





# Cardiovascular Information Guide for **DOWN SYNDROME**

A guide to understanding risks, improving well-being, and achieving peace of mind via taking control of your heart health

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S3: Improving Usual Care

S2: Impacts and Challenges



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# Section 1: Introduction

#### At a Glance

The health outcomes for individuals with Down syndrome have improved significantly, enabling many to enjoy longer, healthier, and happier lives (1). However, this progress has revealed gaps in research, awareness, and standard of care, particularly in addressing comorbidities that increase with aging (2,3). Cardiovascular diseases (CVD) are important comorbidities that disproportionately affect individuals with Down syndrome (4).

This guide explores the vital connection between Down syndrome and CVD, emphasising the importance of early detection and management. **ecgme**<sup>®</sup> is our innovative solution that improves healthcare delivery for individuals with Down syndrome.

This guide hopes to empower individuals with Down syndrome, their caregivers, and relevant organisations by deepening their understanding of the link between Down syndrome and CVD, raising awareness of CVD progression and advocating for early health management and intervention. This guide seeks to foster informed decisions and improve outcomes.

It also evaluates the strengths and limitations of standard diagnostic practices and demonstrates how **ecgme**<sup>®</sup> extends existing care.

### **Company Overview**

Cardiovascular disease is a leading cause of disability and mortality worldwide, disproportionately affecting individuals with Down syndrome and placing a significant burden on families and healthcare systems. Despite its prevalence, many severe cases are preventable through proactive early detection and management.

Biosignals Diagnostics provides leading-edge medical technology and clinician-led healthcare services. We are committed to improving the health and life outcomes of all individuals. We believe that everyone deserves access to proactive and life-changing healthcare solutions.

We empower individuals with disabilities and their caregivers to take proactive steps toward achieving better heart health and reducing the risk of adverse cardiovascular events.

Our medical devices, such as **ecgme**<sup>®</sup> (a hand-held ECG monitor) delivered with our clinical diagnostic services, gives people the tools they need to take control of their cardiovascular health. Early detection of cardiac rhythm anomalies enables preventative action to avoid severe outcomes and, in turn, reduce the burden of CVD (5,6).





# Section 2: Impacts and Challenges

### **Key Statistics for Down Syndrome**

1 in 14

likely to experience a severe adverse cardiovascular event annually.

## 3x

more likely to have a hospitalisation from adverse cardiovascular events (7).

# 8-22x

more likely to have cardiovascular health complications as key causes of mortality (8,9).

#### **Section Summary**

- Individuals with Down syndrome have a significantly increased risk of cardiovascular complications due to the high prevalence of congenital heart defects and obesity. These risks increase with aging.
- Current care models present limited accessibility to traditional ECG monitoring and limit the availability of regular monitoring.
- These challenges lead to delayed diagnosis and untreated cardiovascular conditions.
- Accessible, frequent, and tailored cardiac monitoring can improve health outcomes, reduce hospitalisations, and alleviate financial and emotional burdens on individuals and families.



### Relationship Between Down Syndrome and Cardiovascular Disease

Down syndrome is a genetic condition caused by a trisomy of chromosome 21, leading to developmental delays and intellectual disability. One of the most significant health risks for individuals with Down syndrome is CVD, particularly congenital heart defects, which affect up to 50% of individuals with Down syndrome (4,10,11).

Individuals with Down syndrome are 3 times more likely than the general population to experience a cardiovascular event that results in hospitalisation. Mortality due to congenital heart defects is 8 to 22 times higher in people with Down syndrome than the general population (8,9,10,12,13).

While the presence of congenital heart defects is a significant risk factor, other health and lifestyle issues (e.g. obesity, reduced physical exercise) further elevate the cardiovascular risk in this population (4). This compounded risk significantly contributes to the higher likelihood of hospitalisation. It is also linked to poorer outcomes when left untreated (7,14,15,16).

An estimated 1 in 14 Australian individuals with Down syndrome will experience a severe adverse cardiovascular event each year. This estimate highlights the urgent need for proactive, preventative measures in maintaining cardiovascular health for people with Down syndrome. Without regular monitoring, diagnosis of CVD is delayed, which could lead to preventable acute adverse events (17).

