



WACHS Intravenous Immunoglobulin (IVIg) Guideline

1. Guiding Principles

Intravenous Immunoglobulin (IVIg) is used in the treatment of several immunologic, haematologic and neurologic illnesses. The use of IVIg is governed by the National Blood Authority (NBA).

IVIg is managed and supplied by the National Blood Authority via the BloodStar and BloodNET platforms. Criteria for the clinical use of intravenous immunoglobulin in Australia was developed to assist clinicians to identify the conditions and circumstances for which the use of intravenous Immunoglobulins (IVIg) is appropriate and funded under the National Blood Agreement . The administration of IVIg for these conditions is supported by WA Country Health (WACHS) hospitals often via same day infusion services.

2. Guideline

2.1 Indications:

Intravenous immunoglobulin (IVIg) is a fractionated blood product made from pooled human plasma, containing a concentrated mix of many antibodies from many hundreds of donors. It is registered for use in Australia for the treatment of a number of diseases where immunoglobulin replacement or immune modulation therapy is indicated, such as primary immunodeficiency and chronic inflammatory demyelinating polyneuropathy. IVIg is also used to treat a growing number of unregistered indications where there is some evidence for its utility.

Examples of indications include:

- Primary Immunodeficiency diseases (PID)
- Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.
- Immunomodulatory therapy in:
 - Idiopathic Thrombocytopenic Purpura (ITP) in adults or children at high risk of bleeding or prior to surgery to correct platelet count.
 - Kawasaki disease
 - Guillain Barre Syndrome (GBS)
 - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
 - Multifocal Motor Neuropathy (MMN)
 - Myasthenia Gravis (MG)
 - Lambert-Eaton Myasthenic Syndrome (LEMS) patients

A full criteria for eligible supply can be found on the [BloodSTAR website](#).

Patients are required to be registered with BloodSTAR with a current authorisation. Product is then sourced via BloodNET.

Access for conditions outside the NBA requires a jurisdictional direct order (JDO). This allows the health service to purchase the product directly from the supplier. Obtaining a JDO is complex and would require an individual patient approval from the hospital

medication safety group or drugs and therapeutic committee as per the Statewide Medicines Formulary Policy.

The brand of immunoglobulin is determined by the clinician when registering the patient with BloodSTAR.

2.2 Dose:

The dose required is based on the patient’s body weight. The recommended dose varies depending on the condition. Approved doses can be found on the [Criteria for Clinical Use of Immunoglobulin in Australia](#) site.

2.3 Contraindications:

Intragam® 10	Privigen®	Flebogamma®	Gamunex®
Intragam® 10 is contraindicated in patients who have had a true anaphylactic reaction to human immunoglobulins (especially in patients with antibodies against IgA) or to the excipient glycine.	Hypersensitivity to the active substance or the excipient. Hypersensitivity to human immunoglobulins, especially in patients with IgA deficiency where the patient has anti-IgA antibodies. Patients with hyperprolinaemia type I or II.	Hypersensitivity to any of the components. Hypersensitivity to homologous immunoglobulins, especially in very rare cases of IgA deficiency, when the patient has antibodies against IgA. Hereditary fructose intolerance Children under 5 years of age due to the risk of hereditary fructose intolerance	Hypersensitivity to the active substance or the excipient glycine. Hypersensitivity to human immunoglobulins, especially in patients with IgA deficiency where the patient has anti-IgA antibodies.

2.4 Precautions:

Aseptic Meningitis Syndrome (AMS)
Aseptic meningitis syndrome has been reported to occur in association with IVIg treatment. Discontinuation of IVIg treatment has resulted in remission of AMS within several days without sequelae.
Hypersensitivity
True hypersensitivity reactions are rare. They can occur in the very seldom cases of IgA deficiency with anti-IgA antibodies. Rarely, IVIg can induce a fall in blood pressure with anaphylactic reaction, even in patients who have tolerated previous treatment with human normal Immunoglobulin.

