





# SOP for the usage of B BRAUN Easypump® II across NHS@Home

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#### 1. Purpose

Elastomeric pumps are designed to deliver a continuous flow of safe and accurate infusions of medication to patients, either in hospital, ambulatory or home settings. This allows patients to be discharged early from hospital or avoid an acute admission altogether.

The NHS@Home service already uses prefilled elastomeric devices through the supplier Baxter. The service however has experienced capacity limitations of Baxter and lead time delays. This is impacting NHS@Home usage, delaying transfers home and at times, resulting in an unavoidable admission to hospital.

The use of B BRAUN Easypump® II **self-fill** elastomeric devices will continue to facilitate discharge or hospital avoidance for patients who could be treated under the NHS@Home service. The option of a self-fill elastomeric device will remove the lead time delay currently experienced with the Baxter prefilled devices.

This document sets out the process and governance related to the BBRAUN Easypump® II to enable its safe and effective use in practice.

The use of BBRAUN Easypump® II is only applicable to patients referred to and accepted under the BNSSG NHS@Home service.

#### 2. Key Messages

The use of B BRAUN Easypump® II is only for patients who have been accepted under the NHS@Home service.

The use of the B BRAUN Easypump® II will be subject to the agreement of an infection specialist (Microbiology or Infectious diseases consultant). Overall clinical responsibility for each patient will remain with the referring clinician (Consultant/GP) and their respective team until the patient is discharged from the pathway.

The B BRAUN Easypump® II will be used to gap fill the lead time delay of the Baxter prefill elastomeric device. The Easypump® II will be replaced by a Baxter elastomeric device at the earliest opportunity.

#### Features of an Easypump® II elastomeric pump

- Disposable, single-use system
- Small, portable, lightweight design for transportation in a carry pouch
- Does not require batteries or electrical connection for operation
- Does not require programming or rate changes
- Flow rate is determined by the combination of the flow regulation device (flow restrictor) and positive pressure of the elastomeric membrane









## 3. Relevant Policies & Guidance

#### NHS@Home

- NHS@Home SOP
- NHS@Home OPAT Policy
- Use of pre-filled IV elastomeric pumps Baxter Infusor LV10 device

#### **NBT**

- CG-167 Trust Medicines Policy
- MED / 012 Prescribing, Preparing and Administering Injectable Medicines in Clinical Areas.
- IC01 Overarching Infection Control Policy
- IC37 ANTT Policy
- IC06 Hand Hygiene Policy
- CG-210 Vascular Access Device Policy

#### **UHBW**

- Medch M09 Standard Operating Procedure for Administration of Medicines
- Hand Hygiene Policy
- Aseptic Non- Touch Technique Policy
- Decontamination Policy
- Infection Prevention and Control Policy
- Central Venous Catheter Management And Procedure For Adult Patients

#### Sirona

Prescribing Policy







	<ul> <li>Medicines Policy (for people receiving care in the community)</li> <li>Administration of Intravenous Therapy to Adults within the Community</li> <li>Care and Maintenance of Peripherally Inserted Central Catheter PICC) for Adults Policy</li> <li>Standard Operating Procedure Care and Maintenance of Midline for Adults in Community</li> <li>Standard Infection Control Precautions (SICPs) Policy</li> <li>Aseptic Non-Touch Technique (ANTT) Policy</li> <li>National Guidelines</li> <li>Medusa – Injectable Medicines Guide</li> </ul>				
4. Operational Areas Included	Sirona, NBT and UHBW NHS@Home teams.				
5. Operational Areas Excluded	All other clinical areas outside the NHS@Home service.				
6. Who should read this	Sirona, NBT and UHBW NHS@Home team members involved with the administration of intravenous medication via a B BRAUN Easypump® II.				
	Pharmacy teams involved with NHS@Home services.				
7. Roles responsible for carrying out this procedure	Clinical Operational Leads – oversight and governance Senior Sister – staff training and competence assessment Registered Practitioner – using B BRAUN Easypump® II according to SOP. NHS@Home Pharmacy – oversight, ensuring that IV community prescription charts reflect B BRAUN Easypump® II and dispensing of medication and diluents.				
8. Clinical indications and patient suitability	All proposed intravenous antimicrobial treatment via the B BRAUN Easypump® II must be approved by a microbiologist or infections specialist as per the OPAT policy.  Patients will be assessed by a member of the NHS@Home teams for service suitability.  In addition, the patient will be assessed for the B BRAUN Easypump® II using the proforma (Appendix 1). The patient will sign the proforma, consenting to receiving an unlicensed treatment.				







