

Instructions for Use

ASSIGN: Cardiovascular risk score calculator

within Calculator Suite

Document Control	
Product	ASSIGN: Cardiovascular risk score calculator within Calculator Suite
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1 Contents

1	Contents.....	2
2	Product Details.....	3
2.1	Key Product Information	3
2.2	List of Calculators.....	4
2.3	Purpose, Scope and Audience	4
2.4	Latest Version of Instructions for Use	5
2.5	Accessing the calculator	5
3	Document Purpose	6
3.1	Summary.....	6
3.2	Intended Audience	6
3.3	Referenced Standards	6
3.4	General guidance.....	7
3.5	Intended users.....	7
3.6	Calculator version labelling	7
3.7	Browsers and operating systems supported	8
4	Raising issues and support.....	8
	Appendix A: Residual risks	10

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
ASSIGN: Cardiovascular risk score 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 ASSIGN: Cardiovascular risk score calculator 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)
Antimicrobial calculators (gentamicin and vancomycin)
IV Fluid prescribing calculator
ASSIGN: cardiovascular risk score calculator

2.3 Purpose, Scope and Audience

The purpose of the calculator is to provide an ASSIGN cardiovascular risk score which estimates the 10-year percentage risk of developing cardiovascular disease (diseases of the heart and blood vessels including coronary heart disease, stroke, and transient ischaemic attack). The calculator is for use with adults from 25 to 90 years of age, in Scotland, who do not currently have a diagnosis of CVD.

This score helps clinicians to prioritise the prevention of cardiovascular disease in those currently free of it by identifying those at highest risk and to have a shared decision-making conversation with patients about the approaches that will work best for them in reducing their risk levels. The score is a number between 0 and 100. Those with a score of ≥ 10 are considered high risk and should be offered targeted risk reduction advice and treatments in line with current guidelines. Those with a score less than ten are not necessarily risk-free and should be offered general advice on risk reduction.

The calculator also prompts clinicians to consider the possibility of a diagnosis of Familial Hypercholesterolaemia if the subtracted difference between 'Total cholesterol' minus 'HDL cholesterol' is $\geq 6\text{mmol/L}$

This calculator updates the ASSIGN score originally developed in 2006 by Professor Hugh Tunstall-Pedoe and Professor Mark Woodward of the University of Dundee, Scotland, working with the SIGN (Scottish Intercollegiate Guidelines Network) group on cardiovascular risk estimation. In 2024, the equation underwent a recalibration and updating of baseline hazards, based on contemporary cohort studies, to reflect changing trends in population cardiovascular disease event rates since its initial development in 2006. At time of building the new calculator, the Scottish Index of Multiple Deprivation (SIMD) tables were also updated from the 2012 version to the latest version (2020).

The calculator is intended to be used by suitably qualified healthcare staff. It is mainly intended for use by primary care clinicians in general practice – general practitioners, advanced nurse practitioners, practice nurses, practice pharmacists. Secondary user groups include consultants, doctors in training and nurses in outpatient clinics and inpatient settings.

The calculator is only to be used for adults aged between 25 and 90 years of age. This is stated within the "Notes" section of the Age field within the calculator.

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/assign-v20/instructions-for-use/>

2.5 Accessing the calculator

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

3 Document Purpose

3.1 Summary

This document provides the Instructions for Use for the ASSIGN cardiovascular risk score calculator within the Calculator Suite.

3.2 Intended Audience

The intended audience are the end users of the calculator.

The calculator is intended to be used by suitably qualified healthcare staff. It is mainly intended for use by primary care clinicians in general practice – general practitioners, advanced nurse practitioners, practice nurses, practice pharmacists. Secondary user groups include consultants, doctors in training and nurses in outpatient clinics and inpatient settings.

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.

3.3 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)
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3.4 General guidance

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

- 1) Hint text, notes, data validation prompts and alerts associated with data entry fields.
- 2) Supporting information pages, including an “About this toolkit” section, provide information on:
 - Purpose, intended users and scope of the calculator.
 - Information on the ASSIGN equation.
 - The evidence base which underpins the calculator.
 - The fact that the calculator is only regulated for use in Great Britain (not Northern Ireland.)
- 3) Information on accessibility and on recommended browsers and operating systems.

3.5 Intended users

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



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

3.6 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

3.7 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)

4 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

Safety issues and near misses should also be reported to the Incident Reporting and Investigation Centre (IRIC) within NHS National Services Scotland using the appropriate [reporting form](#).

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