Thromboembolism
There is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thromboses. Caution should be exercised in prescribing and infusing IVIg in obese patients and in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, and patients with diseases which increase blood viscosity).
Acute renal failure
There have been occasional reports of renal dysfunction and acute renal failure in patients receiving IVIg products. Patients at increased risk are those with pre-existing renal insufficiency, diabetes mellitus, age greater than 65 years, volume depletion, sepsis and paraproteinaemia, and those taking concomitant nephrotoxic drugs.
Haemolytic Anaemia
IVIg products can contain blood group antibodies which may act as haemolysins and induce in vivo coating of red blood cells with immunoglobulin, causing a positive direct antiglobulin reaction (direct Coomb's test) and, rarely, haemolysis. Haemolytic anaemia can develop subsequent to IVIg therapy due to enhanced red blood cell (RBC) destruction or sequestration. IVIg recipients should be monitored for clinical signs and symptoms of haemolysis.
Infusion rate
Certain reactions to IVIg tend to be related to higher rates of infusion rate and are most likely to occur during the first hour. It is recommended that the patient's vital signs and general status are monitored regularly throughout the infusion.
Live vaccines
Immunoglobulin infusion may interfere with the response to live attenuated vaccines. Therefore administration of such vaccines e.g. poliomyelitis or measles should be deferred until approximately three months after intravenous immunoglobulin administration. See product insert for further information.

For additional information on precautions refer to the product information available from the Australian Red Cross Blood Service [Intravenous Immunoglobulin product information](#)

2.5 Presentation:

Please note: Administration rates and protocols will vary between products and presentations.

Products/presentations are not interchangeable.

Brand selection is determined by the medical specialist when registering the patient with BloodSTAR.

All products should be clear or slightly opalescent liquids ranging from colourless to pale yellow, If the product appears turbid or to contain any sediment it must not be used and the product returned unopened to the Australian Red Cross Blood Service.

Intragam ® 10	Privigen ® / Gamunex®	Flebogamma ®
Immunoglobulin G 10% At least 98% pure <ul style="list-style-type: none"> • 2.5g / 25ml • 10g / 100ml • 20g / 200ml 	Immunoglobulin G 10% At least 98% pure <ul style="list-style-type: none"> • 5g / 50ml • 10g / 100ml • 20g / 200ml 	Immunoglobulin G 5% At least 97% pure <ul style="list-style-type: none"> • 0.5g / 10ml • 2.5g / 50ml • 5g / 100ml • 10g / 200ml • 20g / 400ml Immunoglobulin G 10% At least 97% pure <ul style="list-style-type: none"> • 5g / 50ml • 10g / 100ml • 20g / 200ml

2.6 Storage Conditions:

Intragam ® 10	Privigen ®	Flebogamma ®	Gamunex
Store between 2° – 8°C May be removed and stored below 25°C for up to 3 months prior to use. Do not re-refrigerate Do not freeze Keep bottle in the original box to protect from light until in use	Store below 25°C Keep bottle in the original box to protect from light until in use.	Store below 25°C Keep bottle in the original box to protect from light until in use	Store between 2° – 8°C May be removed and stored below 25°C for up to 6 months prior to use. Do not re-refrigerate

2.7 Consent:

All patients are required to be admitted under a medical officer credentialed at the hospital. The admitting medical team are required to ensure the [MR 30G Consent to Blood Products](#) is completed and current prior to the infusion. The consent is valid for 12 months from the date of consent for recurrent infusions to manage chronic illness unless clinical condition changes or the consent is withdrawn.

Patients must be provided with appropriate written information such as the [NBA Patient Information: Immunoglobulin Treatment](#) at the time of consent.

2.8 Ordering:

Product is not able to be supplied for patients who do not have a current authorisation on BloodSTAR or are not linked to the sites BloodNET location via the BloodPortal. Product is ordered through BloodNET on the BloodPortal. Contact the pharmacy or Pathwest to arrange delivery prior to the booked admission.

The batch of the products issued to the patient is recorded against the patient record on BloodNET portal. Product not administered to the patient must be returned for the transaction to be reversed prior to being reissued to another patient.

