

# **LRI Children's Hospital**

# Administration of subcutaneous human normal immunoglobulin

Staff relevant to:	Health Professionals caring for children and young people undergoing subcutaneous human normal immunoglobulin therapy.
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## 1. Introduction and Who Guideline applies to

Human Normal Immunoglobulin's are a blood product. These products are a source of pooled antibodies. The main indication and use of these products is the provision of antibody replacement therapy.

This guideline has been developed to provide Health Professionals guidance in the safe and effective administration of subcutaneous human normal immunoglobulin when treating children and young people.

#### 2. Related Documents

This guideline should be used in conjunction with the:

- Consent to Examination or Treatment UHL Policy
- IV (Intravenous Therapy) UHL Policy
- Blood Transfusion UHL Policy
- Aseptic Non Touch Technique UHL Guideline
- Topical Local Anaesthetics in Children Undergoing Anaesthesia UHL Guideline
- Subcutaneous Immunoglobulin for Immunodeficiency UHL Immunology Guideline

# 3. Guideline standards and background

Subcutaneous immunoglobulin (SCIG) is a method for administering immunoglobulin through a small needle to the subcutaneous tissue or fatty tissue just under the skin.

Subcutaneous injections can be given in the arms, legs or abdomen.

#### **Prescription:**

The subcutaneous immunoglobulin should be prescribed according to UHL NHS prescribing guides

The subcutaneous immunoglobulin is obtained from pharmacy on prescription with an associated immunoglobulin request form.

The subcutaneous immunoglobulin request form should indicate the -

- child's details
- clinical indication
- specific product
- dose
- frequency
- date of request
- when the supply is due to be given
- name of person completing the form and their signature

## Dosing:

The dose is usually -

0.1 - 0.2g / kg / week

But this is based on response to treatment

#### Administration:

The total volume of subcutaneous immunoglobulin is usually administered over at least one hour via one or two injection sites (Older children may use up to 4 sites per infusion).

# Storage:

The subcutaneous immunoglobulin should be stored according to the product guidelines.

\*Refrigerated products should be removed from the fridge at least one hour prior to administration.

Products are usually dispensed for use within 4-7 days for scig weekly infusion, usually longer for IVIG which is administered every 3 weeks -14-21 days.

	4. Pre-administration checks/Preparation						
No.	Action						
4.1	One qualified nurse to check the prescription and supply of subcutaneous immunoglobulin according to UHL drug administration guideline and policy.						
4.2	Prepare all equipment for preparation and administration of subcutaneous immunoglobulin.						
	Tray						
	Area sheet						
	Luer-lock syringes						
	Safe Sharp Needles						
	Giving sets – currently UnomedicalNeria extension line and needles set						
	Yellow sharps burn bin						
	Non-sterile gloves						
	70% alcohol surface wipes						
	Alcohol swabs						
	Medical infusion device – currently CME T34 for 'Immunoglobulin Only'						
	Subcutaneous immunoglobulin vials as prescribed						
	Gauze swabs						
	• Plasters						

	4. Pre-administration checks/Preparation					
4.3	Wash hands prior to the preparation of subcutaneous immunoglobulin.					
4.4	Decontaminate the tray using soap and water if physically dirty, dry, and then disinfect with Chlor-Clean or 'distel wipes'					
4.5	Place an area sheet in the tray opening it out touching only the corners of the sheet to maintain a sterile field.					
4.6	Open the packets of syringes, needles and giving sets onto the sterile field.					
4.7	Confirm that the subcutaneous immunoglobulin is in date and there are no signs of contamination or degradation.					
4.8	Remove plastic caps from the top of the vial and clean the bung with an alcohol 2% chlorhexidine in 70% alcohol wipe					
4.9	Use hand sanitiser to gel cleanse their hands and put on non-sterile gloves.					
4.10	Wearing gloves, following an aseptic non-touch technique (ANTT) the needles are attached to the syringes which are to be used to draw up the subcutaneous immunoglobulin.					
4.11	It is advisable to draw the same volume of air into the syringe as the volume to be drawn out of the immunoglobulin vial (the air within the syringe can then be injected into the glass vial to create positive pressure inside and aid the removal of the immunoglobulin product).					
4.12	Use the needle to pierce the bung and place into the air space in the glass vial. Once the air has been injected into the air space, the needle is lowered into the immunoglobulin and the required volume of immunoglobulin is extracted.					
4.13	The procedure is repeated with additional syringes, needles and vials until the required volume of immunoglobulin has been extracted from all of the supplied vials for the infusion.					
4.14	The safe sharp needles used for extraction are made safe, removed and placed into the yellow sharps burn bin.					
4.15	The giving sets are attached to the Luer-lok syringes.					

