PROCEDURE	RATIONALE
1. Draw up 10mls 0.9% sterile saline solution into 1 x 10ml syringe without handling ampoule	
2. Holding line with sterile gauze, remove single use bungs. Clean end of line with 2% Chlorhexidine 70% Isopropyl alcohol for 30 seconds and allow to dry	To maintain asepsis
3. Insert empty syringe into bung and gently aspirate, allowing a few seconds for valve to open. Withdraw urokinase and 5mls blood and discard	To ensure catheter is now patent and remove urokinase from line
4. Flush with 10mls normal saline 0.9% using a push pause technique. Before the last 1-2mls is inserted, start to remove the syringe while still pushing in the saline	To remove blood from the line. To ensure positive pressure is maintained in the line and prevent backflow into the line
5. Replace steristrips and Statlock securing dressing	To prevent dislodgement of the catheter
6. Apply new transparent semi-permeable dressing, making sure the exit and the whole of the line is covered	To provide complete occlusion and prevent movement of the line during further interventions
7. Position a piece of gauze under the bung	To prevent pressure on the skin from the bung and the line
8. Remove gloves and decontaminate hands	To reduce the risk of infection
9. Apply Tubifast/light bandage to patients' arm (optional for outpatients)	To prevent excessive movement of the line
10. Dispose of sharps and other waste correctly	To prevent needle-stick injury and comply with Trust policy
11. Document date and time of this procedure in the nursing notes along with any problems	Maintain accountability

If, following this procedure, blood can still not be aspirated, medical opinion should be obtained. Management will depend on what the cause of the occlusion is thought to be and may involve radiological intervention.

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13 PICC REMOVAL

PICC's must only be removed by a **competent clinician**

Equipment

- Cleaned dressing trolley with **orange** bag attached
- Sterile basic procedure pack
- Plastic apron
- Sterile gloves of the correct size
- ChloroPrep 3ml
- Transparent semi-permeable occlusive dressing (eg IV3000)
- Bandage

REMOVAL OF CATHETER

PROCEDURE	RATIONALE
1. Check patient identity	Ensure correct patient
2. Explain the procedure to the patient giving the opportunity for questioning.	To ensure patients' understanding and obtain informed consent.
3. Establish appropriate positioning; make the patient comfortable, with the arm supported on a pillow and the insertion site below the level of the heart. Ensure that there is adequate lighting and ventilation.	Ensuring comfort and safety for patient and nurse. Arm position minimises the risk of air embolus.
4. Carefully lift the edge of the dressing without removing it or exposing the exit site.	To allow access to the line.
5. Decontaminate hands using: <ul style="list-style-type: none"> • alcohol hand rub for visibly clean hands. • otherwise wash hands then apply alcohol rub. 	To minimise the risk of cross infection.
6. Open out sterile pack. Open all required sterile equipment onto pack with a drop technique	To maintain asepsis
7. Decontaminate hands with alcohol rub and apply well fitting sterile gloves	To minimise risk of infection and maintain asepsis.
8. Place sterile sheet under end of line	To maintain asepsis.
9. Remove all dressings	
10. Clean exit site with the 3ml Chlorhexidine 70% Isopropyl alcohol back, forth, up and down technique working from the centre outwards.	To minimise contamination of exit site.
11. Allow to dry for 30 seconds.	To minimise the risk of contamination and destroy skin flora.

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PROCEDURE	RATIONALE
12. Hold a piece of gauze above the insertion site to support the surrounding skin.	
13. Apply traction on the PICC and gently pull the catheter in a steady even manner moving the hand along the length of the PICC and pulling from near the insertion point.	
14. When the line is completely removed, sterile gauze should be held over the insertion point apply gentle finger pressure until any bleeding has stopped.	To prevent blood loss If clinically indicated, the tip should be sent for culture. In this case cut off 5cm of the distal catheter tip with sterile scissors and place directly into a sterile universal container. Complete the Microbiology form and label the container before sending to Microbiology for MC+S.
15. Once any bleeding has stopped, replace the gauze with further sterile gauze, apply transparent dressing and then apply a bandage around and over the site to act as a gentle pressure dressing.	To minimise blood loss and prevent formation of haematoma.
16. Remove gloves and decontaminate hands.	To reduce the risk of infection.
17. Dispose of sharps and other waste correctly.	To prevent needle-stick injury and comply with Trust policy.
18. Document date and time of this procedure in the nursing notes along with any problems.	Maintain accountability.