2.9 Treatment Order:

The treatment order for intravenous immunoglobulin must be charted on the [MR 175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart](#)

At each episode of care, each vial must be charted on a separate line to enable tracking of specific batches in the case of a reaction.

2.10 Administration:

Prior to administration

- Check the patient identity using 3 identifiers
- Check the right dose for the patient (if multiple bottles is the full dose available)
- Check the patient is due by confirming the date of the last infusion.
- Confirm consent is completed and current
- Check the rate of infusion

All IVIg products contain no antimicrobial preservative and must be used immediately after opening the bottle. Unused portion should be discarded appropriately.

All products must be at room temperature prior to administration, see storage conditions for how long products can be maintained at room temperature (below 25°C) prior to administration.

Inspection:

- Immunoglobulin is a sterile, clear or slightly opalescent, colourless or pale yellow solution for intravenous injection
- Do not use if the solution appears cloudy or contains deposits

Infusion Equipment:

- IVIg may be administered through any standard IV infusion giving set.
- Allow the product to reach room temperature, before infusing to the patient.
- IVIg should NOT be mixed or diluted with any solution, it is given in pure concentration form.

- Administer pre-medication, if prescribed, at a suitable time before the infusion commences to allow it to be effective.

Priming and Flushing:

- Using aseptic non-touch technique, prime the line with 0.9% normal saline. The line volume can be administered as a bolus (16ml) then commence the IVIg as per protocol.
- Administer intravenously through an infusion pump to ensure accurate delivery rates
- Administration from a glass bottle requires a vented system.
- Use immediately after opening the bottle as it does not contain an antimicrobial preservative.
- The line may be flushed with Normal Saline 0.9% following infusion. 5% Glucose can be used, however Intragam10 is only compatible with Normal Saline 0.9% .
- During an infusion, subsequent vials may commence at same rate that the preceding vial finished.

Rates vary depending on the product. See below for the rates for each product. Subsequent vials can be commenced at the rate used at the end of the last vial.

Intragam ® 10	Privigen ®	Flebogamma ®	Gamunex®
Commence at 1ml / min	Commence at 0.3ml / kg / hr	Flebogamma 5% commenced at 0.01-0.02 ml / kg / min	Commence at 0.01ml/kg/min for 30 minutes
After 15 minutes increase gradually to a maximum of 4ml / min	Gradually increase to 4.8ml / kg/ h	Gradually increased to 0.1 ml / kg / min	Gradually increase to 0.08ml/kg/min
Maximum rate 4ml / min	Maximum rate 4.8ml / kg / hr	Maximum rates 5% 0.1 ml / kg / min 10% 0.08ml / kg / min	Maximum rate 0.08ml / kg / min

2.11 Monitoring

Perform and document on the appropriate observation and response chart the patient’s temperature, pulse, respiration rate and blood pressure at the following points **as a minimum**:

- prior to commencing
- 15 minutes after commencing
- prior to each rate increase and hourly once maximum rate achieved
- on completion of the infusion
- if patient experiences any new or increased symptoms
- observe all patients for 20 minutes post completion. Patients who are having IVIg for the 1st time or have had a long interval between infusions should be monitored for 1hr after their first infusion
- if a patient experiences an adverse reaction to IVIg infusion more frequent observations may be required.

Reaction	Management
Minor reactions <ul style="list-style-type: none"> - headache - nausea - vomiting - malaise - non-urticarial skin reactions - flushing - chills - pain or swelling at the IV site 	<ul style="list-style-type: none"> - Temporarily stop the infusion - Contact the medical officer - Consider recommencing the infusion at half the previous rate - Document the reaction and ensure the ordering physician is informed.
Moderate to Severe reactions ‘ <ul style="list-style-type: none"> - Chest tightness - Coughing - Dyspnoea or respiratory difficulty - Sudden fall in blood pressure - Anaphylactic reaction 	<ul style="list-style-type: none"> - Stop the transfusion - Provide emergency care - Arrange urgent medical review (MET call if necessary) - Monitor vital signs every 15 minutes until stable - Report the suspected reaction to the admitting medical officer and order physician

Delayed reactions:

- | | |
|--|--|
| <ul style="list-style-type: none"> - nausea - vomiting | <ul style="list-style-type: none"> - chest pain - rigor - aching legs |
|--|--|

These reactions may occur post infusion, normally within 24 hours. Please ensure medical staff are notified and report in accordance with the WA Haemovigilance Reportable Adverse Events Review and Data Collection Process in appendix 3 of the [WACHS Blood Management Clinical Practice Standard](#).

