Lessons Learned from the Development of Wearable Cardiac Remote Monitors

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- Dr. Branislav Vajdic, Dr. Ihor Gussak, Dr. Sam George, Dr. Bosko Bojovic
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- Dr. Dejan Vukajlovic, Dr. Vladan Vukcevic
- Mr. Sasha Mastilovic and Mr. Gilbert Molina.
CardioBip™, a wireless, handheld system for remote monitoring of patients with various forms of heart disease, has the potential to improve outpatient assessment of patients with atrial fibrillation.

CardioBip may address problems with current monitoring systems by providing full 12-lead ECG data and accurate remote assessment of the patient’s atrial activity, thereby improving diagnosis of recurrent AF.

We undertook this study to evaluate the implications of intermittent but frequent remote monitoring by CardioBip of patients with AF, particularly to determine its ability to assess 6 month, or longer, atrial activity trends in such patients.
Methods: The CardioBip System

Cardiobip features:
- A wireless, hand-held device
- Non-invasive and no lead wires and 5 integrated electrodes
- Accurate, immediate reconstruction of a complete 12-lead ECG
- Recordings are simply made by holding the instrument against the patient’s chest
Methods: The CardioBip System

The CardioBip system has 2 major components: (1) a mobile handheld device for ECG acquisition and transmission, (2) a web portal database for receiving transmitted ECGs, and (3) a calibration system:

- The mobile ECG device is a pocket sized, with 5 integrated electrodes, 2 on the device top (A, B), contacted by the patient’s index fingers; and 3 precordial electrodes (C, D, E) on the device bottom. The potential difference between A and B represents ECG Lead I. Electrodes C and D are positioned with A and B to provide an orthogonal lead system.

- Data are transferred via wireless Internet to a call center database for interpretation and monitoring.

- The calibration system simultaneously records signals from 12 standard ECG leads and 3 special leads from the same position as electrodes C, D, and E of the mobile device.

- The computer software calculates and stores an individual transformation matrix for every patient, enabling reconstruction of 12-lead (12L) ECG. The transformation matrices are stored in a patient database for further use during remote monitoring sessions.
Methods: The CardioBip System

- **Standard 12 Lead ECG**
- **SIMPLE CardioBip**: 3 Rear Contacts, 2 Front Contacts
- **SIMPLE Mobile Phone Connection & ECG Transmission**
Methods: CardioBip Monitor

- Hand-held wireless event monitor
- Five electrodes provide 3 lead recording (500 Hz 0.05-100 Hz 10-bit ADC)

Acquired signal ➔ BT ➔ Cell phone ➔ Call Center ➔ Web
Methods: The CardioBip System
Methods: Signal processing

12-lead ECG
3 lead CardioBip

Individual transformation matrix calculation

Synthesized 12-lead ECG
Inverse Dower transform
X, Y, Z leads Vectorcardiogram

CardioBip transmission
Methods

**Transform** 12-Lead ECG input to X, Y, Z heart vector components using available algorithm, eg, Inverse Dower (ID):

\[ \vec{H} = \text{ID} \times \vec{V}, \text{ where} \]

\[ \vec{V} = (I, II, V_1-V_6), \text{ and} \]

\[
\text{ID} = \begin{pmatrix}
0.156 & -0.00893 & -0.173 & -0.0747 & 0.122 & 0.231 & 0.239 & 0.194 \\
-0.223 & 0.875 & 0.056 & -0.018 & 0.104 & -0.0209 & 0.0408 & 0.0476 \\
0.0225 & 0.101 & -0.229 & -0.310 & -0.246 & -0.0626 & 0.0550 & 0.109
\end{pmatrix}
\]

**Normalize** lead vectors to equalize electrical representation from all regions of the heart

- Calculate electrical attenuation factors \( r_i \) for each precordial lead \((V_1-V_6)\)
- Generate common attenuation factor \( r \) from individual \( r_i \)
- Use \( r \) to determine time-dependent normalized voltage in any measured or virtual ECG Lead
Use $\rho$ to derive time-dependent voltage at any virtual lead site:

$$V_d(t) = H(t) * L(t)^* \rho$$

Can be used to generate “virtual sphere” of normalized electrical activity.
Methods

Normalized voltage can be determined for any point on the virtual sphere at any time.
Methods