The B BRAUN Easypump® II can only be used with a Peripherally Inserted Central Catheter (PICC). The use of a Midline device can only be considered through agreement from the Vascular Access Practitioner.

The B BRAUN Easypump® II will be used to gap fill the lead time delay of the Baxter prefill elastomeric device and replaced at the earliest opportunity.

### 9. Product Stability

The use of 0.3% citrate buffered sodium chloride 0.9% solution, used in the preparation of intravenous medication into B BRAUN Easypump® II, is an unlicensed product.

The stability of citrate-buffered piperacillin/tazobactam and flucloxacillin for continuous infusion in an elastomeric pump device has been assessed and complies with UK national standards – Yellow Cover Documents (YCD). It supports the storage of both piperacillin/tazobactam and flucloxacillin for up to 13 days 2°C–8°C plus 24 hours at 32°C 'in-use' within elastomeric devices<sup>1</sup>,

The B BRAUN Easypump® II should not be made in advanced or stored. Once prepared, the B BRAUN Easypump® II requires changing or removing after 24hrs.

## 10.Infusion progress monitoring

All patients will be provided with:

- 1) B BRAUN Easypump® II Patient Information
- 2) B BRAUN Easypump® II Infusion Progression Chart

The infusion progress is carried out by comparing the size of the reservoir with the B BRAUN Easypump® II – Infusion Progression Chart. Patient training and education will be provided as part of the assessment process and subsequent pump changes. The patient will be advised to contact the NHS@Home team if the reservoir size does not change with time as per chart.

Factors that can influence the flow rate:

- **Temperature** Designed to work at room temperature 23°C ± 2°C. The flow rate is calibrated to work at skin temperature of 31°C. To maintain a stable flow rate, the flow restrictor should be in contact with the patient's skin at all times (31°C). For every 1°C above or below this temperature, the flow rate will increase or decrease by approximately 2.5%.
- Underfilling and/or overfilling Filling the pump less than normal volume generally results in shorter delivery time. Filling the pump more than the nominal volume results in a longer delivery time.
- External pressure such as squeezing or lying on the pump increases flow rate.
- Activity that increases patient's body temperature or blood pressure may affect flow rate.







	Pump Height – pumps should be positioned approximately at the same level as the venous access device.
11.Prescribing and supply	Drug and diluent – dispensed from UHBW and NBT Pharmacy's  IV community prescription chart  Consumables:  • Easypump® II – held and ordered in pharmacy at both acute sites.  • Carry pouches – held and ordered in pharmacy at both acute sites.  • All other equipment for preparation and administration – held and ordered locally at all NHS@Home bases.  The flow diagram demonstrates the supply and delivery processes:
12. Anaphylaxis Risk Assessment and Mitigation	The NHS@Home Antimicrobial Anaphylaxis Risk Assessment will be completed as per the OPAT policy.  The prime volume of the Easypump® II is approximately 8mL, leading to a delay in initial drug administration. The standard mitigation and monitoring period for the Amber or Red Risk Assessment Outcome must be adjusted for the first Easypump® II connection and include either:  Option 1  A STAT full dose of the medication should be administered before Easypump® II connection with standard mitigation. The duration of the STAT dose and subsequent time of Easypump® II connection will be dose and drug specific.  Option 2  The patient must be monitored for two hours from the start of the infusion for the first dose only.
13. Staff training and competency assessment	All Registered Nurses must receive training and supervision on the use of a B BRAUN Easypump® II from a recognised trainer (level 5) using a competency assessment framework (Appendix 2).  All Registered Nurses must be competent in the following areas before B BRAUN Easypump® II can commence:  - Competent in intravenous administration - Competent in aseptic non-touch technique (ANTT) - Competent in the management of PICC devices







