U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K000609 - 213 pages
COMPANY:	CARDIAC TELECOMMUNICATIONS (CARDTELEA)
PRODUCT:	ELECTROCARDIOGRAPH,AMBULATORY(WITHOUT ANALYSIS) (MWJ)
SUMMARY:	Product: CARDTEL, MODEL NT-100
DATE REQUESTED:	Jun 26, 2016
DATE PRINTED:	Jun 26, 2016
Note:	Printed

K000609 p.1/2

MAY 2 3 2000

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. Submitter

Name:	Cardiac Telecommunications	or	Delphi Consulting Group
Address:	17448 Highway 3, Ste. 175 Webster, Texas 77698 USA		P. O. Box 932 Stafford, Texas 77047
Telephone Number:	(281) 332-7587		(713) 723-8169
Contact Person:	Karim Alhussiny, Ph.D.		J. Harvey Knauss (as Regulatory Consultant
Date Prepared:	2/17/00		to Cardiac Telecommunications)

2. Device

Proprietary name:	CardTel, Model NT-100
Common name:	ECG
Classification name:	Electrocardiograph

3. Classifications Names & Citations:

21 CFR 870.2340 Electrocardiograph
21 CFR 870.2910 Radiofrequency Physiological signal transmitter and receiver

3. Predicate Device

Burdick Eclipse Plus, Burdick, Inc., K946281

4. Description

The CardTel Model NT-100 provides a portable device to continuously monitor ambulatory patient 12 lead electrocardiographic (ECG) data. The unit is designed to acquire and display up to twelve ECG vectors in a standard diagnostic ECG analysis format. The twelve leads consist of the standard twelve ECG leads, I, II, III, aVR, aVL, aVF, V1 and V6. The Model NT-100 is used to monitor patients in the operating room, recovery rooms, intensive care units, in the emergency room, in research settings, or other units where additional ECG leads are desired and real time display is desired. The display unit consists of a generally available Pentium® based personal computer or laptop computer with a SVGA monitor and color printer.

The system provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events.

5. Indications for use

The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

6. Contra-indications

May only be operated by trained personnel.

7. Comparison

The CardTel NT-100 ECG System has the same device characteristics as the predicate device, except the predicate device does not have wireless capability.

8. Test Data

The Model NT-100 System has been subjected to extensive safety and performance testing prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. The ECG Analysis system meets the specified clinical output data requirements of the ANSI/AAMI EC38-1994 specification for ambulatory electrocardiography. Standard databases have been used for automated ECG algorithm verification testing. Safety tests have further been performed to ensure the system complies to applicable industry and safety standards.

The NT-100 device labeling includes instructions for safe and effective use. It includes warning, cautions, and guidance for installation and maintenance.

9. Literature Review

A review of literature pertaining to the safety of electrocardiographs has been conducted. Appropriate safeguards have been incorporated in the design of the NT-100 unit.

10. Conclusions

The conclusion drawn from these tests is that the Model NT-100 ECG System is equivalent in safety and efficacy to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2000

Cardiac Telecommunications
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K000609
CardTel, Model NT-100
Regulatory Class: II (two)
Product Code: 74 MWJ
Dated: February 16, 2000
Received: February 23, 2000

Dear Mr. Knauss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhern

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K000609

Device Name: CardTel Model NT-100

Indications for use: The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

Prescription Device: Federal Law (US) restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular Respiratory,
and Neurological Devices
510(k) Number K000609

Prescription Use Yes OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Cardiac Telecommunications
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K000609
CardTel, Model NT-100
Regulatory Class: II (two)
Product Code: 74 MWJ
Dated: February 16, 2000
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for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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Sincerely yours,

for Mark N Milhous

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K000609

Device Name: CardTel Model NT-100

Indications for use: The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

Prescription Device: Federal Law (US) restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000609

Prescription Use Yes OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Dana Hunsicker

Subject: 510(k) Number K000609

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☐ NO

- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

- ☑ A 510(k) summary OR ☐ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☑ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 74 MWJ II

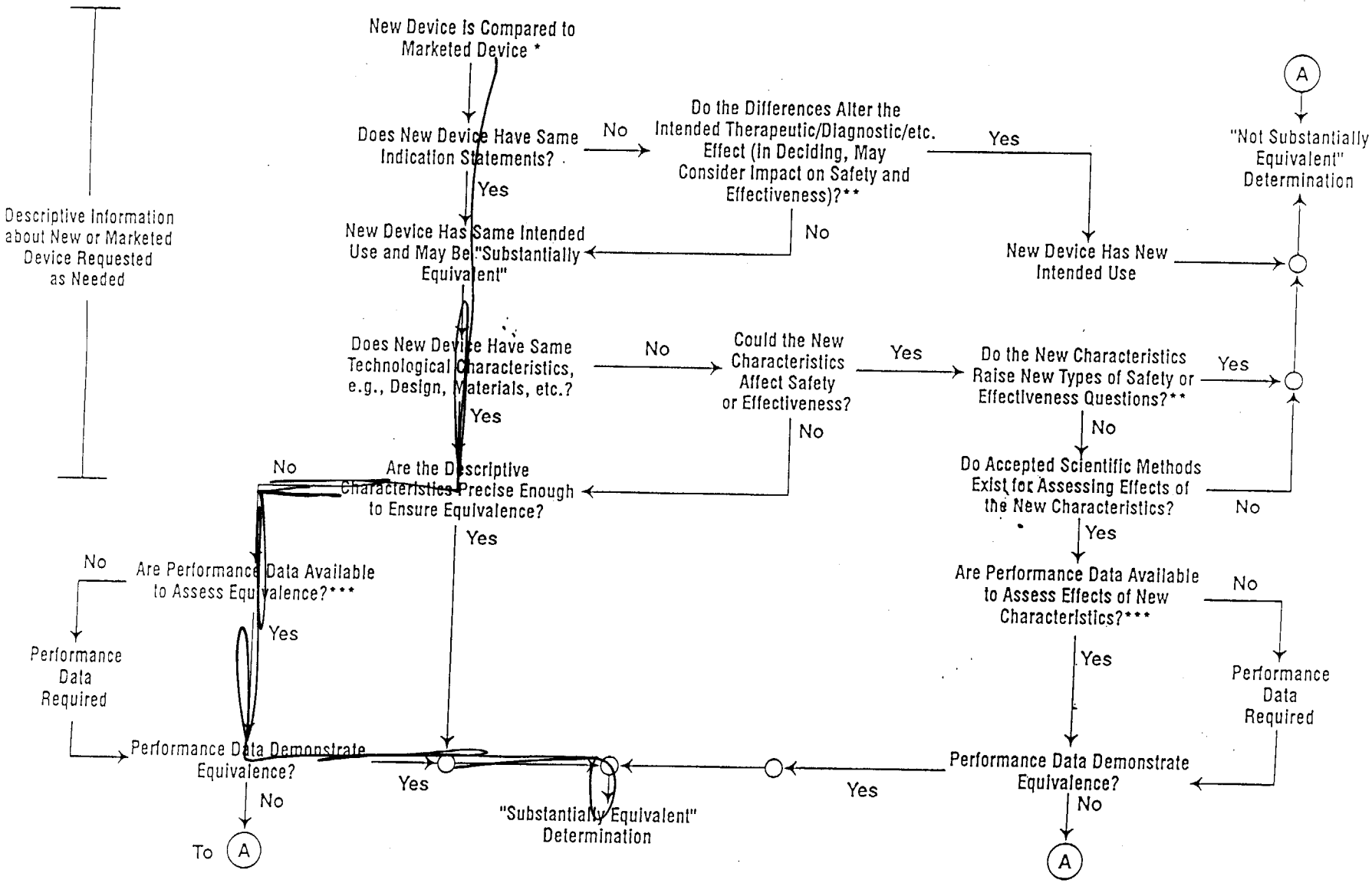
Additional Product Code(s) with panel (optional):

Review: Acting Miriam C. Provost (Branch Chief) PNDB (Branch Code) 5/19/00 (Date)

Final Review: for Mark N. Melkerson (Division Director) 5/22/00 (Date)

Revised:8/17//99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submi... Compare New Devices to Marketed Devices. FDA Requests Additional In... n If the Relationship Between Marketed and "Predicate" (Pre-Amendm... , Reclassified Post-Amendments) Devices Is Unclear.

** This De... 's Normally Based on Descriptive Information Alone, But Limited... Information Is Sometimes Required.

*** Data Ma... the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K000609

Reviewer: Dina Fleischer

Division/Branch: DCRND/PEDG

Device Name: Cardiac Telecommunications CardTel NT-100

Product To Which Compared (510(K) Number If Known): SEE MEMO

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?	X		If **NO** = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

MEMORANDUM

DATE: **May 17, 2000**

FROM: Dina Fleischer, Biomedical Engineer

TO: K000609

RE: Cardiac Telecommunications CardTel NT-100

CONTACT: Karim Alhussiny, Ph.D., Chief Technical Officer; (877) 228-2666

NARRATIVE DEVICE DESCRIPTION

A. INTENDED USE: The CardTel Model NT-100 is intended to be used under the supervision of a licensed healthcare practitioner. The Model NT-100 is intended to be used to display, record, and transmit ECG signals from surface electrodes. The device is intended to acquire, display, and record real time electrocardiographic information from relevant populations.

B. DEVICE DESCRIPTION:

	YES	NO
1. Life-supporting or life-sustaining:		✓
2. Implant (short-term or long-term):		✓
3. Is the device sterile?		✓
If yes, is the sterility information provided?		
4. Is the device for single use?	✓	
5. Is the device for prescription use?	✓	
If yes, is prescription labeling included?	✓	
6. Is the device for home use or portable?	✓	
7. Does the device contain a drug or biological product as a component?		✓
8. Is this device a kit?		✓
If yes, and some or all of the components are not new, does the submission include the required kit certification?		
9. Is this device software driven?	✓	
10. Estimated level of concern: (major, moderate, minor):	Minor	
11. Electrically operated?	✓	

The CardTel Model NT-100 provides a portable device to continuously monitor ambulatory patient 12 lead electrocardiograph (ECG) data. The unit is designed to acquire and display up to twelve ECG vectors in a standard diagnostic ECG analysis format. The twelve leads consist of the standard twelve ECG leads, I, II, III, aVR, aVl, aVF, V1 and V6. The device is used to monitor patients in the operating room, recovery room, intensive care units, in the emergency room in research settings or where additional ECG leads are desired and real time display is desired.. The display unit consists of a generally available Pentium based PC or laptop with a SVGA monitor.

The NT-100 is a patient worn ECG recording system. It consists of a 12-lead ECG amplifier module that is powered from a separate battery module. The amplifier is connected via a serial port to a battery powered wireless transmitter for sending the ECG waveforms to a receiver located within a range of 500 ft. The receiver is connected to a personal computer via a serial prot. The PC has software from display, storage, and hard copy printout of the ECG waveforms.

The system provides a means for continuous monitoring of ECG signals in order to detect abnormal cardiac rhythms, including life-threatening events.

C. SUBSTANTIAL EQUIVALENCE CLAIM

The sponsor states that the NT-100 is equivalent to the Burdick Eclipse Plus (K946281). The sponsor provided a detailed comparison table (page 50) that outlines all specs and highlights the similarities and differences between the subject and predicate devices. The differences between the two devices are as follows:

- The predicate has a computer built into the device for display, storage and printing whereas the subject device utilizes a standard PC computer and color printer.
- The NT-100 is smaller, the transmitter part may be worn by the patient if desired. This feature thus requires the radio link to the display and storage unit.
- The NT-100 does not feature interpretive analysis/software of patient ECG.

These differences can be qualified through performance, verification and validation testing.

D. SOFTWARE

The sponsor provided some software documentation, however, I was able to verify the information in accordance with the FDA guidance document, "Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices, May 1998". ~~The following items were addressed, however, some are deficien~~t. The sponsor did provide a software testing certification (Tab 8). The following software documentation was provided:

3.1 Software Level of Concern

The device software is considered **MINOR** level of concern because the device supplies data from the patient, so failures or design flaws are not expected to result in death or injury to the patient.

3.2 *Software Description* –Tab 10.

3.3 Device Hazard Analysis – The sponsor provided (Tab 14) a tabular hazard/risk assessment which identifies the all of the hazards presented by this device to the patient and the operator, the risk classification, and the risk control, i.e., specific system and/or components whose failure could cause each hazard, the specific software modules associated with each hazard, and the methods used to eliminate or mitigate each hazard including a traceability matrix identifying the verification/validation activities addressing each identified hazard.

3.7 Software Verification and Validation Activities – The sponsor provided a software functional test plan with pass/fail criteria, data, and an analysis of the results (Tab 19).

E. HARDWARE TESTING

Electrical Safety and EMC

The sponsor has provided testing information and data performed on the device as a system for general safety and electromagnetic compatibility. The sponsor provided a complete summary in Tab 17 identifying all required tests and the document number.

Electrical safety and electromagnetic compatibility of the NT-100 were tested to the following standards:

The device met the applicable parts of ANSI/AAMI EC13 with regard to electrical safety and EMC. The sponsor provided testing information data for EMC, radiated and conducted immunity, ESD, and radiated, conducted, and magnetic emissions, in accordance with IEC 60601-1 (am1 & am2), IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-27. For each test, the sponsor provided the applicable clause of the IEC document referencing the test, the test acceptance criteria, results and pass/fail criteria. The device passed all required testing.

F. PERFORMANCE TESTING - AAMI EC38: Ambulatory Electrocardiographs

The sponsor provided performance testing (Tabs 15, 16, and 18) for their device in accordance with AAMI EC38. The protocols are enclosed and correctly follow the standard's protocols. The system passed the following tests and the results provided are acceptable for:

- ECG input channels;
- leakage current (lead to ground);
- AC overload protection;
- gain accuracy;
- multi-channel crosstalk;
- hysteresis;
- frequency response;
- baseline stability;
- pacemaker pulse; and
- time floatation.

G. LABELING

The proposed labeling for the device is enclosed and is comparable to the labeling of the predicate device.

H. BIOCOMPATIBILITY AND STERILITY

This device is not directly patient connected (the ECG electrodes are prepackaged from Lead-Lok, Inc., Model PO-6). Therefore, biocompatibility testing information is not required.

The device is not provided sterile, therefore, sterility information does not need to be provided.

I. SUMMARIES

The sponsor provided a Summary of Safety and Effectiveness Information, the Indications for Use form, and a Truthful and Accuracy Statement.

J. EXPLANATIONS TO "YES" AND "NO" QUESTIONS AS NEEDED

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH.

   The sponsor needs to provide adequate performance testing to qualify the proposed device changes.

11. IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT.

    The sponsor provided software and hardware verification and validation information and data to support the safety and effectiveness of the proposed device modifications. No additional testing needs to be provided.

    Classifications:

870.2800	MWJ	Ambulatory Electrocardiograph without analysis	Class II

RECOMMENDATION: substantial equivalence

Dina Justice Fleischer
Pacing and Electrophysiology Devices Group

Concur.

Miriam C. Provost

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name:	K
Submitter (Company):	

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5		
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED YES	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)							
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA					✓	
e) address of manufacturer						✓	
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*						✓	
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)						✓	
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:						✓	
i) Labeling						✓	
ii) intended use						✓	
iii) physical characteristics						✓	
iv) anatomical sites of use						✓	
v) performance (bench, animal, clinical) testing	NA					✓	
vi) safety characteristics	NA					✓	
m) If kit, kit certification						✓	

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*			* If no - STOP not a special	

*USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED**				
c) *STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED**			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below					
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed					
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device					
v) A specification of any deviations from each applicable standard that were applied					
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference					
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations					
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards					

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:						✓	
i) component & material						✓	
ii) identify patient-contacting materials						✓	
iii) biocompatibility of final sterilized product						✓	
b) Sterilization and expiration dating information:						✓	
i) sterilization method						✓	
ii) SAL						✓	
iii) packaging						✓	
iv) specify pyrogen free						✓	
v) ETO residues						✓	
vi) radiation dose						✓	
c) Software validation & verification:					✓		
i) hazard analysis					✓		
ii) level of concern					✓		
iii) development documentation					✓		
iv) certification					✓		

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ____**Yes**__✓__**No** **Reviewer:** Willie E Taylor Jr

Date: 3/1/00 **Concurrence by Review Branch:** ____

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 24, 2000

CARDIAC TELECOMMUNICATIONS
C/O DELPHI CONSULTING GROUP
11874 SOUTH EVELYN CIRCLE
HOUSTON, TX 77071
ATTN: J. HARVEY KNAUSS

510(k) Number: K000609
Received: 23-FEB-2000
Product: CARDTEL, MODEL NT-100

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

17

K000609

CardTel NT-100

Electrocardiograph

21 CFR 870-2340

Class II

510(k) Submission

NEW

Cardiac Telecommunications
17448 Highway 3, Ste. 175
Webster, Texas 77598
877-228-2666

CV II

File Name:

CardTel NT-100
510(k) Submission

Notes:

Sumission produced by:

Delphi Consulting Group
POB 932
Stafford, TX 77477

713-723-8169
713-723-4080 fax
delphi15@wt.net

www.delphiconsulting.-com

Date	Description	
	Premarket Submission Cover Sheet	1
	List of Reference Documents	2
	Refuse to Accept Checklist	3
	Cardiac Telecommunications Cover Letter	4
	Draft Lebel(s) and Labeling	5
	Draft Operators Manual	6
	Summary	7
	Indications for Use Page	8
	Photographs of Unit	9
	Description of Unti	10
	Drawings of Device	11
	Substantial Equivalence Chart	12
	Predicate Device Labeling	13
	Hazard Analysis	14
	Bench Test of Input/Output of System	15
	Electrical Safety Testing	16
	EMI Testing	17
	ANSI/AAMI EC38 Testing	18
	Overview of Software Validation	19
	Truthful and Accurate Statement	20
	Y2K Certification	21
	Submission correspondent Letter	22
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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission:	FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 — Reason for Submission — PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):

Section B3 — Reason for Submission — IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol– other
  - ☐ Sponsor
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver
- ☐ Other reason (specify):

	FDA Document Number:

Section C — Product Classification

Product code: 74BRS	C.F.R. Section: 870.2340	Device class: ☐ Class I XX ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: 74 Cardiovascular		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: ☒ 510(k) summary attached ☐ 510(k) statement
1 K4BRS	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K946281	1 Burdick Exlipse Plus	1 Burdick, Inc.
2	2	2
3	3	3
4	4	4
5	5	5
6	8	8

Section E — Product Information — Applicable to All Applications

Common or usual name or classification name:

Electrocardiography

Trade or proprietary or model name	Model number
1 CardTel	1 NT-100
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K984454	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling): The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

	FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: FDA Form 2891 has been sent	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Cardiac Telecommunications			
Division name (if applicable):		Phone number (include area code): (877) 228-2666	
Street address: 17448 Highway 3, Ste. 175		FAX number (include area code): (281) 332-6000	
City: Webster	State / Province: Texas	Country: USA	ZIP / Postal Code: 77598
Contact name: Karim Alhussiny, Ph.D.			
Contact title: Chief Technical Officer			

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

	FDA Document Number:

Section G **Applicant or Sponsor**

Company / Institution name: Cardiac Telecommunications	FDA establishment registration number: Form has been sent in.
Division name (if applicable):	Phone number (include area code): (877) 228-2666
Street address: 17448 Highway 3, Ste. 175	FAX number (include area code): (281) 332-6000

City:	State / Province:	Country:	ZIP / Postal Code:
Webster	Texas	USA	77598

Signature: Karim A. Alhussiny

Name: Karim Alhussiny, Ph.D.

