

Instructions for Use IV Fluid prescribing calculator

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2 Product Details

2.1 Key Product Information

Product Name	Calculator Suite	
	InnoScot Health 272 Bath Street Glasgow Scotland G2 4JR	
CE / UK CA Marking Details	UK	
Class of Device	This device is classified as a Class I medical device in accordance with Annex IX Rule 1 and Rule 12 of Council Directive 93/42/EEC of 14 June 1993 and amending Directive 2007/47/EEC	
Notes on Usage	This tool is only intended for use in jurisdictions where it has regulatory approval	

2.2 List of Calculators

Calculator	Latest Version
IV Fluid prescribing calculator.	1.0

This calculator forms part of the wider Right Decision Service Calculator Suite, which includes the calculators listed below. Like the other calculators in this suite, the iv fluid prescribing calculator can be implemented and used within RDS toolkits as individual entities separate from the other calculators in the suite.

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Cal	ıcu	lator

FeverPAIN Score for Streptococcal Pharyngitis

Centor Score (Modified, McIsaac) for Streptococcal Pharyngitis

Risk Score for Asthma Exacerbation (RSE)

Asthma Control Questionnaire 5 Questions (ACQ5)

4AT – 4 A's Assessment test for delirium and cognitive impairment

Diagnosis and management of suspected lower urinary tract infection in non-pregnant women under 65 years:

Symptoms assessment: LUTI in women < 65 years

Dipstick test: LUTI in women < 65 years

Malnutrition Universal Screening Tool (MUST)

Antimicrobial calculators (gentamicin and vancomycin)

2.3 Purpose, Scope and Audience

The purpose of the calculator is to support clinicians in the safe prescribing and intravenous administration of IV fluids for adult hospital inpatients, aged sixteen and over.

Many adult hospital inpatients need IV fluid therapy to prevent or correct problems with their fluid and/or electrolyte status. Deciding on the optimal amount and composition of IV fluids to be administered and the best rate at which to give them can be complex and requires to be based on assessment of the individual patient's needs.

This calculator is designed to mitigate risks of clinical error in prescribing of IV fluids and consequent harm to patients.

The IV fluid calculator processes clinical data entered by clinicians for individual patients. It delivers recommendations about volume, administration rate and choice of IV fluid, together with any safety alerts arising from the patient's specific clinical parameters.

The calculator uses patient parameters (weight, presence of frailty, potassium and sodium values, source and volume of previous 24h losses, anticipated 24h fluid intake) to calculate the volume and rate of administration of IV fluid. Based on the sources of 24h losses, it will prompt the user to select one of two choices of IV fluid (Hartmanns or other balanced crystalloid) or will recommend use of 0.9% sodium chloride.

The calculator can be re-used and embedded in web and mobile applications created using the Right Decision Service toolset provided by NHS Healthcare Improvement Scotland (NHS HIS).

There is a clear statement at the top of the calculator that it is only to be used for adults aged 16 years and over. Cautions relating to use of the calculator in special circumstances are detailed at the top of the calculator.

The calculator is intended to be used by suitably qualified healthcare staff. Key user groups include junior doctors, hospital pharmacists, medical and nursing staff of all grades. The calculator should not be used by healthcare staff without suitable qualifications and should not be used by the general public as a substitute for professional advice.

The calculator is only intended for use in NHS Scotland. Within NHS Boards in Scotland, it should be used in conjunction with local guidance and protocols.

2.4 Latest Version of Instructions for Use

The latest version of this document can be found at the following location:

https://rightdecisions.scot.nhs.uk/iv-fluids-calculator/instructions-for-use/

2.5 Accessing the calculator

The calculator is accessed via the <u>Right Decision Service website</u> and the Right Decision Service mobile app (<u>Apple download</u> / <u>Android download</u>.)

3 Document Control

3.1 Version Control

Version	Date	Author	Comments
1.0 (Draft 1)	17/8/2024	Ann Wales	
1.0	25/8/2024	Ann Wales	Final version

4 Document Purpose

4.1 Summary

This document provides the Instructions for Use for the IV Fluid prescribing calculator within the Calculator Suite.

4.2 Intended Audience

The intended audience are the end users of the calculator.

Key user groups include junior doctors, hospital pharmacists, medical and nursing staff of all grades. The calculator should not be used by healthcare staff without suitable qualifications and should not be used by the general public as a substitute for professional advice.

The calculator is only intended for use in NHS Scotland. Within NHS Boards in Scotland, it should be used in conjunction with local guidance and protocols.

The calculator is not intended to be used by members of the public as a substitute for professional advice.

4.3 Referenced Standards

Standard	Version	Purpose
Medical device	2015	Details the regulatory requirements governing Medical
software – Software		Device Software and Software Lifecycle Processes
lifecycle processes: BS		
EN 62304: 2006		
+A1:2015		
Medical devices –	2021	Specifies terminology, principles and a process for risk
Application of risk		management of medical devices, including software as a
management to		medical device.
medical devices: ISO		
14971:		
2019+A11:2021		
Medical devices –	2016	Specifies requirements for a quality management system
Quality management		that can be used by an organization involved in one or
systems –		more stages of the life-cycle of a medical device,
Requirements for		including design and development, production, storage
		and distribution, installation, servicing and final

regulatory purposes.	decommissioning and disposal of medical devices, and
ISO 13485:2016	design and development, or provision of associated
	activities (e.g. technical support)

4.4 General guidance

Advisory information on how to use the calculator safely is clearly available within the calculator:

- 1) A statement that the calculator is only for use in adults over 16 years.
- 2) Information is highlighted about cautions in special circumstances.
- 3) Hint text, prompts and alerts associated with data entry fields.
- 4) A link to an "About this calculator" page provides information on:
 - Purpose, intended users and scope of the calculator.
 - Information on how to conduct the calculation manually.
 - The evidence base, including the NICE guidance, which underpins the calculator.
 - The fact that the calculator is only regulated for use in Great Britain (not Northern Ireland.)
- 5) Information on accessibility and on recommended browsers and operating systems.

4.5 Intended users

The calculator is intended to be used by suitably qualified healthcare staff.



The calculator is <u>not</u> intended to be used by members of the public as a substitute for professional advice.

4.6 Calculator version labelling

The calculator displays version information in the Regulatory Details section. This contains the following information:

Calculator name

Version id for the calculator

4.7 Browsers and operating systems supported

The calculator will support the following operating systems when deployed on the Right Decision Service mobile app:

Android app: Android 10+

• iOS app: iOS 13+

The calculator suite will be optimised for the following desktop and mobile browsers:

• Desktop: Chrome, Firefox, Safari, Edge (latest versions)

• Mobile: Chrome, Safari (latest versions)

5 Raising issues and support

Issues or support requests should be raised with the HIS Decision Support email address in the first instance: his.decisionsupport@nhs.scot

Users should include the following information when raising an issue:

- Calculator version (found in *Regulatory Information* section)
- Browser and version
- Operating system and version
 - Windows or other operating system for desktop
 - o iOS or android for mobile
- Mobile device name and model (if relevant)
- Whether it is accessed via the Right Decision Service website or mobile application

Appendix A: Residual risks

The table below is intentionally blank as there are no Residual Risks other than those classed as Low.

Risk ID	Risk	Current Mitigations	Future Mitigations