**Characterization of the lead vectors**

Useful characteristics, called markers, are extracted from normalized leads in order to determine the presence or absence of acute myocardial infarction (AMI):

- ST elevation
- Ratiometric (e.g., R peak to ST elevation),
- Angular (e.g. angle QRS to T loops)
- Cluster-specific (e.g. BER, RBBB specific clusters)

There are a total of 15 proprietary markers derived from the normalized leads and the heart vector used in the current version of my3KG (see following examples)
3-D ECG markers
Cardiac Safety Markers Classification

**ECG - Based**
- **Time (duration)**
  - QT, QTc, QTa-TaTe, Q,R,S, QRS
- **Voltage (amplitude)**
  - Tmax, R max
- **Combined time-voltage**
  - Area over some portion of VM or X,Y,Z, T-wave slope, QRS slope

**3D - Based**
- **ST-T**
  - Velocity
  - Angles
  - Morphology (planarity, roundness, symmetry)
- **QRS-complex**
  - Velocity
  - Angles
  - Morphology (planarity, roundness, symmetry)
- **Combined QRS – ST-T**
  - Angles between directions and planes of QRS and ST-T planes

**Holters Markers**
- QT/RR hysteresis, use-dependence/adjustment

**P-Wave Markers for AF**

**(Beat-to-beat) Alternance**
Combined Time-voltage Markers

- **Twave area**
- **Tmax**
- **Tend**

- **J-Tend area**
- **J**
QRS-T angle

T loop

QRS loop

QRS-T angle
1. Reduction in 3D velocity of the first half of the T-wave loop and around the Tmax
2. Change in direction of T-wave loop (reduction in the angle between heart vector in R and Tmax)
3. T-wave loop becomes less elongated and more asymmetric
4. QRS loop is not affected
Background / Spatial QRS-T angle

1. Spatial QRS-T angle is a strong and independent predictor of cardiac mortality in the elderly
   - It is stronger than any of the classical CV risk factors and ECG risk indicators (Rotterdam Study; prospective population-based study, 6134 men and women > 55 years, mean follow-up time - 6.7 yrs)¹

2. Spatial QRS-T angle was the most significant predictor of CV mortality
   - outperforming all other ECG measurements and diagnostic statements (in-hospital, based on the first ECG digitally recorded from 46,573 consecutive patients; mean follow-up of 6 years)²

T-wave Loop Angular Width Markers

- T loop angular width, left
- T loop angular width, right
- T loop angular width, all
Calculation of T-wave Loop Areas

Elemental triangles

$\vec{H}(T_{\text{max}})$

$T_{\text{loop}}$

Elemental triangles

$\vec{H}(T_{\text{max}})$

$T_{\text{loop}}$

Slide 22
Principal Components, Projection of the Loops on Preferential Plane, Best Fitted Ellipse

T or QRS loop

best fitted ellipse

projection of loop

preferential plane
Applications to Cardiac Monitoring and Diagnosis
Atrial fibrillation monitoring and detection
Objectives: AF Detection

• To assess the feasibility of averaging and 3-dimensional reconstruction of atrial signal (3-DA) obtained via wireless event monitor transmission

• To assess the feasibility of 3-DA in diagnosing Atrial Fibrillation (AF) without using RR interval information
Hypothesis

Low signal/noise ratio

Limited A signal morphology

Signal averaging

3-Dimensional Atrial Signal Reconstruction (3-DA)

Improved Rhythm Diagnosis based on atrial signal
Methods: Signal averaging

Blue signal – Synthesized 12-lead ECG

Red signal – Averaged beat
3-DA signal pattern: the “Loop”

- Frontal plane
- L Sagittal plane
- Transverse plane

0.1 mV
3DA signal pattern: the “Loop”

Frontal plane

L Sagittal plane

Transverse plane

CCW inscription

A signal size = D1+D2+D3

0.1 mV
The “Loop”: Azimuth and Elevation
3-DA signal pattern: the “Clew”
“Clew” size measurement

Frontal plane

Sagittal plane

Transverse plane

\[ A \text{ size} = D1 + D2 + D3 \]