Title: Chief Technical Officer

Section H **Submission correspondent (if different from above)**

Company / Institution name: Delphi Consulting Group	
Division name (if applicable):	Phone number (include area code): (713) 723-8169
Street address: 11874 South Evelyn Circle	FAX number (include area code): (713) 723-4080

City:	State / Province:	Country:	ZIP / Postal Code:
Houston	Texas	USA	77071-3404

Contact name: J. Harvey Knauss

Contact title: Consultant

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

510(k) Elements List

510(k) Elements	Authority (21 CFR)	Page #
Device trade or proprietary name	807.87	14
Device common or usual name or classification	807.87	14
Establishment registration number (only applies if establishment is registered)	807.87	14
Class in which the device has been put under section 513 of the act and, if known the appropriate panel; or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.	807.87	4
Action taken by the party required to register to comply with the requirements of the act under section 514 for Special controls.	807.87	14
Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. (Blue Book Memo #G91-1)	807.87	16 -
510(k) summary or a 510(k) statement.	807 87(h)	35 & 36
For class III only, a class III certification and a class III summary	807 87(i)	N/A
Photographs of the device.	807 87	38 -
Engineering drawings of the device.	807.87	48 -
Identification of the marketed device(s) to which equivalence is claimed including labeling and description of the device. Affiliated 510(k) numbers and product codes are voluntary in cover sheet.	807.87	50 & 51 -
Statement of similarities and/or differences with marketed device(s)	807.87	50
Data to show consequences and effects of a modified device	807.87	N/A
Submission Correspondent name and address	807.87	6 & 190
Contact person, telephone number and fax number	807.87	6, 35, 190
Representative/Consultant if a applicable	807.87	6 & 190
Table of Contents	807.87	2,7 & 8
Name and address of manufacturing/packaging/sterilization facilities. Registration number of each facility when one exists.	807.87	5, 14 & 35

Comparison table of the new device to the marketed device(s)	807.87	50
Action taken to comply with voluntary standards	807.87	14
Performance Data (bench, animal, clinical)	807.87	79, 84, 88, 129
Sterilization information (Blue Book Memo #K90.1)	807.87	N/A
Software information (Blue Book Memo #K91-1)	807.87	61, 42, 183
Hardware information	807.87	42
Information requested in specific guidance documents (if applicable for this device)	807.87	N/A
Kit Certification Statement	807.87	N/A
Truthful and Accurate Statement	807.87 (j)	187

Reference Documents

This submission considers the following FDA Blue Book Guidelines, Guides, other reference documents:

1. Premarket Notification 510(k): Regulatory Requirements for Medical Devices, HHS Publication FDA 954158, August 1995.
2. Providing Regulatory Submissions in Electronic Format – General Considerations, January 1999.
3. Instructions for Premarket submission Cover Sheet, March 14, 1995.
4. 510(k) Refuse to Accept Procedures, 5/20/94 (K94-1).
5. PMA/510(k) Triage Review Procedures 5/20/94 (G94-1).
6. Premarket Notification Truthful and Accurate Statement.
7. General/Specific Intended Use Guidance, May 21, 1998.
8. Information Paper on FDA Activities Related to the Year 2000 Date Problem and Medical Devices.
9. Safe Medical Devices Act of 1990.
10. Medical Device Commercialization in the United States of America, DCG, 1994.

Center for Devices and Radiological Health
Premarket Notification for 510(k)

Refuse to Accept Checklist
(Revised 3-14-95)

K _____ Date DMC Received _____

Device Trade Name: _____

Reason for 510(k) _____

Division/Branch: _____

Administrative Reviewer Signature: _____ Date _____

Supervisory Signature: _____ Date _____

Did the firm request expedited review? _____ Yes _____ No

Did we grant expedited review? _____ Yes _____ No

Truthful and accurate statement enclosed? _____ Yes _____ No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

_____ accepted

_____ refuse to accept

	Yes Present Omission Justified	No Inadequate Omitted
1 Critical Elements;		
A. Is the product a device?		
B. Is the device exempt from 510(k) by regulation or policy?		
C. Is the device subject to review by CDRH?		
D. (I) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?		
E. (I) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer		
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N-0332, September 10, 1991.)		
F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(I) of the Federal Food, Drug, and Cosmetic Act(Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:		
I. Device trade or proprietary name		
2. Device common or usual name or classification name		
3. Establishment registration number (only applies if establishment is registered)		
4. Class into which the device is classified under (21 CFR Parts 862 to 892)		
5. Classification Panel		
6. Action taken to comply with Section 514 of the Act		
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use Blue Book Memo # G91-1)		

	Yes Present Omission Justified	No Inadequate Omitted
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request		
9. For class III devices only, a class III certification and a class III summary		
10. Photographs of the device		
11. Engineering drawings for the device with dimensions and tolerances		
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device		
13. Statement of similarities and/or differences with marketed device(s)		
14. Data to show consequences and effects of a modified device(s)		
15. Truthful and accurate statement		
II. Additional Information that is necessary under 21 CFR 807.87 (h):		
A. Submitter's name and address		
B. Contact person, telephone number and fax number		
C. Representative/Consultant if applicable		
D. Table of Contents with pagination		
E. Address of manufacturing facility/facilities and , if appropriate, sterilization site(s)		
III. Additional Information that maybe necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)		
B. Action taken to comply with voluntary standards		
C. Performance data		
I. marketed device		
bench testing		
animal testing		

	Yes Present Omission Justified	No Inadequate Omitted
clinical data		
2. new device		
bench testing		
animal testing		
clinical testing		
D. Sterilization information		
E. Software information		
F. Hardware information		
G. If this 510(k) is for a kit, has the kit certification statement been provided?		
H. Is this device subject to issues that have been addressed in specific guidance documents(s)?		
If yes, continue review with checklist from any appropriate guidance documents.		
If no, is 510(k) sufficiently complete to allow substantive review?		
I. Other (specify)		

Realizing Tomorrow's Vision Today

CARDIAC
TELECOMMUNICATIONS

MEDICAL PRODUCTS

CONSULTING

SOFTWARE/HARDWARE
DEVELOPMENT

WIRELESS
NETWORKS &
DATABASE
MANAGEMENT

Bharat Patel, M.D.
Chief Medical Officer
Clinical Instructor, Baylor College of Medicine

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Chief Technical Officer

17448 Highway 3, Suite 175
Webster, TX 77598 USA
(tel) 877-CAT-COMM
(fax) 281-332-6000

Toll Free: 1-877-228-2666

e-mail:
patel@cardiactel.com
karim@cardiactel.com

www.cardiactel.com

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Canter (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Re: 510(k) Notification, New

Attention: Document Mail Clerk,

This is to notify you of the intention by Cardiac Telecommunications, to market a new electrocardiograph device.

Classification Name:	**Electrocardiograph**
Common/Usual Name:	**EKG**
Proprietary Name:	**CardTel, Model NT-100**
Establishment Reg. No.	**Forms have been submitted**
Classification:	**21 CFR 870.2340, Electrocardiograph Performance Standards**
Performance Standards:	**None established**
Labels & Labeling	**Label specimens enclosed.**
Substantial Equivalence:	
Reason for Submission:	**New**
Triage:	**Tier 1**
Confidentiality:	**Cardiac Telecommunications considers our intent to market these devices as confidential commercial information and request that it be considered as such by the FDA.**

More . . .

In response to the requirements addressed by the SMDA of 1990. Enclosed is **a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.**

Sincerely Yours,
Cardiac Telecommunications

Karim Alhussiny, Ph. D.
Chief Technical Officer

Date: 2/16/2000

Enclosures: 510(k) Submission

Preliminary Labels and Labeling

All labels and labeling presented in this submission are considered "draft." Advertising material has not been produced for this device at this date.

On the following pages are "draft" device labels, computer screen views, device photographs that display label placement and an Operator's Manual.

Unit

CardTel Electrocardiograph	
Model	NT-100
Serial No.	XXX-XX
Battery	9 Volt
Manufacturer	Cardiac Telecommunications Webster, Texas 77598 1-888-228-2666
Date Mfg.	XX/XX/XXXX
Risk Class	I

O I

RA LA LL RL V1 V2 V3 V4 V5 V6

Electrodes

Data Output Connection

Battery Compartment
Replace with
9 Volt Battery

BOX LABEL

CardTel Electrocardiograph
Model NT-100

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

Read Operator's Manual before placing into service.

Cardiac Telecommunications
17448 Highway 3, Suite 175
Webster, Texas 77598
1-888-228-2666

One each, fully assembled, non-sterile, and non-disposable.

Risk Class I
Serial No. XXX-XXX

9 Volt
Mfg. XX/XX/XXXX

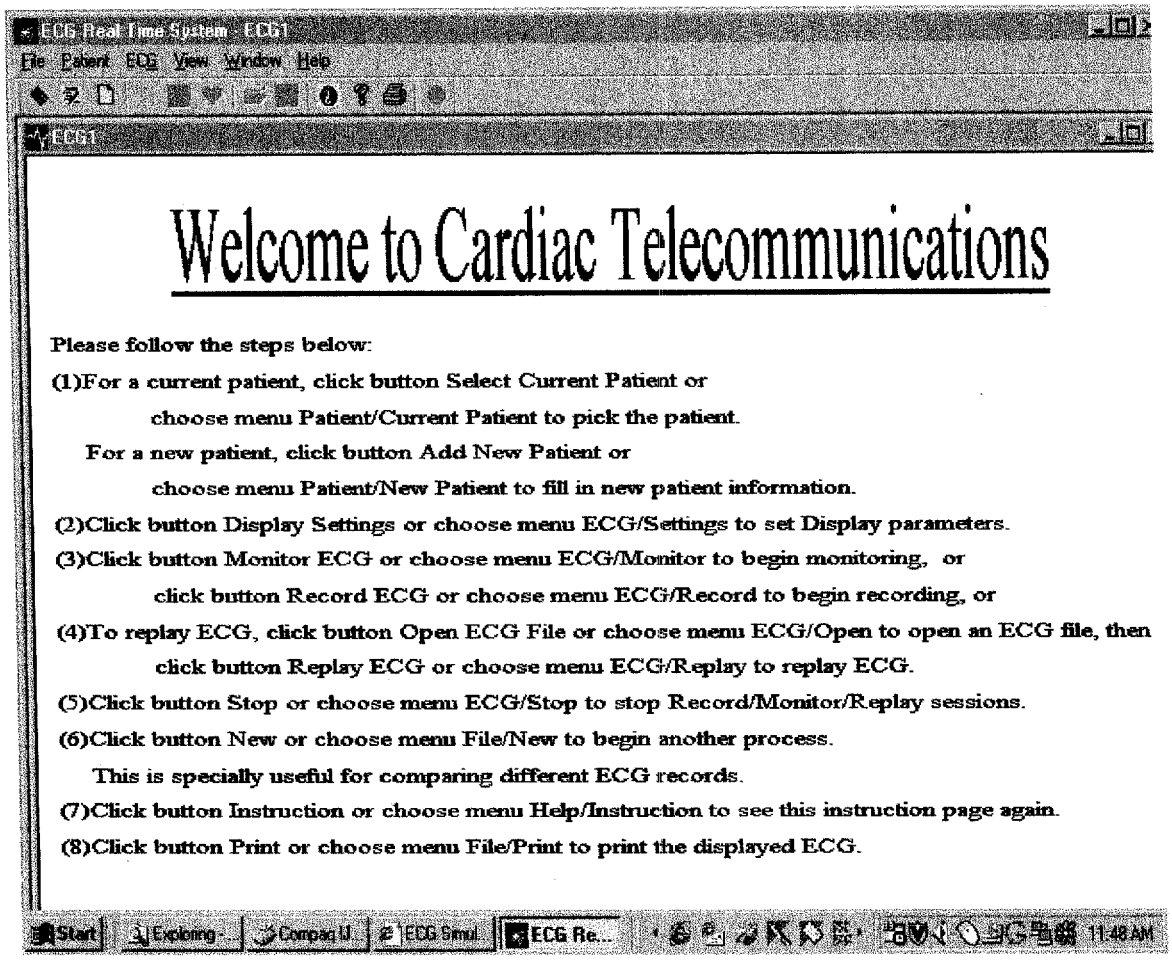


Figure 1, This is the first screen seen by user. It appears when program is initiated.

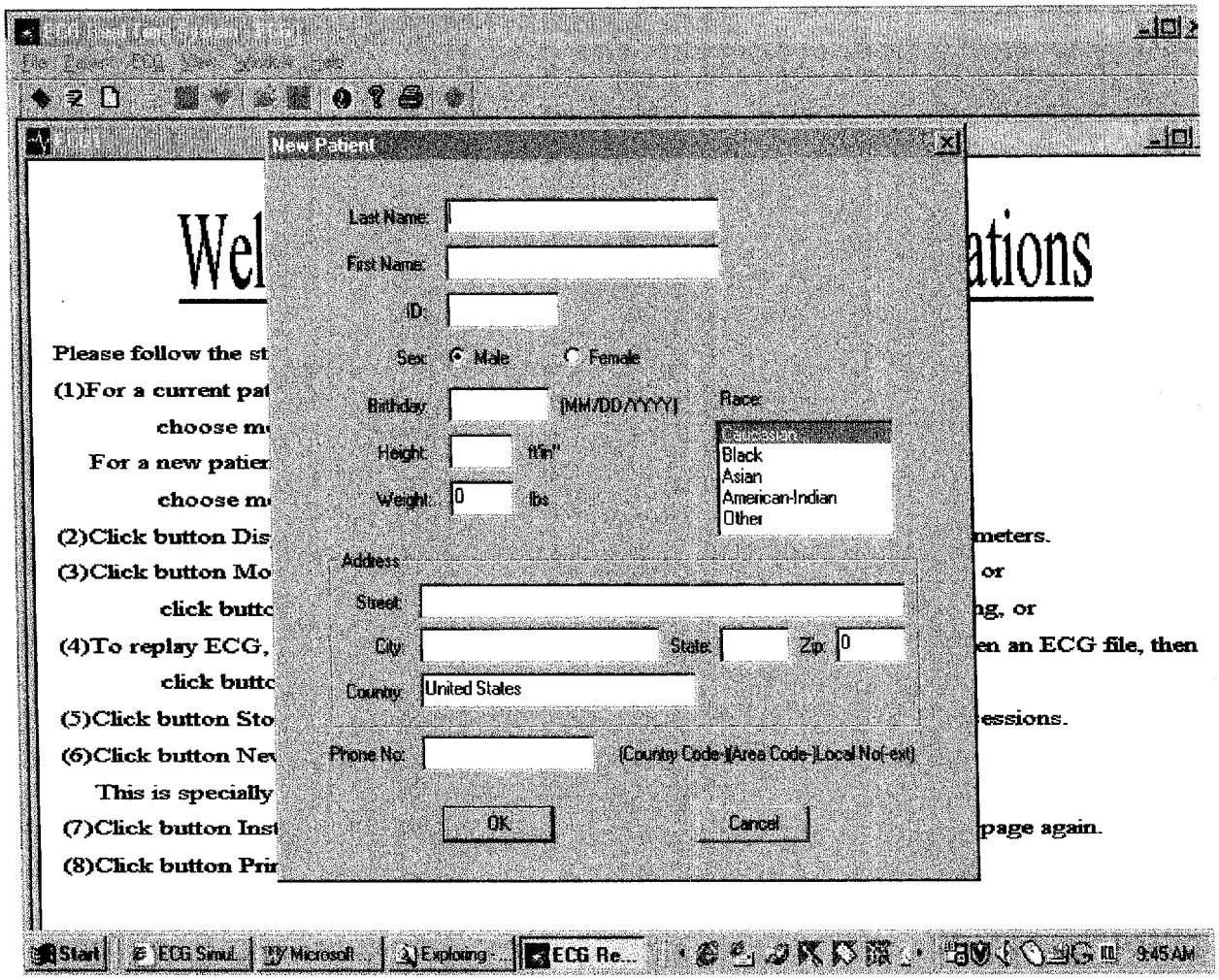


Figure 2, **New Patient** form requires that all blanks be filled in. **Last Name** and **First Name** will hold a maximum of 30 characters each, while the **Patient ID** will hold a maximum of 11.

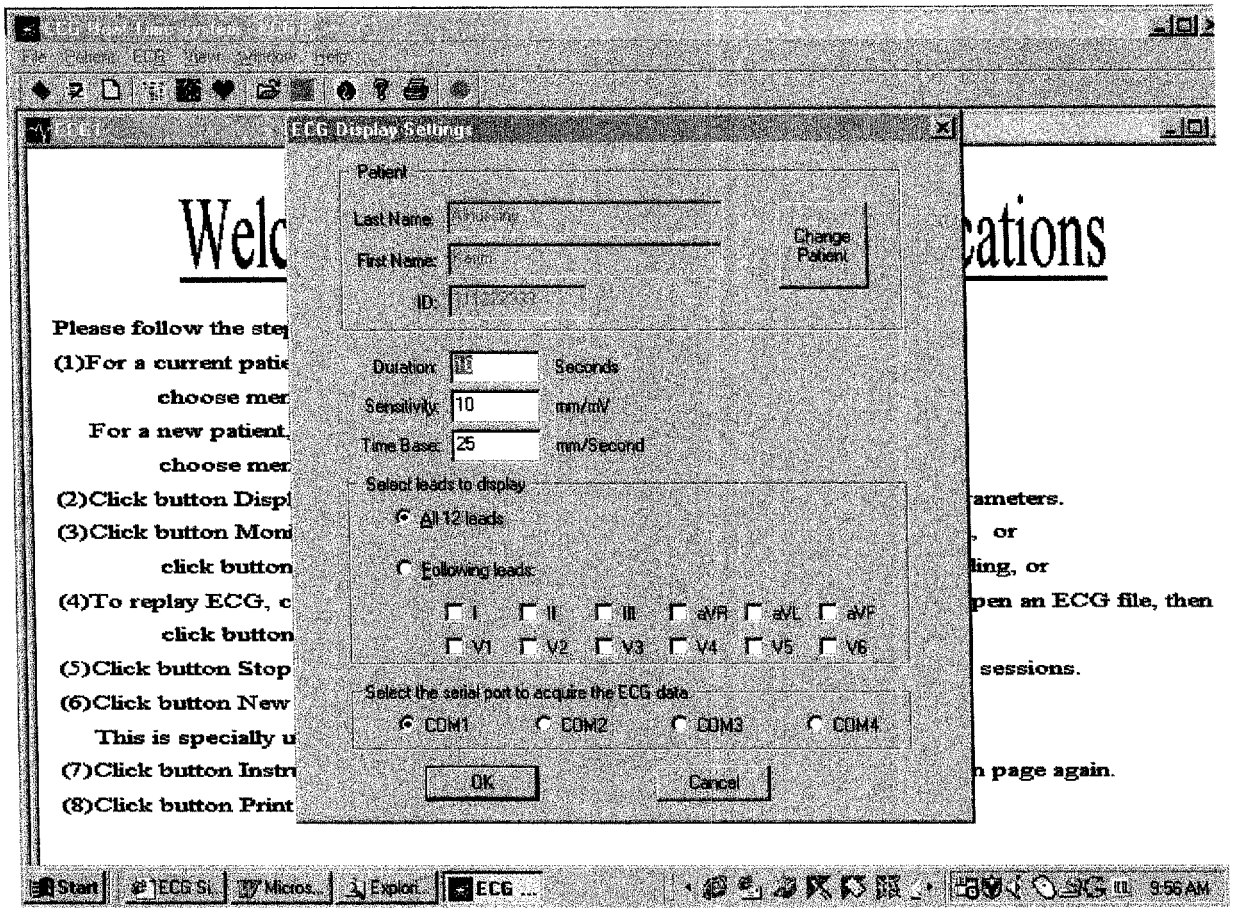


Figure 3, **Settings** is the first sub menu option in **ECG**. **Duration** of the ECG to be viewed or recorded is in seconds. For 10 minutes, enter 600 seconds, etc. Default is 10 seconds for this parameter and maximum time is 86,400 seconds. **Sensitivity** is in mm/mV. Default for this parameter is 10 with maximum value 99. You can select leads to display by selecting **All 12 Leads** or by selecting **Following Leads**. With this option, you can select any one or combination of leads. **Select the Serial Port to acquire the ECG data** option allows the user to select a communications port other than Com1 if their computer supports more than 1 serial port.

