

VersaRate and Infuset FlowCalc Output Variables

No.	Variable	Abbreviation	Description	Units	Rounded Decimals	Calculation
1	Total Flow Rate	FR (Tot)	The expected average total flow rate of the drug through all needle sites combined.	ml/hr	0	Lookup from flow rate table
2	Flow Rate Per Site	FR (Site)	The expected average flow rate of the drug passing through each needle site.	ml/hr	0	$\frac{FR(Tot)}{No. of Needles}$
3	Dosage Volume per Site	Vol (Site)	The volume of drug infused per needle site of the patient	ml	1	$\frac{Dosage}{No. of Needles}$
4	Infusion Time	T (inf)	The expected time for the drug dosage to be infused to the patient.	hrs min	0	$\frac{Dosage}{FR(Tot)}$

EXAMPLE: The following screenshot shows the input variables on the left that result in the output variables in the “Infusion Results” box in blue color.

1

Country:

USA

2

Drug:

Gammagard

Dosage (ml):

25

Patient weight:

Below 40kg

3

Infusion Pump:

SClg60 Infuser

4

No. of Needles:

4 Needles

Needle Gauge:

27 ga

Select specific set:

SUB-400

Needle Length:

6 mm

5

VersaRate® Position:



Infusion Results

☒ Show warnings for initial infusions



Total Flow Rate

56 ml/hr

Flow Rate Per Site

14 ml/hr

Dosage Volume Per Site

6.3 ml



Infusion Time

0 hrs 26 min

Error Handling and Warning Messages

Error handling in general needs to be built into the calculators to ensure that no inappropriate selections or input variables are entered – for example, the dosage text box should only be able to receive or process positive number values and all selections need to be made before output variables are shown – especially when the user changes/updates a previously made selection.

Specific warning messages need to appear when the user makes a selection that exceeds the prescribed limits (for the output variables) determined by the drug manufacturer (so called prescribing information). These limits may be different for each drug and even depends on which country the drug is being used. There are also two different thresholds for the warning limits – one for new patients doing their first few initial infusions and another (higher) threshold for experienced patients with their bodies used to receiving the drug.

If a warning message is triggered, the applicable output variable that has exceeded the threshold limit should be made a different color until a selection change is made. The applicable output variable should be highlighted in a light yellow with dark yellow text when exceeding initial infusion limits and light red background with dark red text if subsequent infusion limits have been exceeded. **Please include a check box which will allow the user to turn off ONLY warnings for initial infusions, so that experienced users will not be hassled by unnecessary warnings all the time.**

The following warnings need to appear if the given conditions apply:

The following warnings need to appear if the given conditions apply:

No.	Description	Condition	Warning Message																																												
1	Needle site limit	IF Country = USA AND Drug = Hizentra AND No. of Needles > 4 Needles	OFF LABEL USE NOTE: This message should appear next to the No. of Needles dropdown box.																																												
2	Total Flow Rate Limit	<table><tr><th colspan="2"></th><th colspan="3">Max Flow Rate Limits (ml/hr)</th></tr><tr><th>Drug\Country</th><th></th><th>USA</th><th>Canada</th><th>UK</th></tr><tr><td>Hizentra</td><td></td><td>9999 (no limit)</td><td>70</td><td>50</td></tr><tr><td>Gammagard or Kiovig (PW < 40kg)</td><td></td><td>160</td><td>160</td><td>160</td></tr><tr><td>Gammagard or Kiovig (PW >= 40kg)</td><td></td><td>240</td><td>240</td><td>240</td></tr><tr><td>Subcuvia or Gammanorm</td><td></td><td>N/A</td><td>N/A</td><td>9999 (no limit)</td></tr></table>			Max Flow Rate Limits (ml/hr)			Drug\Country		USA	Canada	UK	Hizentra		9999 (no limit)	70	50	Gammagard or Kiovig (PW < 40kg)		160	160	160	Gammagard or Kiovig (PW >= 40kg)		240	240	240	Subcuvia or Gammanorm		N/A	N/A	9999 (no limit)	Total flow rate limit exceeded														
		Max Flow Rate Limits (ml/hr)																																													
Drug\Country		USA	Canada	UK																																											
Hizentra		9999 (no limit)	70	50																																											
Gammagard or Kiovig (PW < 40kg)		160	160	160																																											
Gammagard or Kiovig (PW >= 40kg)		240	240	240																																											
Subcuvia or Gammanorm		N/A	N/A	9999 (no limit)																																											
3	Flow Rate Limit per Site	<table><tr><th colspan="2"></th><th colspan="3">Max Flow Rate Limits per Site (ml/hr)</th></tr><tr><th>Drug\Country</th><th>Infusion</th><th>USA</th><th>Canada</th><th>UK</th></tr><tr><td rowspan="2">Hizentra</td><td>Initial</td><td>15</td><td>15</td><td>15</td></tr><tr><td>Subsequent</td><td>25</td><td>34</td><td>25</td></tr><tr><td rowspan="2">Gammagard or Kiovig (PW < 40kg)</td><td>Initial</td><td>15</td><td>15</td><td>15</td></tr><tr><td>Subsequent</td><td>20</td><td>20</td><td>20</td></tr><tr><td rowspan="2">Gammagard or Kiovig (PW >= 40kg)</td><td>Initial</td><td>20</td><td>20</td><td>20</td></tr><tr><td>Subsequent</td><td>30</td><td>30</td><td>30</td></tr><tr><td rowspan="2">Subcuvia or Gammanorm</td><td>Initial</td><td rowspan="2">N/A</td><td rowspan="2">N/A</td><td>10</td></tr><tr><td>Subsequent</td><td>20</td></tr></table>			Max Flow Rate Limits per Site (ml/hr)			Drug\Country	Infusion	USA	Canada	UK	Hizentra	Initial	15	15	15	Subsequent	25	34	25	Gammagard or Kiovig (PW < 40kg)	Initial	15	15	15	Subsequent	20	20	20	Gammagard or Kiovig (PW >= 40kg)	Initial	20	20	20	Subsequent	30	30	30	Subcuvia or Gammanorm	Initial	N/A	N/A	10	Subsequent	20	Limit for first time infusion exceeded. OR Exceeds limit for subsequent infusions.
		Max Flow Rate Limits per Site (ml/hr)																																													
Drug\Country	Infusion	USA	Canada	UK																																											
Hizentra	Initial	15	15	15																																											
	Subsequent	25	34	25																																											
Gammagard or Kiovig (PW < 40kg)	Initial	15	15	15																																											
	Subsequent	20	20	20																																											
Gammagard or Kiovig (PW >= 40kg)	Initial	20	20	20																																											
	Subsequent	30	30	30																																											
Subcuvia or Gammanorm	Initial	N/A	N/A	10																																											
	Subsequent			20																																											

4	Volume per Site	Volume Limits per Site (ml)				Volume limit per site exceeded
		Drug\Country	Infusion	USA	Canada	UK
		Hizentra	Initial	15	15	15
			Subsequent	25	25	25
		Gammagard or Kiovig (PW < 40kg)	Initial	20	20	20
			Subsequent	20	20	20
		Gammagard or Kiovig (PW >= 40kg)	Initial	30	30	30
			Subsequent	30	30	30
		Subcuvia or Gammanorm	Initial	N/A	N/A	15
			Subsequent			25

EXAMPLE: The following screenshot shows warning messages that appear and appropriate colors applied to the output variables in both conditions of exceeding initial and/or subsequent infusions.

1

Country:

USA

2

Drug:

Gammagard

Dosage (ml):

63

Patient weight:

Below 40kg

3

Infusion Pump:

SCIg60 Infuser

4

No. of Needles:

3 Needles

Needle Gauge:

27 ga

Select specific set:

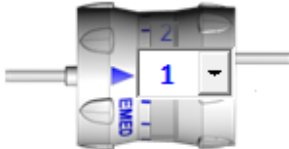
SUB-310

Needle Length:

6 mm

5

VersaRate® Position:



Infusion Results

☒ Show warnings for initial infusions



Total Flow Rate

47 ml/hr



Flow Rate Per Site

16 ml/hr

Caution: Limit for first time infusion exceeded



Dosage Volume Per Site

21.0 ml

Exceeds limit for subsequent infusions



Infusion Time

1 hrs 20 min