# 4. Pre-administration checks/Preparation

- 4.16 A second nurse checks the
  - Prescription
  - Patient details
  - Subcutaneous immunoglobulin expiry date
  - Dose in grams and millilitres
  - Date and time for administration
  - Ensures that the batch number sticker(s) are attached to the prescription chart.
- 6.17 The qualified nurse preparing the subcutaneous immunoglobulin primes the giving sets ready for administration.

Updated guidance in adults is to avoid immunoglobulin exiting the subcutaneous needle to reduce skin irritation from contact with the immunoglobulin product. The immunoglobulin IS NOT being administered into a vein. A small amount of air into the subcutaneous tissue is not believed to cause a problem. (Our needle lines from syringe to tip have a 'dead space' of 0.2mls.)

- 4.18 The medical device for the administration of subcutaneous immunoglobulin is checked for -
  - decontamination,
  - turned on.
  - the syringes loaded into the mechanism,
  - the volume confirmed,
  - the hourly rate set and
  - the programme settings confirmed.
  - \* It is useful to check the battery life of the pump prior to administration (T34 pumps are for the administration of 'Immunoglobulin Only' by Children's Day Care Nurses and the Children's Immunology Specialist Nurse who are trained in their use).

Ensure battery is seated correctly prior to every use.

	5. Administration			
No.	Action			
5.1	The qualified nurse and colleague confirm the identity of the person due to receive the subcutaneous therapy by checking –			
	Name			
	Date of birth			
	Unit number			
	Allergies to medications			
	Reactions experienced to previous infusions			
5.2	Use hand sanitiser to cleanse hands and ask the child or parent to remove any local anaesthetic gel/cream that has been used if they have not already done so.			
5.3	Insert each needle into the child or young person's chosen sites for administration ensuring that they are at least two or three centimetres apart.			
5.4	Commence the administration of subcutaneous immunoglobulin at the desired hourly rate and sign the prescription chart.			
5.5	Any additional prescribed medication for potential reactions that has not been given prior to administration may be given at this time if required.			

6	6. Monitoring the infusion & completion of treatment
6.1	The subcutaneous needle site should be checked at the start of the infusion and after 15 minutes to observe for leakage, localised skin reactions e.g. inflammation, redness and reports of side effects such as itching.
	Management of minor reactions can be by administration of medication (see 4.17) or by slowing or stopping the infusion until the reaction subsides. If the reaction persists or develops despite initial interventions or the child shows signs of moderate /severe reaction stop the infusion, ensure emergency management has been started and seek medical advice.
	N.B moderate to severe reactions are rare (1:1000 SCIG infusions) but can occur at any time.
6.2	When the administration has been completed a member of staff /parent can use hand sanitiser to cleanse their hands and remove the needles before disposing of them in a yellow sharps burn bin at the bedside.
6.3	Spot plasters can be applied to the injection sites if required.

7.	7. Documentation and preparation for next course of therapy				
No.	Action				
7.1	The procedure and administration of subcutaneous immunoglobulin with any side effects or reactions is documented in the medical records.				
7.2	An order form is completed to obtain a supply for the subsequent dose and the subcutaneous immunoglobulin ordered from their appropriate supplier – pharmacy or transfer to a homecare provider.				
	* the prescription chart and batch numbers recording allow approximately 6 weeks before the prescription chart will need to be re-written.				
7.3	All non-disposable equipment is cleaned and returned to its storage area.				
7.4	Wash hands.				