If resistance is encountered when removing the line then it is usually due to venospasm within the arm. Stop traction on the catheter. Apply a warm compress to the arm for 20 minutes to encourage venous dilation. Again attempt to remove the line. Do not stretch the PICC or apply undue force; the PICC may break. Always inspect the PICC after removal to ensure it is the same length as that documented. If any problems are suspected or cannot be resolved, then a PICC specialist clinician should be contacted.

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**14 REGISTERED PRACTITIONER COMPETENCY ASSESSMENT
FOR MANAGEMENT OF PICC**

KSF dimension to which this Competency applies HWB5/6/7

Education / training required:	Date	Signature of trainer/Supervisor
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To have attended a Medway NHS Foundation trust PICC		
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Equivalent training other than Medway NHS Foundation trust (specify type of training)	Place where training undertaken	Date training undertaken	Signature of line manager
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Record of Supervised Practice

Minimum times skill to be performed under supervision: (6)
Minimum competency level 2 (Can perform activity without assistance and/or direct supervision)

Date	Self assessment by Practitioner	Competent Practitioner acting as Supervisor

NAME:	JOB TITLE:	DIRECTORATE:	WARD/DEPT.
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15 KSF dimension to which this Competency applies – (HWB5/6/7)				
Education / training required: To have attended a formal training session		Minimum times skill to be performed under supervision(10)	Minimum required competency: level 2 Can perform activity without assistance and/or direct supervision	
Component	Performance Evidence Source	Statement of Competence	Registered Practitioner Signature/Date	Supervising Practitioner Signature/Date
Interpersonal skills / behavioural	Policy for Patient Identification Mental Capacity Act (DH, 2005)	<ul style="list-style-type: none"> • Introduces self to patient. • Positively identifies patient by asking patient to identify him/herself and by checking name band. • Thoroughly explains procedure to patient and considers individual, cultural and diversity needs. • Ensures patients understanding / awareness and gains informed verbal consent. • Ensures patient comfort and dignity prior to, during and after the procedure. • Recognises own limitations and asks for assistance as required. 		
Performance of procedure (skill)	Trust Policy	<ul style="list-style-type: none"> • Positively identifies verbally and by checking name band • Prepare patient and environment for procedure • Correct preparation of trolley and equipment for procedure • Decontaminate hands • Performs procedures in accordance with Trust policy and clinical practice guidelines: <ul style="list-style-type: none"> • Taking blood • Accessing the line for treatment • Turbulent flushing of the line • Dressing change • <u>Management of complications:</u> <ul style="list-style-type: none"> Phlebitis Accidental Removal Fluid leak Potential movement or migration of line Pain, inflammation Suspected Infection Blocked PICC PICC Repair <p>Correct disposal of equipment and sharps</p>		

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15 KSF dimension to which this Competency applies – (HWB5/6/7)				
Education / training required: To have attended a formal training session		Minimum times skill to be performed under supervision(10)	Minimum required competency: level 2 Can perform activity without assistance and/or direct supervision	
Component	Performance Evidence Source	Statement of Competence	Registered Practitioner Signature/Date	Supervising Practitioner Signature/Date
Related knowledge	The Code: Standards of conduct, performance and ethics for nurses and midwives (NMC, 2008). Standards of conduct performance and ethics (HPC, 2008) The Royal Marsden Hospitals Manual of Clinical Nursing Procedures 7 th Edition	<ul style="list-style-type: none"> • Demonstrates understanding of Code of Conduct, be able to identify own individual accountability and have a knowledge of Trust vicarious liability in relation to the management of PICC's • Competency in administration of intravenous drugs. • Have managers approval and support • A working knowledge of related Trust policies e.g. Sharps, infection control guidelines • Can discuss potential complications • Able to outline action to be taken in the event of adverse reaction Have a working knowledge of all related guidelines and policies		
Documentation	NMC Documentation Guidelines	<ul style="list-style-type: none"> • Document all interventions in appropriate nursing notes. 		
NAME:	JOB TITLE:	DIRECTORATE:	WARD/DEPT.	NAME:

- Once completed give a copy of your competency form to your line manager. .
- Retain the original competency form in your portfolio for future reference.