### **Accessibility of Usual Care**

Cardiovascular health management presents significant accessibility challenges. The 12-lead ECG is a medical tool that provides critical diagnostic insights into cardiovascular health. Logistical, financial, and procedural barriers often impede timely and routine access to these services (18). Addressing these barriers is crucial to improving health outcomes across diverse populations, particularly for individuals with Down syndrome.



This figure highlights five key barriers to accessible healthcare that contribute to significant challenges in delivering equitable and inclusive healthcare for individuals with disabilities based on the Australian Institute of Health and Welfare (AIHW) data (18). The standard diagnostic tool for detecting abnormal cardiovascular activity is the 12-lead ECG, which allows healthcare professionals to monitor the electrical activity of the heart. Unfortunately, accessibility to this technology remains a significant barrier for individuals with Down syndrome. The Australian Institute of Health and Welfare (AIHW) has highlighted that people with disabilities face multiple obstacles in accessing healthcare services generally, including long wait times, high costs, and physical inaccessibility of healthcare facilities (18). These barriers are especially daunting for individuals with high support needs, who may struggle to navigate the health system, from communicating symptoms with caregivers to scheduling and attending GP consultations.

There is a distinct absence of regular cardiovascular monitoring in usual care plans for individuals with disabilities at higher risk for CVD. This is despite clinical for routine cardiovascular auidelines advocating assessments (4,19,20,21,22,23). As these guidelines are rarely implemented, many individuals with Down syndrome are left at risk of undiagnosed heart diseases. Many people with Down syndrome may also find it challenging to adhere to the recommended monitoring guidelines due to the reliance on in-clinic diagnostics, further exacerbating the challenges in managing their cardiovascular health.

In Australia, the Medicare Benefits Schedule (MBS) requires a GP referral and the presence of symptoms to reimburse the cost of standard cardiovascular assessments; screening tests for CVD are often not subsidised through Medicare these Medicare Australia criteria add to the financial burden of accessing regular cardiovascular assessments (24).

#### **Unmet Healthcare Needs**

The increased risk of severe cardiac complications, combined with the barriers to accessing standard diagnostic tools, significantly reduces the quality of care and health outcomes for individuals with Down syndrome.

This gap in healthcare provision not only impacts individual health outcomes but also places an avoidable strain on healthcare systems and resources. Timely and regular cardiovascular monitoring through accessible diagnostic technologies can enhance early disease detection, resulting in earlier health interventions and an improved quality of life for individuals with Down syndrome.

Regular ECG monitoring for individuals with Down syndrome can also lead to significant cost savings for healthcare systems and disability support services (National Disability Insurance scheme, NDIS), through reducing the need for acute medical care and hospitalisation (5,6,25,26).

These unmet needs underscore the critical importance of tailored, disability-specific cardiovascular health management focused on individuals with Down syndrome.

#### Benefits of Regular ECG Monitoring Regular ECG Monitoring Reduced Complications Harly Diagnosis Larly Diagnosis Reduced Healthcare Burden

# Section 3: Improving Usual Care

### **Key Solutions**

### Regular Monitoring

facilitates the early detection of cardiovascular disease.

### Early Diagnosis

allows for early health interventions, reducing the likelihood of worsening CVD outcomes.

#### **Section Summary**

- Regular cardiovascular monitoring and early diagnosis are critical for improving health outcomes in individuals with Down syndrome.
- Current care models rely on patient reporting and 12lead ECG, and often lack the frequency and immediacy required for early intervention.
- NDIS guideline emphasises that consistent monitoring facilitates timely detection and reduces severe cardiovascular complications.
- **ecgme**<sup>®</sup> bridges these gaps, offering accessible regular monitoring and clinical assessments to improve cardiovascular outcomes.

### Advantages and Disadvantages of Usual Care

Managing cardiovascular health and detecting abnormalities in individuals with Down syndrome relies on patient reporting, regular GP visits and referrals for diagnostic tests. This traditional pathway to accessing healthcare has significant limitations, especially for those with disability (23,24).

The value of early CVD detection is well established, particularly for individuals at higher risk of CVD (5,6,27). Early health intervention can significantly improve health outcomes in individuals with Down syndrome (28). Regular monitoring facilitates timely interventions, reducing the risk of life-threatening events (e.g. heart attack, stroke) and decreasing the need for hospital admissions, ultimately improving the quality of life for individuals.

The NDIS recognises the higher prevalence of CVD among individuals with disabilities as compared to the general population. Consequently, the NDIS advocates for regular comprehensive heart health monitoring for individuals with disabilities (22).

