

# **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 integrity, with transparent performance results provided openly to our customers for even greater certainty.

# Regulatory standards

Under our parent company CardioScan, the business is ISO9001:2015 certified for diagnostic and cardiac services and has 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

Cardiac Monitoring Service 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.



We are compliant with the Health Insurance Portability and Accountability Act of 1996, US legislation on data privacy and security provisions for safeguarding medical information.

Learn more about HIPAA from the Department of Health & Human Services: www.hhs.gov/hipaa/for-professionals/

Cardiac Monitoring Service has a double checkpoint quality assurance system, which requires that at least two clinical team members review results



# **Qualifications and training**

### Globally recognized qualifications

All Cardiac Monitoring Service cardiac technicians have graduated from an accredited school with a Cardiovascular Technician certificate.

Additionally, they must have completed globally recognized Certified Cardiac Technician qualifications – which includes completing 6 units per year of ongoing cardiovascular education.

# 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 Cardiac Monitoring Service.

# **Pediatric specialization**

Led by Head of Pediatric Cardiology Brian Edis with more than 49 years' experience specialized in the field, our clinical team receives ongoing training in pediatric Holter analysis. Analyzing more than 5000 pediatric Holters each year, we continue to capture rare traces and provide regular education back to the team to upskill pediatric Holter knowledge.

# **Security training**

Data protection and privacy remains our highest priority. As such, Cardiac Monitoring Service 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.

### 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 →

# <sub>Dr</sub> Brian Edis

Pediatric Cardiologist

49+ years
experience
practicing as
a pediatric
cardiologist in
both Australia
and the US



Dr Brian Edis upskills our clinical teams in pediatric ECG & Holter analysis through unique casebased training & education.

View Brian's profile online  $\longrightarrow$ 



# **QA** system and processes

### **Double checkpoint QA process**

Cardiac Monitoring Service 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 minimize 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.

# **Incident reporting**

In the rare circumstances that an error occurs, we have strict protocols to ensure complete transparency with client incident reporting.

All incident reports include a summary of the event and an action plan to minimize 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.

### Randomized QA checks

Our quality standards are fortified with randomized 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.

# **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

99.9%

On-time Holter reporting

1.5%

Repeat rate across all tests

99.9%

Reporting accuracy

View our latest performance results online

cardiacmonitoringservice.com/services/accuracy-performance/



# **Capturing data**

# Monthly performance data

Most of the clinical diagnostic systems that Cardiac Monitoring Service 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.

errors, with the only difference being that internal errors are captured by our quality assurance processes before the clinician sees the report. They are still documented for internal monitoring and feedback.

Internal errors are treated the same as external

# **Error grading**

As part of our internal processes, Cardiac Monitoring Service has developed an 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.

# **Error grades**

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