0.1 mV
Methods: Patients

- 28 patients undergoing electrical cardioversion (CV)
- 22 Male (79%)
- Age 58.5 ± 2.1 years (range 33-77)
- CardioBip recordings obtained before and after CV (at least 2 recordings/pt)
- HR 75 ± 7.5 min⁻¹
- Rhythm diagnosis confirmed by 12-lead ECG recording
- 3-DA analyzed blindly for the presence of typical signal patterns
Results:

67 transmissions were received;
64 successful signal reconstructions
SR: 20  AF: 43  Atrial flutter: 1

<table>
<thead>
<tr>
<th></th>
<th>SR</th>
<th>AF</th>
<th>A Flutter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loop</td>
<td>19</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Clew</td>
<td>1</td>
<td>42</td>
<td>0</td>
</tr>
</tbody>
</table>

P< 0.01 SR vs non-SR
## 3-DA signal size

<table>
<thead>
<tr>
<th>P signal size, mV</th>
<th>SR (n=20)</th>
<th>AF (n=43)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.33 ± 0.15</td>
<td>0.95 ± 0.17</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
“Loop” atrial signal characteristics:

• Direction:
  – All 19 SR loops had elevation 0 to + 90 degrees
  – All 19 SR loops had azimuth +90 to -90 degrees
  – Both AF (n=1) and A flutter (n=1) loops had different from SR spatial orientation

• Inscription:
  – All 19 SR loops had CCW inscription in left sagittal plane
  – AF and A flutter loop inscription was variable
Atrial flutter: Loop pattern with different spatial direction
Conclusions

• 3-DA can be successfully accomplished in the majority of wirelessly transmitted signals

• Analysis of 3DA distinguished between SR and AF in majority of cases based on the signal pattern (“loop” vs. “clew”)

• Spatial orientation and inscription of SR loop can potentially help to distinguish it from other regular atrial arrhythmias (atrial flutter, ectopic atrial tachycardia)
Limitations

• The method requires the presence of visible Tend-QRS segment (Performance at rapid rates)
• R wave-based alignment (Performance in variable PR interval in SR, variable conduction in atrial flutter), or frequent ectopy
• Individual CardioBip-ECG calibration needs to be performed on each patient
• Sinus rhythm preferred for initial matrix calibration
Objective: Post-ablation Atrial Fibrillation Monitoring

 Reliable remote outpatient detection of recurrent atrial fibrillation (AF) after catheter ablation (CA) is an important objective that could improve clinical decision making and clinical outcomes in AF patients.

 Because of the low amplitude of atrial electrical activity and noise associated with use of remote monitoring, current systems predominantly rely on heart rate variability to detect AF. As a result, some patients, especially post-CA, may be misdiagnosed.

 At present, the primary methods of monitoring such patients for recurrent AF include intermittent 12-lead, 24 hour Holter and event monitoring, which may delay diagnosis of recurrent AF or delay key diagnostic decisions regarding the need for continued anticoagulation or antiarrhythmic drugs.

 Implantable monitors show significant promise for continuous monitoring, but only provide single-lead data, which precludes accurate assessment of atrial activity and may lead to misdiagnosis.
AF Monitoring

Methods: Clinical Study Design

The study enrolled 25 patients who underwent RF catheter ablation for AF.

23 pts had only PV isolation lesions. 2 pts received additional cavo-tricuspid isthmus lesions. All patients received anti-arrhythmic medication for at least 2 months: propafenone (9), amiodarone (9), beta-blockers (4), sotalol (2) or verapamil (1).

Patients required to transmit up to 3 times per day when asymptomatic, and whenever symptoms developed.

CardioBip monitoring periods were:
- (1) approximately the first 60 days post-ablation (during the blanking period).
- (2) for 30 days at month 5-6 post-ablation (outside the blanking period).

Holter ECGs were obtained at approximately 30, 60 and 180 days post-ablation.

4 patients (#22 – 25) were monitored daily, for 180 days.

Cardiac rhythm diagnosed by 2 blinded expert readers, with differences resolved by consensus. Holter results were reviewed by a 3rd blinded expert.
Results: Months 1 and 2

Patients made 2635 TXs while asymptomatic; AF or atrial flutter (AFL) was observed in 180 asymptomatic TXs from 15 out of the 25 pts. This shows that daily monitoring with CardioBip frequently detects asymptomatic recurrences of AF/AFL.

