

Why use an expert ECG interpretation service when most ECG machines have on-board ECG interpretation algorithms?

Technomed Limited trading as ECG On-Demand

Mark Hashemi

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CONTENTS

INTRODUCTION.....	2
METHOD.....	3
RESULTS.....	5-7
KEY FINDINGS.....	8-9



Introduction

ECG machines equipped with built-in ECG interpretation algorithms are frequently used by non-cardiologists as an aid to determine the most appropriate patient care pathway following a 12-lead ECG. It is the author's belief that although ECG machine algorithms reduce the probability of missing important ECG abnormalities, reliance on them is responsible for significant unnecessary secondary care referral and patient anxiety. The precision of diagnosis of commonly encounter ECG abnormalities, claimed by ECG machine manufacturers, are rarely reproduced in real life clinical practice.

This white paper attempts to identify and quantify the difference in ECG interpretation performance between ECG machine algorithm and human expert.

Technomed use digital ECG machines to record 12-lead ECGs. The ECG On-Demand service is device agnostic, being able to use multiple ECG machine models including those manufactured by Mortara Instrument. The Mortara Veritas algorithm is a well regarded and commonly used ECG interpretation algorithm. Veritas has been adopted by the US Food and Drugs Administration (FDA) ECG Warehouse and is used to categorise all ECG data originating from US Phase 1 clinical trials.

ECG interpretation is open to considerable inter-clinician and intra-clinician variability. A significant difference in opinion can occur in the interpretation of a single ECG between 2 ECG experts. An ECG expert may interpret the same ECG differently on 2 separate occasions. An ECG expert is more likely to reach concurrence of opinion with the consensus opinion of a consultant cardiologist panel than a non-expert [1]. ECG machine algorithms frequently outperform a non-expert even when identifying the most common arrhythmias [2]

[1] Competency in Interpretation of 12-Lead Electrocardiograms: A Summary and Appraisal of Published Evidence - Stephen M. Salerno - Ann Intern Med. 2003;138(9):751-760 - American College of Physicians

[2] Accuracy of diagnosing atrial fibrillation on electrocardiogram by primary care practitioners and interpretative diagnostic software: analysis of data from screening for atrial fibrillation in the elderly (SAFE) trial - Hobbs FD - BMJ. 2007 Aug 25; 335(7616): 380.



Method

12-lead ECGs were recorded and transmitted for expert interpretation from multiple primary care sites over a 1 year period. Digital ECGs sampled at 1000 Hz were recorded using a Mortara ELi-10 ECG machine with on-board Veritas algorithm. The digital ECGs, together with the corresponding computer generated interpretations, were transmitted to Technomed ECG On-Demand service for interpretation by expert cardiac physiologists using Technomed's ECG Cloud platform. To ensure the cardiac physiologists were categorising the ECGs appropriately, the cardiac physiologists work was sampled and audited by a panel of consultant cardiologists to estimate the concurrence of agreement with consultant cardiologist opinion.

The risk classification of the Veritas ECG algorithm was compared to the risk classifications of the cardiac physiologist using the same ECG data.

To simplify the comparison between on-board ECG machine algorithm and ECG expert, only the "condition" statement generated by ECG machine algorithm was considered. The condition statements included in the analysis are listed below:



Condition Statement and RAG Definitions

Veritas Condition Statement	Condition Statement as defined by Mortara Instrument	Corresponding Technomed ECG On-Demand RAG Rating
Normal ECG	Normal	Green (normal)
Atypical ECG	An unusual pattern has been observed but has no specific significance.	Green / Amber (no significant abnormality observed)
Borderline ECG	Criteria have limited specificity or prognostic significance or where only minimal criteria are met.	Green / Amber (no significant abnormality observed)
Abnormal Rhythm ECG	Abnormal rhythm	Amber (significant abnormality observed)
Abnormal ECG	Abnormal	Amber (significant abnormality observed)
ACUTE MI	Criteria for new or recent myocardial infarction are true or an epicardial injury pattern has been detected.	Red (significant abnormality observed)
		Blue (poor quality ECG - please repeat)

The Technomed ECG expert will assign either a red or amber rating to either an abnormal rhythm ECG or abnormal ECG with the logic that a small proportion of abnormal ECGs will warrant urgent medical attention.