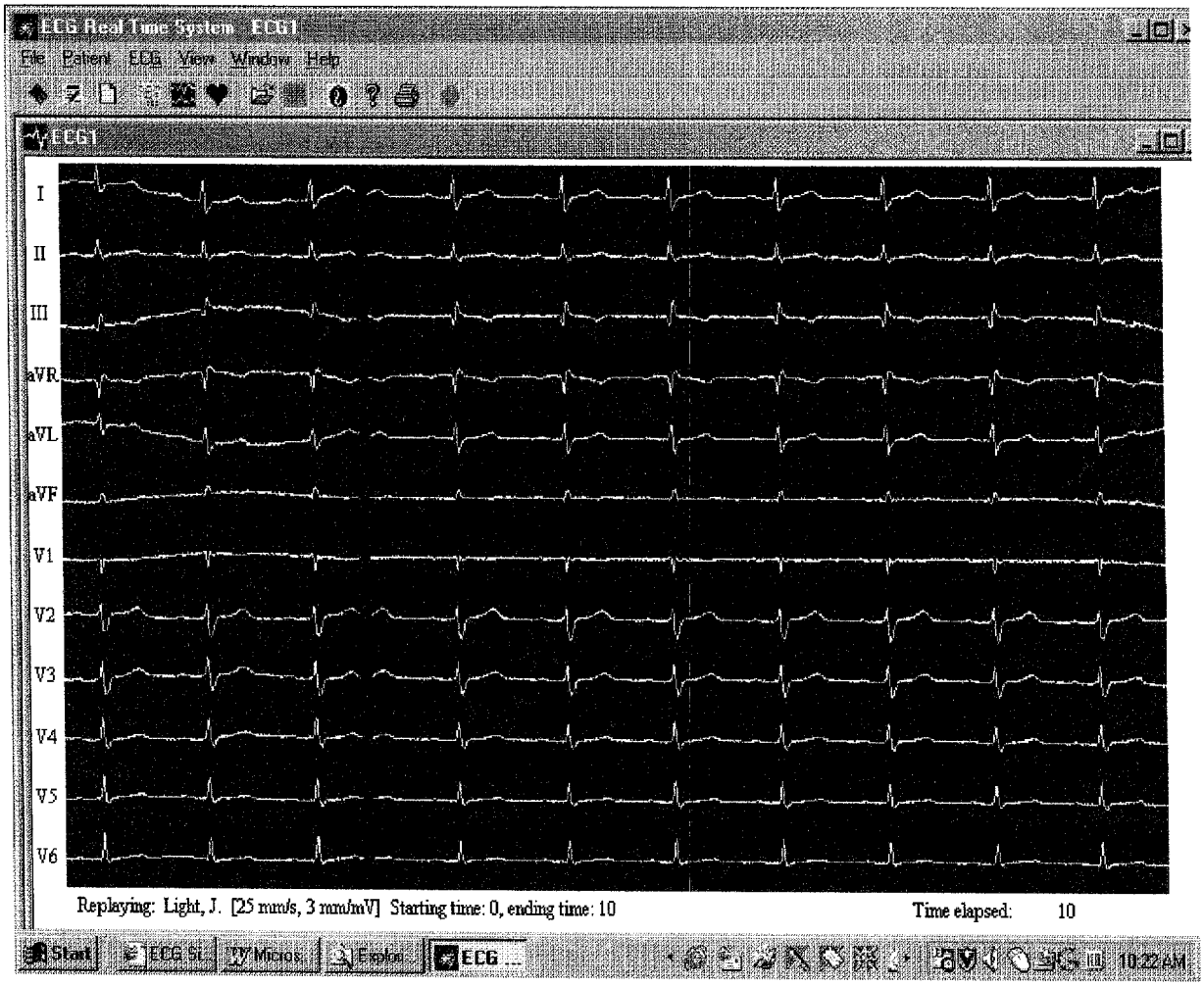


Figure 4, 11 shows the status bar with patient's name, Sensitivity selection, Start and End Time displayed and Elapsed time. This menu can be removed, making the display area larger by removing check mark on **View** option, sub menu **Status Bar**.

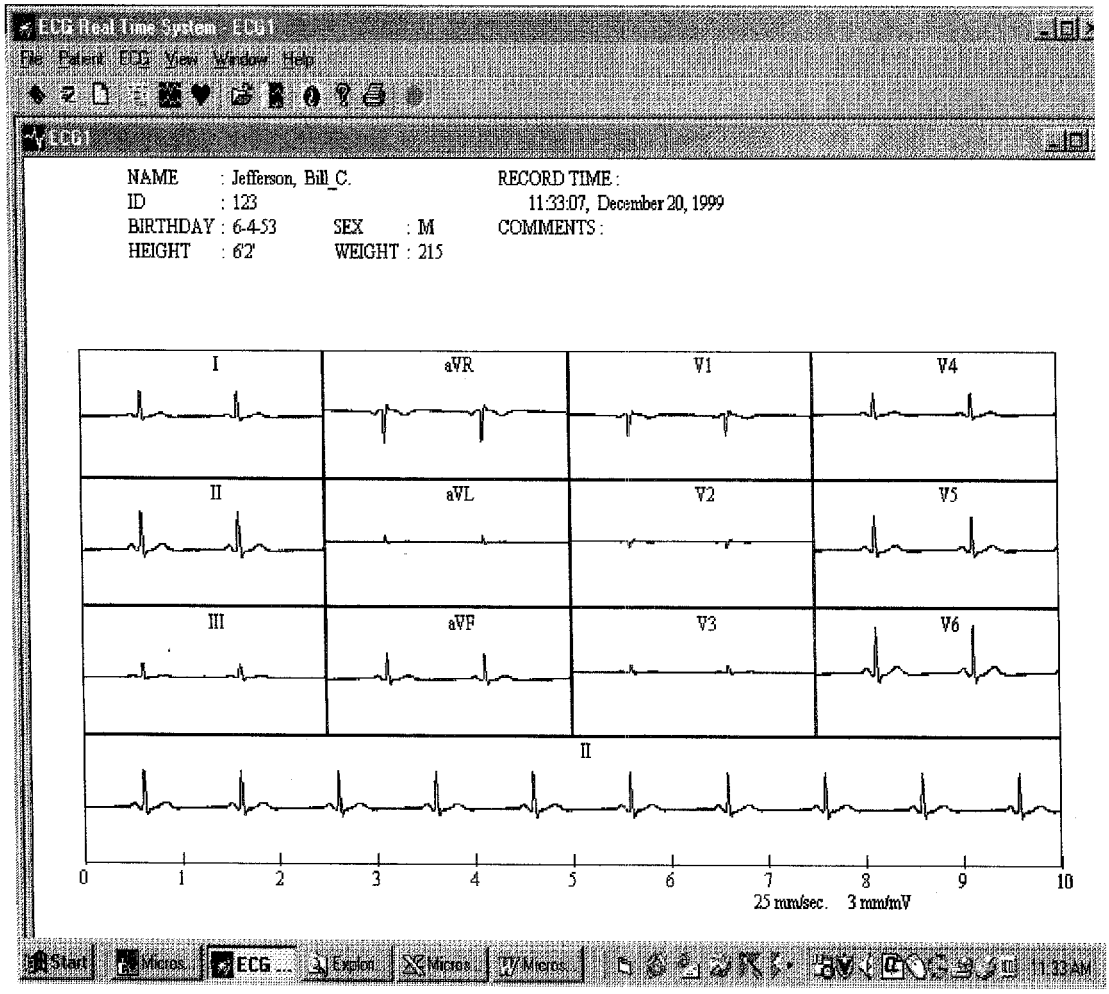
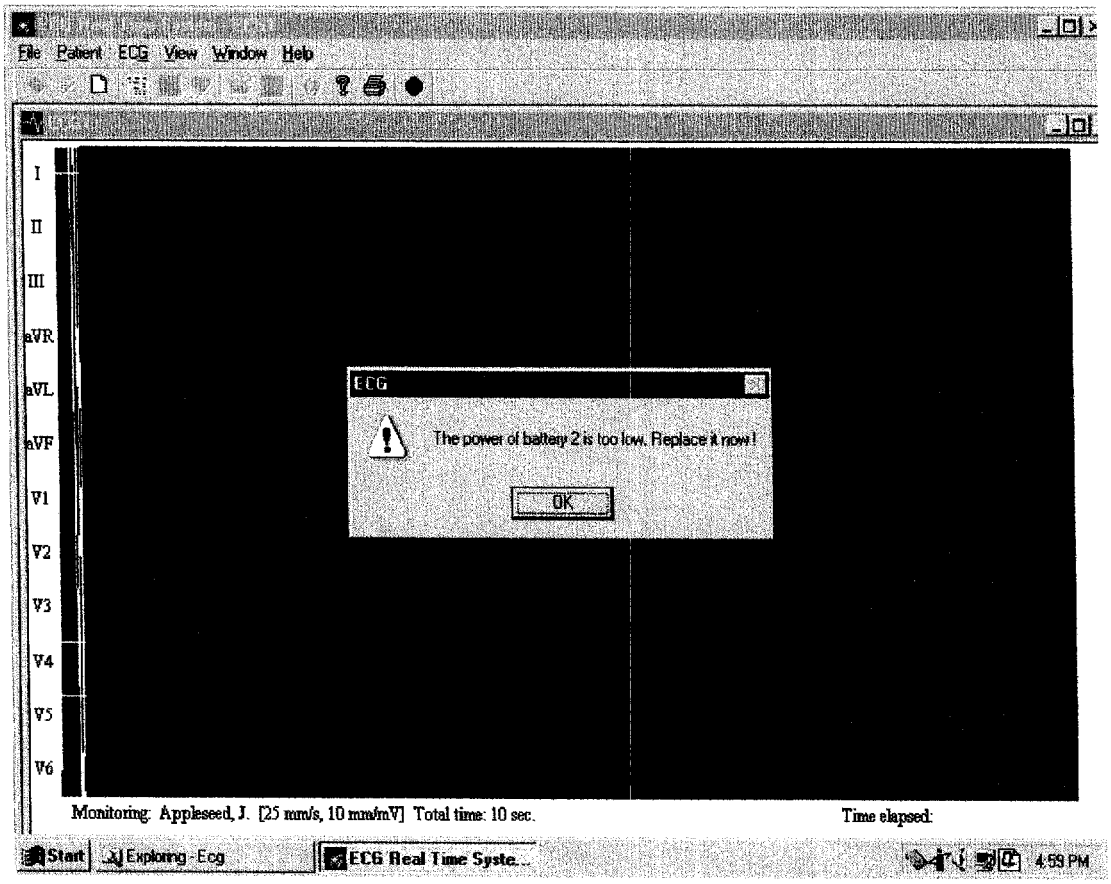
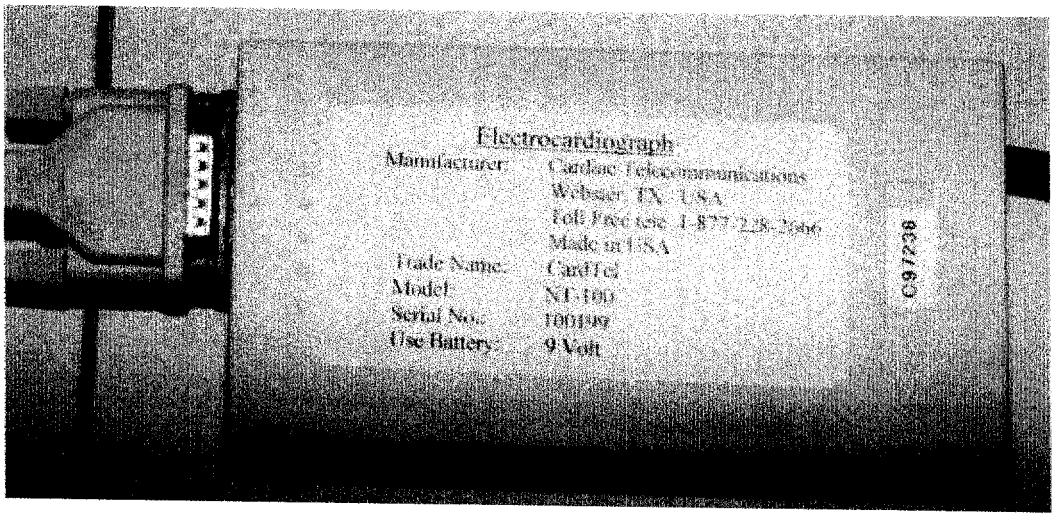


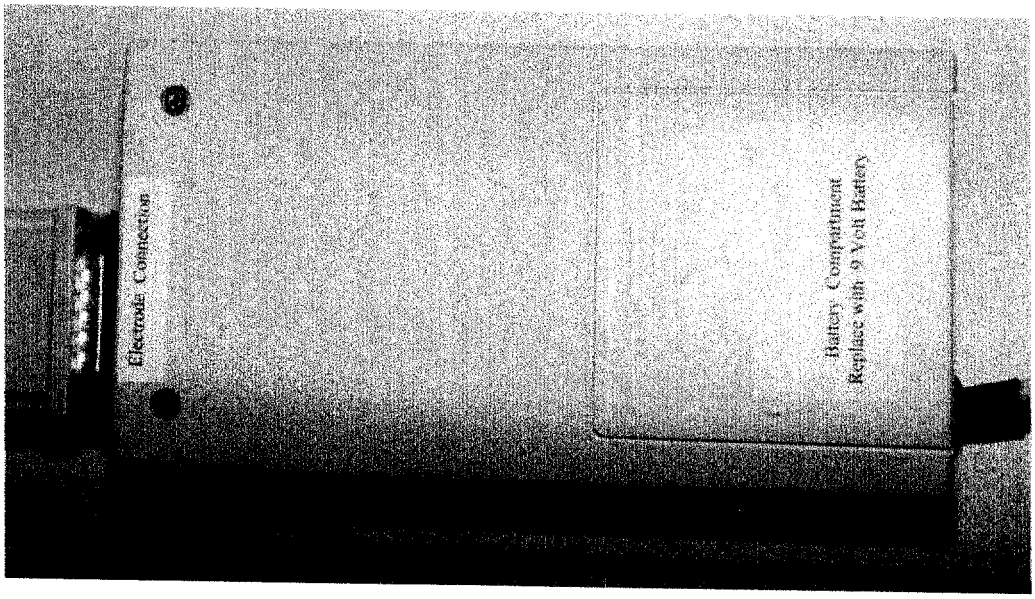
Figure 5, 15 shows a standard 12 lead ECG



WARNING – Replace battery



Label on top of NT-100 Unit



Label on bottom of Unit

OPERATORS MANUAL

NT-100 CARDTEL ELECTROCARDIOGRAPH SYSTEM

D R A F T

Cardiac Telecommunications
17448 Highway 3
Webster, Texas 77598
877-228-2666

READ FIRST
SAFETY & OPERATION PRECATUTIONS

CAUTION

Regulations in the USA and Canada restrict this device to sale by or on the order of a licensed physician.

ELECTRICAL PRECAUTIONS

Make sure the power source is compatible with the electrical specifications shown on the computer power supply and battery chargers. For proper grounding reliability, connect the AC power cords only to a properly grounded 3-wire receptacle. In hospital use ensure the receptacle is of the "green dot" type. Do not remove the ground pin. Do not use extension cords.

The NT-100 System does no contain any user serviceable components except batteries.

Servicing should be performed only by authorized personnel.

EXPLOSION RISK

The NT-100 system is not designed for use in an explosive atmosphere or in the presence of flammable anesthetics. Use in such environments may present an explosion hazard.

Do not use in an oxygen tent, or in the presence of pure oxygen. A fire hazard exists in the presence of oxygen enriched atmospheres.

WARNINGS

Do not load any new or different programs onto the computer hard drive. The computer should have only the NT-100 program loaded on the hard drive.
Do not load any "run in the background" utilities.

QUESTIONS

Any questions regarding the Safety and Operations – contact Cardiac Telecommunications, 17448 Highway 3, Suite 175, Webster, Texas 77598. Telephone 1-877-228-266, Fax 281-332-6000.

SECTION I
GENERAL INFORMATION

INTRODUCTION

This manual provides instructions for installation, use, and troubleshooting of the Cardiac Telecommunications CardTel Model NT-100. Cardiac Telecommunications can not be responsible for the performance of the Card-Tel Model NT-100 if the user does not operate the unit in accordance with provided instructions, uses accessories other then those designed for the system, or effects any repairs with unauthorized components. Repair should be performed only by qualified authorized service personnel.

This manual should be read, thoroughly understood, and readily accessible to all personnel who will be operating and using the CardTel Model NT-100 system.

WARNING

The NT-100 System is intended to be used under the direct supervision of a licensed Healthcare practitioner, by trained operators in a hospital or medical professional's facility.

DESCRIPTION

The CardTel Model NT-100 provides a portable device to continuously monitor ambulatory patient 12 lead electrocardiographic (ECG) data. The unit is designed to acquire and display up to twelve ECG vectors in a standard diagnostic ECG analysis format. The twelve leads consist of the standard twelve ECG leads, I, II, III, aVR, aVL, aVF, V1 and V6. The Model NT-100 is used to monitor patients in the operating room, recovery rooms, intensive care units, in the emergency room, in research settings, or other units where additional ECG leads are desired and real time display is desired. The display unit consists of a generally available Pentium® based personal computer or laptop computer with a SVGA monitor.

The system provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events.

WARNING

DO NOT OPERATE NEAR FLAMMABLE GAS.

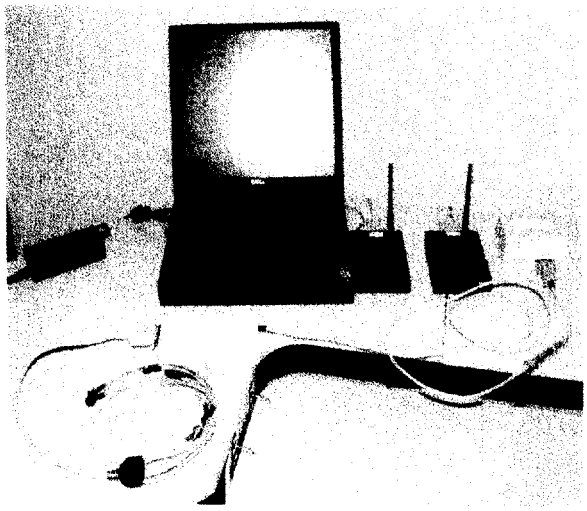
SECIFICATIONS

Specifications for the Cardiac Telecommunications CardTel Model NT-100 are provided in Section 2. All specifications and accessories are subject to change without notice.