17 pts made a total of 307 TXs during symptoms. Recurrent AF was observed in 204 TXs from 15 patients, with AFL in 41 TXs from 4 patients (all of whom also had AF TXs). In 62 TXs during symptomatic episodes, underlying arrhythmia was frequent APCs/VPCs, and no AF/AFL was observed. Thus, full 12-lead ECG monitoring with CardioBip enables accurate differential diagnosis of symptomatic arrhythmias.
Results: Months 1 and 2

Recurrent AF was noted in 342 CardioBip TXs from 21 pts and AFL was noted 83 TXs from 7 pts (all of whom also had AF TXs).

Of the 21 pts with AF/AFL, 13 pts (62%) had negative Holters (no AF or AFL).

All 8 Holter-positive patients had been previously identified by CardioBip monitoring as having recurrent AF/AFL, an average of 27.2 ± 5.8 days earlier (mean ± 90% CI) than Holter detection.

Thus, daily monitoring with CardioBip detects recurrent AF/AFL earlier and more consistently than periodic Holter monitoring.

All 25 pts completed the full 2 month monitoring period with an average of 2.17 CardioBip TX/day.

Thus, the patients’ compliance was relatively good.
Results: Month 6

- 2 pts were dropped from the study due to unrelated cardiac interventions.
- The remaining 23 patients were monitored for an additional 30 days, from about 150 to 180 days post-ablation. 4 were monitored for all 180 days.
- All 23 patients also had a 24 hour Holter at about 180 days post-ablation.

Patients made 1012 TXs while asymptomatic; AF or AFL was observed in 28 asymptomatic TXs from 7 patients.
- Daily monitoring with CardioBip frequently detects asymptomatic AF/AFL recurrences.

- 15 pts made a total of 88 TXs during symptoms.
- Recurrent AF was observed in 53 TXs from 11 patients, with AFL in 4 TXs from 1 pt. Thus, CardioBip detected symptomatic recurrent AF/AFL in a total of 12 patients.
- In 31 symptomatic TXs from 7 pts, the underlying arrhythmia was frequent APCs/VPCs; 3 of these pts had other TX showing AF, and 4 of these pts had no AF or AFL.
- Thus, full 12-lead ECG monitoring with CardioBip enables accurate differential diagnosis of symptomatic arrhythmias.
Results: Month 6

- Recurrent AF was noted in 72 CardioBip TXs from 14 pts and AFL was noted 13 TXs from 2 pts (one of whom also had AF TXs)
- Of the 15 pts with AF/AFL, 8 pts (53%) had negative Holters (no AF or AFL) at Month 6
- All 7 Holter-positive pts had been previously identified by CardioBip monitoring as having recurrent AF/AFL, an average of 23.6 ± 4.9 days earlier (mean ± 90% CI) than Holter detection
- Thus, daily monitoring with CardioBip detects recurrent AF/AFL earlier and more consistently than periodic Holter monitoring

All 23 patients completed the full monitoring period with an average of 1.81 CardioBip TX/day.
Thus, even after 180 days of monitoring, the patients’ compliance was relatively good
Results: Illustrative Clinical Story

Patient 7 was a 53 year old male who underwent pulmonary vein isolation for long-standing paroxysmal AF. After the ablation procedure, he was treated with propafenone.

He made 117 CardioBip TXs during Month 1-2, 113 of which were asymptomatic and showed NSR with occasional APCs, and 4 of which were symptomatic and showed AF.

During Month 6, he made 52 CardioBip TXs, 48 of which showed asymptomatic NSR, and 4 of which were symptomatic and showed AF.

All Holter recordings – Months 1, 2 and 6 – were negative for AF and AFL.

Recurrence of symptomatic AF in Month 6 suggested the possibility of pulmonary vein reconnection, and repeat ablation was recommended.
Results: Illustrative Clinical Story

Sinus Rhythm

Onset of AF

AF with ST depression
Conclusions

Long-term intermittent CardioBip monitoring is a viable approach to recurrent arrhythmia detection in post-ablation AF patients.

Daily remote monitoring by CardioBip for 6 months or longer periods of time is feasible, and reveals important clinical information regarding AF recurrence that may have a significant impact on clinical decision-making.

All patients provided high-quality transmissions and showed good long-term compliance with the study protocol, supporting the idea that CardioBip is convenient, easy to use and well-tolerated by patients.
Conclusions

- CardioBip was substantially more sensitive and timely in detecting recurrent AF/AFL than periodic Holter monitoring.