# 8. Education and Training

All nursing staff caring for and setting up Subcutaneous immunoglobulin must be IV competent and have attended and signed off competent. This will ensure that staff:

- Can give an explanation to the child and family
- Can programme the pump
- Can check, programme and change the pump if the child's condition changes
- Able to troubleshoot the pump
- Able to troubleshoot any problems or associated complications.
- Have an understanding of the side effects of Subcutaneous immunoglobulin and are able to deal with complications effectively

# 9. Monitoring Compliance

None

### 10. Supporting References

Guo, Y., Tian, X., Wang, X. and Xiao, Z. 2018. Adverse Effects of Immunoglbobulin Therapy. Frontiers in Immunology. 9:1299 doi: 10.3389/fimmu.2018.01299

Patel, N. C. et al., 2015. Subcutaneous immunoglobulin Therpay with Hizentra is Safe and Effective in Children Less Than 5 Years of Age. Journal of Clinical Immunology. 35; 558-565.

Harrison. J, Sabu.J, Duddridge. M. 2010. Review of safety of subcutaneous immunoglobulin (SCIG) therapy with or without prior intravenous immunoglobulin (IVIG) therapy with or without a trained buddy in a UK centre. Department of Immunology, University Hospitals of Leicester NHS Trust. Leicester

Kobrynski, L. 2012, **Subcutaneous immunoglobulin therapy: a new option for patients with primary immunodeficiency diseases.** Biologics, 6; 277-287.

Malcolmson, C. et al. 2015. Intravenous and Subcutaneous Immunoglobulin Guideline. Great Ormond Street Hospital.

The Code Professional standards of practice and behaviour for nurses, midwives and nursing associates Publication date: 29 January 2015 Effective from: 31 March 2015 Updated to reflect the regulation of nursing associates: 10 October 2018

Leicestershire Medicines Code UHL Policy Version 5.8 Reviewed PGC 21 February 2020 Trust ref: E12/2016 Date of next review May 2023 Page 13.3 **Section Update February 2020 v5.8** 

Personal Protective Equipment at Work UHL Policy

Infection Prevention UHL Policy

Patient ID Band UHL Policy

PID UK (2019) Patient information re: treatment options <a href="http://www.piduk.org">http://www.piduk.org</a>

PID UK (2019) Immunoglobulin therapy

University Hospitals of Leicester Insite (2019) Injectable Medicines Guide http://medusa.wales.nhs.uk/LocalSelect.asp

UK PIN (2004) Potential Transmission of Infective Agents http://www.library.leicestershospitals.nhs.uk

UK PIN (2018) Immunoglobulin Product Choice for Patients with Primary Immunodeficiency http://www.ukpin.org.uk/docs/default-source/default-document-library/ukpin-position-statement/ukpin-position-statement.pdf?sfvrsn=3928c8b4 8

Department of Health (2011) Clinical guidelines for immunoglobulin use (second edition update) p4, p15

www.gov.uk/government/publications/clinical-guidelines-for-immunoglobulin-use-second-edition-update

INGID (2019) European Nursing Guidelines for Immunoglobulin Administration, UK version p22-26

https://ingid.org/wp-content/uploads/2016/07/European-Nursing-Guidelines-Immunoglobulin-Administration.pdf

TRIAC (2016) The Compendium of Immunology, Edition 2

# 11. Key Words

Human immunoglobulin, subcutaneous

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs. As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

	Contact & review details	
Ī	Guideline Lead (Name and Title)	Executive Lead
	Richard Cawthorn Specialist Nurse	Chief Nurse

**Details of Changes made during review:** 

October 2023:

Added dispensing info -

Products are usually dispensed for use within 4-7 days for scig weekly infusion, usually longer for IVIG which is administered every 3 weeks -14-21 days

## Appendix 1

McKinley T34 Ambulatory Syringe Pump:

# Administration of subcutaneous immunoglobulin infusions within the Children's Hospital Business Unit

The McKinley T34 Ambulatory Syringe Pump is the infusion device of choice within the UHL NHS Trust as a replacement for the Graseby MS16a syringe drivers.

The standard set up of the McKinley T34 Ambulatory Syringe Pump is configured and designed for use within Oncology and Hospice settings where infusions are administered over a 24 hour period. Rate and duration defaults are configured to reflect a slow infusion rate over a prolonged period of time i.e. 24 hours.

#### The T34 will accommodate

- BD Plastipak 20ml syringes to a fill volume of 17mls (available in the Children's Hospital)
- <u>BD Plastipak 30ml syringes to a fill volume of 22ml (not currently available within the Children's Hospital).</u>

The occlusion pressure of a pump is the pressure in the tubing registered at the pump, when the pump is still operating but cannot sustain the flow rate. The resultant build-up of pressure sets off the occlusion alarm (MDA, 2003).