SYSTEM SET UP

The system is easy to set up. A complete NT-100 system consists of the following items:

- NT-100 unit
- NT-100 Battery Box
- ECG Cables and disposable electrodes
- Radio Transmitter
- Radio Receiver
- Radio Transmitter/Receiver Battery Charger
- Laptop Computer w/NT-100 software
- Laser or Ink Jet printer



The NT-100 System

Set up the system of operation as follows:

1. Charge Radio batteries.
2. Ensure that new fresh batteries are in the NT-100 Battery box.
3. Connect Radio Receiver to Laptop computer turn radios ON.
4. Connect NT-100 to Battery Box and Radio Transmitter.
5. Connect ECG leads to NT-100.
6. Turn Laptop computer on and load NT-100 program.

ECG

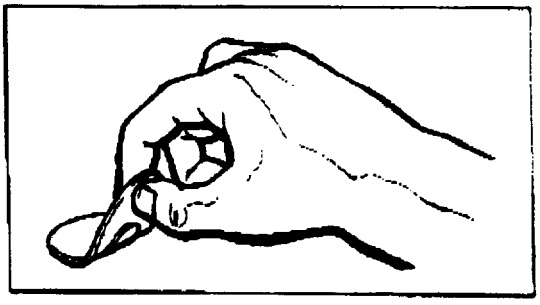
The total collective electrical activity associated with the waves of excitation of the heart's nerves and muscles can be recorded by electrodes placed on the skin and connected to the NT-100 unit. The NT-100 system displays and records the ECG electrical activity on the heart at a standard rate.

Different types of ECG measurements can be made which are in essence different "views" of the heart's electrical activity from different angles around the body dependent upon the installation and connection of electrodes. Licensed Healthcare Professionals shall make the selection and placement of the ECG electrodes.

Electrode Site Preparation

Cleanse all sites thoroughly with alcohol or sterile wipes. Rub sites with wipes about 5 seconds each (this abrading increases electrical conductivity of skin).

Remove electrodes from package (open just prior to use). Apply to site (start at top edge and roll downward).



Press entire surface of electrode onto skin.

Connection of Electrode Wires

Snap electrode wires from the NT-100 to the surface electrodes by the color code.

CAUTION
Do not allow tension to be placed on any of the wiring connections between patient and the NT-100 unit. Dress wires form patient electrodes to NT-100 in a manner that minimizes the "over the body" routing of the wires.

Causes of unsatisfactory ECG's

Improper application of electrodes due to:

- Excessive hair
- Oily, dirty, scaly skin
- Excessive perspiration
- Broken or defective ECG cables
- Electrode paste dehydrated

Operation of Laptop Computer

- Turn on power.
- Load NT-100 program.

WARNING

Do not load any new or different programs onto the computer hard drive. The computer should have only the NT-100 program loaded on the hard drive.
Do Not Load any "run in the background" utilities.
Should another program be loaded onto the hard drive, remove the computer from use and contact Cardiac Telecommunications.

Select:

1. For a current patient, click button Select Current Patient or choose menu Patient/Current Patient to pick the patient.
   For a new patient, click button Add New Patient or choose menu Patient/New Patient to fill in new patient information.
2. Click button Display Settings or choose menu ECG/Settings to set Display parameters.
3. Click button Monitor ECG or choose menu ECG/Monitor to begin monitoring, or click button Record ECG or Choose menu ECG/Record to begin recording, or
4. To replay ECG, click button Open ECG File or choose menu ECG/Open to open an ECG file, then click button Replay ECG or choose menu ECG/Replay to replay ECG.

5. Click button Stop or choose menu ECG/Stop to stop Record/Monitor/Replay sessions.
6. Click button New or choose menu File/New to begin another process.
   This is specially useful for comparing different ECG records.
7. Click button Instruction or choose menu Help/Instruction to see this instruction page again.
8. Click button Print or choose menu File/Print to print the displayed ECG.

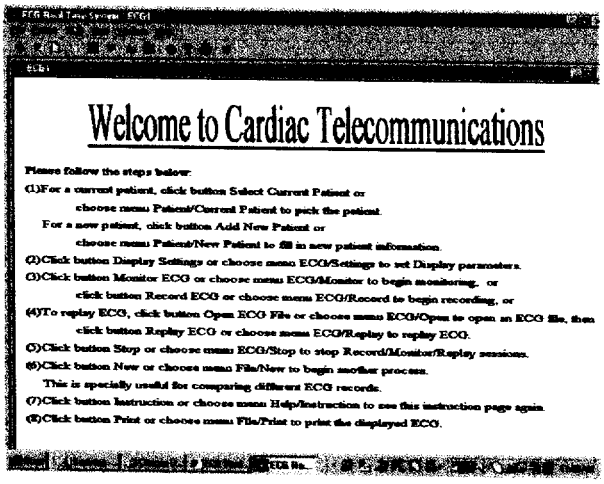


Figure 1, Opening Page

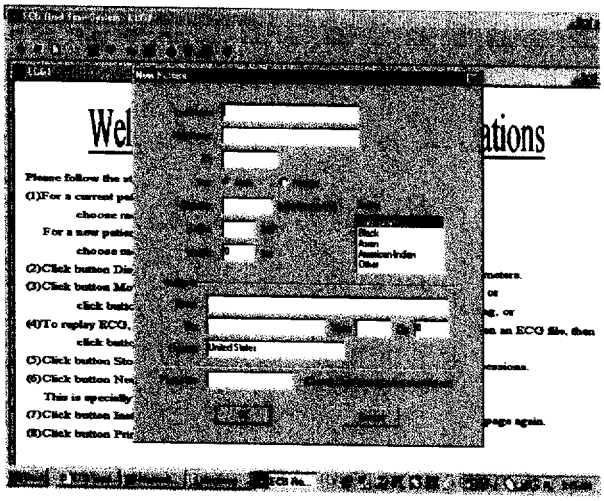


Figure 2, New Patient form. All fields must be filled in.

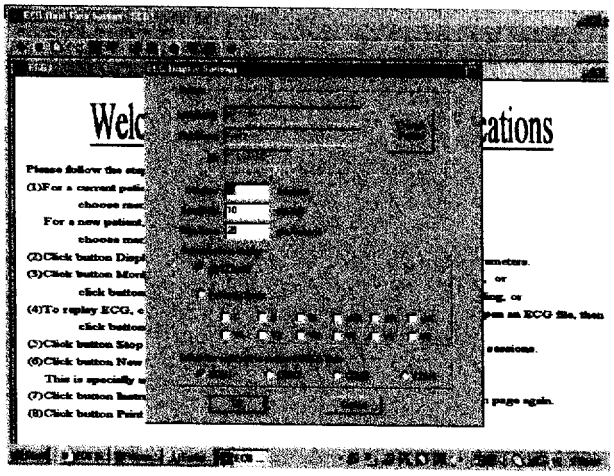


Figure 3, With this form the Duration, Sensitivity, Time Base, and lead selection is made. The computer communication port is selected for the radio receiver.

Figure 4, ECG display with patient name, Sensitivity selection, Start and End Time displayed and Elapsed total time.

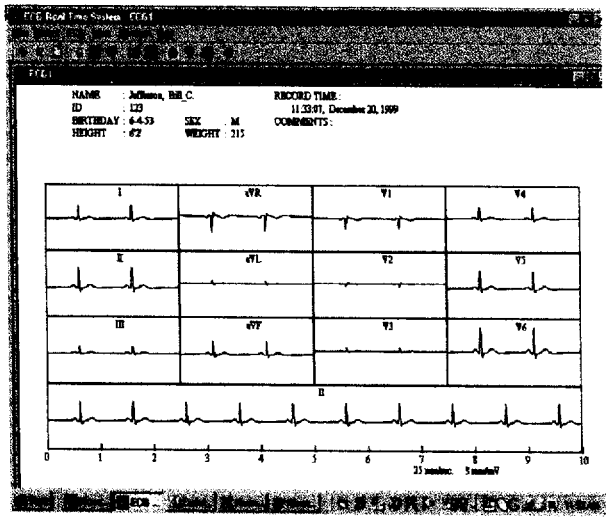


Figure 5, Display with standard 12 lead ECG, Patient information.

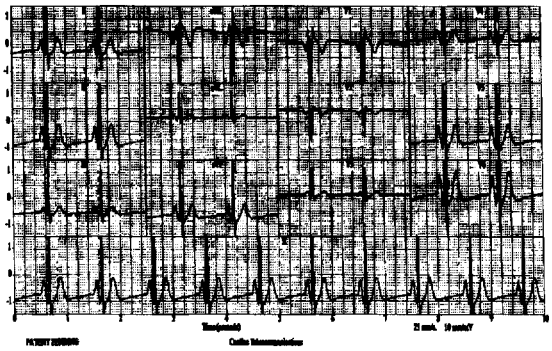


Figure 6, Hard copy printout of 12 lead ECG.

Section 2

Cleaning and Service

Cleaning

The exterior enclosure of the NT-100 unit is made of plastic and should be cleaned using a soft, damp cloth with a mild detergent. Care should be taken to not allow any liquid to inter the inclosure. Hypocarbonate and phenolic based cleaning solutions should NEVER be used as they will cause deterioration of the plastic. The NT-100 may be disinfected using a hyperchlorite solution (1000 ppm). Do not sterilize the NT-100 unit by any method.

The ECG electrodes are single use devices and are not designed to be cleaned or reused.

Preventive Maintenance

A qualified biomedical service technician to assure proper operation of the system should routinely inspect the NT-100 unit (not less than once a year). Any worn or damaged components that could result in a hazard to safety or potential product malfunction should be identified and the system sent to authorize service.

Troubleshooting

WARNING: The NT-100 system does not contain any user serviceable components except for the replacement of batteries.

CAUTION: Electrical shock hazard. Opening any of the components of the computer must be done only by authorized qualified service personnel.

See next page for Troubleshooting Guide Chart.

Troubleshooting Chart

Symptom	Possible Cause	Suggested Solution
Computer Screen has "The power of battery 2 is too low" warning box	Battery No. 2 in Battery Box is low or missing.	Replace battery
Computer Screen has "The power of battery 1 is too low" warning box	Battery No. 1 in Battery Box is low or missing.	Replace battery
Communications between NT-100 and Computer is lost	Battery in Radio Transmitter or Receiver is low	Recharge battery or replace Radio unit with a Radio with a charged battery.
Computer "Low Battery" alert is on.	Computer battery is low.	Recharge battery or operate Computer from Mains.
Computer screen has ERROR message or mouse pointer will not move.	Computer Operating System is locked.	Turn Computer OFF, wait one minute and turn back ON.

Specifications

Feature	Description
Model Number	NT-100
NT-100 Size	6.5 X 3.25 X 1.25 inches
NT-100 Battery Box Size	4.5 X 3.75 X 2 inches
System Weight, less computer	3.5 Lbs.
Computer Screen Size	>11 inches, Computer Model Dependent
Radio Range from NT-100 to Computer	Approx. 6/10 of a mile.
Battery life	> 24 hours
Number of ECG leads	12 or less as selected by Health Professional
No of leads displayed	12
Archival storage for ECGs	> 60
Access to directory functions	Single screen
Record identification	By patient name or alphanumeric identification
Safety Testing	UL 2601,

Radio Transmitter and Receiver Specifications

Power Specifications

Vcc Input Range: 3.3v to 10.0v
Vcc Ripple: <1%
Operating Temperature Range: -20C to +70C
Current Consumption (Max transmit power, 230.4Kbps 1/0)

Mode	Remote	Base Station
Sleep	5OpA	N/A
Standby	2OmA	N/A
Typical	5OmA	l2OmA
Peak (Tx)	200mA	200mA

RF Specifications

FCC Certification	Part 15.247, no license required
ETSI (European) Certification	brETSI 300.328, no license required
Rated RF Power	+18 dBm (+20 dBm effective radiated)
Line-of-site Range	approx. 6/10 of a mile
Frequency Range	2401 — 2495MHz
Number of Channels	*75* US; Canada, France, Spain & Japan: *25*
Receiver Sensitivity	-93dBm
Channel Data Rate	460Kbps
IF Adjacent Channel Rejection	>55dB

Mechanical Specifications

Weight	35g
Dimensions (including shield)	80.2 x *46.5* x 8.6mm (refer to section 7.6 for mechanical drawing)

RF Connector:

WIT	Huber/Suhner:	85 MMCX 50-0-1
Mating	Huber/Suhner:	11 MMCX-50-2-3 (straight)
	Huber/Suhner:	16 MMCX-50-2-2 (rt. angle)

Data/Power Connector:

WIT	Samtec:	DIS5-108-51-L-D
Mating	Samtec:	FFSD-08 (IDC cable)
	Samtec:	CLP-108-02-G-D (PCB mount)

Signal	WIT24IOM OEM Pinout	WIT24IOE DB9 Pinout
GND	**1**	**5**
TXD	2	3
RXD	**3**	2
CFG	**4**	
RTS	**5**	7
SLEEP	**6**	**4**
DCD	7	***1***
CTS	**8**	**8**

The WIT2410E is wired as a DTE device and as such can be connected to DTE devices such as PCs with a straight-through cable. When connecting a WIT2410E to a DCE device, a "null modem" cable is required. To effect a null modem cable, cross-wire TXD and RXD and connect ground. The WIT2410E can operate with just these three wires connected. However, as the W1T2410 does not support software flow control, there will be no flow control in this mode. If the DCE device fails to respond, connect DCD from the WIT2410E to the DTR and RTS inputs to activate the DCE device whenever the W1T2410 asserts carrier.

When connecting to the WIT2410M, make sure that all of the inputs (TXD, CFG, RTS and SLEEP) are terminated for proper operation.

Approved Antennas

The WIT2410M is designed to ensure that no antenna other than the one fitted shall be used with the device. The end user must permanently affix the antenna by using an adhesive on the coupling such as *Loctite*, or ensure the antenna has a unique coupling. The table below lists the antennas which can be purchased directly from Digital Wireless Corporation. Contact DWC Technical Support with any questions.

Description	Gain	Part Number	Coupling
YD24/15 Yagi Directional	14 dB	YAG12415	N
0m24/9 Omnidirectional	9 dB	OMN 1249	N
DWC Patch	6 dB	PA2400	MMCX
Dipole	2 dB	RWA249R	Reverse SMA

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. Submitter

Name:	Cardiac Telecommunications	or	Delphi Consulting Group
Address:	17448 Highway 3, Ste. 175 Webster, Texas 77698 USA		P. O. Box 932 Stafford, Texas 77047
Telephone Number:	(281) 332-7587		(713) 723-8169
Contact Person:	Karim Alhussiny, Ph.D.		J. Harvey Knauss (as Regulatory Consultant
Date Prepared:	2/17/00		to Cardiac Telecommunications)

2. Device

Proprietary name:	CardTel, Model NT-100
Common name:	ECG
Classification name:	Electrocardiograph

3. Classifications Names & Citations:

21 CFR 870.2340 Electrocardiograph
21 CFR 870.2910 Radiofrequency Physiological signal transmitter and receiver

3. Predicate Device

Burdick Eclipse Plus, Burdick, Inc., K946281

4. Description

The CardTel Model NT-100 provides a portable device to continuously monitor ambulatory patient 12 lead electrocardiographic (ECG) data. The unit is designed to acquire and display up to twelve ECG vectors in a standard diagnostic ECG analysis format. The twelve leads consist of the standard twelve ECG leads, I, II, III, aVR, aVL, aVF, V1 and V6. The Model NT-100 is used to monitor patients in the operating room, recovery rooms, intensive care units, in the emergency room, in research settings, or other units where additional ECG leads are desired and real time display is desired. The display unit consists of a generally available Pentium® based personal computer or laptop computer with a SVGA monitor and color printer.

The system provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events.

5. Indications for use

The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

6. Contra-indications

May only be operated by trained personnel.

7. Comparison

The CardTel NT-100 ECG System has the same device characteristics as the predicate device, except the predicate device does not have wireless capability.

8. Test Data

The Model NT-100 System has been subjected to extensive safety and performance testing prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. The ECG Analysis system meets the specified clinical output data requirements of the ANSI/AAMI EC38-1994 specification for ambulatory electrocardiography. Standard databases have been used for automated ECG algorithm verification testing. Safety tests have further been performed to ensure the system complies to applicable industry and safety standards.

The NT-100 device labeling includes instructions for safe and effective use. It includes warning, cautions, and guidance for installation and maintenance.

9. Literature Review

A review of literature pertaining to the safety of electrocardiographs has been conducted. Appropriate safeguards have been incorporated in the design of the NT-100 unit.

10. Conclusions

The conclusion drawn from these tests is that the Model NT-100 ECG System is equivalent in safety and efficacy to its predicate device.

510(k) Number K000609

Device Name: CardTel Model NT-100

Indications for use: The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

Prescription Device: Federal Law (US) restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number _____

Prescription Use Yes OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

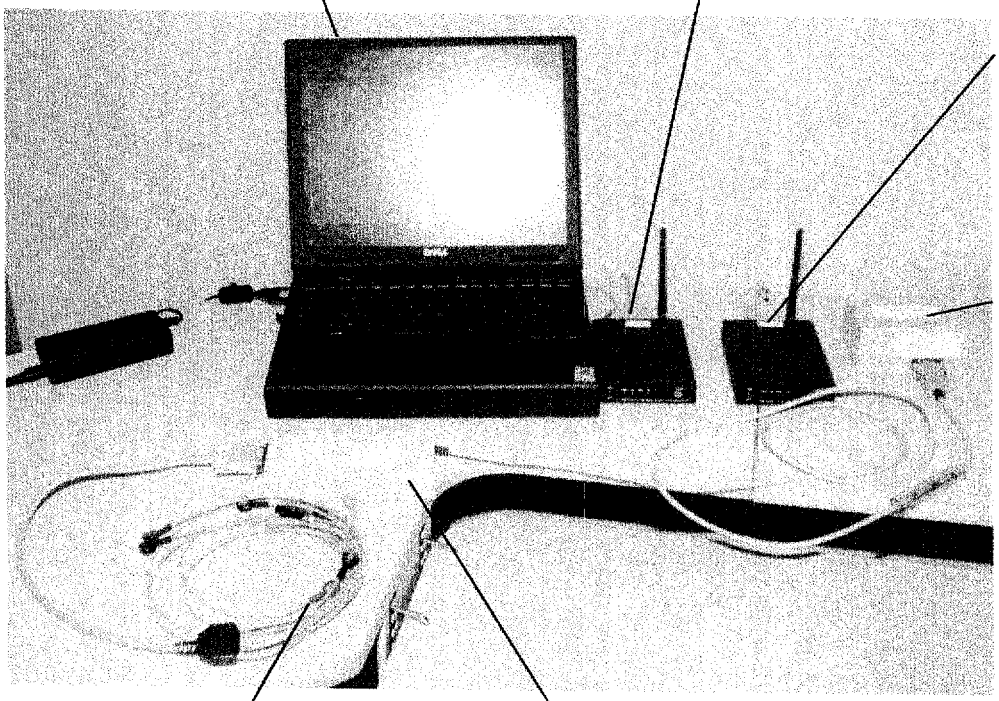
(Optional Format 1-2-96)

Photographs of Unit

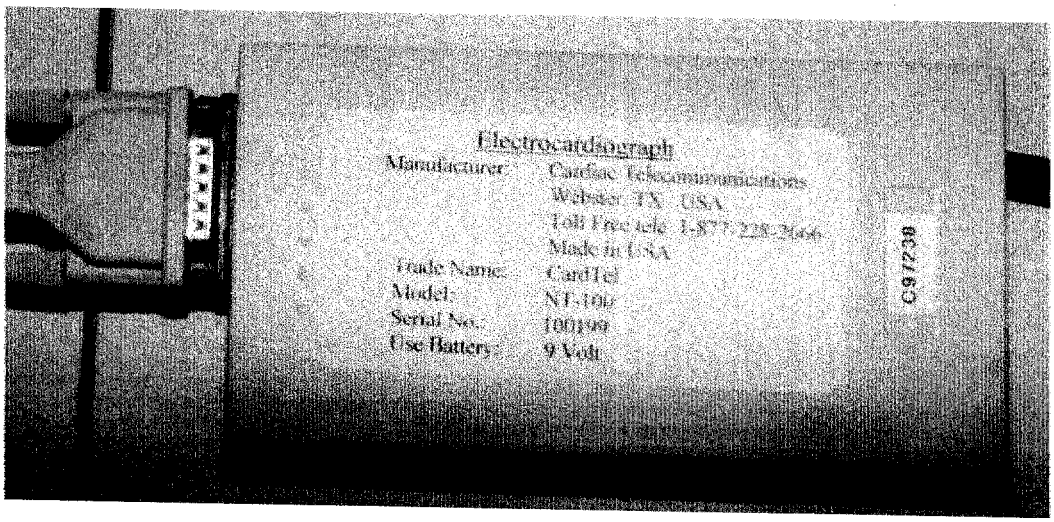
On the following pages are photographs of the CardTel NT-100 unit.