- CardioBip frequently detected asymptomatic AF recurrences – an important result because asymptomatic recurrences carry the same high risk of embolic events as symptomatic episodes.

- In symptomatic patients, CardioBip distinguished recurrent AF and AFL from each other and from other arrhythmias – a direct result of CardioBip’s full 12-lead ECG monitoring capability.
Acute Myocardial Infarction Detection
Objective: Acute MI Detection in Diabetes Patients

Total N=155

ED N=125

CCL N=30

Total N=155

ACS N=44

Non-ACS N=111

STEMI N=17

NSTEMI N=27
Methods

Two blinded cardiology experts read the first standard 12L ECG obtained for each patient and classified them either as:

- STEMI
- NSTEMI
- Non-ACS

Same 12L ECGs were also analyzed using my3KG and classified as ACS (STEMI or NSTEMI), or non-ACS

Cardiology experts’ and my3KG results were then compared:

- “Gold standard” was the confirmed clinical diagnosis of STEMI, NSTEMI, or non-ACS
- Statistical comparisons made with McNemar’s test with continuity correction
my3KG showed significant gains in sensitivity for ACS diagnosis in Type II DM patients, with no loss in specificity.

Sensitivity gains were particularly high in NSTEMI – the most common form of ACS in Type II DM.

Showed sensitivity gains for STEMI, but not statistically significant.

<table>
<thead>
<tr>
<th></th>
<th>Standard 12L ECG - Cardiology Expert Readers</th>
<th>Cardio3KG - Quantitative 3D analysis</th>
<th>Absolute Diagnostic Gain for Cardio3KG</th>
<th>Relative Diagnostic Gain for Cardio3KG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(TP/[TP+FN])</td>
<td>48% (21 TP/44)</td>
<td>68% (30 TP/44)</td>
<td>+20% (p&lt;0.01)</td>
<td>+43%</td>
</tr>
<tr>
<td><strong>STEMI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>65% (11 TP/17)</td>
<td>82% (14 TP/17)</td>
<td>+17%</td>
<td>+27%</td>
</tr>
<tr>
<td><strong>NSTEMI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37% (10 TP/27)</td>
<td>59% (16 TP/27)</td>
<td>+22% (p&lt;0.05)</td>
<td>+60%</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(TN/[TN+FP])</td>
<td>86% (95 TN/111)</td>
<td>87% (96 TN/111)</td>
<td>+1%</td>
<td>+1%</td>
</tr>
</tbody>
</table>
Conclusions

Type II DM patients have a 2-4x increased incidence of ACS and account for 20-30% of ACS cases.

Diagnosis of ACS in type II DM is difficult due to several factors (e.g., autonomic neuropathy, multivessel diffuse CAD at presentation, prior silent coronary events).

Standard 12L ECG is insensitive for detecting ACS in type II DM patients – particularly for NSTEMI, the most common form of ACS in type II DM.

Improved diagnostic sensitivity provided by my3KG may improve speed and accuracy of ACS diagnosis in type II DM patients.
Safety and Performance Standards
Why is Specific Absorption Rate (SAR) important?

- The incident and internal electromagnetic fields can be very different, depending upon size and shape.

- SAR is the common unit for comparing and extrapolating laboratory results (bioeffects studies).
Goals of Literature Assessment

During the literature assessment procedure, classifications of findings were made *without* prejudgement of mechanisms of effects.

Intent was to protect exposed human beings from harm by *any* mechanism, including those arising from excessive elevations of body temperature.
FINDINGS:
The most sensitive measures of potentially harmful biological effects were based on the disruption of food-motivated behavior in several animal species under widely-varying field parameters
## Comparison of Power Density and SAR Thresholds of Behavioral Disruption