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16 EQUALITY IMPACT ASSESSMENT STATEMENT

- 16.1 All public bodies have a statutory duty under the Equality Act 2010 to have due regard to the elimination of discrimination, harassment, victimisation and any other conduct prohibited by the Act
- 16.2 The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none is placed at a disadvantage over others. This document was found to be compliant with this philosophy.
- 16.3 Equality Impact Assessments will ensure discrimination does not occur also on the grounds of any of the protected characteristics covered by the Equality Act 2010. Refer to appendix 3.

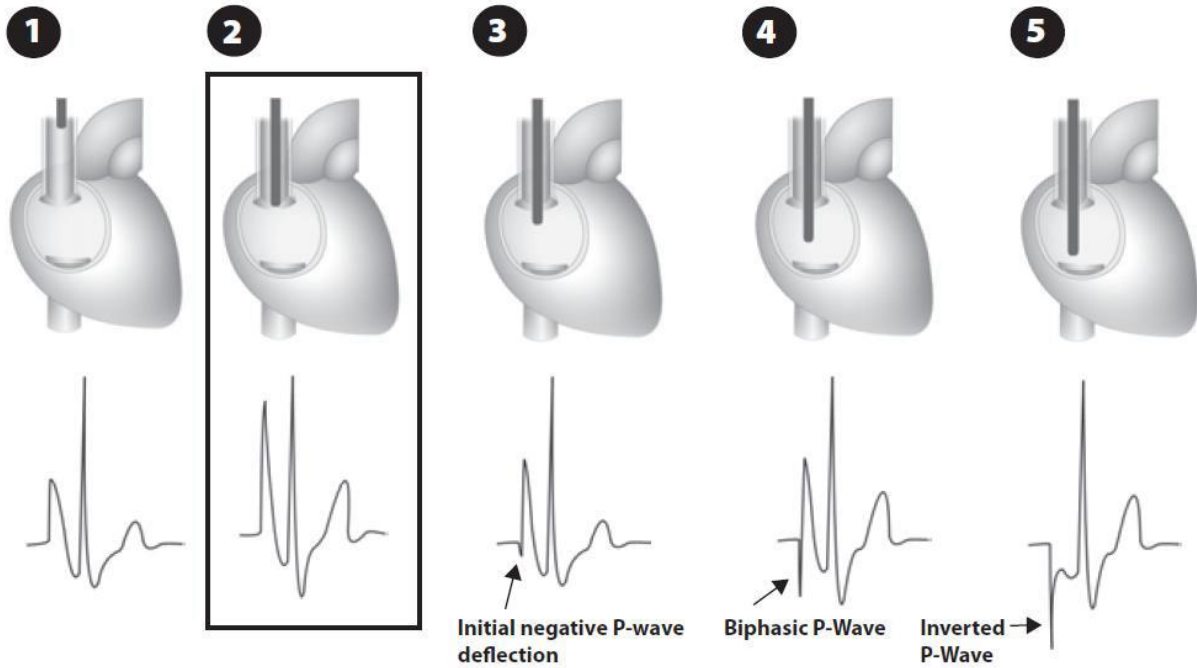
17 MONITORING & REVIEW

What will be monitored	How/Method/ Frequency	Lead	Reporting to	Deficiencies/ gaps Recommendations and actions
Policy	First review in one year and then every two years	Author	Policy and Procedures Committee	Review, amend and replace edition on intranet.

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18 Sherlock 3CG* Tip Positions and ECG waveforms – Appendix 1

Tip Positions and ECG waveforms



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19 Sherlock 3CG* - Appendix 2

Post-Market Clinical Study

The Sherlock 3CG* Tip Confirmation System (TCS) is Bard's next generation, fully integrated magnetic tracking and ECG-based peripherally inserted central catheter (PICC) tip confirmation technology, which represents the next evolution of the Sherlock* II Tip Location System and the previously-marketed Sapiens Tip Confirmation System. Sherlock 3CG* TCS is indicated for use as an alternative method to chest x-ray and fluoroscopy for PICC tip placement confirmation in adult patients. Any alterations of cardiac rhythms that change the normal presentation of the P-wave limit the use of ECG tip confirmation technology. In these instances, confirm PICC tip location using an alternative method. Please consult Instructions for Use (IFU) for additional safety information.