	A competency level 4 must be demonstrated to provide assurance of knowledge and skills required to be perceived as being safe to continue without further education or assessment.  Re-assessment of this competency will be undertaken at 3 years.  Training videos and resources are available from B BRAUN but must be used in conjunction with local policy and training.
14. Incident Reporting	<ul> <li>If a B BRAUN Easypump® II is found to be damaged or faulty the following actions must be taken:</li> <li>1) Escalate to the NHS@Home coordinator who will advise on ongoing treatment plan.</li> <li>2) Record the batch number, product code (REF) and expiry date.</li> <li>3) Return the product to base.</li> <li>4) Where possible, take a photo.</li> <li>5) Complete a local incident report.</li> <li>6) Inform the NHS@Home pharmacist who will contact B BRAUN.</li> </ul>
15. Procedure for administration	This step-by-step procedure describes the usage of a <b>B BRAUN Easypump</b> ® <b>II</b> .  The medicine should be prepared and administered according to local guidelines and the NHS@Home 'Adult Community IV Treatment: Authorisation to Administer and Administration Record' (IV Community Prescription Chart).

#### **Equipment:**

(In addition to the equipment required for the drug preparation)

Please note, for each individual medication vial or ampule, a dedicate luer lock syringe and blunt fill needle with filter must be used.

- B BRAUN Easypump® II– product model indicated on IV Community Prescription Chart
- 60mL luer lock syringe
- B BRAUN non-venting dispensing pin
- Tray
- Gloves (non-sterile)
- Apron
- Clinell Universal wipes
- Sharps bin
- Carry pouch (x1 per patient/treatment course)





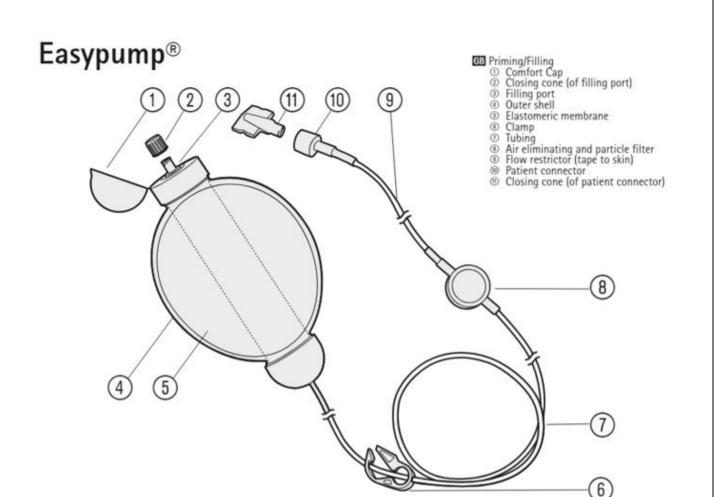


- Adhesive tape
- Clinell wipe (2% chlorhexidine in 70% alcohol wipe)
- B BRAUN Easypump® II labelling sticker

#### Procedure:

This is an Aseptic Non-Touch Technique (ANTT). The key parts of ANTT are:

- Tip and end of the non-venting dispensing pin
- Filling port (3)
- Closing cone (of filling port) the cap (2)
- Closing cone of patient connector (11)
- Patient connector (10)
- Tip of syringes









### Please refer to your local trust policy for the correct use of gloves and apron during ANTT and drug preparation.

- Decontaminate hands.
- 2. Apply gloves and clean the surface of your work area and tray with Clinell Universal Wipes. Wipe in an 'S' shaped pattern and allow to dry. Remove gloves and decontaminate hands.
- 3. Gather all required equipment, medication, diluents and flushes.

#### Check:

- Patient details
- IV community prescription chart
- The Easypump® II product specification matches the IV community prescription chart.
- The expiry date on all items
- 4. Peel open all equipment into tray.

**<u>Do not</u>** place any packaging in the tray at any time once the tray has been cleaned or when other equipment has been emptied out and their key parts exposed – for example drug ampules or bottles.

After all the equipment has been placed into the tray, do not touch the equipment until hands decontaminated.

Decontaminate hands.

Apply gloves and apron if required.

6. Prepare the intravenous medication as per IV Community Prescription Chart and place into the tray.

For each individual medication vial or ampule, a dedicate luer lock syringe and blunt fill needle with filter must be used.

#### Priming the Easypump® II

- 7. Clean access port of the diluent bag with Clinell wipe (2% chlorhexidine in 70% alcohol wipe) for 30 seconds and allow to dry completely. Insert the non-venting dispensing pin into the Citrate Buffered Sodium Chloride 0.9% (diluent) access port.
- 8. Using the 60mL luer lock syringe, withdrawl 10mls of Citrate Buffered Sodium Chloride 0.9% through the dispensing pin and place the syringe back into the tray.
- 9. Stretch outer membrane of the Easypump® II to remove creases and tubing to ensure no links are present.
- 10. Close the clamp.
- 11. Flip open the comfort cap.