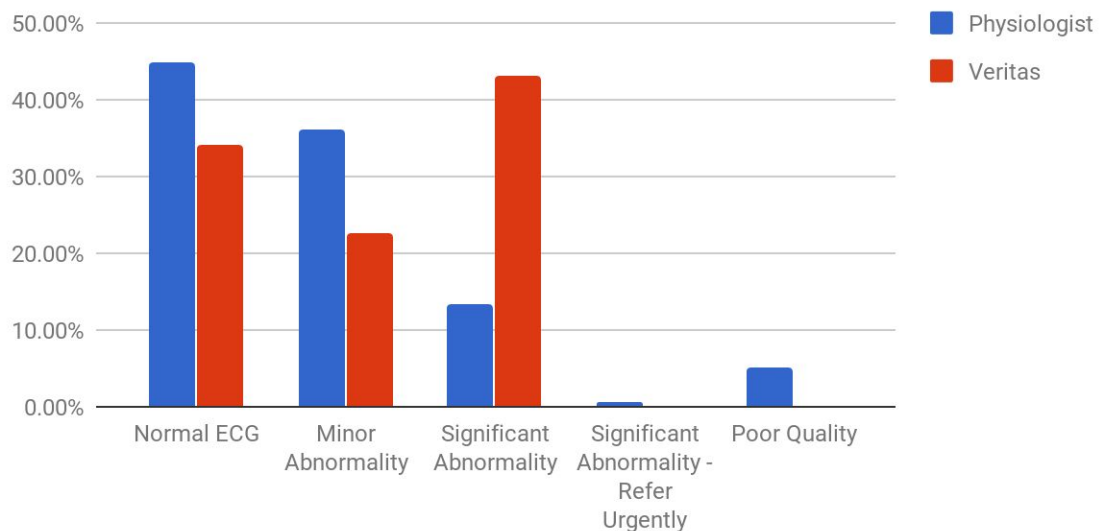


Results

Human ECG expert risk rating vs ECG machine algorithm condition statement

TM Traffic Light	Mortara Veritas Condition Statement						Totals	Percentage
	Normal ECG	Atypical ECG	Borderline	Abnormal Rhythm	Abnormal ECG	Acute MI		
Green	1164	72	476	7	420	1	2140	44.78%
Gr-Amber	421	65	320	112	811	1	1730	36.20%
Amber	32	19	16	57	516	1	641	13.41%
Red	0	0	1	0	25	0	26	0.54%
Blue	16	92	18	8	107	1	242	5.06%
Total	1633	248	831	184	1879	4	4779	100.00%
Percentage	34.17%	5.19%	17.39%	3.85%	39.32%	0.08%		

Patient Risk Classification (ECG Expert vs Mortara Veritas Algorithm)

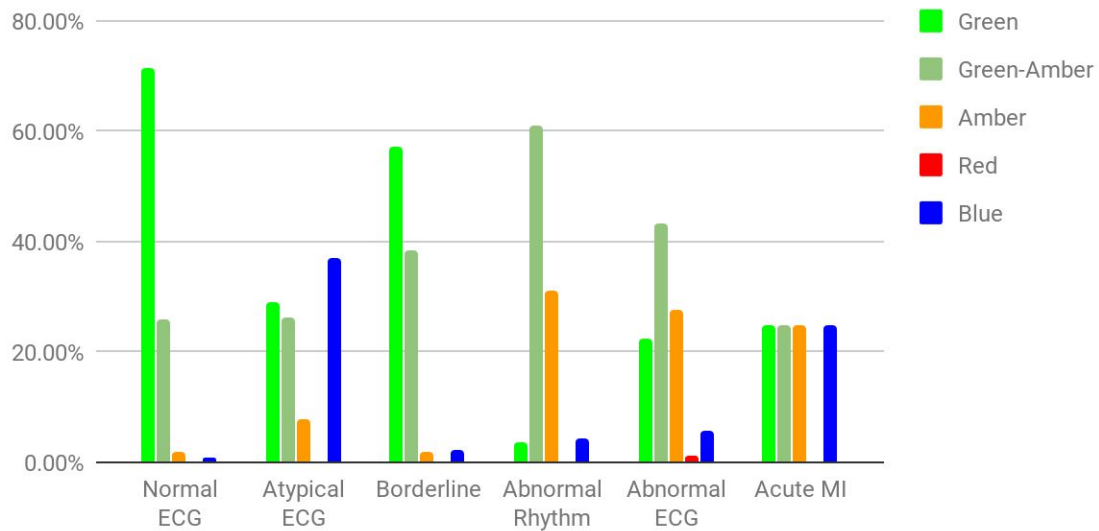




ECG expert risk rating expressed as percentage of ECG machine condition statement

