EMC HOME PAGE ADDRESS

http://www.ecn.uoknor.edu/~emc

EMC CLEARING HOUSE

A Repository of all Wireless EMC Information

- EMC Research
  - Wireless Technology Developments
  - EMC Device Interaction Studies
  - Who's Who in EMC Research
- EMC Education
  - Conferences
  - Short Courses
  - Degree Programs
- EMC News
  - Legislative Hearings
  - Government Regulations
  - Labeling Guidelines

CENTER FOR THE STUDY OF WIRELESS ELECTROMAGNETIC COMPATIBILITY

University of Oklahoma - Industry Advisory Board

1995-1996

AT&T Bell Labs
Donald N. Heirman
Manager, Global Product Compliance
Room 11C-165
101 Crawfords Corner Rd.
P.O. Box 3030
Holmdel, NJ 07733-3033
Phone: 908-834-1801
FAX: 908-834-1807

AT&T Network Systems
Arlene Strege
Manager, Industry Relations
Network Wireless Systems
P.O. Box 903
Room 2A-380
67 Whippany Road
Whippany, NJ 07981-0903
Phone: 201-386-6863
FAX: 201-386-4555

AT&T Wireless
Candy Castle
Director, External Affairs
5400 Carillon Point
Kirkland, WA 98033
Phone: 206-828-8407
FAX: 206-828-8452

Bell South Wireless, Inc.
M.D. Frerking
Senior Manager-Strategic Technology
Room 803
1100 Peachtree Street, N.E.
Atlanta, Georgia 30309-4599
Phone: 404-249-4566
FAX: 404-249-5157

CTIA
Elizabeth F. Maxfield
1250 Connecticut Avenue, NW
Suite 200
Washington, DC 20036
Phone: 202-736-3235
FAX: 202-887-1629

Ericsson, Inc.
Barry Kratz, Director
Business & Industry Relations
Radio Systems
740 East Campbell Road
Richardson, TX 75081
Phone: 214-952-8619
FAX: 214-705-7666

Hewlett Packard
Marc Saunders
5301 Stevens Creek Blvd.
Santa Clara, CA 95051-8059
Phone: 408-553-7460
FAX: 408-553-7705

Motorola
Ray Millington
Vice President & Director of Engineering
Advanced Products & Technologies Div.
Cellular Subscriber Group
600 North U.S. Highway 45
Libertyville, IL 60048-1286
Phone: 708-523-5184
FAX: 708-523-5557

Nokia, Inc.
Chris Wallace

2300 Valley View Lane
Suite 100
Irving, Texas 75062
Phone: 214-257-9947
FAX:

Northern Telecom Inc.
Dinesh Pai, Sr. Manager
Wireless Standards & Regulation
2221 Lakeside Blvd.
P.O. Box 833858
Richardson, TX 75083-3858
Phone: 214-684-4878
FAX: 214-684-3662

SBC Communications Inc.
John Stupka, Sr. Vice President
Strategic Planning
175 East Houston Street
Room 1305
San Antonio, TX 78205
Phone: 210-351-2802
FAX: 210-351-2029

Southwestern Bell Mobile Systems
Walter Patterson
Vice President - Corporate Communications
17330 Preston Road
Suite 100A
Dallas, TX 75252
Phone: 214-733-2132
FAX: 214-733-2883

Alpha by Compa

NSF Industry University Cooperative Research Center
Wireless Electromagnetic Compatibility
Project Summary

Project Name: Study of the Interaction of Pacemakers and Cellular Telephones

Project Investigators: Robert Schlegel, Hank Grant, A. Ravindran, Shivakumar Raman, Leon Zelby (OU) and Ed Berbari (IUPUI)

Description:

The objective of this study is to document the types of interactions that may occur when pacemakers and cellular telephones are placed in proximity to each other. Specifically, the possible health consequences of using a cellular phone in proximity to a person with a pacemaker is to be evaluated. The experimental program will include an evaluation of all the major types of pacemakers as they interact with cellular phones that use both analog and digital signal technology. A program of coordination and cooperation has been established with the FDA, the cellular telephone industry and the principal pacemaker manufacturers. The laboratory facilities for conducting the study are excellent and the staff is well qualified. The results will guide both the pacemaker manufacturers and the cellular telephone industry in systems design to avoid any health consequences of any possible or potential interaction. The FDA may use the results to promulgate guidelines or standards for the pacemaker industry. Likewise, the FCC may use the results to regulate the cellular phone industry.