<table>
<thead>
<tr>
<th>Species and Conditions</th>
<th>CW 225 MHz</th>
<th>Pulsed 1.3 GHz</th>
<th>CW 2.45 GHz</th>
<th>Pulsed 5.8 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norwegian Rat</td>
<td>-----</td>
<td>10 mW/cm²</td>
<td>28 mW/cm²</td>
<td>20 mW/cm²</td>
</tr>
<tr>
<td>Power Density:</td>
<td>-----</td>
<td>2.5 W/kg</td>
<td>5.0 W/kg</td>
<td>4.9 W/kg</td>
</tr>
<tr>
<td>SAR:</td>
<td>-----</td>
<td>2.5 W/kg</td>
<td>5.0 W/kg</td>
<td>4.9 W/kg</td>
</tr>
<tr>
<td>Squirrel Monkey</td>
<td>-----</td>
<td>45 mW/cm²</td>
<td>40 mW/cm²</td>
<td>7.2 W/kg</td>
</tr>
<tr>
<td>Power Density:</td>
<td>-----</td>
<td>4.5 W/kg</td>
<td>7.2 W/kg</td>
<td>140 mW/cm²</td>
</tr>
<tr>
<td>SAR:</td>
<td>-----</td>
<td>4.5 W/kg</td>
<td>7.2 W/kg</td>
<td>140 mW/cm²</td>
</tr>
<tr>
<td>Rhesus Monkey</td>
<td>8 mW/cm²</td>
<td>57 mW/cm²</td>
<td>67 mW/cm²</td>
<td>140 mW/cm²</td>
</tr>
<tr>
<td>Power Density:</td>
<td>3.2 W/kg</td>
<td>4.5 W/kg</td>
<td>4.7 W/kg</td>
<td>8.4 W/kg</td>
</tr>
<tr>
<td>SAR:</td>
<td>3.2 W/kg</td>
<td>4.5 W/kg</td>
<td>4.7 W/kg</td>
<td>8.4 W/kg</td>
</tr>
</tbody>
</table>
The MPEs are based on limiting the SAR to:

<table>
<thead>
<tr>
<th></th>
<th>Controlled/Occupational</th>
<th>Uncontrolled/General Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole-Body-Averaged</td>
<td>0.4 W/kg</td>
<td>0.08 W/kg</td>
</tr>
<tr>
<td>Spatial Peak (per gram)*</td>
<td>8.0 W/kg</td>
<td>1.6 W/kg</td>
</tr>
</tbody>
</table>

*Per gram of tissue in the shape of a cube
Controlled Environments

Controlled environments are locations where there is exposure which may be incurred by persons who are aware of the potential for exposure as a concomitant of employment, by other cognizant persons or as the incidental result of transient passage through areas where analysis shows that the exposure levels may be above the maximum permissible exposure (MPEs) for the uncontrolled environment but do not exceed the MPEs for the controlled environment.
Uncontrolled Environments

Uncontrolled environments are locations where there is exposure of individuals who have no knowledge or control of their exposure. The exposures may occur in living quarters or workplaces where there are no expectations that the exposure levels exceed the MPEs for the uncontrolled environment.
IEEE C95.1-1991 - Spatial Averaging

The exposure values (the values that are compared with the appropriate MPEs) in terms of electric and magnetic field strengths are the mean values obtained by spatially averaging the squares of the fields over an area equivalent to the vertical cross-section of the human body (projected area)
The averaging time decreases with increasing frequency (above 15 GHz) from 6 and 30 minutes for the controlled and uncontrolled environments, respectively, to 10 seconds at 300 GHz.
Summary of Standard

“Recommendations are made to prevent harmful effects in human beings exposed to electromagnetic fields in the frequency range of 3 kHz to 100 GHz”
Medical electrical equipment –

Part 2-47:
Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
51.5.7 System noise

The internal noise referred to input shall not exceed 50 μV p-p over any 10 s period when all inputs are connected through a 51 kΩ resistor in parallel with a 47 nF capacitor in series with each PATIENT ELECTRODE connection. Any SUPPLY MAINS frequency notch filters in the equipment, if so equipped, shall be operating at the appropriate SUPPLY MAINS frequency during this test.

Compliance is checked by the following test:

Insert in series with each PATIENT ELECTRODE connection a 51 kΩ resistor in parallel with a 47 nF capacitor, as shown in Figure 105, and then connect all PATIENT ELECTRODE connections including the right leg connection together. Do not connect the input signal generator and the 100 pF capacitor for this test. At the highest gain possible, record for 2 min. Ignore the first 10 s and last 10 s of the recording. Divide the remaining 100 s into 10 intervals of 10 s each, then check the output for noise levels in each interval. The P-p noise level shall be within the limit for at least nine of the ten intervals.