The first photograph is of the system with radio units less a color printer. The computer shown is a generically available IBM type PC with color display.

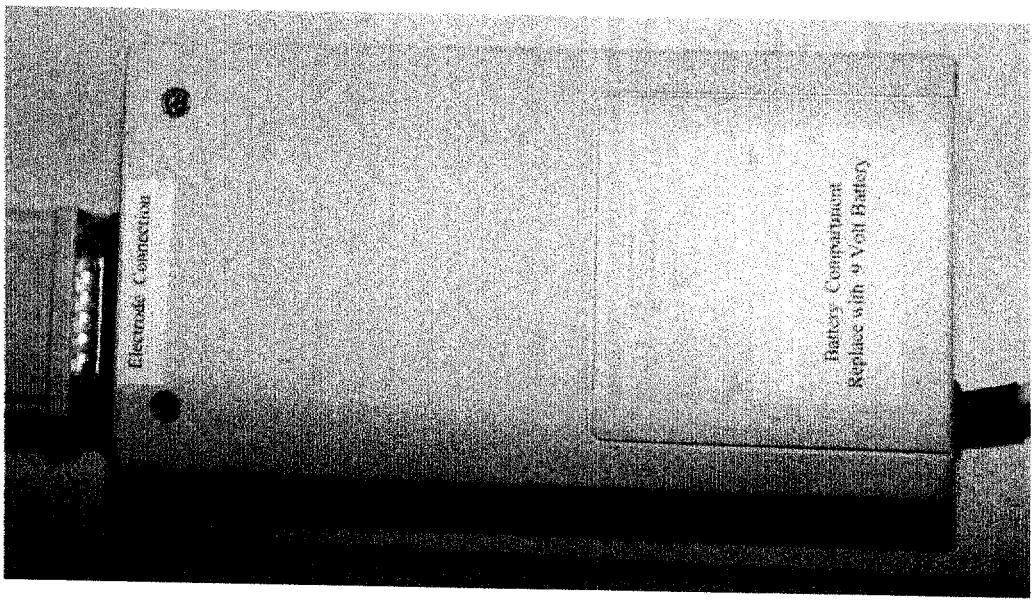
The next two pages have photographs of the device with sample labels in place. The labels shown are for location indications only.



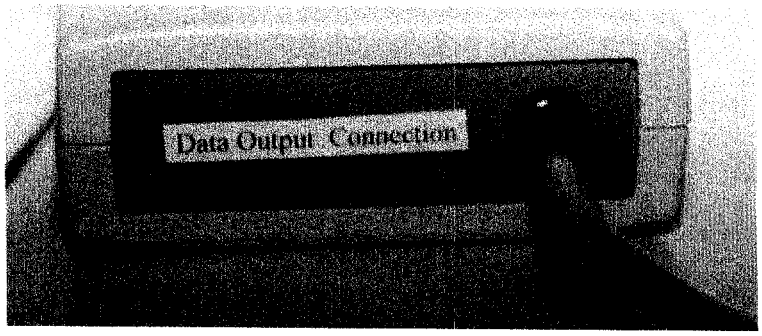
Cardiac Telecommunications CardTel Model NT-100 System



Top of NT-100 Unit



Bottom of Unit



Data Output Cable to Radio Transmitter

Description of CardTel NT-100 Device

The CardTel Model NT-100 provides a portable device to continuously monitor ambulatory patient 12 lead electrocardiographic (ECG) data. The unit is designed to acquire and display up to twelve ECG vectors in a standard diagnostic ECG analysis format. The twelve leads consist of the standard twelve ECG leads, I, II, III, aVR, aVL, aVF, V1 and V6. The Model NT-100 is used to monitor patients in the operating room, recovery rooms, intensive care units, in the emergency room, in research settings, or other units where additional ECG leads are desired and real time display is desired. The display unit consists of a generally available Pentium® based personal computer or laptop computer with a SVGA monitor with CardTel software loaded.

The NT-100 is a patient worn ECG recording system. It consists of a 12-lead ECG amplifier module that is powered from a separate battery module. The amplifier is connected via a serial port to a battery powered wireless transmitter for sending the ECG waveforms to a receiver located within a range of 500 ft. The receiver is connected to a personal computer via a serial port. The personal computer has software for display, storage and hard copy printout of the ECG waveforms.

The system provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events.

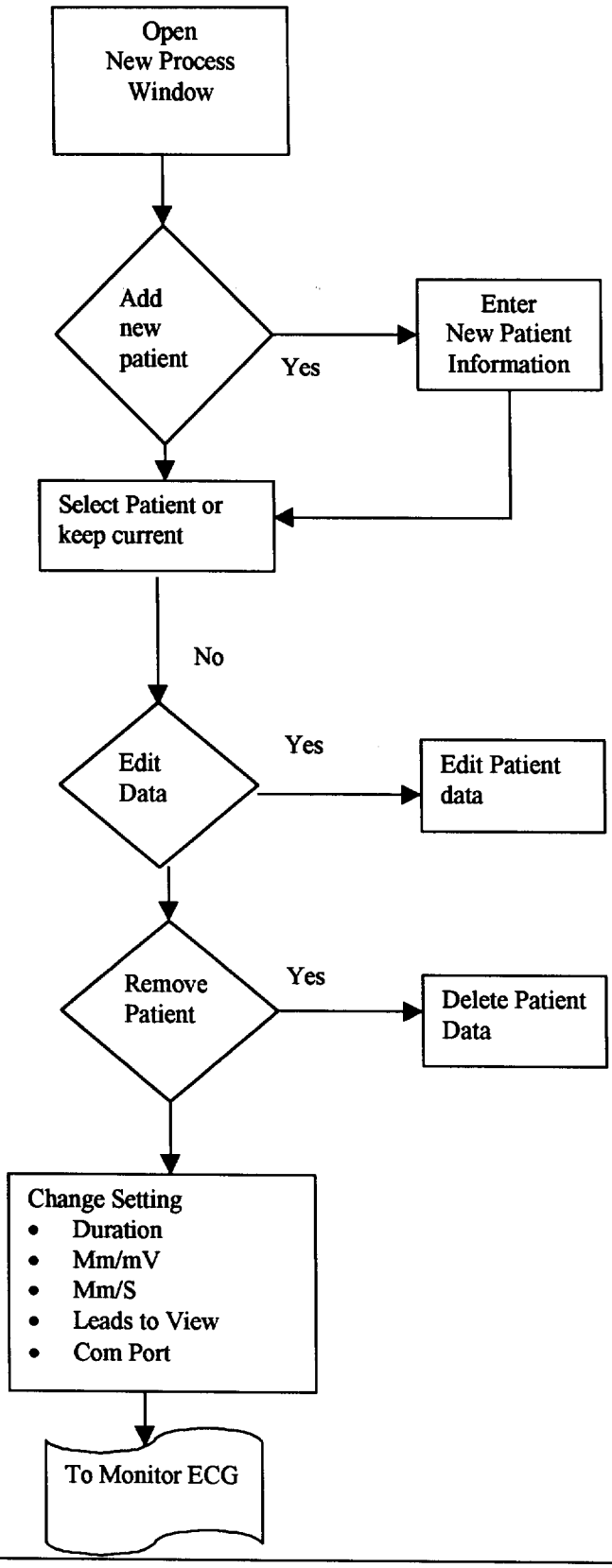
A complete NT-100 system consists of the following items:

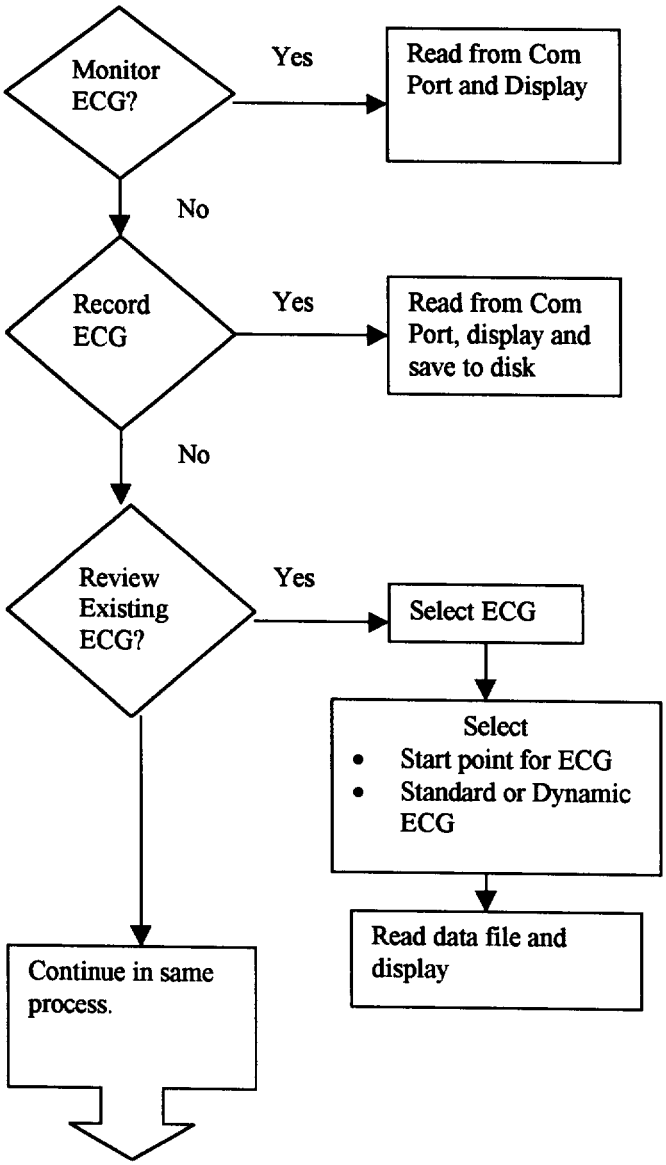
- NT-100 unit
- NT-100 Battery Box
- ECG Cables and disposable electrodes
- Radio Transmitter
- Radio Receiver
- Radio Transmitter/Receiver Battery Charger
- Laptop Computer – supplied or user provided
- NT-100 Software
- Laser or Ink Jet printer – supplied or user provided

Optional Accessories:

- Extra batteries for radios
- Extra battery charger for radios

Operation Flow




Monitor ECG?
Yes
Read from Com Port and Display
No
Record ECG
Yes
Read from Com Port, display and save to disk
No
Review Existing ECG?
Yes
Select ECG
Select
Start point for ECG
Standard or Dynamic ECG
Read data file and display
Continue in same process.

Radio Transmitter and Receiver Specifications
Digital Wireless Corp. model WIT2410

Power Specifications

(b)(4)

[redacted]

RF Specifications

(b)(4)

[redacted]

Mechanical Specifications

(b)(4)

[redacted]

Signal	WIT241OM OEM PInout	WIT241OE DB9 Pinout
GND	1	5
TXD	2	3
RXD	3	2
CFG	4	
RTS	5	7
SLEEP	6	4
DCD	7	1
CTS	8	8

The WIT241OE is wired as a DTE device and as such can be connected to DTE devices such as PCs with a straight-through cable. When connecting a WIT241OE to a DCE device, a "null modem" cable is required. To effect a null modem cable, cross-wire TXD and RXD and connect ground. The WIT241OE can operate with just these three wires connected. However, as the W1T2410 does not support software flow control, there will be no flow control in this mode. If the DCE device fails to respond, connect DCD from the WIT241OE to the DTR and RTS inputs to activate the DCE device whenever the W1T2410 asserts carrier.

When connecting to the WIT241OM, make sure that all of the inputs (TXD, CFG, RTS and SLEEP) are terminated for proper operation.

Approved Antennas

The WIT241OM is designed to ensure that no antenna other than the one fitted shall be used with the device. The end user must permanently affix the antenna by using an adhesive on the coupling such as *Loctite,* or ensure the antenna has a unique coupling. The table below lists the antennas which can be purchased directly from Digital Wireless Corporation. Contact DWC Technical Support with any questions.

Description	Gain	Part Number	Coupling
YD24/15 Yagi Directional	14 dB	YAG12415	N
0m24/9 Omnidirectional	9 dB	OMN 1249	N
DWC Patch	6 dB	PA2400	MMCX
Dipole	2 dB	RWA249R	Reverse SMA

(b)(4) Engineering Drawing

Drawings of Device

Attached are sketches of the device. Production drawings are on file with the plastic molder.

(b)(4) Engineering Drawing

SUBSTANTIAL EQUIVALENCE

Parameter	CardTel NT-100	Burdick Eclipse Plus K946281
Records, stores, and displays electrocardiograms	Yes	Yes
12 Lead Std.	Yes	Yes
Defibrillator-protected input leads	Yes	Yes
Pacemaker spike detection	Yes	Yes
Wireless Operation	Yes	No
Archival storage for >60 ECGs	Yes	Yes
VGA color display	Yes	Yes
Color printer	Yes	No
Single screen access to all directory functions	Yes	Yes
Records identified by patient name, as well as alphanumeric identification	Yes	Yes
ECG Electrodes	Lead-Lok, Inc. PO-6	Lead-Lok, Inc. PO-6
On cart	No	Yes
SCP-ECG data storage standard	No	Yes
Interpretative software	No	Yes

The CardTel NT-100 and Burdick Eclipse Plus are of the same basic design with the same basic indications for use.

The differences are:

- The Burdick Eclipse Plus has a computer built into the device for display, storage and printing where as the NT-100 utilizes a standard PC computer and color printer.
- The NT-100 is smaller, the transmitter part may be worn by the patient if desired. This feature thus requires the radio link to the display and storage unit.
- The NT-100 does not feature interpretative analysis of patient ECG.

Burdick Eclipse Plus labeling is supplied on the following pages.

best copy available

Burdick
ECLIPSE PLUS™

Burdick Eclipse Plus – Predict Device Labeling

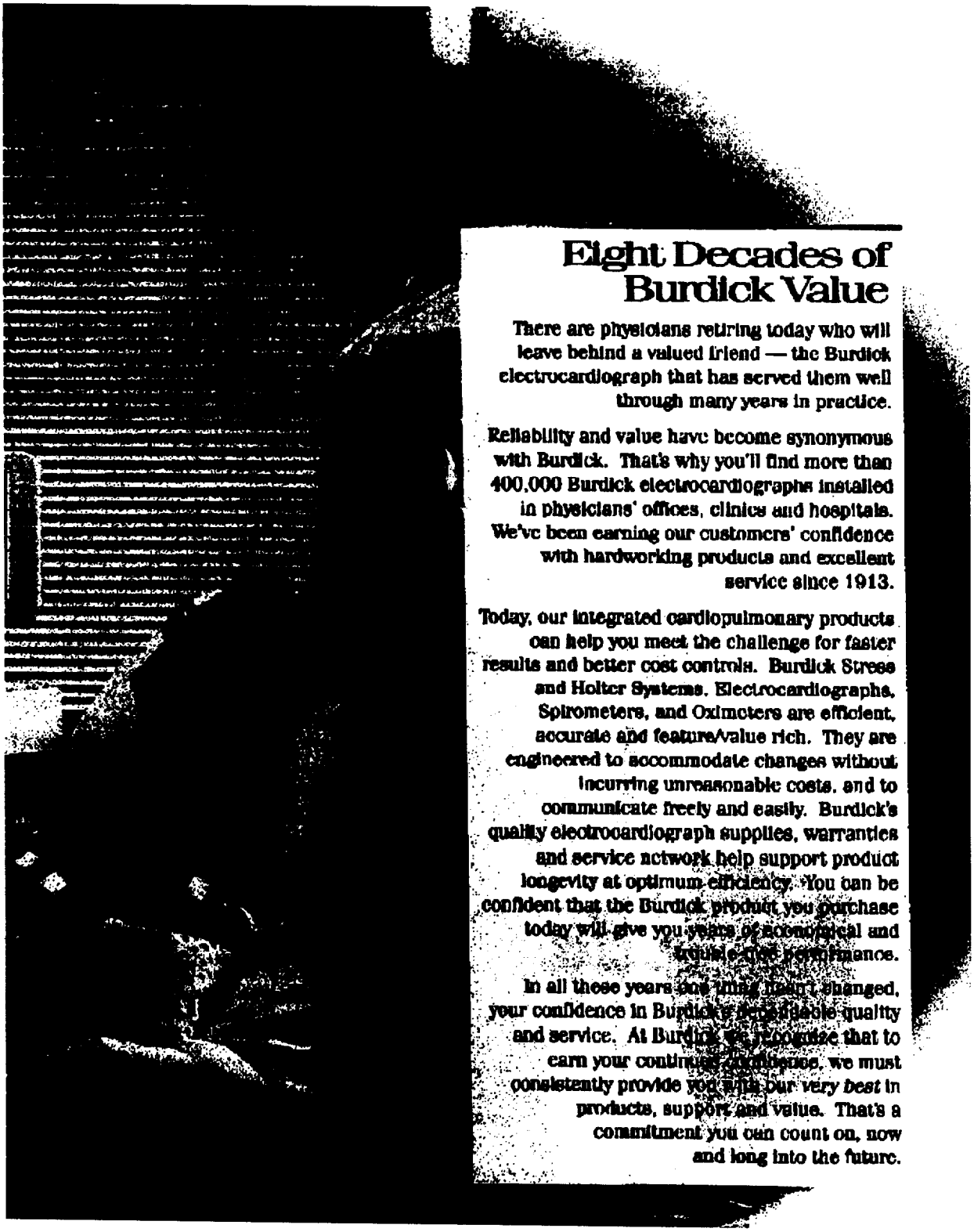
ECLIPSE PLUS™

You'll See the Difference, Any Way You Look at It.

Even from a casual glance, it is obvious that the ***Eclipse Plus*** electrocardiograph is unlike any you have ever seen. From its stunning features and rugged design to its non-proprietary communication technology, the ***Eclipse Plus*** is a value unsurpassed in the industry today. But look closer... Once you learn the whole story, it will forever change the way you look at electrocardiographs.

Cost-Effective, Quality Outcomes are Your Highest Priority...