Experimental Plan:

A working group has been formed of the pacemaker industry, the cellular phone industry and the FDA. This group has agreed on the protocol to test all possible interactions of the pacemakers and cellular phones that could pose a health risk. This involves several combinations of pacemaker type and cellular phone type in a variety of configurations. All of the evaluations are conducted at an electromagnetic compatibility test center.

Related Work Elsewhere:

Limited testing at U.S. FDA and Health Canada laboratoriess.

How Ours is Different:

Use of a Base Station to simulate actual calls in an RF shielded room.

Related Work in the Center

Interference between cellular phones and hearing aids.

Milestones:

12 month project

Deliverables:

1. Testing protocol acceptable to the FDA, pacemaker manufacturers and the wireless telephone industry.
2. Test results for potential interference of digital cellular phones with different types of pacemakers.

Budget:

$100,000 total

Final breakdown pending negotiations with the pacemaker and cellular industry representatives.

Potential Benefits to Member Companies:

The pacemaker manufacturers will receive assurance that their product is safe for use around cellular phones.

The cellular phone industry will be able to use the new digital technology without potential interference with an important medical device.

The FDA will be provided with a test protocol and test results to fulfill their regulatory responsibility for safe medical devices.

September 28, 1995

The University of Oklahoma

CENTER FOR THE STUDY OF WIRELESS ELECTROMAGNETIC COMPATIBILITY
SCHOOL OF INDUSTRIAL ENGINEERING

PACEMAKER - CELLULAR PHONE INTERACTION STUDY

SCOPE

- Investigate interaction between cellular phones and pacemakers
- 5 major pacemaker companies
- TDMA, GSM, MIRS, PCS, CDMA and ANALOG phones

PHASE I OBJECTIVES

1. Define the testing protocol for the evaluation of the interaction of cellular phones with pacemakers. The resulting protocol shall produce repeatable results;

2. Determine if and what interactions exist between cellular phones and pacemakers as well as conditions which might promote these interactions; and

3. Understand and explain the mechanism for this interaction.

PHASE II OBJECTIVES

1. Include other wireless devices such as
   a. PCS (Personal Communication Systems) Technology
   b. 2 way radios and similar technology
   c. Radio Frequency (RF) data collection systems (scanning devices; low power 100MW, high frequency 900 MHZ-2.4 GHZ

2. Include other medical devices such as implantable cardiac difibrillator.

PRELIMINARY RESULTS

Seventeen pacemaker models from 5 major pacemaker companies have been tested with 4 different TDMA phones. More than 300 different pacemaker-phone interaction tests have been completed for ten different interference types. Less than 10% of tests exhibited any interference (some minor) between the pacemakers and the phones. Some pacemaker models had no interference with any of the phones tested. In all cases, no permanent reprogramming or damage to the pacemakers under tests were observed. In other words, even when an interference was observed, the pacemaker returned to normal operation as soon as the phone was removed from its vicinity.

FUTURE PLANS

- More testing with Analog, GSM, and CDMA phones will be carried out
- Will include high frequency (1900) PCS testing
- Will add implanted difibrillators in the next testing phase