51.5.8 Multichannel crosstalk

The crosstalk between the channels of the equipment shall not produce in any channel an output referred to input greater than 0.2 mV p-p.

Compliance is checked by the following test:

a) Connect the recorder to the test circuit of Figure 104 with switches S1 and S2 closed, S5 open, switch S3 in position A and the positive PATIENT ELECTRODE connections for each channel joined to P1.

b) Join the reference PATIENT ELECTRODE connections for each channel through P2 to the reference lead wire through a 51 kΩ resistor in parallel with a 47 nF capacitor.

c) Adjust the signal generator to produce a sinusoidal signal of an amplitude of 4 mV p-p and a frequency of 10 Hz across P1 and P2. Record at least 10 s of signal.

d) Reconnect all but one of the positive PATIENT ELECTRODE connections from P1 to P2. Record at least 10 s of signal.

e) Repeat this for as many channels as can be recorded. Join only one positive PATIENT ELECTRODE connection to P1 at a time.

The output of the channels with the positive PATIENT ELECTRODE connection connected to P2 shall not exceed 0.2 mV p-p referred to input.

51.5.9 Frequency response

The equipment shall meet the following requirements:

a) Response of a recorder to a 3 mV 100 ms rectangular pulse shall not show a baseline amplitude displacement after the pulse of more than 0.1 mV referred to the baseline before the pulse. The slope outside the pulse shall be less than 0.3 mV/s. The leading edge overshoot shall be less than 10%.

and either

b) The amplitude response to sinusoidal signals within the frequency range 0.67 Hz to 40 Hz shall be between 140 % and 70 % (+3 dB to –3 dB) of the response at 5 Hz.

If the manufacturer claims ST segment measurement capability for the equipment, lower cut-off frequency shall be 0.05 Hz for a first-order high-pass filter or its functional equivalent.
Figure 103 – Test signal for input dynamic range test according to 51.5.1

Figure 104 – General test circuit for 51.5
51.5.11 Function in the presence of pacemaker pulses

If the manufacturer claims that the AMBULATORY RECORDER is capable of recording ECG signal in the presence of implanted pacemaker pulses, the function of the EQUIPMENT shall not be adversely affected by the operation of an implanted pacemaker.

Compliance is checked by the following test:

a) Connect the EQUIPMENT to the circuit of figure 106, with the positive PATIENT ELECTRODE connection for each channel connected to P1 and the negative ELECTRODE connection for each channel, as well as the reference ELECTRODE connection, to P2.

b) Adjust the sine wave generator so that a 10 Hz (2.0 ± 0.2) mV p-p sinusoidal signal is present across the 111 Ω resistor. The pulse generator adds 200 mV ± 25 mV pulses with a duration of 1.0 ms ± 0.1 ms, a rise time ≤100 μs and a repetition rate of 100 pulses/min.

c) Record at least 30 s.

d) Reverse the positive and negative ELECTRODE connections in a) and repeat the recording.

e) Confirm on playback that for all pulses the height of the second peak of the sine wave after the pulse does not differ more than 0.2 mV from the height of the sine wave peak immediately preceding the pulse.

If the manufacturer claims that EQUIPMENT is capable of recording the activity of an implanted pacemaker, the EQUIPMENT shall produce a visible recording for pacemaker pulses with amplitudes between 2 mV and 200 mV, durations between 0.1 ms and 2.0 ms and a rise time of <100 μs.

Compliance for such EQUIPMENT is checked by the following test:

Tests with four different pulses with a rise time of <100 μs shall be made: a first pulse having an amplitude of 2 mV and a duration of 2.0 ms, a second pulse having an amplitude of 200 mV and a duration of 2.0 ms, a third pulse having an amplitude of 20 mV and a duration of 0.1 ms and a fourth pulse having an amplitude of 2 mV and a duration of 0.1 ms.

Record at least 30 s with the sinusoidal generator settings of item b) above and a repetition rate of the pulses of 100/min and verify that for every pulse, a mark at least 2 mm high is printed on the hard copy record at the same repetition frequency and same inter-pulse interval as the pulses input into the EQUIPMENT.
Figure 106 - Test circuit for pacemaker pulse tolerance according to 51.5.11

(ppm = pulse per minute)
THANK YOU!

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