And ours, too. That's why ***Eclipse Plus*** is designed to meet the productivity and budget demands of managed care head-on. ***Eclipse Plus*** delivers the features you need for superior functionality, day in and day out. Simplified operation and ergonomic design make it efficient to use, simple to learn. Its accurate [illegible] help clinicians make faster diagnoses. And if you have a special need? Communications and networking capabilities are available options. You get *exactly* what you need, without the burden of expensive extras you are not likely to use.



Eight Decades of Burdick Value

There are physicians retiring today who will leave behind a valued friend — the Burdick electrocardiograph that has served them well through many years in practice.

Reliability and value have become synonymous with Burdick. That's why you'll find more than 400,000 Burdick electrocardiographs installed in physicians' offices, clinics and hospitals. We've been earning our customers' confidence with hardworking products and excellent service since 1913.

Today, our integrated cardiopulmonary products can help you meet the challenge for faster results and better cost controls. Burdick Stress and Holter Systems, Electrocardiographs, Spirometers, and Oximeters are efficient, accurate and feature/value rich. They are engineered to accommodate changes without incurring unreasonable costs, and to communicate freely and easily. Burdick's quality electrocardiograph supplies, warranties and service network help support product longevity at optimum efficiency. You can be confident that the Burdick product you purchase today will give you years of economical and trouble-free performance.

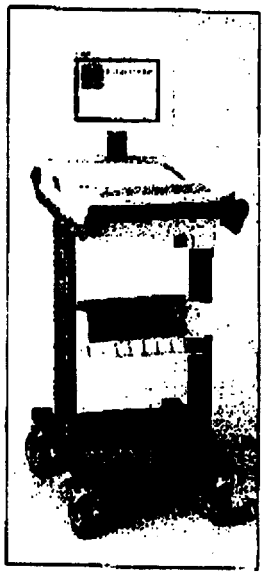
In all these years one thing hasn't changed, your confidence in Burdick's dependable quality and service. At Burdick we recognize that to earn your continued confidence, we must consistently provide you with our *very best* in products, support and value. That's a commitment you can count on, now and long into the future.

Compare the Advantages of Eclipse Plus™

No other system delivers the level of integrated performance and value you'll find in ***Eclipse Plus***. We urge you to compare ***Eclipse Plus*** feature for feature with any other electrocardiograph. Ask about technical support programs. Evaluate warranties. Compare training and service. Add to all of these advantages truly sensible pricing, and you'll see why ***Eclipse Plus*** so clearly goes beyond the ordinary to deliver Burdick total value.

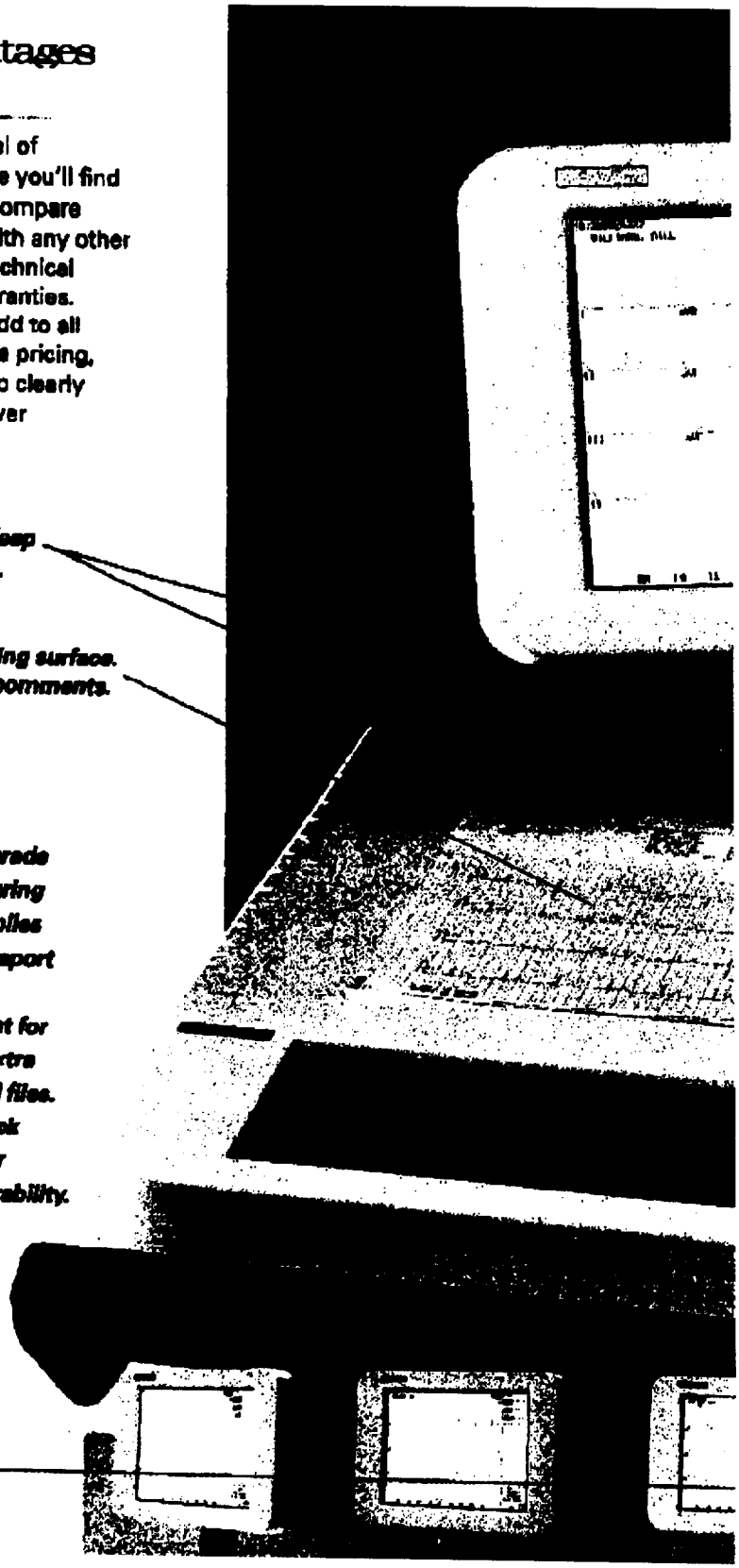
Convenient wells for supplies. Keep what you need at your fingertips.

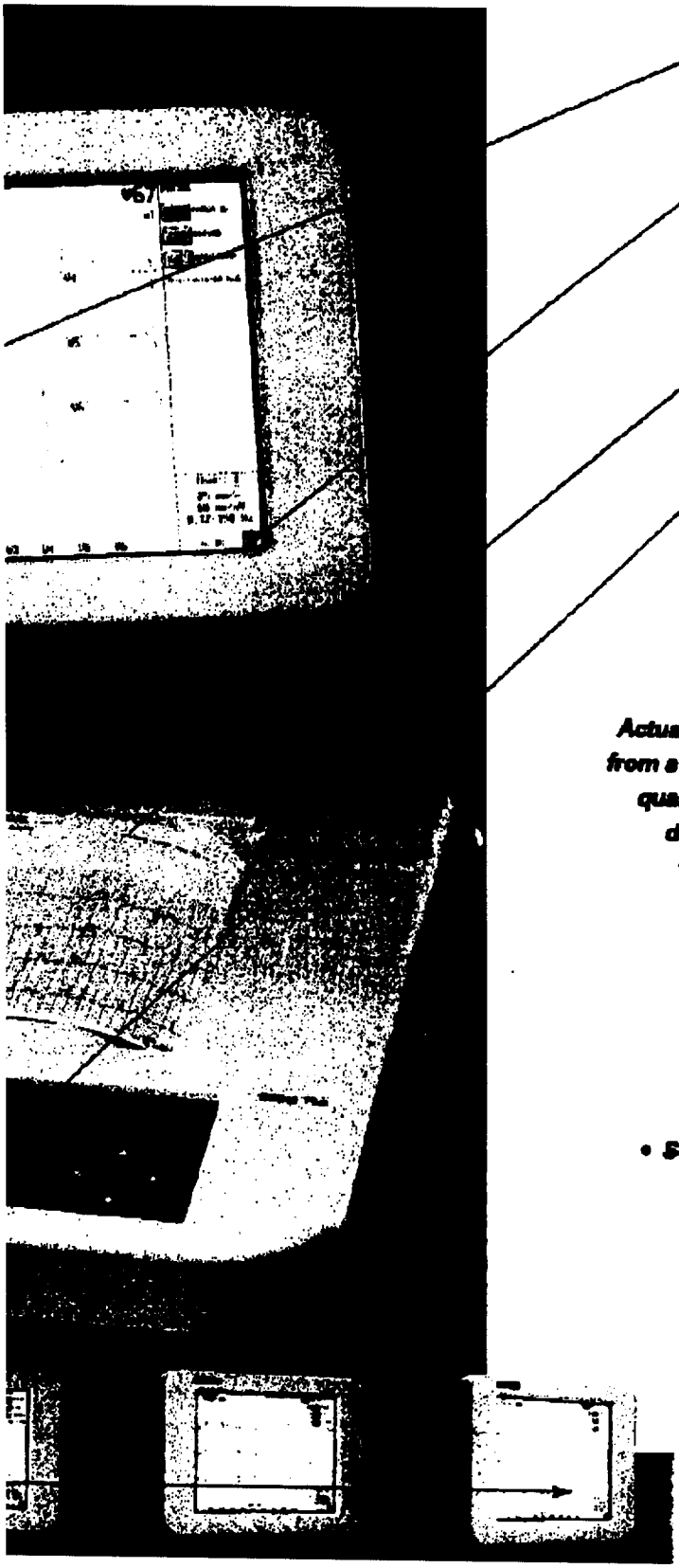
8.5" x 11" report, with large writing surface. Convenient for recording notes, comments.



Rugged hospital-grade cart, featuring large supplies tray and report basket — convenient for holding extra paper and files. Swivel/lock casters for maneuverability.

Unique Swivel and Tilt action. Position the display for optimum viewing.





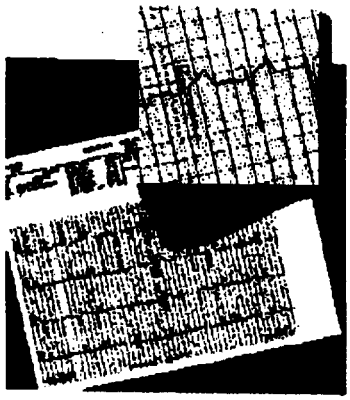
Active matrix color display with wide viewing angle. Intelligent use of color makes operation easy.

Long-life Battery with on-screen battery gauge. No more lost time looking for an outlet.

GRI interpretive analysis program — a "silent second opinion" with clear reason statements.

Full-sized keyboard — sealed to prevent damage from spills.

Fax option. Actual waveform from a diagnostic-quality fax sent directly from the system.



Also ...

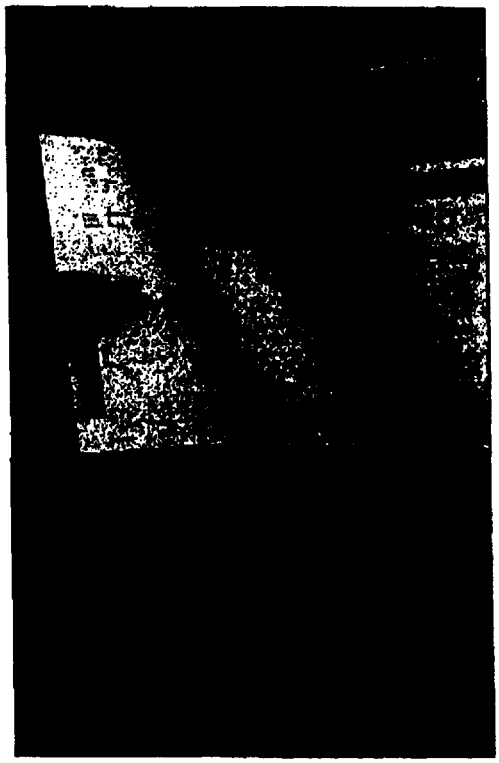
- *12 lead simultaneous acquisition and analysis. Provides a more accurate interpretation of the ECG.*
- *SCP-ECG communication option. Transmit records to other systems using the industry-standard protocol.*
- *Electronic storage for 80 ECGs. Batch transmit records at your convenience.*

Burdick *Eclipse Plus*.
We invite comparisons.

The Ideal Partner for Your Pyramis ECG Management System

The Pyramis system is the answer to your ECG management needs. Designed to integrate seamlessly into your department and your hospital, Pyramis automates the process of managing electrocardiograms, making data available to other systems, when and where the data is needed.

- Simple, intuitive word-processor style report editor makes the system easy to learn and use.
- Automated reporting functions, report logging and distribution save time.



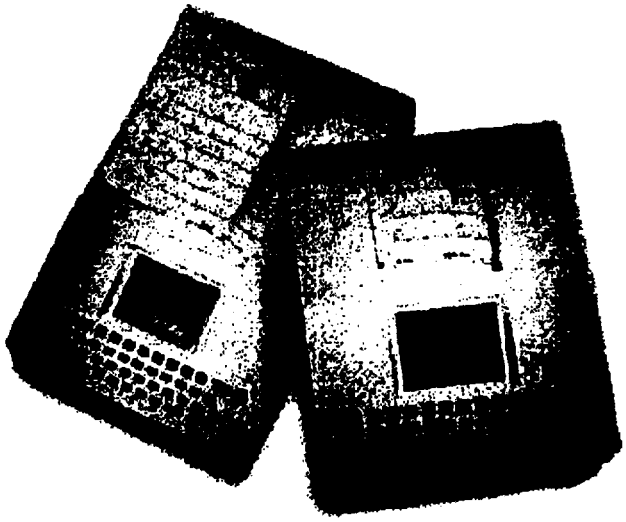
- Windows-based clients integrate easily into the enterprise-wide network.
- HIS interfaces with Burdick's powerful HL-7 integration engine, including requisition and ADT download, results reporting and billing interfaces.
- Fast, user operation increases productivity and cost-effectiveness.

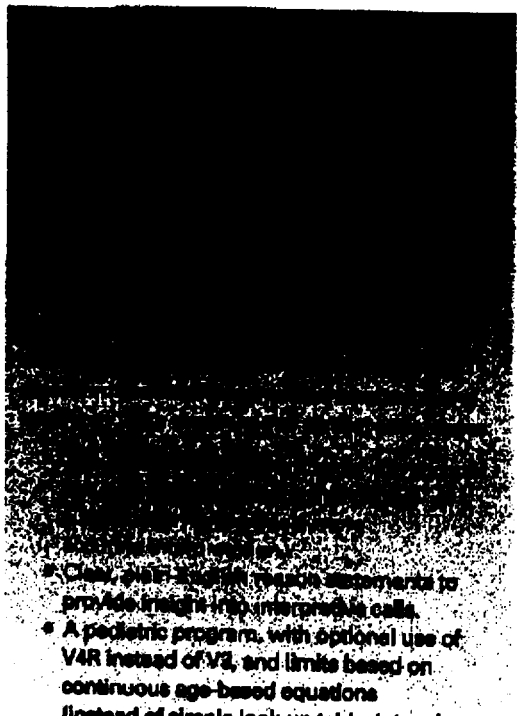
Leading the Way with Non-Proprietary ECG Communication

ECG data transmission and storage are often considered proprietary technology. At Burdick, we believe that this is *your* data and you should not be constrained by a restrictive approach to information management.

STANDARD COMMUNICATIONS PROTOCOL FOR ELECTROCARDIOGRAPHY
SCP-ECG

For this reason, we have adopted a non-proprietary communication technology for transmitting and storing ECGs. This protocol, the Standard Communications Protocol for Electrocardiography (SCP-ECG) is a published, international standard, allowing connectivity between instruments and systems. With SCP-ECG, compatible systems can transmit, store, and receive electrocardiograms with full waveform fidelity — a true open-system.





The Eclipse Family of Electrocardiographs — For All the Ways You Work

Burdick, the world leader in electrocardiograph sales to the alternate care market, offers a full line of systems to complement our top-of-the-line ***Eclipse Plus***™. The ***Eclipse 4*** series features easy portability, perfect for your outreach testing programs, while the ***Eclipse 8*** series is designed for the physician's office. Both offer 3-channel viewing and the same intuitive operation of ***Eclipse Plus***, as well as upgradable performance and a choice of options:

- Storage of up to 40 ECGs
- Fax
- SCP-ECG transmission
- Interpretive, measurements only, and non-interpretive systems

- Clear, clear diagnostic measurements to provide insight into interpretive calls.
- A pediatric program, with optional use of V4R instead of V3, and limits based on continuous age-based equations (instead of simple look-up tables), to take into account the unique anatomy and continuous development of the pediatric patient.

Call today to discuss your needs, or to arrange a free demonstration of the ***Eclipse Plus*** electrocardiograph.

800-777-1777
Or call your Burdick Representative.

Burdick
THE *RIGHT* DECISION FOR TODAY — AND TOMORROW.

ECLIPSE PLUS™

SPECIFICATIONS

■ SYSTEM

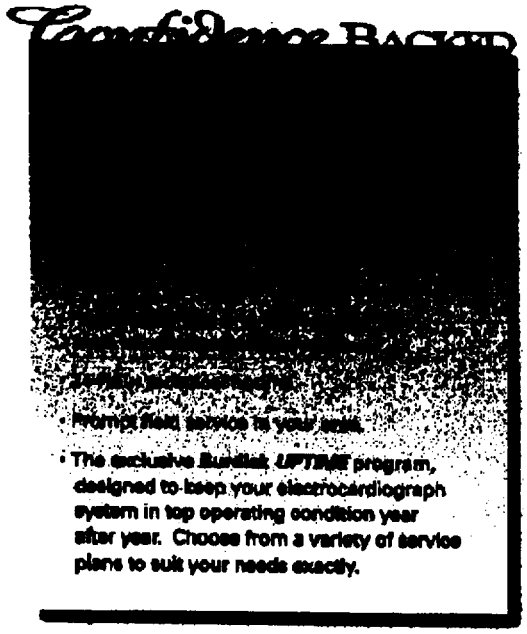
- 10.4" VGA active matrix color LCD display, with 90° tilt/swivel capability.
- Built-in thermal printer uses full-sized (8.5" x 11" or A4) Assurance 50™ archival quality paper, continuous feed, Z-folded.
- Archival storage for 60 ECGs.
- Customizable display/report forms, presenting up to 12 leads on one screen or page.
- Single-screen access to all directory functions.
- Records identified by patient name, as well as alphanumeric identification.
- PC card slot for software upgrades.
- 16.8 VDC NiCd Battery Pack.
- Hospital-grade cart with swivel/lock casters and paper/file storage.

■ OPTIONS

- Fax module.
- SCP-ECG compatibility.

Languages
Available in English, German, French or Spanish versions.

Operating Voltages
Available in 120V, 240V, or 220V operating at either 50Hz or 60Hz.



Burdick
THE RIGHT DECISION FOR TODAY — AND TOMORROW.