FOR ADDITIONAL INFORMATION

Contact: Dr. A. "Ravi" Ravindran
405-325-2429 E-Mail: ARAVI@UOKNOR.EDU

October 24, 1995
Alpha by Company, then by last name

PACEMAKER DESIGN GROUP

COMPANY	NAME	FAX NUMBER
AT&T Bell Laboratories	Don Heirman	908-834-1807
AT&T Global Products	Mike Ruduski	908-834-1807
AT&T Network Systems	Tom Philips	201-386-4555
Cardiac Pacemakers, Inc.	Jim Putzke	612-582-2830
CTIA	Liz Maxfield	202-887-1629
CTIA	Tom Wheeler	202-331-8112
FDA	Howard Bassen	301-443-0023
FDA	Paul Ruggera	301-443-0023
FDA	Mitchell Shein	301-594-3076
FDA	Donald Witters	301-443-0023
GTRI	Hugh Denny	404-894-7358
Health Canada	Kon-Swang Tan	613-993-0281
Health & Env. Sciences	George Carlo	202-833-2801
Health & Env. Sciences	Gretchen Findley	202-833-2801
Hewlett Packard	Wolfgang Krull	508-685-5427
HIMA	Bernie Liebler	202-783-8750
In Control	Ben Timms	206-861-9301
Intermedics	Craig Housworth	409-848-4939
Intermedics	Patrick Paul	409-848-4939
IUPUI/OU Center	Ed Berbari	317-274-4493
Mayo Clinic	David Hayes	507-284-5470
McGill/Jewish General Hospital	Bernie Segal	514-340-7581
Medtronic	George Aram	612-574-6197
Medtronic	Jerry Becker	612-574-6197
Motorola, Inc.	Quirino Balzano	305-475-5611
Motorola, Inc.	Oscar Garay	305-475-5611
Motorola, Inc.	Ray Millington	708-523-5557
Mount Sinai	Roger Carillo	305-674-2865
Northern Telecom	Michael Lynch	214-684-3662
Northern Telecom	Dinesh Pai	214-684-3662
Pacesetter	Ken McNeil	818-362-5851
Pacesetter	Larry Selznick	818-362-3816
SBC Communications, Inc.	John Stupka	210-351-2029
SBC Wireless	Stan Sigma	214-733-2012
Telectronics	Bob Morris	303-799-2213
Telectronics	Doug Schlam	303-799-2213
Ventritex	Dan Goldman	408-735-8750

PACEMAKER DESIGN GROUP

UNIVERSITY OF OKLAHOMA

COMPANY	NAME	FAX NUMBER
OU-EMC Center Chairman of the Board	Hank Grant	405-325-7555
OU-EMC Center Director	A. "Ravi" Ravindran	405-325-2556
OU-EMC Center, IE Dept.	Deji Badiru	405-325-7555
OU-EMC Center, IE Dept.	Shiva Raman	405-325-7555
OU-EMC Center, IE Dept.	Bob Schlegel	405-325-7555
OU-EMC Center, EE Dept.	Leon Zelby	405-325-7066
OU-HSC	Dwight Reynolds	405-271-2619

DRAFT

PROTOCOL FOR IN-VITRO STUDY OF PACEMAKER INTERACTION WITH CELLULAR PHONES

Version 3.2

CENTER FOR THE STUDY OF WIRELESS ELECTROMAGNETIC COMPATIBILITY

SCHOOL OF INDUSTRIAL ENGINEERING
UNIVERSITY OF OKLAHOMA

June 7, 1995

PROTOCOL FOR IN-VITRO STUDY OF PACEMAKER INTERACTION WITH CELLULAR PHONES

Torso Simulation

Torso Simulator

The torso simulator consists of a plastic box (e.g., Rubbermaid "Keepers" Clear Box, 23 inch x 16.75 inch x 6 inch; 28 quart) filled with 0.03 molar (1.8 gm/l) saline solution (AAMI Standard). Larger boxes may be used if required to test larger devices. The 0.03 molar solution produces a conductivity of approximately 3,400 micromhos. A calibrated conductivity meter should be used to verify a conductivity between 3,000 and 3,500 micromhos prior to each test session.

The top surface of the simulator, which supports the radiating source (cellular phone), is a piece of rigid plastic grid (fluorescent light fixture grid). The grid is constructed of 1/16 inch wide, 11/32 inch thick beams spaced 17/32 inch apart in two directions. This forms an array of square holes which are approximately 0.5 inch on a side over the entire surface.

