CardioScan Quality Assurance

Medical excellence and accurate, reliable results have remained at our core for 30+ years

Our Quality Assurance system provides for the highest standards of data accuracy, with transparent performance results provided openly to our customers for even greater certainty.

Regulatory standards

We are ISO9001:2015 certified for diagnostic cardiac services and have an information risk management system based on ISO27001 to ensure our global business delivers the highest clinical and operational standards. In each country of operation, we also meet any local regulatory and government requirement for medical services.

Quality Assurance Systems

CardioScan follows stringent standards outlined in our Standard Operating Procedures (SOPs). These include minimum qualification standards for clinical staff, independent auditing and rigorous ongoing training programs to ensure our cardiac team meet our Service Level Agreements as outlined for each customer.

CardioScan has a double checkpoint quality assurance system, which requires that at least two clinical team members review results before releasing to a customer.

Learn more
Visit our resources library for more detail: www.cardioscan.co
Qualifications and training

Globally recognised qualifications
All CardioScan cardiac technicians / cardiac physiologists are tertiary educated and must have completed at least one of the following university qualifications:

- Bachelor of Biomedical Science
- Bachelor of Science; or Bachelor of Nursing

Additionally, they must have completed:
- Certificate III in Electrocardiography for Cardiac Technicians or equivalent
- Certified Cardiac Technician (global) qualification

These requirements need to be met by all of our clinical teams worldwide.

Ongoing professional development
Our technicians are provided with regular ongoing professional development and education as part of our quality assurance system. Led by our Medical Director Assoc Prof Harry Mond, our team is offered fortnightly clinical training with wide-ranging skills development and subject matter including basic ECG interpretation, advanced level rhythm analysis, and case study examination collated from 500K+ heart studies conducted annually at CardioScan.

Security training
Data protection and privacy remains our highest priority. As such, CardioScan staff undergo regular internal security training managed by our IT department. This training is conducted using KnowBe4, and teaches staff to identify social engineering, spear phishing and ransomware attacks, by simulating these attacks through practical exercises. Our team also follows strict data management practices as set out in our SOPs.

Paediatric specialisation
Led by Head of Paediatric Cardiology Brian Edis with more than 49 years’ experience specialised in the field, our clinical team receives ongoing training in paediatric Holter analysis. Analysing about 5000 paediatric Holters each year, we continue to capture rare traces and provide regular education back to the team to upskill paediatric Holter knowledge.

Medical leadership

Assoc Prof Harry Mond
Medical Director
49+ years as a practicing cardiologist
275+ published manuscripts & 3 books
Dr Harry Mond delivers regular advanced rhythm analysis training and education to our clinical teams.
View Harry’s profile online ➔

Dr Brian Edis
Paediatric Cardiologist
49+ years experience practicing as a paediatric cardiologist in both Australia and the US
Dr Brian Edis upskills our clinical teams in paediatric ECG & Holter analysis through unique case-based training & education.
View Brian’s profile online ➔
QA system and processes

Double checkpoint QA process
CardioScan has a double checkpoint quality assurance system, which requires that at least two clinical team members review results before sending to customers – with each clinical staff required to follow strict QA procedures, that minimise risk of errors. Together, with error grading and open opportunities for customers to query any conclusions for further investigation, we consistently maintain impeccably high standards globally across all cardiac services.

Randomised QA checks
Our quality standards are fortified with randomised checks undertaken by our Medical Director Assoc Prof Harry Mond. With checks conducted on a regular and ongoing basis, we are able to maintain certainty about procedures being followed and accuracy of results.

Incident reporting
In the rare circumstances that an error occurs, we have strict protocols to ensure complete transparency with customer incident reporting. All incident reports include a summary of the event and an action plan to minimise the risk of repeating errors. All errors are subsequently documented and shared with the team as part of our continuous improvement training, including direct feedback to those involved.

Auditing
As part of our continuous improvement process, planned monthly checks as well as random auditing is routinely undertaken. As part of our audits, our clinical operations team will take a sample of tests as outlined in our Standard Operating Procedure, and verify the analysis and reporting qualities.

Any major discrepancies noted are addressed with the relevant team members, with coaching provided to ensure these issues do not become a regular occurrence. Other aspects of our audits include ensuring analysis/reporting turnaround are met, which can be verified using information from our clinical diagnostic systems.

Average global performance results

<table>
<thead>
<tr>
<th>Metric</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-time Holter reporting</td>
<td>99.99%</td>
</tr>
<tr>
<td>Repeat rate across all tests</td>
<td>1.5%</td>
</tr>
<tr>
<td>Reporting accuracy</td>
<td>99.99%</td>
</tr>
</tbody>
</table>

View our latest performance results online

cardioscan.co/services/accuracy-performance/
CardioScan Quality Assurance

Service Level Agreements
CardioScan ensures all reports are processed to meet leading service standards as set out by our Service Level Agreement (SLA) targets:

<table>
<thead>
<tr>
<th></th>
<th>2 hrs</th>
<th>98%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>for urgent ECGs</td>
<td>on time reporting</td>
</tr>
<tr>
<td></td>
<td>4 hrs</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td></td>
<td>for Routine ECGs</td>
<td>Error rate</td>
</tr>
<tr>
<td></td>
<td>24 hrs</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td>for Holters, BPs and Events</td>
<td>customer satisfaction</td>
</tr>
</tbody>
</table>

Capturing data

**Monthly performance data**
Most of the clinical diagnostic systems that CardioScan uses provide an audit trail, which allows us to collate our monthly performance data.

This data is publicly displayed on our websites globally, including the thresholds that have been set internally to measure our performance.

**Error grading**
As part of our internal processes, CardioScan has developed a propriety error grading system that assesses any errors and determines their significance. All errors are graded, even those such as typos, to ensure complete transparency in our error reporting.

Internal errors are treated the same as external errors, with the only difference being that internal errors are captured by our quality assurance processes before being corrected and the finalised reporting sent to our customer. They are still documented for internal monitoring and feedback.

A recent sample of almost 100K Holter tests had only 3 significant clinical reporting errors. Each was picked up and corrected prior to sending to customers.

### Reporting Misdiagnosis/Grading

<table>
<thead>
<tr>
<th>Error Description</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect heart rates</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Pacemaker functionality</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Atrial/ventricular ectopics</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Sinus rhythm instead of junctional rhythm/low atrial rhythm/atrial tachycardia</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Supraventricular tachycardia/Ventricular tachycardia runs</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Pauses</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Typographical Error</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>AF instead of SVT or vice versa</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>4</td>
<td>11</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

**Error grades**

1. No clinical significance
2. Minor clinical significance
3. Major clinical significance
4. Critical error
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