

Instructions for Use Antimicrobial calculators within Calculator Suite.



| Document Control | |
|------------------|---|
| Product | Antimicrobial calculators within Calculator Suite |
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| Version | 1.0 |

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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 |  |
| 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 |
|--|----------------|
| Antimicrobial calculators (Gentamicin, Gentamicin (Hartford), Vancomycin). | 1.0 |

These calculators form part of the wider Right Decision Service Calculator Suite, which includes the calculators listed below. Like the other calculators in this suite, the antimicrobial calculators can be implemented and used within RDS toolkits as individual entities separate from the other calculators in the suite.

| Calculator |
|---|
| 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) |

2.3 Purpose, Scope and Audience

The purpose of the three calculators is to support clinicians in the safe prescribing and intravenous administration of the antibiotics gentamicin and vancomycin for adult hospital inpatients, over the age of sixteen. Both medicines are used in hospital settings for treatment of severe infections.

Gentamicin is used to treat serious infections in multiple parts of the body, caused by aerobic Gram-negative organisms, some Gram-positive organisms (e.g. Staphylococcus aureus) and Pseudomonas aeruginosa. It may also be used for surgical prophylaxis.

Vancomycin is regarded as a medicine of last resort due to its efficiency in treating multiple drug-resistant infectious agents, and the requirement for intravenous administration. It is active against a large number of species of gram-positive cocci and bacilli such as Staphylococcus aureus (including methicillin-resistant strains) and Staphylococcus epidermidis (including multiply resistant strains.)

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

The calculators 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.

2.4 Latest Version of Instructions for Use

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

2.5 Accessing the calculators

Calculators are accessed via the [Right Decision Service website](#) and the Right Decision Service mobile app ([Apple download](#) / [Android download](#).)

4 Document Purpose

4.1 Summary

This document provides the Instructions for Use for the antimicrobial calculators within the Calculator Suite.

4.2 Intended Audience

The intended audience are the end users of the calculator.

The calculators are intended to be used by suitably qualified healthcare staff.

They are 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 software – Software lifecycle processes: BS EN 62304: 2006 +A1:2015 | 2015 | Details the regulatory requirements governing Medical Device Software and Software Lifecycle Processes |
| Medical devices – Application of risk management to medical devices: ISO 14971: 2019+A11:2021 | 2021 | Specifies terminology, principles and a process for risk management of medical devices, including software as a medical device. |
| Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 13485:2016 | 2016 | Specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support) |

5 Safe Use of antimicrobial calculators within the Calculator Suite

5.1 General guidance

Advisory information on how to use the calculators safely is clearly available on the start page of each calculator:

- 1) Information is highlighted about excluded groups and contraindications.
- 2) A prominent warning is displayed advising that the calculators should not be used for patients on renal replacement therapy.
- 3) A statement that the calculators are only for use in adults over 16 years.
- 4) A link to an “About these calculators” page provides information on:
 - Purpose, intended users and scope of each calculator
 - The original guidance from the Scottish Antimicrobial Prescribing Group on which the calculators are based. Signposting to local protocols on action to be taken if the calculators are not available.
 - The fact that the calculators are only regulated for use in Great Britain (not Northern Ireland.)
- 5)

5.2 Intended users

The calculators are intended to be used by suitably qualified healthcare staff.



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

5.3 Calculator version labelling

Each calculator will display version information in the Regulatory Details tab. This will contain the following information:

- Calculator name
- Version id for the calculator

5.4 Browsers and operating systems Supported

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

- Android app: Android 9+
- iOS app: iOS 13+

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

- Desktop: Chrome, Firefox, Safari, IE11, Edge (latest versions)
- Mobile: Chrome, Safari (latest versions)

6 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
 - 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 |
|---------|------|---------------------|--------------------|
| | | | |