1. Overview

A total of 332 patients received a vascular access device utilizing the Sapiens technology at the Catholic University Hospital in Rome, Italy from 2009-2010. Of these, 114 patients received a Peripherally Inserted Central Catheter (PICC). This document details the results of these 114 patients. The lead clinician for this post-market clinical trial at this facility was Dr. Mauro Pittiruti.

2. Objective

The objective of the study was to assess the efficacy of the ECG method for correctly positioning the catheter tip in adult patients. This study assessed the performance of the Sapiens technology with respect to:

Compatibility with Peripherally Inserted Central Catheters (PICCs)

The safety of using an intracardiac electrode for ECG placement

The accuracy of the Sapiens technology in correct positioning of the catheter tip when compared to post-operative chest x-ray

3. Methodology

Informed consent was obtained.

Once the selected vein was cannulated per hospital protocol, the PICC was placed per the manufacturer's Instructions for Use.

The Sapiens technology Instructions for Use were followed to place the tip of the PICC. In all patients the target catheter tip location was the cavoatrial junction within +/- 1 cm.

The placement of the PICC tip location was confirmed with a standard chest x-ray via the hospital's radiology department in accordance with the hospital's guidelines. The potential discrepancies between the catheter tip location as indicated by the ECG method and as indicated by the radiology department were resolved by applying the following standard criteria to the chest x-ray:

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- o Radiological landmark of the cavoatrial junction: 3 cm under the carina, or alternatively, 2 cm under the lower margin of the main right bronchus
- o Radiological landmark of the lower 1/3 of the superior vena cava: under the carina, but within the first 3 distal cm
- o Radiological marker of the upper 1/3 of the right atrium: from 3 to 5 cm under the tracheal carina

4. Patient Selection Criteria

Certain inclusion criteria were:

Patients requiring the need for PICC placement

Patients willing to provide written informed consent for placing the PICC with ECG guidance

The exclusion criteria were:

Patients requiring a catheter placed in the inferior vena cava via the saphenous or femoral vein

Patients requiring a catheter placed for dialysis or aphaeresis procedures

Informed consent was obtained for all study subjects. Patients completed the informed consent process prior to submitting to any test or exam or participation in this clinical study.

5. Results

Patient demographics (PICCs only):

Gender:

Female: 64 (56%)

Male: 50 (44%)

Age:

19-60: 49 (43%)

61-96: 65 (57%)

Min/max/mean age:

Minimum: 19

Maximum: 96

Mean: 60

Disease Type:

Oncology: 76 (67%)

Non-Oncology: 38 (33%)

Insertion Access Location:

Right side: 109 (96%)

Left side: 5 (4%)

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Final Tip Location:

113 patients (99.1%) at the cavoatrial junction or within +/- 1 cm

1 patient (0.9%) at greater than 1 cm and up to 3 cm away from the cavoatrial junction

No adverse events or complications

Device demographics:

PICCs: 114 (100%)

User demographics:

Nurses 3 (60%)

Doctors 2 (40%)

6. Conclusion

The study results demonstrate that the Sapiens technology:

Can be used to successfully position the catheter tip of PICCs in proximity to the cavoatrial junction.

Can be used in adult patients in different demographics (gender, age, disease type, insertion site).

Provides a safe method for PICC tip placement: no adverse events or complications were reported.

May provide an effective and accurate replacement for chest x-ray in terms of catheter tip location with a 99% success rate for PICC tip confirmation.

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20 Equality Impact Assessment Tool – Appendix 3

		Yes/No	Comments
1	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	▪ Race	No	
	▪ Disability	No	
	▪ Gender	No	
	▪ Religion or belief	No	
	▪ Sexual orientation including lesbian, gay and bisexual people	No	
	▪ Age	No	
2	Is there any evidence that some groups are affected differently?	No	
3	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4	Is the impact of the policy/guidance likely to be negative?	No	
5	If so can the impact be avoided?	No	
6	What alternatives are there to achieving the policy/guidance without the impact?	No	
7	Can we reduce the impact by taking different action?	No	

END OF DOCUMENT