### **Current Methods and Their Barriers**

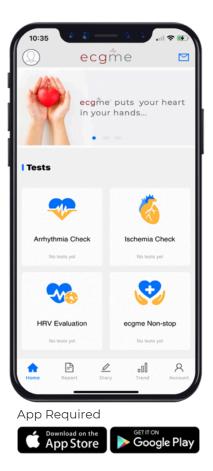
This table provides an overview of current cardiovascular management pathways and their associated barriers, emphasising the unmet healthcare needs discussed earlier.

Current Method	Barriers
GP Visits and Referrals	
<ul> <li>Patient consults GP or other healthcare practitioners to discuss cardiovascular health</li> </ul>	<ul> <li>Reliance on episodic care via patient symptom reporting rather than preemptive care</li> </ul>
Cardiologist Consultations	
<ul> <li>GP referral to a cardiologist or other healthcare practitioners for diagnostic tests</li> </ul>	<ul> <li>GP referral required for frontline treatment</li> <li>Accessibility barriers impeding this process</li> </ul>
12-lead ECG	
<ul> <li>12-lead ECG as a first-line diagnostic tool, following a referral</li> </ul>	<ul> <li>Costly for long-term, frequent care</li> <li>Limited to in-clinic administration</li> </ul>
Hospital-Based Care	
<ul> <li>Hospital management primarily focusing on acute adverse events</li> </ul>	<ul> <li>Symptom-driven, reactive care with high financial and emotional costs</li> </ul>



### **Our Solutions**

**ecgme**<sup>®</sup> provides home ECG monitoring for individuals with Down syndrome and their caregivers, coupled with accurate ECG analysis and cardiologist oversight and reviews.



**ecgme**<sup>®</sup> is a Therapeutic Goods Administration (TGA)-approved hand-held single-lead ECG monitor with secure online analysis of ECG parameters via mobile phone or tablet app. **ecgme**<sup>®</sup> is classified under NDIS as a low-cost, low-risk assistive technology. **ecgme**<sup>®</sup> supports informed decision-making, ultimately improving heart health outcomes.

ecgme® analyses cardiac data rapidly and provides an easy-to-understand analysis, offering immediate insights and early warnings for potential heart health issues. Integration with mobile health а application ensures that participants, caregivers, and healthcare providers have transparent, and timely access to critical health data.

Barriers	ecgme™
<ul> <li>GP referral required for</li></ul>	<ul> <li>Portable and in-home</li></ul>
regular testing <li>Limited access to and</li>	Monitoring <li>Clinical specialist oversight</li> <li>Proactive and regular</li>
resources for specialists <li>Reliance on reactive care</li> <li>Symptoms required for</li>	monitoring <li>Accessibility and</li>
referral	empowerment-focused

### **Healthcare Economic Benefits**

Cardiovascular hospitalisations in Australia create а substantial economic burden, with an average lifetime healthcare cost of \$65,700 per individual, contributing to approximately \$28.2 billion in direct healthcare costs nationally (25). Additionally, the economic impact of CVD between 2020 and 2029 is projected to exceed \$61.89 billion (26). Evidence highlights that early detection and timely a crucial role in intervention can play reducina cardiovascular events, lowering healthcare costs and reducing the demand for medical resources (5,6).

Monitoring systems, such as **ecgme**<sup>®</sup>, address critical gaps in cardiovascular care by providing early diagnosis of CVD in those at higher risk of CVD. Frequent monitoring of ECG data can lead to earlier diagnosis and treatment. **ecgme**<sup>®</sup> can improve patient outcomes and reduce healthcare costs.

By enhancing efficiency and minimising productivity loss, **ecgme**<sup>®</sup> plays a vital role in tackling cardiovascular diseases and economic and health challenges.