3. Definitions

Intravenous Immunoglobulin	Is a solution of human plasma proteins IgG antibodies with a broad spectrum of antibody activity.
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4. Roles and Responsibilities

Medical Officer is to:

Ensure patient has authorisation via the BloodStar or confirm the authorisation is current.

Document the medical order for IVIg on the MR175A. This should include:

- The brand of IVIg and the % concentration
- Dose in grams
- Rate of infusion prescription as per appendices

Ensure informed consent from the parent/carer has been obtained and documented prior to commencement.

Consent is to be obtained on Consent to Blood Product form MR 30.

Explain procedure to patient, including potential adverse reactions and symptoms.

A medical officer must be willing and able to respond if a patient has a reaction to the immunoglobulin.

Registered Nurse is to:

Confirm the consent is current for patients prior to administration

Administer the immunoglobulin as per the medical order and additional information in the appendices

Monitor the patient appropriately and respond to reactions and patient deterioration as required

5. Compliance

WACHS staff are reminded that compliance with all policies is mandatory.

6. Records Management

[Health Record Management Policy](#)

7. Evaluation

Clinical Incident Management system (Datix) to be reviewed at local level and then reported at the WACHS Blood Management Committee (BMC) Meetings.

Complaints from consumers reviewed and actions monitored at local level and reported at the WACHS BMC meetings.

8. Standards

National Safety and Quality Healthcare Standards (Second edition 2017) – 1.14, 1.27, 2.7, 3.5, 4.3, 4.7, 6.6, 7.3, 7.6, 7.7, 8.4, 8.10

9. References

- Flebogamma 5% DIF, product information. Grifols Australia Pty Ltd. 2011
- Flebogamma 10% DIF, product information. Grifols Australia Pty Ltd. 2013
- Intragam® 10, product information. CSL Behring (Australia) Pty Ltd. 2015
- Privigen, Product information. CSL Behring (Australia) Pty Ltd. 2014
- Gamunex Product Information, Grifols Australia Pty Ltd 2019

Further information can be found on the National Blood Authority and Australian Red Cross Blood Service websites:

- <http://www.blood.gov.au/lg-governance>
- Intravenous immunoglobulin (IVIg) Clinical Practice Guideline
http://www.transfusion.com.au/blood_products/fractionated_plasma/IVIg
- Criteria for the clinical use of intravenous immunoglobulin in Australia.
<http://www.transfusion.com.au/>

10. Related Forms

[MR 175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart](#)
[MR30G Consent to Blood Products](#)

11. Related Policy Documents

[WACHS Blood Management Clinical Practice Standard](#)

12. Related WA Health System Policies

[WA Health Consent to Treatment Policy OD - 0657/16](#)
[Statewide Medicines Formulary Policy MP 0077/18](#)

13. Policy Framework

Clinical Governance, Safety and Quality

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on request for a person with a disability**

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Appendix A - Intragam® 10 (10%) infusion rate guide

Adult Patients

- The infusion should be commenced at the rate of 1 mL per minute (60mL/hr).
- Maximum rate 240mL/hr

Paediatric Patients

- Commence 1mL/kg/hr
- If tolerated, increase by 0.5-1mL/kg/hr every 30 minutes as tolerated
- Maximum rate 240mL/hr

Paediatrics: Consideration should be given to running IVIg at slower rates for paediatric/neonatal patients. Consultant Paediatrician or Blood Service Haematologist to determine the best rate for each child/infant/neonate.

Compatible with sodium Chloride 0.9% only.