The viscosity of subcutaneous immunolglobulin, the smaller bore tubing and needle create a higher in-line pressure than intravenous lines and cannulae especially within Children's. The combination of the higher rate, necessary to infuse the contents of the syringe over an hour, 24x faster than a daily dosing regime, lead to more occlusion alarms at configured pressures. (This does not appear to be a problem when using BD Plastipak 10ml syringes).

Many immunoglobulin products for subcutaneous use recommend a maximum of 15ml per site. These volumes have been exceeded in clinical practice based on user preference. Children and adolescents on larger doses administer subcutaneous immunoglobulin via 4 sites using 4 needle set lines (total volume 60mls = equivalent to 6 x10ml vials).

Largest current dose volume for any one child is 50mls. (The family infuse on 2 consecutive days per week: 20ml + 30ml.)

These volumes and the supply of 2 syringe pumps for Home Therapy enables each 15ml syringe to be infused over an hour (infusion time 2 hours).

When configuring the T34 Ambulatory Syringe Pump based on duration of infusion using smaller sized syringes results in the syringe contents being administered over an hour. 6 x10ml syringes would extend the child's infusion to 3 hours weekly.

The McKinley T34 Ambulatory Syringe Pump would therefore need to be configured to administer infusions over an hour to a maximum rate not exceeding 15.1ml/hr: (the aim within the Children's Day Care facility on previous experience of subcutaneous immunoglobulin infusions has been to administer the complete dose over an hour.) It may be necessary to adjust the configuration of the T34 to accommodate a rate default in preference to one hour duration to enable the infusion of one syringe to be completed over 30 minutes i.e. one syringe dose 10 -15mls over 30 minutes to allow a 10ml syringe to infuse over 30 minutes (2 x10mls = an hour, 2 T34 pumps = 40mls per hour).

The McKinley T34 Ambulatory Syringe Pump calculates the infusion rate on time/ duration default based on syringe contents which will vary dependent on whether the infusion set is primed manually prior to loading the syringe or after being loaded using the T34.

For hourly infusions and ease of use common practice would be to prime the infusion line and needle manually so the contents of the syringe are then infused at the set rates or over an hour. (A time duration setting means that slight differences in syringe volume i.e. 0.2ml priming volume would result in a small change in infusion rate to infuse the extra 0.2ml over 60 minutes).

Occlusion alarms can be activated by:

- Kinking of the set (roller clamps and taps are not used on our Neria infusion needle sets)
- A fully occluded set or needle (unlikely for clots to form due to small bore sets, needles and no bleed back via subcutaneous tissues)
- Partially occluded set or cannula due to needle position
- Very long or narrow bore set and/ or cannula

The Occlusion response is characterised by three measurable parameters:

- Pressure to alarm the pump attempts to maintain sufficient pressure on the fluid to cause it to flow through all restrictions and overcome additional resistance. Fluid is incompressible, while the administration set and other components usually have some 'give' (compliance) and the tubing can expand under the increasing pressure – which can take some time.
- 2. Time to alarm If there is an occlusion from the beginning of the infusion, the time to alarm will be increased. The pressure in the pumping chamber increases from zero at the start of the infusion up to the alarm level. This is the most likely situation, as leaving clamps closed is the most usual cause of occlusions. (Neria needles sets do not use clamps). If the occlusion pressure occurs after the pump has stabilised at its set flow rate, the alarm time will not be unusually long as the pressure in the pumping chamber increases from the already high running pressure up to the alarm level. A time to alarm for the T34 at an infusion rate of 1ml/hr is 16 minutes 7 seconds (PASA, 2006).

Generally, shorter time to occlusion alarm occur with high flow rates, small syringes and good quality syringes (hence problems with 20ml syringes at 15ml/hr using small bore needles).

The T34 has a post Occlusion bolus reduction system feature which reverses the operation of the motor to neutralise the pressure and prevent a "bolus" being delivered.

The battery is fitted by:

- a. Sliding the compartment cover off by pressing down on the ridged area whilst sliding the cover backwards.
- b. Push the battery into the compartment taking care to ensure that the battery and pump +/- contacts icons align.
- c. Slide the compartment cover back on by placing the cover as shown press down on the ridged area whilst sliding cover forward.