This grid design minimizes the amount of plastic between the cellular phone and the saline surface. The PUT and leads are submerged in the saline, and rest on top of a second support grid which has plastic legs extending to the bottom of the box. With the second grid and PUT in place, the saline solution depth in the box is adjusted so that it is 1.0 cm below the top edge of the box. The upper surface of the top grid (support for the cellular phone) is aligned with the top edge of the box.

Test Depth Distances

There are three distances of concern in the experiment:

1. top of pacemaker to surface of saline solution;
2. surface of saline solution to bottom of cellular phone; and
3. bottom of cellular phone to top of pacemaker.

Distance 3 is the sum of distance 1 plus distance 2. The apparatus is designed to allow adjustment of these parameters. The pacemaker is placed such that its top surface is either 0.5 cm or 1.0 cm below the saline surface (distance 1) to simulate variation in implant depth. The distance between the bottom surface of the phone and the saline surface (distance 2) will start at 1 cm. If interference is identified, this distance will be increased in 2 cm intervals until no effect is observed. The contact point of the lead tip inserted into the pacemaker head (single chamber) or the point midway between the contact points of the two leads (dual chamber) defines the pacemaker location reference point. The pacemaker is oriented such that the longitudinal axis of the lead holes on the header is parallel to the longest side of the torso simulator.

The pacemaker leads rest on top of the support grid and are anchored with non-conducting string. The leads are configured in a spiral extending 3 inches from the location reference point of the pacemaker at all points, and, if necessary due to long leads, 2 inches from the leads' spiral until the tip is reached.

Interaction Testing

Cellular Phone

All testing is performed with the phone at maximum power output.

The following phone technologies will be tested according to the following priorities:

1. Analog
2. TDMA
   - US Digital Cellular
   - MIRS
   - GSM including DTX mode

Specifics of these technologies are included in Appendix A.

Several actual phones will be tested to determine any interactions. These will include handheld, bag, and mobile phones, if possible. These will be used in conjunction with a base station simulator.

A spectrum analyzer is used to verify phone signal operation.

Pacemaker Under Test (PUT)

Each PUT is programmed for the worst case EMI condition (maximum sensitivity, minimum refractory period). The nominal sensitivity configuration will also be tested.

The configuration of the leads is a planer arrangement with no depth change over the length of the lead. Because effects have been shown to be close to the pacer head (within 4 inches), the specific configuration of the leads does not seem important.

Where possible, the same set of leads will be used for all testing. The following lead configurations will be examined:

- Single chamber/dual chamber, and
- Unipolar/bipolar.

Standard AAMI pacemaker evaluation practice will be used.

The pacemaker will be interrogated before and after the test to examine any changes in internal parameters.

The following will characterize the test outcomes:

No Interference

Crosstalk/safety pacing

Tracking of cellular phone signals

Changes in pacing pulse amplitude and width

Inhibition

Asynchronous pacing

Samples of the pacemaker output and other test results will be recorded for review.

EXPERIMENTAL DESIGN

FACTORS AND LEVELS

- **Experimental Environment**
  - Distance of the Phone from the Pacemaker
  - X-Y Location
  - Orientation of the Antenna
  - Activation of the ECG Simulator
- **Cellular Phone**
  - Mode of Operation
    - Power up
    - Registration function from base station
    - Ringing
    - Change channel / change power
  - Technology
    - Analog
    - TDMA
      - US Digital Cellular
      - MIRS
      - GSM (DTX and non DTX)
  - Phone Movement
    - Fixed
    - Toward PUT
    - Away from PUT
- **Pacemaker**
  - Brand and Model
  - Sensitivity
    - Maximum
    - Nominal
  - Leads
    - Unipolar
    - Bipolar