Infusion Rates	Rate	Volume to be infused
1mL/min for 30 mins	60 ml / hour	30 ml
If well tolerated gradually increase infusion rate as follows:		
2mL/min for 30mins	120 ml/ hour	60 ml
3mL/min for 30 mins	180 ml / hour	90 ml
4mL/min for remainder	240 ml /hour	Until Infusion is complete



Appendix B – Flebogamma®

Flebogamma® 5% DIF infusion rate guide

Maximum Rate: 0.1 ml/kg/min 0.02 mL/kg/min. This may gradually be increased if well tolerated. Do not exceed 0.1 mL/Kg/min – see weight based rates. ***Please note that all infusions are capped at 300mls/hr**

ADULT INFUSION RATES:

The rate of administration is determined by the patient’s body weight. The infusion is commenced slowly and provided there are no adverse events, the rate can be increased according to the table below. **NOTE: Consideration should be given to reducing the rate of infusion in elderly patients and in patients with pre-existing renal disease.**

		PATIENT WEIGHT 40 - 50kg		PATIENT WEIGHT 50 - 60kg		PATIENT WEIGHT 60 - 70kg		PATIENT WEIGHT 70 - 80kg		PATIENT WEIGHT > 80kg	
rate ml/kg/min*	Length of time to infuse	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused
0.02	30 min	48 ml/h	24ml	60 ml/h	30ml	72 ml/h	36 ml	84 ml/h	42 ml	96 ml/h	48 ml
0.04	30 min	96 ml/h	48ml	120 ml/h	60ml	144 ml/h	72 ml	168 ml/h	84 ml	196 ml/h	96 ml
0.07	30 min	168 ml/h	84ml	210 ml/h	105ml	252 ml/h	126 ml	294 ml/h	147 ml	300 ml/h *	remainder
0.1	Until complete	240 ml/h	remainder	300ml/h *	remainder	300 ml/h *	remainder	300 ml/h*	remainder		

Flebogamma® 10% DIF

- Maximum rate: 0.08 ml/kg/min ADULT INFUSION RATES: *Increase the rate by 0.01 mL/kg/min (0.6 mL/kg/hr) every 30 minutes to a maximum of 0.08 mL/kg/min as tolerated by the patient.

		PATIENT WEIGHT 40 - 50kg		PATIENT WEIGHT 50 - 60kg		PATIENT WEIGHT 60 - 70kg		PATIENT WEIGHT 70 - 80kg		PATIENT WEIGHT > 80kg	
rate ml/kg/min*	Length of time to infuse	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused
0.01	30 min	24 ml/h	12 ml	30 ml/h	15 ml	26 ml/h	24 ml	42 ml/h	21 ml	48 ml/h	24 ml
0.02	30 min	48 ml/h	24 ml	60 ml/h	30 ml	72 ml/h	48 ml	84 ml/h	42 ml	96 ml/h	48 ml
0.04	30 min	96 ml/h	48 ml	120 ml/h	60 ml	144 ml/h	96 ml	168 ml/h	84 ml	192 ml/h	96 ml
0.06	30 min	144 ml/h	72 ml	180 ml/h	90 ml	216 ml/h	144 ml	252 ml/h	126 ml	288 ml/h	144 ml
0.08	Until complete	192 ml/h	remainder	240 ml/h	remainder	288 ml/h	remainder	300 ml/h	remainder	300 ml/h	remainder

Appendix C – Privigen® 10% rate infusion guide

Maximum rate: 4.8 mL/kg/hr - 0.3 mL/kg/hr. This may gradually be increased if well tolerated. Do not exceed 4.8 mL/Kg/hr

The rate of administration is determined by the patient’s body weight. The infusion is commenced slowly and provided there are no adverse events, the rate can be increased according to the table below. **NOTE: Consideration should be given to reducing the rate of infusion in elderly patients and in patients with pre-existing renal disease.**