Twist off the closing cone (the cap) from the filling port and place it upwards, in a dedicated section of the clean tray.

Do not touch the inner part of the closing cone (the cap) and maintain ANTT. Do not touch the filling port and maintain ANTT.







- 12. Attach the 60mL luer lock syringe containing the 10mls Citrate Buffered Sodium Chloride 0.9% to the filling port and fill Easypump® II with the 10mL.
- 13. Remove the luer lock syringe from the filling port and place in the tray whilst maintaining ANTT. Reapply the closing cone (the cap) and close the comfort cap.

#### Do not screw the closing cone (the cap) on too tightly.

14. Hold the filter and patient connector upwards, ensuring the filter hole is up.



15. Open the closing cone of the patient connector and release the clamp.

#### **Maintain ANTT throughout.**

- 16. Prime until a drop is observed at the distal end of the line.
- 17. Reapply the closing cone of the patient connector and close the clamp.

#### Filling the Easypump® II

18. Using the 60mL luer lock syringe, withdraw the Citrate Buffered Sodium Chloride 0.9% through the dispensing pin and place the syringe into the tray.

The specific volume of the 1<sup>st</sup> diluent is indicated on the IV Community Prescription Chart 'Order of additions'.

19. Flip open the comfort cap.

Twist off the closing cone (the cap) from the filling port and place it upwards, in a dedicated section of the clean tray.

Do not touch the inner part of the closing cone (the cap) and maintain ANTT.

Do not touch the filling port and maintain ANTT.

- 20. Attach the 60mL luer lock syringe to the filling port and fill the Easypump® II by placing the syringe on a clean surface and push down. Repeat until the total volume of the diluent is reached.
- 21. Add in the prepared intravenous medication to the Easypump® II, using the same technique.
- 22. Add in the 2<sup>nd</sup> diluent to the Easypump® II until the total volume of the diluent is reached.

  The specific volume of the 2<sup>nd</sup> diluent is indicated on the IV Community Prescription Chart 'Order of additions'.
- 23. Reapply the closing cone (the cap) and close the comfort cap. Place back into the tray. The Easypump® II is now ready for connection.

#### Connecting the Easypump® II





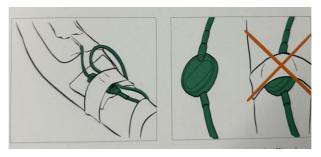


24. Decontaminate hands.

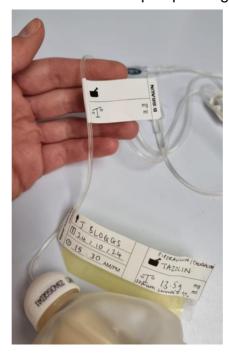
Apply gloves.

- 25. Access and flush the vascular access device as per local policy.
  - If appropriate, disconnect the old Easypump® II and place outside of the tray.
- 26. Open the closing cone of the patient connector and connect to the patient's vascular access device.
- 27. Tape the flow restrictor to the patient's skin.

Ensure the filter and the air eliminator are not covered.



- 28. Open the clamp the infusion should begin automatically.
- 29. Complete the B BRAUN label sticker and attach to pump tubing.



- 30. Insert the Easypump® II into the pouch and position correctly.
- 31. Dispose of waste as per local policy.
- 32. Remove gloves and apron and decontaminate hands.
- 33. Sign the IV Community Prescription Chart and document on EMIS, including the batch number and expiry date of the Easypump® II.

#### Disconnecting a Easypump® II ONLY







- 1. Decontaminate hands.
- 2. Apply gloves and clean the surface of your work area and tray with Clinell Universal Wipes. Wipe in an 'S' shaped pattern and allow to dry. Remove gloves and decontaminate hands.
- 3. Gather all required equipment.
- 4. Peel open all equipment into tray.

<u>Do not</u> place any packaging in the tray at any time once the tray has been cleaned or when other equipment has been emptied out and their key parts exposed – for example drug ampules or bottles.

After all the equipment has been placed into the tray, do not touch the equipment until hands decontaminated.