RESPONSE DATA TO BE COLLECTED

PACEMAKER-CELLULAR PHONE INTERACTION STUDY

PACEMAKER-CELLULAR PHONE INTERACTION STUDY

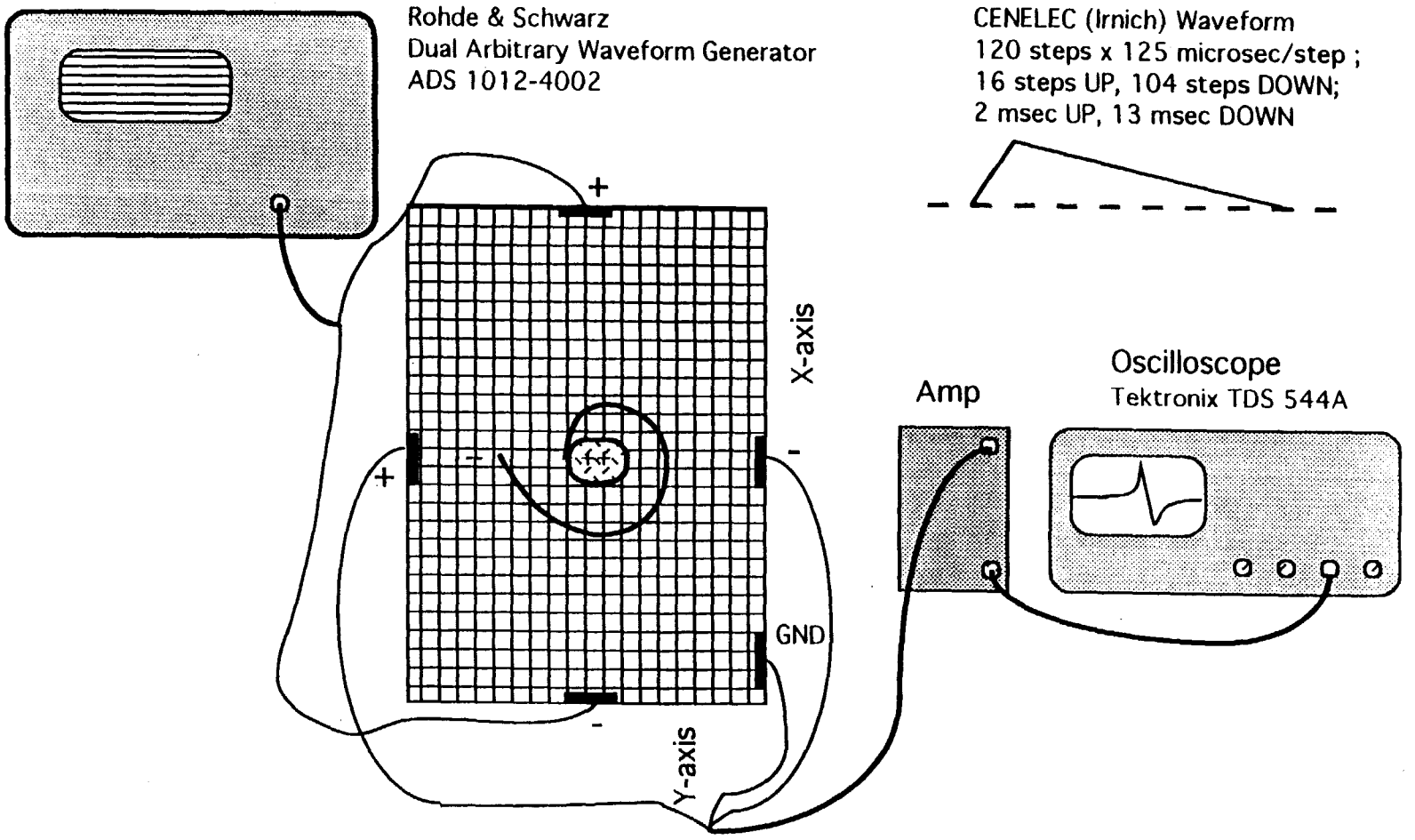
OBJECTIVE

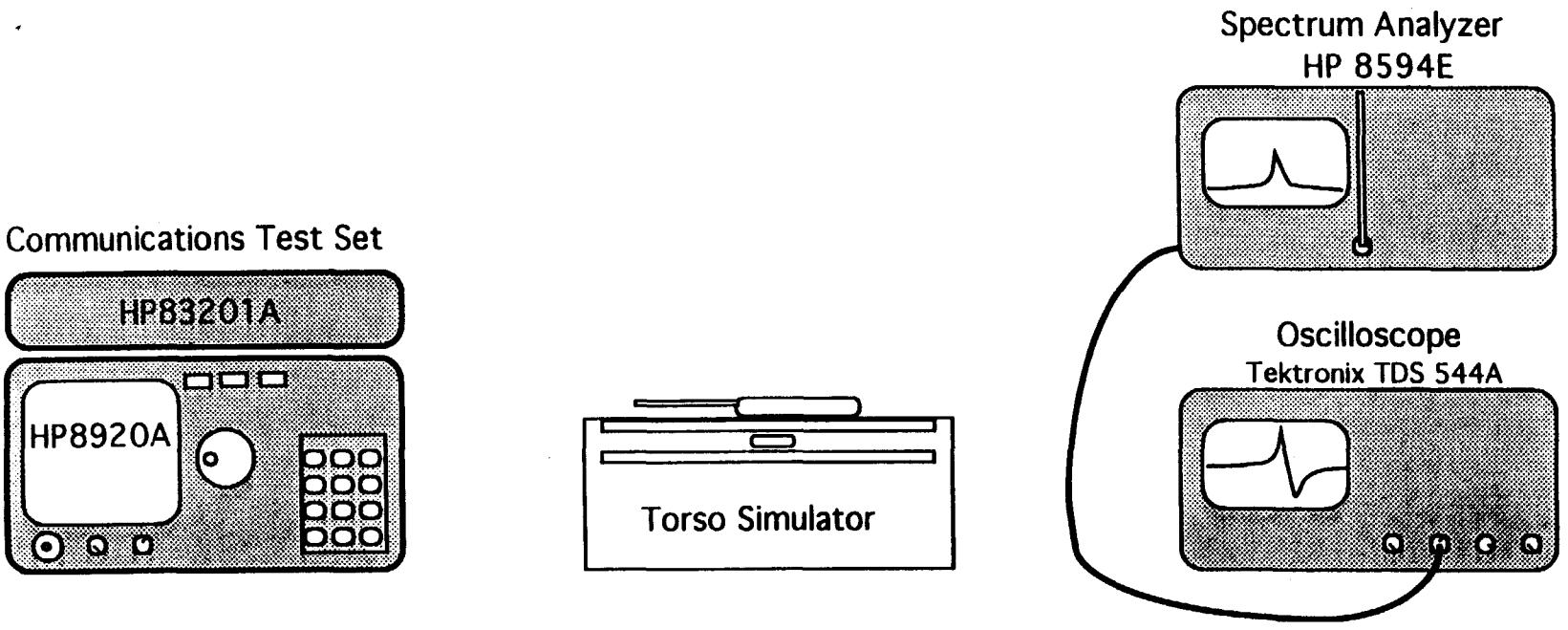
Investigate interaction between cellular phones and pacemakers

SCOPE

Five major pacemaker companies

TDMA, GSM, MIRS, PCS, CDMA and ANALOG


Rohde & Schwarz
Dual Arbitrary Waveform Generator
ADS 1012-4002
CENELEC (Irnich) Waveform
120 steps x 125 microsec/step ;
16 steps UP, 104 steps DOWN;
2 msec UP, 13 msec DOWN
+
-
X-axis
Y-axis
GND
Amp
Oscilloscope
Tektronix TDS 544A


Communications Test Set
HP83201A
HP8920A
Torso Simulator
Spectrum Analyzer
HP 8594E
Oscilloscope
Tektronix TDS 544A

EXPERIMENTAL APPARATUS

- Torso Simulator
- Pacemaker Support
- Lead Support Fixtures
- Cellular Phone Support
- Signal Monitoring Unit
- ECG Simulator
- Pacemakers (PMK)
- Pacemaker Leads
- Cellular Phones