Infusion rate ml/kg/hr	PATIENT WEIGHT 40 - 50kg			PATIENT WEIGHT 50 - 60kg			PATIENT WEIGHT 60 - 70kg		
	Length of time to infuse	Rate per Hour	Volume to be infused	Length of time to infuse	Rate per Hour	Volume to be infused	Length of time to infuse	Rate per Hour	Volume to be infused
0.3	30 minutes	12mls/hr	6 ml	30 minutes	15mls/hr	7 ml	30 minutes	18mls/hr	9 ml
0.6	30 minutes	24mls/hr	12 ml	30 minutes	30mls/hr	15 ml	30 minutes	36mls/hr	18 ml
1.2	30 minutes	48mls/hr	24 ml	30 minutes	60mls/hr	30 ml	30 minutes	72mls/hr	36 ml
2.4	30 minutes	96mls/hr	48 ml	30 minutes	120mls/hr	60 ml	30 minutes	144mls/hr	72 ml
<ul style="list-style-type: none"> • Patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and Primary Immune Deficiency (PID) disorders: maximum infusion rate capped at 2.4ml/kg/hr for the first 3 infusions • Patients with Immune Thrombocytopenia Purpura (ITP): maximum infusion capped at 2.4ml/kg/hr 									
3.6	30 minutes	144mls/hr	72 mls	30 minutes	180mls/hr	90mls	30 minutes	216mls/hr	108 ml
4.8	Until Completed	192mls/hr	Remainder	Until Completed	240mls/hr	Remainder	Until Completed	288mls/hr	Remainder

Infusion rate ml/kg/hr	PATIENT WEIGHT 70 - 80kg			PATIENT WEIGHT > 80kg		
	Length of time to infuse	Rate per Hour	Volume to be infused	Length of time to infuse	Rate per Hour	Volume to be infused
0.3	30 minutes	21 mls/hr	10 ml	30 minutes	24mls/hr	12 ml
0.6	30 minutes	42 mls/hr	21 ml	30 minutes	48 mls/hr	24 ml
1.2	30 minutes	84 mls/hr	42 ml	30 minutes	96 mls/hr	48ml
2.4	30 minutes	168 mls/hr	84 ml	30 minutes	192 mls/hr	96 ml
<ul style="list-style-type: none"> • Patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and Primary Immune Deficiency (PID) disorders: maximum infusion rate capped at 2.4ml/kg/hr for the first 3 infusions • Patients with Immune Thrombocytopenia Purpura (ITP): maximum infusion capped at 2.4ml/kg/hr 						
3.6	30 minutes	252 mls/hr	126 ml	30 minutes	288 mls/hr	144 ml
4.8	Until completed	300 mls/hr	Remainder	Until completed	300mls/hr	Remainder

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Appendix D – Gamunex® 10% rate infusion guide

Maximum rate 0.08ml/kg/hour. Commence infusion at 0.01ml/kg/hour and gradually increase to maximum of .0.08ml/kg/h
Capped rate of 576 ml/hour.

If dilution is required, dilute Gamunex® with Glucose 5% only. Infusion line may be flushed with Normal saline or Glucose 5%.

Use only 16 gauge needles to penetrate the stopper.

		PATIENT WEIGHT 50kg		PATIENT WEIGHT 60kg		PATIENT WEIGHT 70kg		PATIENT WEIGHT 80kg		PATIENT WEIGHT 90kg	
rate ml/kg/min*	Length of time to infuse	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused	Rate per Hour	Volume to be infused
0.01	30 min	30 ml/h	15 ml	36 ml/h	18 ml	42 ml/h	21 ml	48 ml/h	24 ml	54 ml/h	27 ml
0.02	30 min	60 ml/h	30 ml	72 ml/h	36 ml	84 ml/h	42 ml	96 ml/h	48 ml	108 ml/h	54 ml
0.04	30 min	120 ml/h	60 ml	144 ml/h	72 ml	168 ml/h	84 ml	192 ml/h	96 ml	216 ml/h	108 ml
0.06	30 min	180 ml/h	90 ml	216 ml/h	108 ml	252 ml/h	126 ml	288 ml/h	144 ml	324 ml/h	162 ml
0.08	Until complete	240 ml/h	remainder	288 ml/h	remainder	336 ml/h	remainder	384 ml/h	remainder	432 ml/h	remainder