TM Traffic Light	Mortara Veritas Condition Statement					
	Normal ECG	Atypical ECG	Borderline	Abnormal Rhythm	Abnormal ECG	Acute MI
Green	71.28%	29.03%	57.28%	3.80%	22.35%	25.00%
Gr-Amber	25.78%	26.21%	38.51%	60.87%	43.16%	25.00%
Amber	1.96%	7.66%	1.93%	30.98%	27.46%	25.00%
Red	0.00%	0.00%	0.12%	0.00%	1.33%	0.00%
Blue	0.98%	37.10%	2.17%	4.35%	5.69%	25.00%
Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

ECG Expert Classification of Mortara Veritas Algorithm Outputs





Concurrence of opinion between ECG expert and consultant cardiologist panel

	Mortara Veritas Condition Statement						
TM Traffic Light	Normal ECG	Atypical ECG	Borderline	Abnormal Rhythm	Abnormal ECG	Acute MI	Totals
Total Audited	85	8	40	8	90	0	231
Total where significant difference of opinion occurred	2	1	4	0	3	0	10
% disagreement between physiologist & cardiologist	2.35%	12.50%	10.00%	0.00%	3.33%	0.00%	4.33%



Key Findings

KEY FINDING 1: ,THERE WAS GOOD AGREEMENT (97%) BETWEEN THE ECG ALGORITHM AND THE ECG EXPERT WHEN THE ECG MACHINE CONDITION STATEMENT WAS “NORMAL ECG”.

Significant abnormal findings were found in approximately 2% of the “normal” ECGs checked by the ECG expert. The author believes this is due to the ECG algorithm not having the benefit of knowing why the patient was undergoing an ECG test. (e.g. Veritas classified the ECG of a 45 year old female with a heart rate of 45 b.p.m. as “normal” when the patient symptoms were “dizziness”.)

KEY FINDING 2: THERE WAS POOR AGREEMENT (31%) BETWEEN THE ECG MACHINE ALGORITHM AND THE ECG EXPERT WHEN THE ECG CONDITION STATEMENT WAS “ABNORMAL“ ECG.

This would suggest that 2 out of every 3 patients referred to secondary care on reliance of the on-board ECG algorithm would be sent inappropriately, resulting in unnecessary expense and patient anxiety.

2017/18 tariff (excluding market forces factor) for a 1st attendance cardiology outpatients appointment is £174.

The author estimates that reliance on the on-board ECG machine algorithm may result in up to 29 unnecessary outpatient appointments per 100 ECGs performed in a GP practice environment. Averaged out this would be an unnecessary spend of £50.46 for every ECG recorded.

KEY FINDING 3: 6% OF THE ECGs WERE CATAGORISED BY THE ECG EXPERT AS BEING TOO POOR A QUALITY FOR RELIABLE ECG INTERPRETATION. DISTRIBUTION WAS NOT EQUAL BETWEEN THE ALGORITHM DERIVED CONDITIONS

The prevalence of poor quality ECGs was highest in the “Atypical” algorithm derived condition. Unhelpfully there was also a significant percentage of abnormal ECGs within the “Atypical” group also. This means an ECG with an “Atypical” condition statement is probably poorly recorded but may be abnormal.

KEY FINDING 4: 1% OF ECGs WITHIN THE ABNORMAL ECG CONDITION GROUP REQUIRED URGENT SECONDARY CARE REFERRAL

The on-board ECG algorithm was unable to differentiate between those abnormal ECGs requiring standard and urgent attention.



KEY FINDING 5: AGREEMENT BETWEEN THE ECG EXPERT AND CONSENSUS OPINION OF THE AUDITING CONSULTANT CARDIOLOGIST PANEL WAS 96% WHICH IS WITHIN THE EXPECTED RANGE. AGREEMENT WAS NOT EQUAL BETWEEN THE ALGORITHM DERIVED CONDITIONS

Divergence of opinion was highest in the “Atypical” and “Borderline” ECG conditions suggesting that ECG recording quality has a negative impact on ECG interpretation reproducibility. Unsurprisingly divergence of opinion was also relatively high in the “Borderline” ECG condition.

Conclusion

The Mortara Veritas algorithm has good specificity for normal ECG patterns but poor specificity for abnormal ECG patterns (high false positive rate). Reliance of on-board ECG algorithms is likely to cause unnecessary secondary care spend and patient anxiety.

FOR MORE INFORMATION CONTACT: Mark Hashemi
mark.hashemi@technomed.co.uk
+44 (0) 345 521 2992