TORSO SIMULATOR

- Plastic Box (23" x 16.75" x 6")
- Contents (0.03 molar [0.18%] saline)
- Conductivity (3400 micro-mhos/cm)
  (340 milli-siemens/m)
- Stainless Steel Plates

  50mm x 50mm x 2mm

  One Pair - ECG Simulator (ends)

  One Pair - PMK/ECG Monitor (sides)

PACEMAKER SUPPORT

- Plastic Grid (0.5" rib spacing)

LEAD SUPPORT FIXTURES

- Plastic Grid (flat in vertical plane)

  and

- Secured with String (fixed layout)

CELLULAR PHONE SUPPORT

- Plastic Grid (0.5" rib spacing)

SUPPORT SPACING

ECG SIMULATOR

- Rohde & Schwarz Generator (ADS 1012-4002)
- CENELEC / Irnich Waveform (2 ms rise, 13 ms fall)
- Single-Chamber Operation
- Level Set to (2 x threshold)

SIGNAL MONITORING UNIT

- Narco Hi-Gain Coupler/ECG Amp
- Tektronix TDS 544A Oscilloscope

PACEMAKER LEADS

- Number of Leads
  - Single Chamber
  - Dual Chamber
- Unipolar vs. Bipolar
- Single Manufacturer
- Fixed Lead Length
- Fixed Layout
- Pacemaker-Lead Connection

PROCESS

- Bring up equipment and apparatus
  - Base Station Simulators
  - Torso Simulator
  - Cardiac Simulator
  - Monitoring Equipment
  - Pacemaker Operation
- Prototype Study to evaluate experimental design and to explore areas to reduce test time requirements
- Detailed Testing Underway
- Industry/Researcher/Government Advisory Group Participated Throughout

TEST CONDITIONS
Pacemaker Modes and Lead Polarity

Pacemaker Modes - AAT, VVT, DDD

Lead Polarity - Unipolar, Bipolar

Potential Combinations = 3 x 2 = 6 per Pacemaker

All 30 Pacemakers

Potential Test Runs = 30 x 6 = 180

Actual Test Runs = 130

TEST CONDITIONS
One Pacemaker, One Phone Mode

Orientation - 8 antenna directions (N, NE, E, SE, ...)

Face up/dn - 2 directions (keyset up vs. down)

ECG Signal - 2 states (on vs. off)c

Test Grid - 37 x 25 = 925 pts. (not all accessible)
- 13 x 13 = 169 pts. (reduced grid)

Potential Tests per Pacemaker (one phone mode)

= 6 modes x 8 x 2 x 2 x 925 = 177,600

Revised Tests per Pacemaker (one phone mode)

= 6 modes x 4 x 1 x 2 x 169?= 8,112?