Use alkaline or lithium 9v battery

Average battery life is approximately 3-5 days (continuous use: 72-120 hours)

Repeated key presses and activation of the screen backlight contribute towards battery depletion, use only as required (setting the T34 for hourly infusions will result in battery depletion being more rapid: ? 24x quicker = 3-5 hours?)

When being monitored by healthcare professionals or following instruction of parents/children, the low battery alert can be used as an indication to change the battery. A minimum of 40% battery life at infusion start is needed to cover a 24 hour infusion.

### Choice of administration set:

Latex free
Micro-bore anti-kink tubing to prevent occlusion
? colour coding on lines,
priming volume 0.2 - 0.5ml

#### Syringe brands and sizes:

The T34 ambulatory syringe pump is calibrated to operate with the most commonly used luer lok syringe brands and programmed to recognise most commonly used syringe sizes ranging from 2ml to 50ml.

Default syringe brands and sizes are:

BD Plastipak 3, 5, 10, 20, 30 and 50ml

All but the brands in regular use should be disabled via the BodyComm communication software to prevent accidental selection of the incorrect syringe brand during set up.

#### Syringe maximum volumes:

Due to the physical length of the screw that drives the syringe plunger forward there are limits to the maximum amount that can be delivered from larger syringes:

20ml syringe = 18mls; 30ml syringe = 24ml; 50ml syringe = 35ml

Luer Lok syringes must always be used to ensure secure connection of the infusion set and the pump is calibrated for luer lok only. DO NOT use slip tip syringes, using slip-tip syringes may result in under or over infusion as the dimensions of some manufacturers slip-tip syringes differ from their own luer lok variants.

#### Power on:

Press and hold down the ON/OFF key until screen illuminates: - this screen displays when no syringe is in place and the barrel clamp arm is down. Pre-loading will then commence.

#### Pre-loading and automatic actuator movement:

On powering on and during Pre-Loading, the display screens provide pump information and the actuator moves automatically.

Pre-Loading and automatic actuator movement will not occur if the barrel clamp arm is raised when the pump is powered on.

Software version and pump identification – default is "syringe pump".

<u>Advisory notice</u> – it is advisable not to interrupt the automatic actuator movement to ensure that a previous programme is deleted.

<u>Pump parameters and mode of operation display</u> – note: the battery status value fluctuates during automatic actuator operation, do not rely on this value as the true battery percentage.

#### Screen prompt to load syringe

The automatic actuator movement will delete any previous programme in the pump memory. At the end of Pre-Loading the actuator returns to the start position of the last infusion programmed.

Warning: Do not use force to try to move the actuator manually, this could damage the device and/or affect calibration.

Warning: If a foreign body is trapped in front of, or behind the actuator (during Pre-Loading or when manually adjusting the actuator) the user must:

Power the pump off

Raise barrel clamp arm

Power on

Lower barrel clamp arm and use either the FF or Back key to release the object. Ignore screen prompts as the prompt that may display is in relation to the alarm not the trapped object.

#### Info menu:

- a) Press the INFO key to access the INFO menu (pause infusion if running).
- b) Scroll through the options using the arrows  $(\uparrow/\downarrow)$ :
- c) View battery level
- d) View event log
- e) Change ml/hr infusion default rate rate setting (this is access code protected to specified limits)
- f) Change Set Up change and configure programming functions (this is access code protected)
- g) Exit Info Menu

# Syringe Loading, Detection and Confirmation;

#### Manual adjustment of actuator

- a) Ensure the barrel clamp arm is down
- b) Place the syringe above the pump to align the syringe collar to the collar sensor If required, use the FF/Back keys to move the actuator to the correct position for placing the syringe into the plunger sensor.

#### Syringe fitting:

- a) Lift the barrel clamp arm fully and turn the arm 90°
- b) Place the syringe collar vertically into the pump collar slot and the syringe into the pump plunger slot (the syringe should click into position)
- c) Turn and lower the barrel clamp arm onto the syringe.

As you correctly seat each point of the syringe the flashing indicator for that sensor becomes solid on the screen display, when all three sensors detect, a syringe size and brand display.