[redacted]

DETAILED INFORMATION

Device Classification Name	SYSTEM, ECG ANALYSIS
Regulation Number	
510(k) Number	K946281
Device Name	ECLIPSE 4 ELECTROCARDIOGRAPH
Applicant	BURDICK, INC. 15 PLUMB STREET MILTON, WI 53563
Contact	PAUL E APPEL
Product Code	LOS
Date Received	12/27/94
Decision Date	04/23/96
Decision	Substantially Equivalent
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Indicator	Summary only
Summary/Approval Letter	SUMMARY
Type	Traditional

RETURN TO SEARCH | FORM HOME PAGE | FDA HOME PAGE | SEND COMMENTS

(Database Updated September 7, 1999)

FDA Data Base Listing of Predict Device – Burdick Eclipse

K946281

510(k) Summary

Effectiveness

The pediatric enhancement to the interpretative program was developed by Dr. Peter MacFarlane in the University of Glasgow Department of Cardiology, Glasgow Royal Infirmary (GRI), Glasgow, Scotland. Dr. MacFarlane has been involved in computerized ECG interpretation since its inception in the 1960s. The GRI pediatric criteria is based on a large study of 2,196 neonates, infants and children.

The Burdick Eclipse 4 performs the same functions and meets the same performance standards as the Marquette MAC PC. This version of the Burdick GRI interpretative program and Marquette's interpretative program used in the MAC PC both provide adult and pediatric resting ECGs on patients ranging in age from birth to 99 years. Both programs analyze 10 seconds of data simultaneously from the 12 standard leads and identify essentially the same set of abnormalities.

Safety

The addition of pediatric interpretation does not change the analysis of potential risks as outlined in the Eclipse 4 510(k) submittal (# K943959) concerning electrical shock, misrepresentation of the patient's ECG, inability of the operator to sucessfully record an ECG, mechanical pinch points and device falling.

Burdick conducted a review of the literature pertaining to safety of pediatric interpretative capabilities in electrocardiographs. Appropriate safeguards have been incorporated in the design of the Eclipse 4.

The device labeling includes instructions for safe and effective use. It includes warnings, cautions, and guidance for installation and maintenance.

Summary of Burdick Eclipse Predict Device.

Cardiac Telecommunications

CardTel NT-100 Electrocardiograph

Preliminary Hazard Analysis
and
Failure Mode and Effects Analysis

Table of Contents

1 Purpose and Scope

This document identifies the possible risks and hazards to a patient, operator or bystander that could occur if a component or subsystem of the CardTel NT-100 Electrocardiograph system fails. Any use of the equipment in an unforeseeable or unintended fashion is not covered by this analysis.

This document will:

- Identify possible risks and hazards that could occur to a patient, operator, or bystander if a component or subsystem of the CardTel NT-100 Electrocardiograph patient monitor system fails;
- Estimate the risk by determining the occurrence probability of the hazard;
- Estimate the maximum possible severity of the risk;
- Determine the risk reduction, or severity reduction necessary to make the risk acceptable;
- Estimate the resulting risk, and severity of the controlled or mitigated hazard.

2 Standard References

This hazard analysis will cover the CardTel NT-100 Electrocardiograph systems in stand-alone or connected status. It is based on the methodologies described in:

1. IEC 601-1-4: 1996, Part 1: General requirements for safety -Programmable electrical medical systems- Bureau Central de la Commission Electrotechnique Internationale (IEC), Rue de Varembre, Geneve, Switzerland
2. EN1441: 1997: Medical Devices - Risk analysis (10/94) - CEN - European committee for Standardization, Rue de Stassart 36, B-1050 Bruxeles
3. ISO 9000 -3: 1991, Quality management and quality assurance standards - Part 3: Guidelines for the application of /SO 9001 to the development, supply and maintenance of software.
4. ISO 9001: 1994, Quality systems - Mode/ for quality assurance in design, development, production, installation and servicing
5. CEI-IEC 1508: Functional Safety - Safety Related Systems,Bureau Central de la Commission Electrotechnique Internationale (IEC), Rue de Varembre, Geneve, Switzerland
6. Reviewer Guidance for Computer Controlled Medical Devices undergoing 510(k) Review, Rockville, MD, FDA 8/1991.
7. ODE Guidance for the content of Premarket Submission for Medical Device Containing Software, FDA-CDRH, Rockville, MD, 9/1996. (DRAFT)
8. CEI-IEC 601-2-22: Particular Requirements for the safety of diagnostic and therapeutic laser equipment (11/95) - Bureau Central de la Commission Electrotechnique Internationale (IEC), Rue de Varembre, Geneve, Switzerland
9. IEC 825-1: Safety of laser products: Equipment classification, requirements and user's guide (11/93) - Bureau Central de la Commission Electrotechnique Internationale (IEC), Rue de Varembre, Geneve, Switzerland
10. ODE Guidance For Off-The-Shelf Software Use In Medical Devices, FDA-CDRH, Rockville, MD, 6/1997. (DRAFT)
11. General Principles of Software Validation, Draft Guidance, FDA- CDRH, Rockville, MD, 6/1997.

Any use of the equipment in unforeseeable, unintended, or careless fashion may lead to a potentially hazardous condition. The Users Manual provides instructions on proper system operation. Any use outside the scope and procedures described in the system documentation is NOT covered by this analysis.

3 Document References

Document #	Title
	FDA 510(k) Submission

4 DEFINITIONS

4.1 OPERATING ENVIRONMENT

The s CardTel NT-100 Electrocardiograph system is part of a comprehensive system for monitoring ambulatory and bedridden patients. The monitored and recorded parameters are interpreted by trained and licensed medical professionals, however the patient is not under continuous supervision. The user interface and the operating instructions are designed to avoid misunderstandings and prevent foreseeable misuse.

The safe state of the device is defined as the de-energized state. This is in contrast to a lung ventilator or a defibrillator, for example, where absence of energy could lead to a hazard. Absence of energy in a patient-monitoring system might result in unavailability of diagnostic data but will not generate an immediate hazard.

4.2 DEFINITIONS

- Hazard -- Potentially detrimental effect on the patient, other persons, animals, or the surroundings, arising directly from the medical electrical equipment.
- Risk -- Probable rate of occurrence of a hazard causing harm, and the degree and severity of the harm.

Incredible -- highly improbable.

4.3 ACRONYMS AND ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
A/D	Analog to Digital Converter
C	Consequence
D/A	Digital to Analog Converter
DC/DC	DC to DC converter (converts DC voltages)
EMI	Electro-Magnetic Interference
EMS	Electro-Magnetic Susceptibility
ESD	Electro-Static Discharge
F	Frequency
FMEA	Failure Mode and Effect Analysis
FMECA	Failure Mode Effect and Criticality Analysis
FTA	Fault Tree Analysis
Hazard	A possible source of danger
HCF	Healthcare Facility
I/O	Input / Output of electrical signals
MCU	Main Control Unit (Processor that controls the laser unit)
O	Observability
PS	Power Supply
R	Risk
RC	Risk Class
S	Severity
Vcc	Supply Voltage for Logic Circuits

5 RESPONSIBILITY

It is the responsibility of the Project Engineer, with the aid of qualified personnel, to develop and maintain this document.

6 PROCEDURE

On the basis of the identified list of potential hazards, and their criticality level, a detailed analysis will be performed:

1. Failure Mode Effects and Criticality Analysis (FMECA). The "bottom-up" approach of the FMECA will be used to investigate known failure modes of system components, and their capability to create a hazard. This analysis will be based on a "single fault" assumption that no single point of failure shall create any of the identified hazards. The assessment schema will therefore not account for multiple (catastrophic) or 'chain of events' faults, or faults deliberately induced. The FMECA methodology will determine whether a sub-system or component failure could lead to a hazard. The advantage of FMECA is the fact, that every component of the system becomes part of the evaluation.

This Hazard Analysis will develop a comprehensive collection (matrix) of potential hazards. This matrix may be refined as the implementation of the device becomes more defined, but it is free from implementation details. All hazards are collected taking various factors into account. Specifically, the following sub-set of the hazards identified in EN 1441 are assumed to be the only factors that cause, or contribute to a hazard for this specific type of equipment.

However, because the direct cause-effect relationship may not be obvious, not all hazards are immediately identifiable. Specifically, long-term hazards, and secondary hazards or 'cloaked hazards' are not easily identified. This hazard analysis will therefore be periodically reviewed and updated.

6.1 Hazard Causes

6.1.1 Energy Hazards

The purpose of the devices is not to deliver energy to the patient. The devices are however powered by electrical power (battery or mains) and use secondary energy to measure physiological parameters The energy levels of the APM device are deliberately kept as low as possible to extent the battery life.

The following sources of energy will be evaluated as having either "direct" risk potential, or "secondary" risk potential (due to energy transformation -- a transformation such as light ⇒ heat could cause a hazard even though the primary energy property will not cause a hazard).

Hazard Energy Source	Primary Hazard	Secondary Hazard
Electrical Energy (conducted)	Electric shock (Cardiac fibrillation)	Tissue damage (burns)
Electro-Magnetic Energy (radiated)	External interference (Cardiac pacemakers)	EM susceptibility
Mechanical Energy	Tissue damage/impact	N/A
Optical Energy	Tissue damage	Explosion hazard

Hazard Energy Source	Primary Hazard	Secondary Hazard
Thermal Energy	Tissue damage	Fire hazard Explosion hazard
Chemical Energy	N/A	N/A
Ionizing Radiation	N/A	N/A
Pressure	N/A	N/A

Table 1 Primary and Secondary Hazards

6.1.2 Information Hazards

The primary purpose of the device is to measure, record, evaluate and transmit measurements of physiological parameters. During each of the data processing steps the data is vulnerable to be incorrect, ie. not reflect the physiological parameter monitored. The following hazards will be evaluated:

- Incorrect data processing

6.1.3 Biological Hazards

The CardTel NT-100 Electrocardiograph is in patient contact through non invasive sensors. The sensors are not meant to be in contact with mucous membranes.. The following hazard will be evaluated:

- Patient/Operator/Device Contact.

6.1.4 Environmental Hazards

The device has to avoid hazards resulting from materials used in its design. Since the device, or its operation may require the use of toxic, caustic, or otherwise hazardous materials, it is necessary to determine whether materials used in the device's construction can lead to a hazard due to leaching, evaporation, or fumes generated by high temperatures; or due to material degradation through aging, excessive temperature, cleaning substances, or exposure to specified environmental conditions.

The device interactions with the environment will be minimized. Critical environmental parameters such as electromagnetic susceptibility, or emissions will have to comply with currently applicable international standards.

The following hazards will be evaluated:

- Materials used.
- Inadequate supply of power, or inadequate cooling.
- Electro-Magnetic Susceptibility, see separate EMI testing report.

6.1.5 Hazards related to the use of the device

The operator interface and the data transfer and processing is a crucial part of the device's safety system, since false information presented to the operator or patient as well as the absence of predetermined alarms can lead to improper treatment, and potential hazards. The primary information sources provided by the device are visual To ensure that critical operating parameters are correctly set, and to minimize the possibility of user error and foreseeable misuse, the information presented to the user has to be easily readable, correct, and comprehensive.

The risk potential of the device's "information" content, and its software "dependencies" will be evaluated. Specifically, the following hazard will be evaluated:

- Information presented to the operator/patient.
- Data processing
- Data transfer
- User Interface

6.1.6 Hazards arising from functional failure, maintenance and aging

Time is needed for a hazard to develop into a risk; the amount of time needed depends on the nature of the hazard. Therefore, the hazard analysis matrix will account for a latency time in which a hazard control is possible without causing harm (hazard tolerance time).

The amount of substance, or energy delivered over time is also a factor that is hazard specific.

Long term effects are very difficult to predict. The application of patient monitoring equipment however is well understood over several decades. Currently no long-term hazards have been identified, or substantiated.

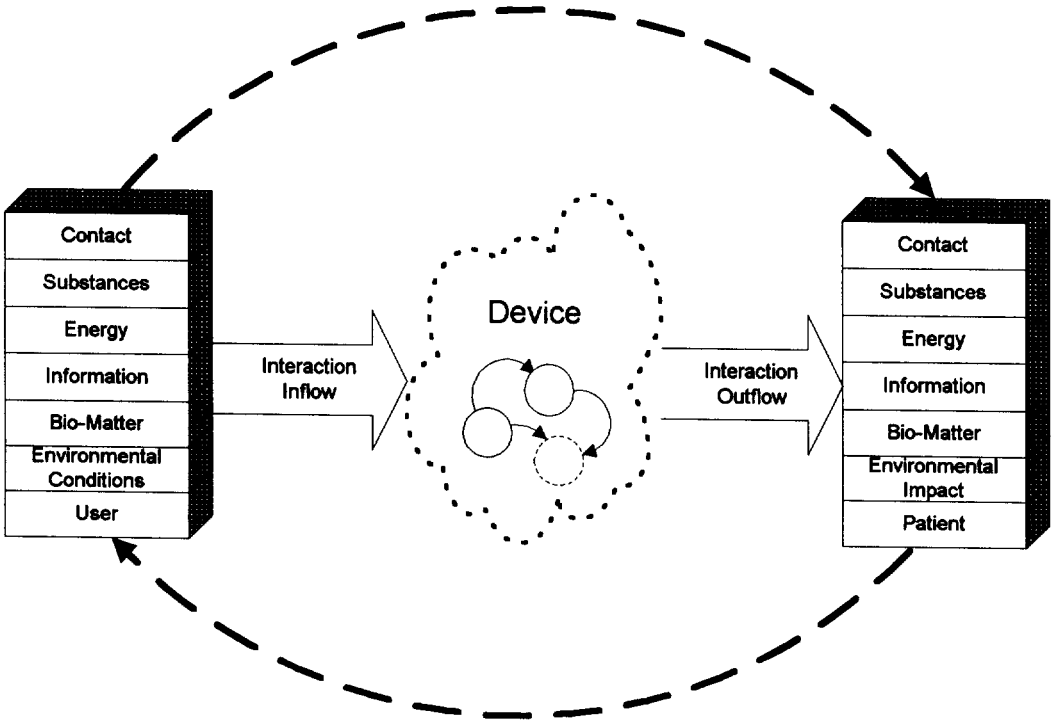


Figure 1: Device Properties and Interactions

6.2 *RISK ANALYSIS*

The severity of the hazardous events, combined with their occurrence probability determines the total risk potential of a device.

This analysis uses the following risk class ratings:

Risk Class	Interpretation
Class I	Intolerable risk
Class II	Undesirable risk and tolerable only if risk reduction is impracticable or if the costs are grossly disproportionate to the improvements gained
Class III	Tolerable risk if the cost of risk reduction would exceed the improvement gained
Class IV	Negligible risk

Table 2: Risk Classes

These risk classes are linked to occurrence probability, and the consequence of the event:

Frequency	Consequence			
	Catastrophic	Critical	Marginal	Negligible
Frequent	I	I	I	II
Probable	I	I	II	III
Occasional	I	II	III	IV
Remote	II	III	IV	IV
Improbable	III	III	IV	IV
Incredible	IV	IV	IV	IV

Table 3: Risk Matrix

The device shall not generate a risk greater than Class III under normal operating and single fault conditions. However, frequent risks should not be tolerated, and incredible frequency will not be assumed. Catastrophic risks like the multiple deaths can be excluded due to the limited damage potential of the device. Therefore, the following sub-set from Table 3 is used:

Frequency	Consequence		
	Critical	Marginal	Negligible
Probable	I	II	III
Occasional	II	III	IV
Remote	III	IV	IV
Improbable	IV	IV	IV

Table 4: Acceptable Risks (ALARP)

The shaded part of the table represents the risk area, which is considered to be within the ALARP range.

The final risk assessment grades the "risk of a device" based on the mitigated or controlled risks. To enhance clarity, and to better identify the effectiveness of the control/mitigation measures, the unmitigated risk is also graded using the same rating. Figure 3 illustrates the risk reduction concept.

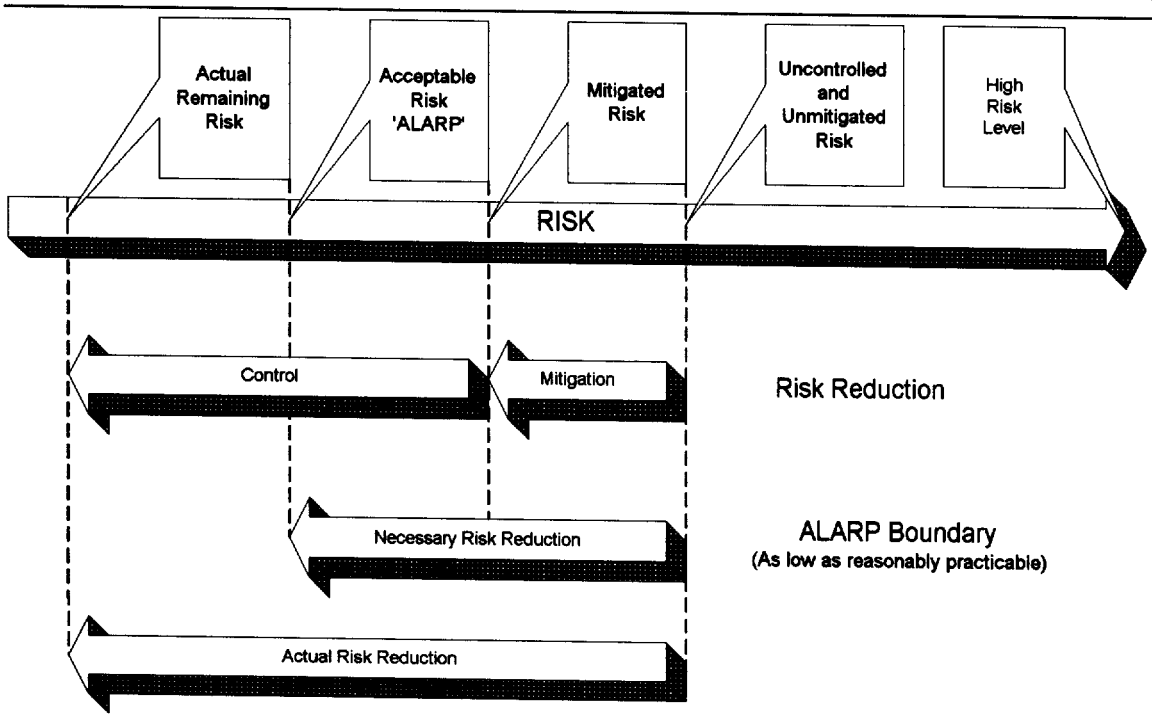


Figure 2: Risk, Acceptable Risk and Risk-Reduction

7 Qualitative and Quantitative Characteristics

7.1 *Intended use*

The intended use of the CardTel NT-100 Electrocardiograph device is the monitoring of the following physiological parameter:

- Electro-Cardiogram

The device is used to monitor a supervised patient.

7.2 *Intended Patient Contact or Contact with Other Persons*

The CardTel NT-100 Electrocardiograph is in patient contact through:

- ECG electrodes (electrical contact, mechanical contact)

7.3 *Materials and Components*

The devices use standard materials and components with well-understood properties.

7.4 *Energy Delivered or Extracted from the Patient*

- The intended use of the device does not energy from the patient.

7.5 *Substances Delivered or Extracted from the Patient*

The device if used as intended does not extract or deliver any substances to or from the patient.

7.6 *Biological Material processed by the Device for Subsequent Use*

The device if used as intended does not process biological material for subsequent use.

7.7 *Sterility and Sterilization*

The intended use of the device requires only sensors to be in contact with the skin surface:

The device itself does not require sterility or sterilization.

7.8 Modification of Patient Environment

The intended use of the device does not modify the patient environment.

7.9 Measurements

The device measures the following physiological parameters:
The intended use of the system is the monitoring of the following physiological parameters:

- Electro-Cardiac Waveforms

7.10 Interpretation of Results

The CardTel NT-100 Electrocardiograph measurements are transmitted, displayed, and recorded. The measurements are not interpreted by the system.