# **Empowering** Individuals with Disabilities

Achieving Peace of Mind via **ecgme**®

### References

1. Torr J, Strydom A, Patti P, Jokinen N. Aging in Down syndrome: morbidity and mortality. Policy Practice Intel Disabi [Internet]. 2010 Mar 3;7(1):70–81. Available from: <u>https://onlinelibrary.wiley.com/doi/10.1111/j.1741-1130.2010.00249.x</u>

Jensen KM, Bulova PD. Managing the care of adults with Down's syndrome. BMJ [Internet].
 2014 Sep 30;349:g5596. Available from: <u>https://www.bmj.com/content/349/bmj.g5596.long</u>.
 Hendrix JA, Amon A, Abbeduto L, Agiovlasitis S, Alsaied T, Anderson HA, et al. Opportunities, barriers, and recommendations in down syndrome research. Transl Sci Rare Dis [Internet].
 2021;5(3–4):99–129. Available from: <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8279178/</u>

4. Dimopoulos K, Constantine A, Clift P, Condliffe R, Moledina S, Jansen K, et al. Cardiovascular complications of down syndrome: scoping review and expert consensus. Circulation [Internet]. 2023 Jan 31;147(5):425–41. Available from:

https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.122.059706

5. Oude Wolcherink MJ, Behr CM, Pouwels XGLV, Doggen CJM, Koffijberg H. Health economic research assessing the value of early detection of cardiovascular disease: a systematic review. PharmacoEconomics [Internet]. 2023 Oct;41(10):1183–203. Available from:

https://link.springer.com/10.1007/s40273-023-01287-2

6. Zwartkruis VW, Groenewegen A, Rutten FH, Hollander M, Hoes AW, Van Der Ende MY, et al. Proactive screening for symptoms: A simple method to improve early detection of unrecognized cardiovascular disease in primary care. Results from the Lifelines Cohort Study. Preventive Medicine [Internet]. 2020 Sep;138:106143. Available from:

https://linkinghub.elsevier.com/retrieve/pii/S0091743520301675

 Sobey CG, Judkins CP, Sundararajan V, Phan TG, Drummond GR, Srikanth VK. Risk of major cardiovascular events in people with down syndrome. Taniyama Y, editor. PLoS ONE [Internet].
 Sep 30;10(9):e0137093. Available from: <u>https://dx.plos.org/10.1371/journal.pone.0137093</u>
 Landes SD, Stevens JD, Turk MA. Cause of death in adults with Down syndrome in the United States. Disability and Health Journal [Internet]. 2020 Oct;13(4):100947. Available from: <u>https://linkinghub.elsevier.com/retrieve/pii/S1936657420300728</u>

9. Motegi N, Yamaoka Y, Moriichi A, Morisaki N. Causes of death in patients with Down syndrome in 2014–2016: A population study in Japan. American J of Med Genetics Pt A [Internet]. 2022 Jan;188(1):224–36. Available from:

https://onlinelibrary.wiley.com/doi/10.1002/ajmg.a.62526

10. Weijerman ME, Van Furth AM, Van Der Mooren MD, Van Weissenbruch MM, Rammeloo L, Broers CJM, et al. Prevalence of congenital heart defects and persistent pulmonary hypertension of the neonate with Down syndrome. Eur J Pediatr [Internet]. 2010
Oct;169(10):1195–9. Available from: <u>http://link.springer.com/10.1007/s00431-010-1200-0</u>
11. Down Syndrome Australia. What is Down syndrome? [Internet]. Down Syndrome Australia: What is Down syndrome.org.au/about-down-syndrome/what-is-down-syndrome/

 O'Leary L, Hughes-McCormack L, Dunn K, Cooper S. Early death and causes of death of people with Down syndrome: A systematic review. Research Intellect Disabil [Internet]. 2018 Sep;31(5):687–708. Available from: <u>https://onlinelibrary.wiley.com/doi/10.1111/jar.12446</u>
 Cooper SA, Allan L, Greenlaw N, McSkimming P, Jasilek A, Henderson A, et al. Rates, causes, place and predictors of mortality in adults with intellectual disabilities with and without Down syndrome: cohort study with record linkage. BMJ Open [Internet]. 2020 May;10(5):e036465. Available from: <u>https://bmjopen.bmj.com/lookup/doi/10.1136/bmjopen-</u> 2019-036465