### Syringe detection and confirmation:

The pump identifies the syringe brand, size and volume by measuring the syringe dimensions from the three sensors.

a) Check that the syringe brand and size inserted into the pump matches the syringe brand and size displaying, if they match confirm by pressing YES.

If the syringe brand displayed is not correct use the  $\uparrow/\downarrow$  arrow keys to scroll between brands of similar dimensions. This will only happen if the syringe selected has dimensions within +/-1mm of other commonly used brands.

## Pump Programming, Resume or New Syringe?

When a syringe has been confirmed the pump calculates the ml/hr rate from the syringe volume and fixed infusion duration:

- a) Review the infusion summary to check that the parameters displayed match the prescription!?
- visibly check if the volume in the syringe matches the volume displayed
- check duration displayed is the duration required for the infusion
- check that the rate displayed is the syringe volume confirmed divided by the duration To confirm infusion parameters, press YES.

### Resume or New Syringe?

This screen prompt displays if the programme is interrupted by alarm activation: syringe displacement and occlusion, the pump is powered off for any reason and powered on with a syringe in place and on completion of purge:

Pressing "YES" retains the current programme

Pressing "NO" deletes the current programme, the pump will then calculate a new programme based on the current syringe volume.

The most important feature to remember is that "Resume" protects the calculated infusion rate for the current programme, so:

If you increase the syringe volume and resume the programme/syringe, the duration of delivery will increase

If you decrease the syringe volume and resume the programme/syringe, the duration of delivery will decrease.

#### Lock On: Prime and Load Start Up Sequence:

Prepare the syringe and infusion set – prepare the syringe with the immunoglobulin as per prescription and local policy, attach drug label and ensure the label lies flat

Manually prime the set – attach prepared syringe to the infusion set and manually prime.

Check the pump – ensure that the device is clean, visually intact and appropriate for the intended use

Insert the battery - use correct method

Power on and observe Pre-Loading:

- a) before powering on ensure the barrel clamp arm is down and no syringe is in place
- b) Press and hold down the ON/OFF key
- c) Observe automatic movement of the actuator (Pre-Loading)
- d) Check information screens
- e) Wait until the actuator stops moving and the syringe sensor detection screen (Load Syringe) displays

Check the battery level %

- a) Press the INFO key to display the Info menu
- b) To view battery meter, press YES
- c) Check the battery level

Wait a few seconds for the "Load Syringe" screen to display

Load and confirm the correct syringe:

- a) Align syringe to fitting areas and load the syringe into the pump
- b) View the display to check that the syringe brand and size displayed matches the one placed in the pump
- c) If they DO NOT match, use the ↑/↓ arrow keys to scroll to the syringe brand to match, press YES to confirm
- if they match, press YES to confirm

Review and confirm infusion programme:

- a) Review the infusion/programme summary to check the parameters displayed match the prescription
- visibly check if the volume in the syringe matches the volume displayed
- check duration displayed is the duration required for the infusion
- check that the rate displayed is the syringe volume confirmed divided by the duration.
- b) To confirm infusion, press YES.

Connect cannula/set to patient:

Site/connect the cannula/infusion set to the patient. (Follow local policy for the recommended cannual and set to use).

Start Infusion:

Press YES/START to commence the infusion when ready to do so.

Check and confirm infusion is running:

Visually check that the infusion running screen is visible and the green light flashes intermittently.

### **Lock on: Load and Prime Start Up Sequence:**

Step 1 – Prepare the syringe with drug – immunoglobulin as above;

DO NOT Prime the set

Step 2 – Check the pump

Step 3 – Insert the battery

Step 4 - Power on and observe Pre-Loading

Step 5 – Check battery level

Step 6 – Load and confirm the correct syringe

# Step 7 – remove syringe, prime the set, re-load syringe, review and confirm infusion programme

- a) DO NOT CONFIRM infusion/programme summary screen
- b) Remove syringe from pump
- c) Attach syringe to the infusion set/cannula and manually prime (assume a priming volume of 0.5ml)
- d) Align syringe with fitting areas and load the syringe into the pump
- e) View the display screen to check that the syringe brand and size displayed matches the one placed into the pump
- f) If they DO NOT match, use the ↑/↓ arrow keys to scroll to the syringe brand to match, press YES to confirm
- if they match, press YES to confirm.
- g) Press "Yes to resume" (to decrease the infusion duration).
- h) Review infusion programme/summary to check that the parameters displayed match the prescription:
- visibly check if the volume in the syringe matches the volume displayed
- check the duration is less than the default duration
- check that the rate displayed is the syringe volume confirmed divided by the duration
- i) To confirm infusion, press YES

Step 8 – Connect the cannula set to the patient

Step 9 – Start the infusion

Step 10 – Check and confirm infusion is running

#### Alerts and Alarms:

When an ALERT is activated:

The infusion continues:

2/3 beeps are heard approximately every 3 to 4 minutes

A screen message indicating the cause of the alert displays intermittently with the infusion running screen.