Test Conditions

Date: _____

Time: _____

Temp: _____

Salinity: _____

Conduct.: _____

Pacemaker

Company: _____

Model: _____

S/N: _____

Type: _____

Leads: _____

Sensitivity: _____

Lower Rate: _____

Safety Rate: _____

Inject Rate: _____

Phone Rate: _____

Cellular Phone

Company: _____

Model: _____

S/N: _____

Technology: _____

Mode: _____

MODE

DDD AAT VVT

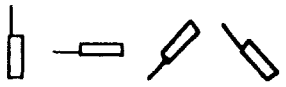
LEAD POLARITY

UNI- BI-

ECG SIGNAL

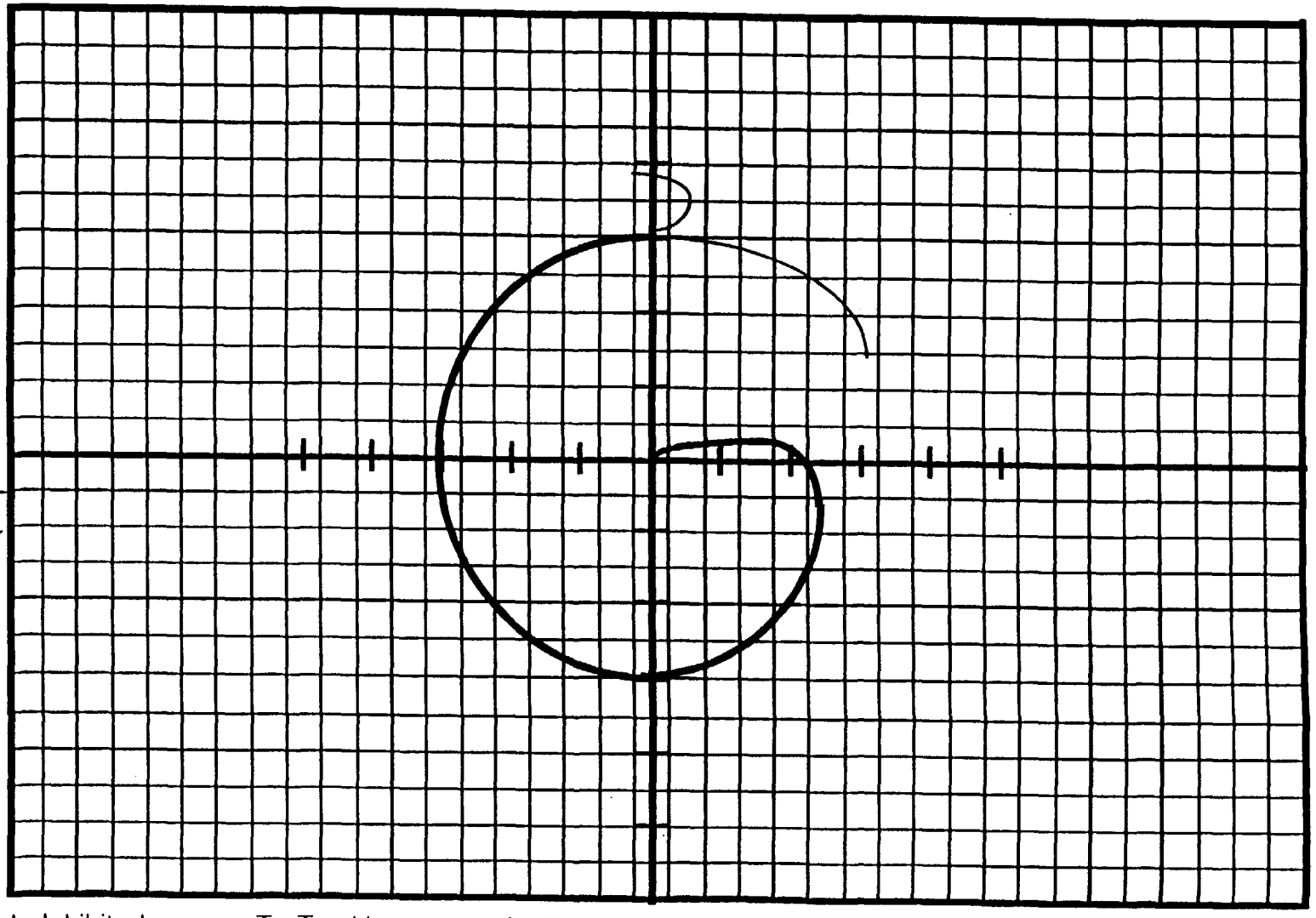
NO YES

ORIENTATION



NOTES

1. phone is placed face down or face up for antenna closest to grid
2. test central grid ±6 in X and Y directions (12 x 12 grid)
3. when interaction is found, test further until there is no interaction for 3 test points



I - Inhibited T - Tracking A - Async. Pacing Red - Regular Blue - Sporadic

TEST CONDITIONS
Phone Modes

MIRS Phones - Transmit Carrier

TDMA Phones - Registration
- Ringing (polling)
- Change channel/power
- Talkback (loopback)

Following pilot tests
- Ringing (polling)
- Talkback (loopback)
- Maximum two phone models