14. Baraona F, Gurvitz M, Landzberg MJ, Opotowsky AR. Hospitalizations and mortality in the United States for adults with down syndrome and congenital heart disease. The American Journal of Cardiology [Internet]. 2013 Apr;111(7):1046–51. Available from:

https://linkinghub.elsevier.com/retrieve/pii/S0002914912025696

15. Guariento A, Cattapan C, Lorenzoni G, Guerra G, Doulamis IP, Di Salvo G, et al. Nationwide hospitalizations of patients with down syndrome and congenital heart disease over a 15year period. Eur J Pediatr [Internet]. 2024 Apr 16;183(7):2945–54. Available from:

https://link.springer.com/10.1007/s00431-024-05542-2

16. Engsner S, Giang KW, Dellborg M, Fedchenko M, Eriksson P, Mandalenakis Z. Impact of down syndrome on survival among patients with congenital heart disease. JAHA [Internet].2024 Jan 16;13(2):e031392. Available from:

https://www.ahajournals.org/doi/10.1161/JAHA.123.031392

17. Cowie MR, Lam CSP. Remote monitoring and digital health tools in CVD management.

Nat Rev Cardiol [Internet]. 2021;18(7):457–8. Available from:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8023506/

18. Australian Institute of Health and Welfare. People with disability in Australia [Internet].

Australian Institute of Health and Welfare; 2024. Available from:

https://www.aihw.gov.au/reports/disability/people-with-disability-in-

<u>australia/contents/summary</u>

19. Down Syndrome Australia. National advocacy [Internet]. Down Syndrome Australia. Available from: <u>https://www.downsyndrome.org.au/vic/advocacy/national-advocacy/</u> 20. Down Syndrome Australia. Health screening tool for people with Down syndrome: birth to adult [Internet]. Down Syndrome Australia; Available from:

https://www.downsyndrome.org.au/services-and-supports/professionals/health-screeningtool/

21. NDIS Quality and Safeguards Commission. Practice alert: comprehensive health assessment. [Internet]. NDIS Quality and Safeguards Commission; 2022. Available from: <a href="https://www.ndiscommission.gov.au/sites/default/files/2022-05/practice-alert-">https://www.ndiscommission.gov.au/sites/default/files/2022-05/practice-alert-</a>

comprehensive-health-assessment.pdf

22. NDIS Quality and Safeguards Commission. Practice alert: cardiovascular disease in people who have a disability [Internet]. NDIS Quality and Safeguards Commission.; 2022. Available from: <u>https://www.ndiscommission.gov.au/sites/default/files/2022-</u>

06/Practice%20Alert%20-

<u>%20Cardiovascular%20disease%20in%20people%20who%20have%20a%20disability.pdf</u> 23. Australian Government Department of Health Aged Care. Adult Comprehensive Health Assessment Program (CHAP) – Annual Health Assessment for People with Intellectual Disability [Internet]. Australian Government Department of Health Aged Care.; 2024. Available from: <u>https://www.health.gov.au/resources/collections/comprehensive-healthassessment-program-chap-annual-health-assessment-for-people-with-intellectualdisability</u>

24. Australian Government Department of Health Aged Care. Understanding medicare: provider handbook [Internet]. Australian Government Department of Health Aged Care; 2024. Available from: Australian Government Department of Health Aged Care 25. Nghiem S, Afoakwah C, Byrnes J, Scuffham P. Lifetime costs of hospitalised cardiovascular disease in australia: an incidence-based estimate. Heart, Lung and Circulation [Internet]. 2021 Aug;30(8):1207–12. Available from:

https://linkinghub.elsevier.com/retrieve/pii/S1443950620315316

26. Marquina C, Talic S, Vargas-Torres S, Petrova M, Abushanab D, Owen A, et al. Future burden of cardiovascular disease in Australia: impact on health and economic outcomes between 2020 and 2029. Eur J Prev Cardiol [Internet]. 2022 May 27;29(8):1212–9. Available from: <u>https://doi.org/10.1093/eurjpc/zwab001</u>

27. Preejith SP, Dhinesh R, Joseph J, Sivaprakasam M. Wearable ECG platform for continuous cardiac monitoring. Annu Int Conf IEEE Eng Med Biol Soc [Internet]. 2016 Aug;2016:623–6. Available from: <u>https://doi.org/10.1109/EMBC.2016.7590779</u>

28. Caro M, Conde D, Pérez-Riera AR, De Almeida AP, Baranchuk A. The electrocardiogram in Down syndrome. Cardiol Young [Internet]. 2015 Jan;25(1):8–14. Available from:

https://www.cambridge.org/core/product/identifier/S1047951114000420/type/journal\_article

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#### **Feedback and Contact**

We value your feedback! If you have any suggestions, questions, or comments, please don't hesitate to reach out to us at info@biosigdx.com



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