Alerts activate approximately 15/30 minutes prior to infusion and battery end.

When an ALARM is activated:

#### The infusion stops:

A continuous audible alarm activates (this will continue until either the YES key is pressed to mute or the problem is rectified).

A screen message displays to indicate the cause of the alarm.

The infusion status indicator (LED) light turns red.

Press the YES key to silence the alarm noise for 2 minutes (device is paused) and read screen prompt which indicates the causes.

#### **Troubleshooting:**

Screen	Description	Implication/Action
Low Battery	Alert: Battery is almost	Prepare to change the
	depleted	battery
Programme nearly	Alert: Infusion will end	Prepare to change syringe
complete	soon	or turn pump off
Pump paused too long	Alarm: Pump has been left	Either start the infusion,
	in STOP mode (on hold)	continue pause or turn the
	for 2 minutes	pump off
End Battery	Alarm: Battery is depleted	Change battery
End program/Syringe	Alarm: Infusion is	Close down or start new
	complete	infusion
Syringe displaced, check	Alarm: One or more of the	Check screen messages,
syringe	syringe detection sensors	for assistance
	is not detecting	Check the syringe and re-
		seat as necessary
Occlusion Check Line &	Alarm: Pt access device is	Flush/replace access
Syringe	either blocked, occluded,	device, release the clamp
	clamped or kinked	or un-kink the set

#### Technical problem/error and failure identification

Two examples of system failure screen messages are shown:

The pump alarms if an internal system fault has been detected and the unit will be inoperative, screen information and user prompts will vary, depending on the cause of the fault.

Power the pump off and then power on again, this may rectify the problem. If the problem cannot be rectified: Power the pump off and remove from patient use.

Follow local policy and/or contact your authorised Medical Engineering Department for advice if necessary. (If possible, record the code number (if available) and a summary of the fault).

#### **Keypad Lock and Lockbox:**

Keypad Lock – allows locking the operation of the keypad during infusion to prevent tampering and/or inadvertent key presses or power off.

- a) To activate, press and hold the INFO key until the graphic fills left to right and an audible beep is heard.
- b) To deactivate, repeat the procedure (the graphic empties from right to left).

Lockbox – the rigid lockbox helps protect the syringe from displacement and is suitable for most syringe sizes up to 30ml.

Open the lockbox using the standard key that operates all T34 lockboxes. The lockbox has an additional open area to allow battery change during the infusion.

Lockboxes are made from Polycarbonate due to its high impact, temperature resistance and optical properties, durability tests confirm that the overall design and construction of the T34 lockbox ensures that they are fit for their intended purpose of protecting the T34 syringe driver from damage caused through normal daily use and drops within the accepted normal range of one metre.

NOTE: Lockboxes are designed for use with CME Medical administration sets. If using an alternative brand administration set, that set design may prevent the lockbox from fully closing and locking.

# **Pump Monitoring During Infusion:**

It is recommended that procedures are established for regular checks on the progress of the infusion.

Check:

For signs of physical damage to the pump and/ or accessories
The LCD display screen to confirm the pump is still infusing
That the LED green light flashes intermittently (a continuous red light indicates the infusion is paused)

NOTE: The last line alternates with the syringe size and brand confirmed by the user during programming.