5. Decontaminate hands.

Apply gloves.

- 6. Close the clamp on the Easypump® II and disconnect the pump from the vascular access device.
- 7. Access and flush the vascular access device as per local policy.
- 8. Dispose of waste as per local policy.
- 9. Remove gloves and decontaminate hands.
- 10. Document on EMIS.

Training videos and resources are available from B BRAUN but must be used in conjunction with local policy and training.







#### References

- Jamieson C, Ozolina K, Seaton R Andrew et al Assessment of the stability of citrate- buffered piperacillin/tazobactam for continuous infusion when stored in two commercially available elastomeric devices for outpatient parenteral antimicrobial chemotherapy: a study compliant with the NHS Yellow Cover Document requirements. Eur J Hosp Pharm 2022;29:212–216. doi:10.1136/ejhpharm-2020-002340
- Allwood M, Stonkute D, Wallace A et al Assessment of the stability of citrate-buffered flucloxacillin for injection when stored in two commercially available ambulatory elastomeric devices: INfusor LV (Baxter) and Accufuser (Woo Young Medical): a study compliant with the NHS Yellow Cover Document (YCD) requirements Eur J Hosp Pharm 2020;27:90–94. doi:10.1136/ejhpharm-2018-001515



To be completed by patient:

Date:....

treatment administered via the elastomeric device

Patient Name:....





#### **Appendix 1: Elastomeric Device Assessment and Consent Form**

#### **Elastomeric Device Assessment and Consent Form**

Ass	es	sment Checklist
		The patient understands that treatment via the elastomeric device is unlicensed and agrees to receive it. (Unlicensed treatment patient information leaflet available, on request)
		The patient or carer is able to follow the Infusion Progression chart and report the progress to a member of the NHS@Home team. (The device should be checked approximately every four hours during waking hours and compared against the chart)
		e Checklist using the device, ensure the following:
		The infusion line is kept unobstructed with no kinks or bends in the tubing.  The white connector is taped directly to the skin to ensure it reaches body temperature.  It is kept in a pouch, away from direct sunlight and heat sources such as a fire or radiator.  Excessive exercise is avoided.  The device is at the same height as the PICC – it is not placed on the floor or above the patient's head.  The device is not submerged in water.  The PICC entry site is monitored for swelling or pain and the PICC is kept dry, as per vascular access team.
For	Ba	exter LV10 devices only
[		There is sufficient space at the patient's home for a fridge to store the devices (dimensions: 735mm x $450\text{mm}$ x $510\text{mm}$ )
		The patient/patient's representative accepts to be present to receive delivery from Baxter within the allocated time slot
For	В	BRAUN Easypumps® II only:
		Ensure the clamp is unlocked Ensure the filter and air bubble are facing upwards Understands that the Easypump® II will be replaced with a Baxter device at the earliest opportunity.
	rm	Pation to be provided to patient Patient information leaflet for specific device Infusion progression chart
	I	nitial assessment and advice completed by:
	١	Vame: Designation: Designation:
	S	Signature: Date:

I confirm that I have received, and understand the information listed above and consent to having my

Signature.....







#### **Appendix 2: Competency Assessment**

#### Competency Assessment form for usage of B Braun Easypump® II

<u>Practical assessment</u> will be undertaken in the clinical area by another member of staff who is an experienced registered practitioner undertaking this skill on a regular basis. All criteria must be met to achieve competence.

Methods of Assessment include: Within both elements of this competency there must be at least a minimum of 2 examples of evidence from the list below.

1	Direct observation by Mentor The mentor directly observes the learner demonstrating a competency in the practice area and records the level of achievement.
2	Direct observation by an Expert Witness*/Work based Assessor Statement An Expert Witness or qualified work based assessor, who directly observes the learner demonstrating a competency in the practice area and records the level of achievement.
3	Interview Their mentor interviews the learner in order to assess understanding. The mentor/coach will record the level of achievement.
4	eLearning Evidence of successful complication of the online eLearning package. Evidence of successful completion of the knowledge assessment is acceptable
5	Simulation The learner could demonstrate their ability to perform clinical skills in a simulated situation, e.g. a skills laboratory if appropriate.

Formative assessments will be undertaken until the learner and mentor have agreed that a final summative assessment should be held.

Level	Description
1	Knows nothing about the skill.
2	Doubts knowledge and ability to perform the skill safely, without supervision.
3	Could perform the skill safely with supervision.
4	Confident of knowledge and ability to perform the skill safely.
5	Could teach knowledge and skills to others and can demonstrate initiative and adaptability to special problem situations.







#### Competency Assessment form for usage of B BRAUN Easypump® II

I confirm that I am aware of my responsibilities, accountability and limitations in relation to practice relating to the use of B BRAUN Easypump® II.

Pre-requisite standards before competence i.e. qualifications, training:

- Registered Practitioner
- Competent in intravenous administration, Basic Life Support and anaphylaxis
- Competent in aseptic non-touch technique (ANTT)
- Competent in the management of PICC devices

Candidate Name:	Date of Birth:
Designation:	Ward/Department:
Candidate Signature:	
Date training completed:	Date competency achieved:
Assessor Name: (PLEASE PRINT CLEARLY)	
Designation:	
Assessor Signature:	

Please return a photocopy of this page only to your local training department.

Please keep the complete original in your Portfolio







#### Competency Assessment form for usage of B Braun Easypump® II

#### Remember

A competency level 4 (or above) must be demonstrated to provide assurance of knowledge and skills required to be perceived as being safe to continue without further education or assessment.

Re-assessment of this competency must be undertaken at 3 years.

This assessment must be kept in the staff member's personal file and a photocopy must be sent to the Staff Development Department for addition to the staff member's training record.

#### **Knowledge and Understanding Criteria**

By the end of this assessment	(in	sert name)	should
demonstrate knowledge and understanding and be able to appl	ly the fo	ollowing:	

The Practitioner will:	Method of assessment	Level of achievement	Comments from mentor / assessor	Confirmation of competency (please SIGN)	
				Mentor	Candidate
Have clear knowledge and understanding of local policies and guidelines linked to the usage of Easypump® II.					
Understands the correct vascular access device for an Easypump® II.					
Demonstrate knowledge and understanding of the important of aseptic nontouch technique and can identify the "key parts" of the Easypump® II.					
Demonstrates understanding of the key components of a Easypump® II, including how the device administers medication.					
Demonstrates knowledge and understanding of how to identify the correct					







Easypump® II product and has an awareness of the different Easypump® II variations.			
Demonstrates understanding of the factors that can influence infusion time of a Easypump® II, including temperature, viscosity, access, and device height.			
Understand the additional equipment required to use a Easypump® II.			
Demonstrates knowledge and understanding of the environmental factors and ways to minimise risks to both patient and staff member.			
Demonstrates knowledge and understanding of the anaphylaxis risk assessment and additional steps for Easypump® usage.			
Demonstrates knowledge and understanding of the essential mixing regime of the Easypump® II. (prime, diluent, drug, diluent)			
Demonstrates understand and correct interpretation of the IV Community Prescription Charts for the Easypump® II, including Easypump® II identification.			
Demonstrates the correct procedure for priming an Easypump® II, whilst maintaining ANTT.			
Demonstrates the correct procedure for filling an Easypump® II, whilst maintaining ANTT.			







Demonstrates the correct procedure for connecting an Easypump® II, whilst maintaining ANTT.			
Demonstrates the correct procedure for disconnecting an Easypump® II, whilst maintaining ANTT			
Demonstrates the safe disposal of an Easypump® II.			
Demonstrates the correct procedure for securing the Easypump® II to the patient.			
Demonstrates effective patient education and training to ensure safe patient care, include the use of pump infusion progression charts.			
Understands the correct documentation procedure for Easypump® II.			
Understands what do if a Easypump® II is found to be damaged or faulty.			
(record batch number, expiry date, product code (REF), take pictures, return device, complete incident report)			
Can troubleshoot any problems with the Easypump® II and understands internal escalation processes.			
Knowledge of the key differences between Easypump® II and Baxter pumps.			







#### Competency Assessment form for usage of B Braun Easypump® II

#### **Performance Criteria**

By the end of the assessment	(insert name)	should
demonstrate performance and be able to undertake the following:		

The Practitioner will demonstrate knowledge of the	Method of assessment	Level of achievement	Comments from mentor / assessor	Confirmation of competency (please SIGN)	
following:				Mentor	Candidate
Equipment					
Patient					
Staff					
Documentation					
Overall assessment of skill					