7.11 Control or Interactions with other Devices or Drugs

The system does not independently control other medical devices.

7.12 Unwanted Output of Energy or Substances

The intended use of the device does not cause unwanted output of energy or substances.

7.13 Susceptibility to Environmental Influences

The susceptibility of the device to environmental influences could lead to malfunction or incorrect measurements.

7.14 Essential Consumable or Accessories

Essential consumable required for the use of the device are:

- ECG electrodes (single patient use)

7.15 Routine Maintenance and Calibration

The device will require routine maintenance and calibration.

7.16 Software

The device will incorporate the majority of its functionality using two software systems.

7.17 Restricted shelf-life

The shelf life of the APM and SC systems is limited only by battery life. The essential consumables will have a limitation on shelf-life depending on the manufacturers specifications for these components.

7.18 Delayed and Long-Term Effects

The application of patient monitoring equipment is well understood over several decades. Currently no long-term hazards have been identified, or substantiated.

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

Bench Test of Input/Output System

1. Purpose

   The purpose of this test is to verify that the signal in to the CardTel NT-100 is not compromised by the system or the radio link.

2. Test Procedures

(b)(4) Testing

[redacted]

3. Conclusion

   The NT-100 system received and transmitted, stored, and printed the input wave shapes without any alteration.

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

1.0 Purpose

The purpose of this test is to verify that the Cardiac Telecommunications NT-100 ambulatory wireless ECG monitor meets a selected group of the UL2601-1 Medical Electrical Test - General Safety Requirements.

2.0 Description of the Device

The NT-100 is a patient worn ECG recording system. It consists of a 12-lead ECG amplifier module that is powered from a separate battery module. The amplifier is connected via a serial port to a battery powered wireless transmitter for sending the ECG waveforms to a receiver located within a range of 500 ft. The receiver is connected to a personal computer via a serial port. The personal computer has software for display, storage and hardcopy printout of the ECG waveforms.

3.0 Test Procedures

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

4.0 Test Results

4.1 Continuous Leakage Currents and Patient Auxiliary Currents (UL2601-1 section 19)

4.1.1 Enclosure Leakage Current for Internally Powered Equipment (UL2601-1 sec 19.4g 3)

Measurement between Modules			Power		Limits	Units
ECG-Batt	ECG-Xmitter	Batt-Xmitter	ECG	Xmitter	Min/Max	
			Off	Off	----/100	microamps
			Off	On	----/100	microamps
			On	Off	----/100	microamps
			On	On	----/100	microamps

4.1.2 Measurement of Patient Leakage (Source) Current for Internally Powered Equipment (UL2601-1 sec 19.4h 6)

Measurement between Electrodes and Module			Power		Limits	Units
Elec -ECG	Elec-Xmitter	Elec-Batt	ECG	Xmitter	Min/Max	
			Off	Off	----/10	microamps
			Off	On	----/10	microamps
			On	Off	----/10	microamps
			On	On	----/10	microamps

4.1.3 Measurement of Patient Leakage (Sink) Current for Internally Powered Equipment (UL2601-1 sec 19.4h 7)

Measurement between Leadwire and Module			Power		Limits	Units
Elec -ECG	Elec-Xmitter	Elec-Batt	ECG	Xmitter	Min/Max	
			Off	Off	----/50	microamps
			Off	On	----/50	microamps
			On	Off	----/50	microamps
			On	On	----/50	microamps

4.1.4 Measurement of Patient Leakage (Sink) Current for Internally Powered Equipment (UL2601-1 sec 19.4h 7)

Measurement between Leadwire to Leadwire										Power		Limits	Units
RA	LA	LL	RL	V1	V2	V3	V4	V5	V6	ECG	Xmitter	Min/Max	
										Off	Off	----/10	microamps
										Off	On	----/10	microamps
										On	Off	----/10	microamps
										On	On	----/10	microamps

4.2 Dielectric Strength (UL2601-1 section 20)

Measurement between Leadwires and Module			Power		Limits	Units
Elec -ECG	Elec-Xmitter	Elec-Batt	ECG	Xmitter	Min/Max	
			On	On	Pass/Fail	N/A

5.0 Conclusion

The NT-100 passed all of the selected tests for electrical safety as performed. The one discrepancy noted was a failure during test 3.1.3 in which the mains voltage was applied between the electrodes and the exposed metal on the ECG cable housing. This failure was corrected by covering the exposed metal with insulation. It is recommended that a cable with a plastic connector housing be used in future revisions.

I certify that the tests were performed as written and that the results were as indicated.

Signed : _(b) (6)_____ Date: 1-26-00

PE License #: (b) (6)

Reviewed and Accepted

Signed: (b) (6) Date: 1-28-00

Signed copy on file.

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Appendix A Radiated Emissions Data Sheets

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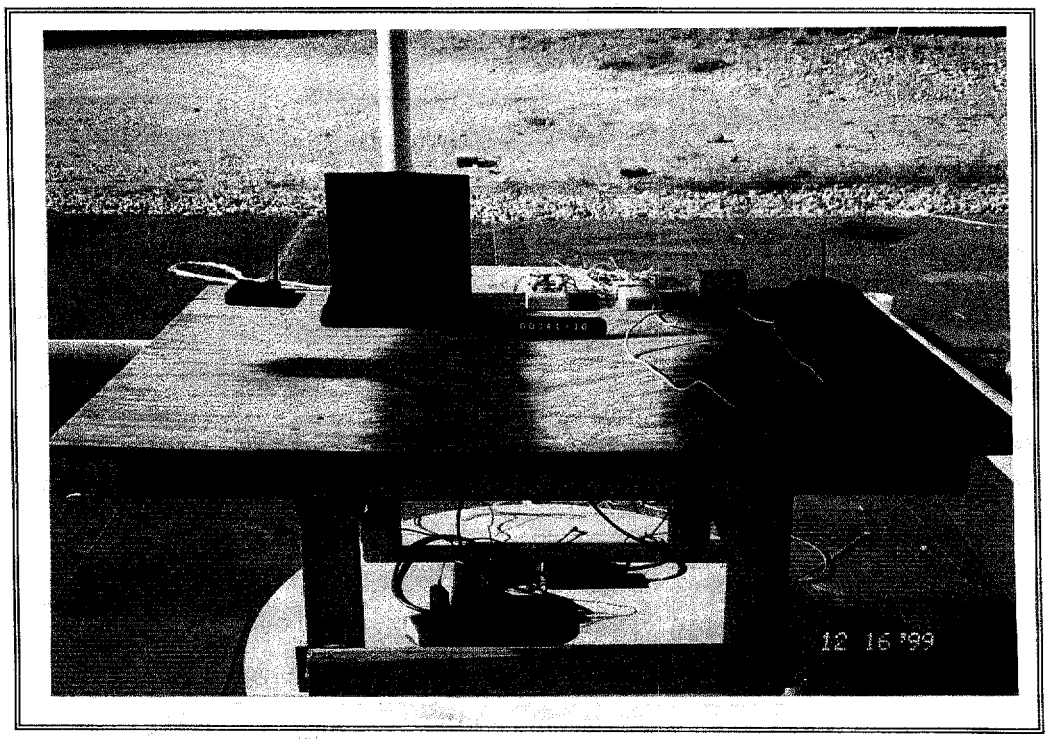
Appendix C

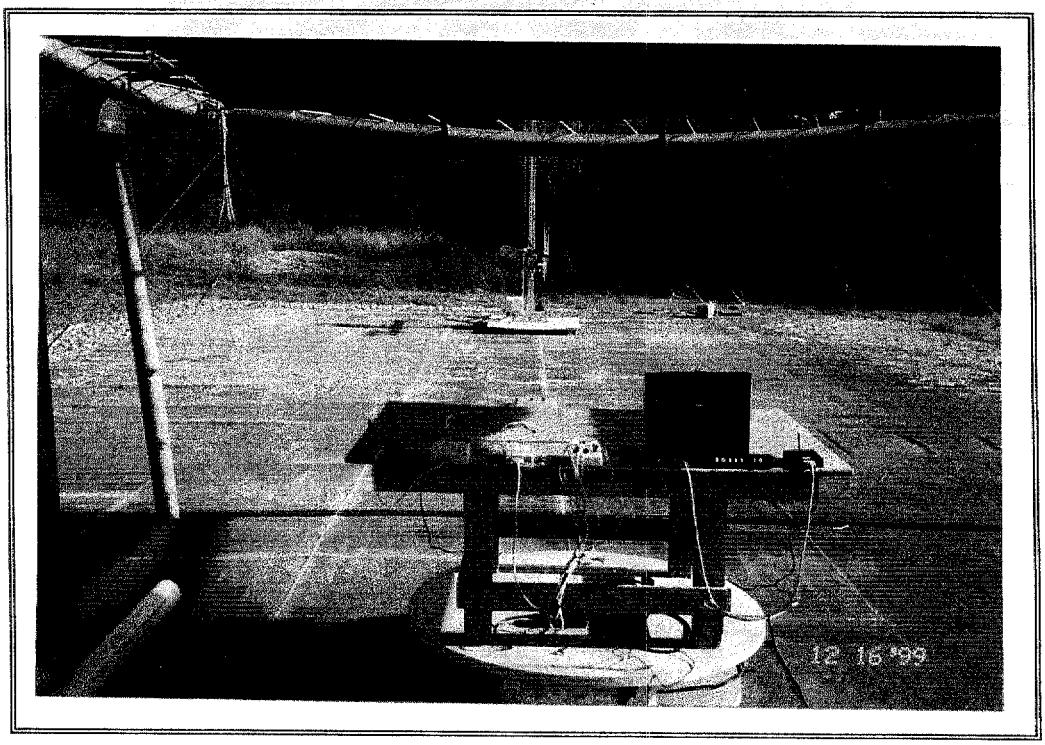
Photographs

Cardiac Telecommunications
NT-100 Battery Powered EKG Device

Radiated Emissions - Front View

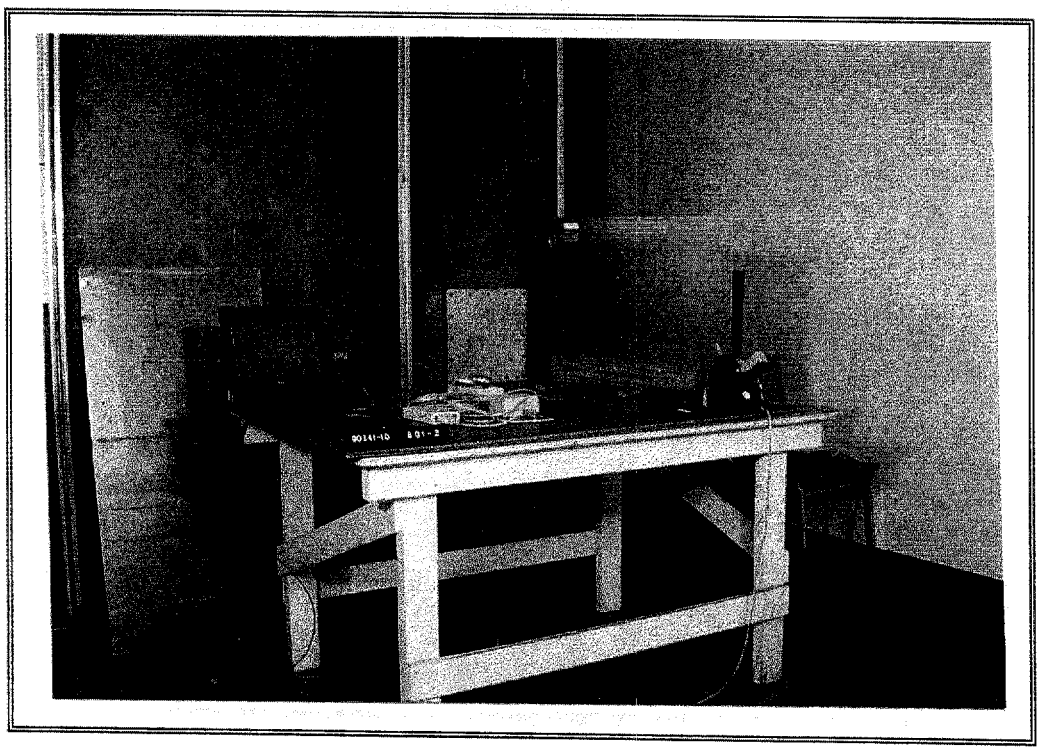


Radiated Emissions - Back View

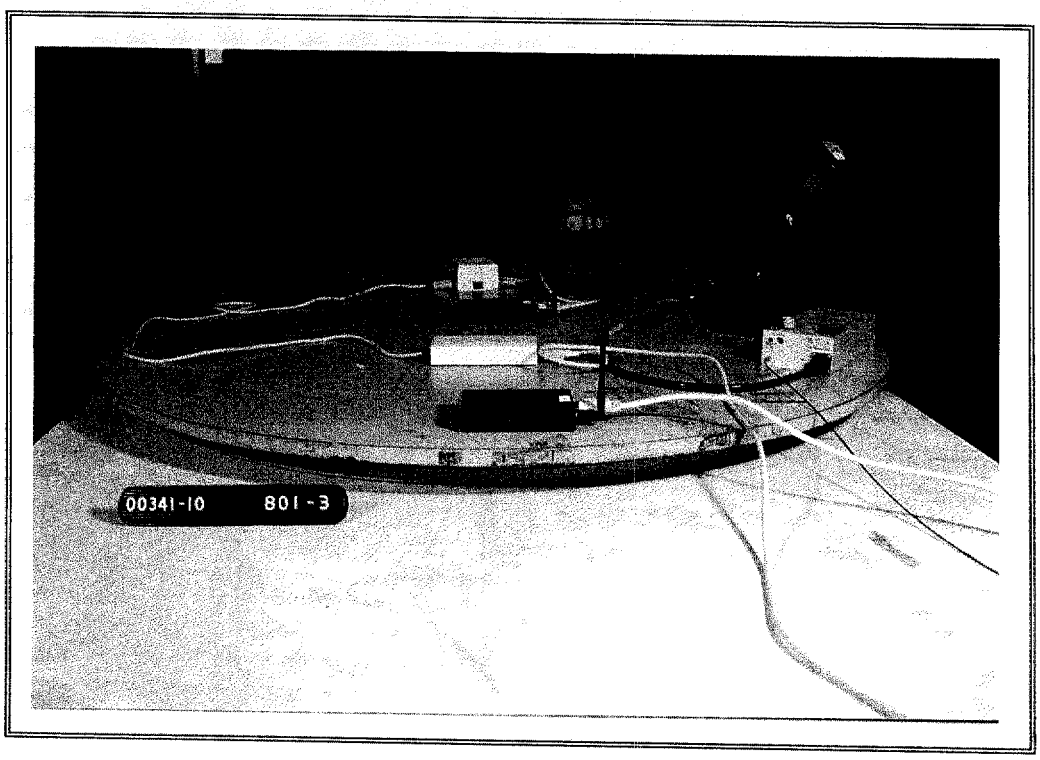


Cardiac Telecommunications
NT-100 Battery Powered EKG Device

Electrostatic Discharge Test Setup



Radiated Immunity Test Setup



Appendix D

Policy, Rationale and Evaluation of EMC Measurement Uncertainty

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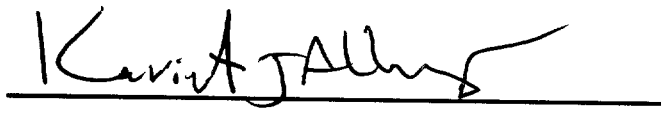
PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87 (j))

I certify that, in my capacity as Chief Technical Officer of Cardiac Telecommunications, I believe to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.



Signature 2/16/2000

Karim Alhussing, Ph. D.

For: CardTel, Model NT-100 Electrocardiograph

Y2K Certification

Cardiac Telecommunications, warrants that each item of hardware, software, and firmware in the CardTel Model NT-100 System shall be able to accurately process date/time data (including, but not limited to, calculating, comparing, and sequencing) from, into, an between the twentieth and twenty-first centuries, and the years 1999 and 2000 and leap year calculations to the extent that other information technology, used in combination with the information technology being acquired, properly exchanges date/time data with it.

Karim Alhussiny, Ph.D.
Chief Technical Officer

Date: Feb 16, 2000

For: 510(k) submission, New, CardTel Model NT-100 ECG

Form approved: OMB No. 0910-0397
Expiration Date: February 29, 2000
See OMB Statement on reverse

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, Federal Y2K Biomedical Equipment Clearinghouse
Additional Information Request Form – Manufacturer Reporting Y2K Compliant Products – FORM FDA 3473

Please verify and correct, or provide any missing information and return as indicated in the enclosed **Options for Reporting** page.
For detailed instructions, please refer to the appropriate line number on the **BACK** of this form.

Line #	Manufacturer Information	
	Manufacturer Name	Cardiac Telecommunications
	Division *(see instructions on the back of the form)*	
	Enter Your FDA Assigned Owner/Operator Number	Applied for
	Contact Information	
	Y2K Contact's Name *(First and Last)*	Karim Alhussiny, Ph.D.
	Y2K Contact's Address	17448 Highway 3, Suite 175
	Y2K Contact's City, State/Province and Postal Code	Webster, Texas 77598
	Y2K Contact's Country	USA
	Y2K Contact's Telephone	877-228-2666
	Y2K Contact's Fax	281-332-6000
	Y2K Contact's Email	karim@cardictel.com

Y2K Status Information

In addition to the Y2K status information previously provided, your company is requested to report all products that are Y2K compliant. Please see Line #12 for the options available for reporting medical devices and/or scientific research equipment that are Y2K compliant.

Additional Information

Use one of the three options below to report medical devices and/or scientific research equipment that are Y2K compliant to the Clearinghouse:

(1) Paper Reporting – Complete a **Compliant Products – FORM FDA 3474** for each product that is Y2K compliant.

(2) Online at FDA's Web Site – http://www.fda.gov/cdrh/yr2000/y2kform.html

(3) Electronic File Submission (E-File) – Please see the enclosed instructions entitled, **Options for Reporting Biomedical Equipment That Is Y2K Compliant**.

For details about each option, please see the enclosed instructions entitled **Options for Reporting Biomedical Equipment That Is Y2K Compliant**.

CardTel NT-100 ECG

INFORMATION CURRENT AS OF 9/15/1999

DCG

J. Harvey Knauss
Consultant

Delphi Consulting Group
Regulatory Office
P. O. Box 932
Stafford, Texas 77497-0932

Phone 713-723-8169
Fax 713-723-4080
E-Mail delphi15@wt.net
www.delphiconsulting.com

Subject: Submission correspondent - 510(k) Notification

To Whom It May Concern:

Delphi Consulting Group (a State of Texas, Harris County d.b.a.), acting under contract from Cardiac Telecommunications, 17488 Highway3, Ste. 175, Webster, Texas 77598, produced this submission. Raw data for this submission was obtained from Cardiac Telecommunications, Consultants, and the Food and Drug Administration (FDA). Current Federal and FDA documents and guidelines were utilized to ensure compliance with the FD&C Act.

Accuracy of submission data is based on material and documents provided by client and testing laboratories.

Sincerely yours,
Delphi Consulting Group
For and on behalf of:
Cardiac Telecommunications,

J. Harvey Knauss
Consultant

Date: Feb 16, 2000

D:\Word Processor Files\DCG\CLIENTS\Cardiac\510 Submission\Submission correspondent letter.doc

Reviewer's Notes

K _____ Date Received: _____