To view the volume to be infused (VTBI), volume infused (VI) and battery level, with the infusion running:

Press INFO key once – VTBI, VI; press INFO key twice – battery level

# Appendix 2

# Subcutaneous Immunoglobulin Administration Assessment Tool

Parent's assessment for the safe administration of subcutaneous immunoglobulin at home

PROCEDURE	Date and signature 1 <sup>st</sup> Practice	Date and signature 2 <sup>nd</sup> Practice	Date and signature 3 <sup>rd</sup> Practice	Date and signature 4 <sup>th</sup> Practice	Date and signature 5 <sup>th</sup> Practice	Date and signature Final assessment
Remove the immunoglobulin from fridge one hour before use. Check packaging for damage						
Check drug name, dose, and expiry. Documents batch number on infusion record						
Prepares and gathers all equipment required from the list onto a clean work surface						

Appendix 3
University Hospitals' of Leicester NHS Trust
Leicester Royal Infirmary
Home Therapy Programme for Subcutaneous Immunoglobulin

Date:

Names of participants:

#### **WRITTEN ASSESSMENT**

Please attempt to answer all the questions on this paper. If you are unsure of an answer please indicate by answering 'not sure' or 'don't know'.					
For each of the following statements please tick the box indicating whether you think the statement is <b>true</b> , <b>false</b> or you are <b>not sure</b> .					
1	The thalaset needle should be inserted at 45° to the skin	True	False	Not sure	
2	It is safe to carry on using a thalaset needle if blood is seen in the tubing				
3	Subcutaneous injections go under the skin				
4	Immunoglobulins are also known as antibodies				
5	It is safe to have an infusion when you have an untreated infection				
6	An adverse reaction may occur if the infusion rate is too <b>slow</b>				
7	Hepatitis is inflammation of the liver				
8	The batch number of the immunoglobulin product used must be recorded on the infusion record				

For the following questions there may be one or more correct answer for each question: please tick boxes which are correct.

9. If the end of the needle is touched accidentally, what should you do?

Wipe it with an alcohol swab and use as normal Throw it away

	Use a new needle Soak in hot soapy water and then use as normal Do nothing and use as normal	† †
10.	When a needle has been used it should be disposed of by:	
	Placing it in a sharps container	Ť
	Wrapping it in paper and placing it in the domestic rubbish	Ť
	Replacing the plastic cover and placing it into a sharps container	Ť
	Bending with pliers and placing it into a sharps container	Ť
11.	If you notice a raised rash, itching or signs of headache you shou	ld:
	Slow the infusion to half the present speed	Ť
	Stop the infusion immediately	
	Give analgesia e.g. paracetamol and/or an antihistamine e.g piriton as prescribed	Ť
	Do nothing and wait for the symptoms to clear	
12.	Which of the following helps to maintain asepsis:	
	Good hand washing and drying technique	Ť
	Wipe all dirty or contaminated equipment with an alcohol swab and re-use	Ť
	Clear all non-vital equipment such as flowers and ornaments out of the way	Ť
	Not using any equipment which becomes contaminated	Ť
	Washing hands only at the end of the infusion	Ť
13.	Asepsis means to:	
	Increase the risk of introducing infection	Ť
	Keep as dirty as possible	Ť
	Decrease the risk of introducing infection	Ť
	Keep as warm as possible	Ť
	Keep as clean as possible	Ŧ
14.	The thalaset needle should be:	
	Inserted under the skin	Ť

	Inserted at 90° to the skin	Ť	
	Inserted into a vein	Ť	
	Inserted into an artery	Ť	
	Cleaned with an alcohol swab and used again	Ť	
	Please answer the following questions in your own words. If you are unsure, please indicate by writing 'unsure'.		
15.	What would you do if the alarm on the syringe driver sound empty?	ded before the syrir	nge was
16.	What is the correct rate of your infusion?		
17.	Why is it important <b>not</b> to set the infusion rate any higher to maximum rate given?		
18.	Which two sites can you use to insert the thalaset needle in 1.	nto for your infusion	n?
19.	2.  If the area around the thalaset needle starts to ooze or bed should you do?	come uncomfortable	e, what
20.	If another person is accidentally jabbed with a used needle		do?
21.	List two things which may cause an adverse reaction:		
	1.		

	Why is it important for blood samples to be taken regularly?
	When should you send your infusion records to the Immunology Nurse?
	Why is it important to send your infusion records to the Immunology Nurse?
	On what occasions would you contact your GP when giving an infusion at home
	Give two reasons why you should postpone your infusion:  1. 2.
	2. Why are blood samples taken regularly to monitor liver function?
	u have any questions about home therapy and the infusion? e give details:
y ot	her comments:

The end!

Evaluation and outcome of Assessment: