THE WHITE HOUSE

WASHINGTON

April 22, 1971

Dear Mr. Tatoian:

The President has asked me to reply to your recent letter pertaining to miniaturized electrocardiograph (ECG) transmitters developed by your firm.

The President shares your concern for the rapid deployment of technological advances that can expedite recovery of the cardiac patients of our country and provide prompt emergency medical assistance when a heart attack first occurs. He has, in fact, recently initiated a study of the feasibility of providing spectrum space for emergency medical services such as ambulance-based ECG operations.

However, granting licenses and waiving license requirements for operation of any transmitter in the United States and its possessions are matters within the exclusive authority of the Federal Communications Commission (FCC), with the single exception of transmitters owned and operated by agencies of the Federal Government. As you may know, the FCC is an independent regulatory agency and as such, its decisions are not subject to Presidential review. Since, therefore, the specific action which you request is not within the province of the President, you may wish to file a formal petition for the waiver with the FCC.

Thank you for your interest in this matter.

Peter M. Flanigan Assistant to the

President

Mr. George Tatoian Cardiac Electronics, Inc. 4915 Ransom Road Clarence, New York 14031

Vacc: TW-w/incoming Timmons Cong Henry Smith

Office of Telecommunications Policy Route Slip

		To
1 APR 1971	Clay T. Whitehead	
	George F. Mansur	
	Nino Scalia	
	Will Dean	1/ 51.23
	Walt Hinchman	7 30 2
	Charlie Joyce	
	Jack Thornell	
	Frank Urbany	
	Steve Doyle	7011
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	Brian Lamb	
	Linda Smith	
	Eva Daughtrey	
	Timmie White	
	Judy Morton	
	Elaine Christon	
SUSPENSE	COB 5 GAN	71
REMARKS:		

THE WHITE HOUSE WASHINGTON

TO: Mr. Tom Whitehood

FROM: PETER FLANIGAN

REMARKS:

3/3//1/ (Date)

ACTION:	Prepare reply for Mr. Flanigan's signature
-	Direct reply
	Comments/recommendations Please handle
-	Information
	File

Cardiac Electronics, Inc.



4915 RANSOM ROAD CLARENCE, NEW YORK 14031 AREA CODE 716-759-6167 or 759-8304

March 26, 1971

Mr. Richard M. Nixon President United States of America The White House Washington, D.C.

Dear Mr. President:

This letter is a request for a waiver for the license-free operation of an extremely low-powered, battery-operated electrocardiograph (ECG) transmitter in the 40-42 megacycle frequency band.

The Federal Communications Commission has informed us that this band is not within its jurisdiction and that said waiver must be granted by the Executive Office of the President.

Cardiac Electronics has designed a unique miniaturized, state-of-the-art ECG transmitter for eliminating electrical wires which connect patients to hospital heart monitoring equipment. The transmitter will operate continuously for a 7-10 day period on self-contained power. It is sandwiched between two (2) small foam pads containing two (2) pure silver, chlorided electrodes, all of which adheres to the chest area near the patient's heart and WEIGHS LESS THAN ONE OUNCE.

This is one of the most significant advances in the art of patient monitoring.

Our engineers designed this inexpensive, low-powered/disposable unit specifically for short-range heart monitoring (within the patient's room) for the following reasons:

- to relieve patient anxiety
- to help reduce ever-increasing hospital and patient care costs
- to insure patient safety and comply with the Veterans Administration Specification No. X1414

It has long been recognized by the medical profession that a patient's mental and emotional attitude is as important as medication and professional care. Therefore, relief from anxiety, particularly with cardiac patients, will save lives and hasten patient recovery.



The recent Veterans Administration specification No. X1414 dated January 1, 1970, Amendment No. 1, September 1, 1970, para. 3.3.6.2 on Electrical Safety, limits the amount of electrical leakage current passing through the wires connecting the patient to the heart monitor to a maximum of 10 microamperes to prevent electrocution.

As a result, almost all of the more than 100,000 hospital heart monitors now in use must either be replaced or rebuilt in order to meet this specification. This will cost hospitals, both private and governmental, more than \$100 million.

Since our ECG transmitter is wireless, no leakage current path exists from the patient to the heart monitor. Therefore, the system is 100% safe and all electrical safety specifications are met and surpassed.

The receiver is compatible with all brands of heart monitors now in use, thus saving replacement or modification costs of existing equipment.

Presently, any available transmitter-receiver systems are long-range and very expensive. Although the patient has freedom of movement, these ECG transmitters (designed primarily for ambulatory heart patients) are bulky and must be harnessed to a patient. As a consequence, they are almost as anxiety provoking as conventional patient wire connections. (Picture of man on treadmill enclosed.)

Our engineers deliberately chose the 40-42 megacycle band because it was relatively free of other interfering signals and is an area where a simple device could be designed with a minimum of complexity. Additionally, this 2 megacycle band provides the necessary channels for monitoring numerous patients in confined hospital areas.

Other frequency ranges investigated do not have the freedom from interference. Secondly, the unit could not be miniaturized since it would require a more complex design. Thirdly, the cost of the unit would be prohibitive and could not be made available to the hospital industry at a low cost.

Very truly yours,

CARDIAC ELECTRONICS, INC.

eaugh Vaterian George Tatoian

President

GT:gso Encs.

Mr. Dean Burch, Chairman cc: Federal Communications Commission Mr. Elliot L. Richardson, Secretary Department of Health, Education and Welfare Roger O. Egeberg, M.D. Assistant Secretary Department of Health, Education and Welfare Senator Jacob K. Javits Senator James Buckley Representative Jack Kemp Representative Henry P. Smith III Representative Thaddeus J. Dulski Representative Paul G. Rogers Mr. Herman Garlan, Chief, Radio Frequency Devices Branch Federal Communications Commission Administrator of Veterans Affairs





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April 19, 1971

Dear Henry:

In behalf of the President, I would like to thank you for your letter regarding Mr. George Tatoian's request for a waiver for the license-free operation of a low-powered, battery-operated electrocardiograph transmitter in the 40-42 megacycle frequency band.

You may be assured that Mr. 'Tatoian's request will receive full consideration.

Best regards,

Sincerely,

William E. Timmons Assistant to the President

Honorable Henry P. Smith III House of Representatives Washington, D. C. 20515

bcc w/inc to Peter Flanigan - for further ACTION

WET: EF:lrc

HENRY P. SMITH III 40TH DISTRICT, NEW YORK COMMITTEE ON THE JUDICIARY

COMMITTEE ON THE DISTRICT OF COLUMBIA

Congress of the United States House of Representatives

Washington, D.C. 20515 April 13, 1971

RUSSELL A. ROURKE ADMINISTRATIVE ASSISTANT

422 CANNON HOUSE OFFICE BLDG. AREA CODE 202: 225-3231

WILLIAM B. LEWIS DISTRICT REPRESENTATIVE 4 WERSTER STREET NORTH TONAWANDA, NEW YORK TEL.: 695-1577



The Honorable Richard M. Nixon President of the United States The White House Washington, D.C. 20500

Dear Mr. President:

I have reference to the attached correspondence submitted to me by Mr. George Tatoian, President, Cardiac Electronics, Inc., of Clarence, New York.

After carefully reviewing the enclosures, I must admit that I was extremely impressed with Mr. Tatoian's entire presentation. For this reason, I respectfully request that you designate a member of your staff to review the statements and claims made in Mr. Tatoian's letter. If, indeed, Mr. Tatoian's device is possessed of the characteristics stated, I then ask that you grant the requested waiver for the "license-free operation of a ECG wireless electrode transmitter in the 40-42 megacycle frequency band".

Your careful consideration of this request will be deeply appreciated.

With kindest regards, I remain,

Sincerely yours

Henry P. Smith III Member of Congress

HPS:rrq Enclosure WHITE HOUSE MAIL ROOM

1971 APR 15 AM 9 21

1

Cardiac Electronics, Inc. 4915 RANSOM ROAD CLARENCE, NEW YORK 14031 AREA CODE 716-759-6167 or 759-8304 March 27, 1971 The Honorable Henry P. Smith III House of Representatives Washington, D.C. 20510 Dear Mr. Smith: Please refer to the enclosed copy of my March 26, 1971, letter to President Nixon. The medical device discussed therein is germane to the safety and betterment of public health. Fully aware of your concern for the safety and health of our citizenry and, since we are a Western New York State corporation, I trust the letter's contents will be of interest to you. Sincerely yours, CARDIAC ELECTRONICS, INC. George Tatoian President GT:gso Enc.

Cardiac Electronics, Inc.

4915 RANSOM ROAD CLARENCE, NEW YORK 14031 AREA CODE 716-759-6167 or 759-8304

March 26, 1971

Mr. Richard M. Nixon President United States of America The White House Washington, D.C.

Dear Mr. President:

This letter is a request for a waiver for the license-free operation of an extremely low-powered, battery-operated electrocardiograph (ECG) transmitter in the 40-42 megacycle frequency band.

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This is one of the most significant advances in the art of patient monitoring.

Our engineers designed this inexpensive, low-powered/disposable unit specifically for short-range heart monitoring (within the patient's room) for the following reasons:

- to relieve patient anxiety
- to help reduce ever-increasing hospital and patient care costs
- to insure patient safety and comply with the Veterans Administration Specification No. X1414

It has long been recognized by the medical profession that a patient's mental and emotional attitude is as important as medication and professional care. Therefore, relief from anxiety, particularly with cardiac patients, will save lives and hasten patient recovery.

Conventional patient monitoring methods require the attachment of electrical wires to a patient's body and cause anxieties due to the presence of wires on the patient and also due to the patient's so-restricted body movement. Use of our wireless ECG transmitter will eliminate such patient anxieties and hasten patient recovery.

If relief from anxiety hastens the recovery of a patient by only one day, the average coronary care unit could accommodate 40-50 more patients per year, or the equivalent of one extra room per four patient coronary care system. This amounts to a cost savings for U.S. hospitals of \$100 million annually.

Present hospital Coronary Care and Intensive Care room rates are approximately \$200/day with patients' stays averaging 5-7 days. For every 100,000 cardiac patients being treated each year, the savings to patients and medical insurance programs would amount to \$20 million annually.

Regarding patient safety, our transmitter eliminates the everpresent danger of electrocution and would have avoided, for example, the accidents quoted below from the <u>Wall Street Journal</u>'s November 16, 1970, page one article entitled "More Patients Hurt as Electronic Devices Come Into Greater Use":

"When the Melvin Weisbergs took their three-year-old daughter, Elizabeth, to a Miami hospital last year, she was to undergo routine surgery for a middle-ear infection. Several hours later, however, the Weisbergs learned that their only child had almost died on the operating table.

"The near-tragedy had nothing to do with any unforeseen surgical complications. Rather, the little girl had received a severe shock when a common piece of operating room equipment, a heart monitor, short-circuited.

"Each year such faulty or improperly operated electrical devices are killing several hundred patients and injuring thousands of others. The rising number of such accidents is bringing cries of alarm from consumer advocates and proposals for regulation from the Federal Government.

"Such accidents are nothing new, of course. In 1929, Dr. Roger O. Egeberg, now Assistant Health, Education and Welfare Secretary, was injured when he was an intern at Chicago's Wesley Memorial Hospital. 'I was holding a catheter in a patient's bladder while another intern took an X-ray of it,' he remembers. 'Something went wrong. I was shocked and went into convulsions.' The patient was only slightly injured."

Obviously, the hospital patient's safety is of primary concern as indicated also in your fall-of-1969 consumer message requesting legislation imposing federal regulatory controls for medical devices and instruments, and the recently proposed Bill (H.R. 1545) which will require the premarketing clearance of certain categories of medical devices by the Food and Drug Administration introduced by Florida's Representative Paul Rogers.

The recent Veterans Administration specification No. X1414 dated January 1, 1970, Amendment No. 1, September 1, 1970, para. 3.3.6.2 on Electrical Safety, limits the amount of electrical leakage current passing through the wires connecting the patient to the heart monitor to a maximum of 10 microamperes to prevent electrocution.

As a result, almost all of the more than 100,000 hospital heart monitors now in use must either be replaced or rebuilt in order to meet this specification. This will cost hospitals, both private and governmental, more than \$100 million.

Since our ECG transmitter is wireless, no leakage current path exists from the patient to the heart monitor. Therefore, the system is 100% safe and all electrical safety specifications are met and surpassed.

The receiver is compatible with all brands of heart monitors now in use, thus saving replacement or modification costs of existing equipment.

Presently, any available transmitter-receiver systems are long-range and very expensive. Although the patient has freedom of movement, these ECG transmitters (designed primarily for ambulatory heart patients) are bulky and must be harnessed to a patient. As a consequence, they are almost as anxiety provoking as conventional patient wire connections. (Picture of man on treadmill enclosed.)

Our engineers deliberately chose the 40-42 megacycle band because it was relatively free of other interfering signals and is an area where a simple device could be designed with a minimum of complexity. Additionally, this 2 megacycle band provides the necessary channels for monitoring numerous patients in confined hospital areas.

Other frequency ranges investigated do not have the freedom from interference. Secondly, the unit could not be miniaturized since it would require a more complex design. Thirdly, the cost of the unit would be prohibitive and could not be made available to the hospital industry at a low cost. In accordance with FCC Bulletin OCE 11, Part 15, Paragraph 15.63 "The radiation from all radio receivers that operate (tune) in the range 30 to 890 Mc/s, including frequency modulation broadcast receivers and television broadcast receivers, manufactured after the effective date specified in 15.72 shall not exceed the following field strength limits at a distance of 100 feet or more from the receiver:

Frequency of radiation (Mc/s)

Field Strength (uv/m)

Over 25 up to and including 70 . . 32

Cardiac Electronics' transmitter will not interfere with any other users of this band, any more than any available commercial receiver that tunes over this band, since its maximum radiation is less than the maximum allowable radiation that may be generated by receivers certified in this range. Based on the fact that FCC regulations allow up to 32 microvolts/meter (uv/m) receiver radiation at 100 feet, we would like authority to operate our transmitter which measures less than 10 microvolts/meter at 50 feet.

Enclosed are photographs and specifications relating to our transmitter. Also enclosed are copies of actual ECG chart recordings made during a recent test at Kenmore Mercy Hospital, Kenmore, New York, of a 62 year old male cardiac patient wearing our transmitter.

Since there presently is no other miniaturized, inexpensive, light-weight, disposable, short-range (10 foot span) wireless ECG transmitting unit available and, in view of the significant advantages it offers our nations' health industry, we ask that your office grant Cardiac Electronics, Inc. a waiver for the license-free operation of its ECG wireless electrode transmitter in the 40-42 megacycle frequency band.

Very truly yours,

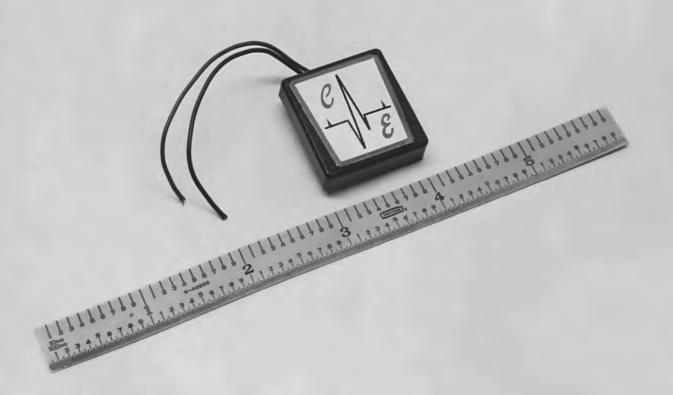
CARDIAC ELECTRONICS, INC.

George Tatoian President

GT:gso Encs. cc; Mr. Dean Burch, Chairman Federal Communications Commission Mr. Elliot L. Richardson, Secretary Department of Health, Education and Welfare Roger O. Egeberg, M.D., Assistant Secretary Department of Health, Education and Welfare Senator Jacob K. Javits Senator James Buckley Representative Jack Kemp Representative Henry P. Smith III Representative Thaddeus J. Dulski Representative Paul G. Rogers Mr. Herman Garlan, Chief, Radio Frequency Devices Branch Federal Communications Commission Administrator of Veterans Affairs



CARDIAC ELECTRONICS, INC. 4915 RANSOM ROAD CLARENCE, N.Y. 14031



CARDIAC ELECTRONICS, INC. 4915 RANSOM ROAD CLARENCE, N.Y. 14031 Cardiac Electronics, Inc.



4915 RANSOM ROAD CLARENCE, NEW YORK 14031 AREA CODE 716-759-6167 or 759-8304

PRELIMINARY SPECIFICATIONS

DISPOSABLE TRANSMITTER SYSTEM

Size $1'' \times 1'' \times \frac{1}{4}''$

Freq. Response 1 - 250 Hz

Input Range ± 5 mV

Input Imped. 5 meg ohms

Range 10 ft. min.

Life 7 days min.

Signal/noise > 40:1

Modulation FM

Antenna None

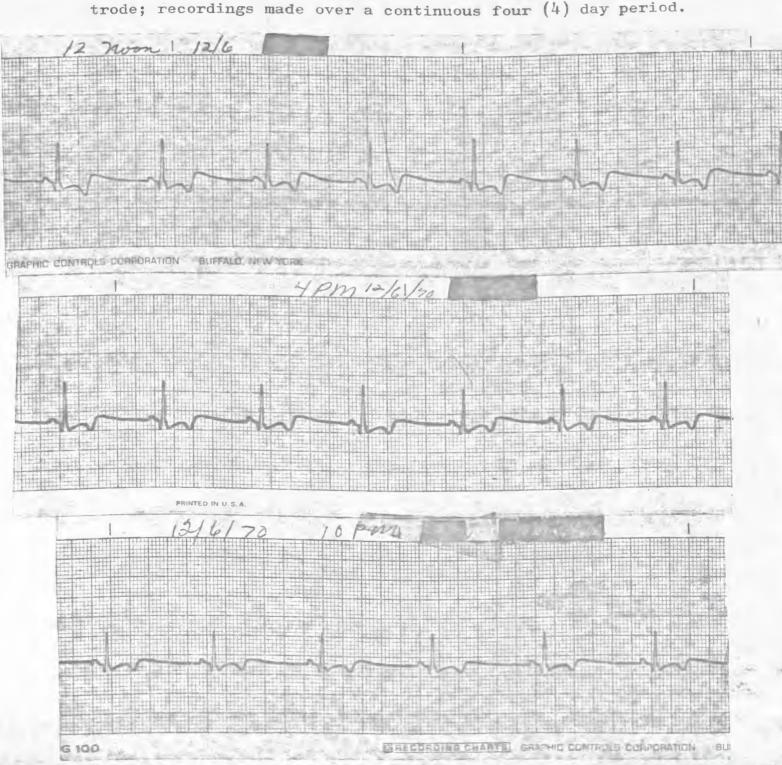
Adjustments None

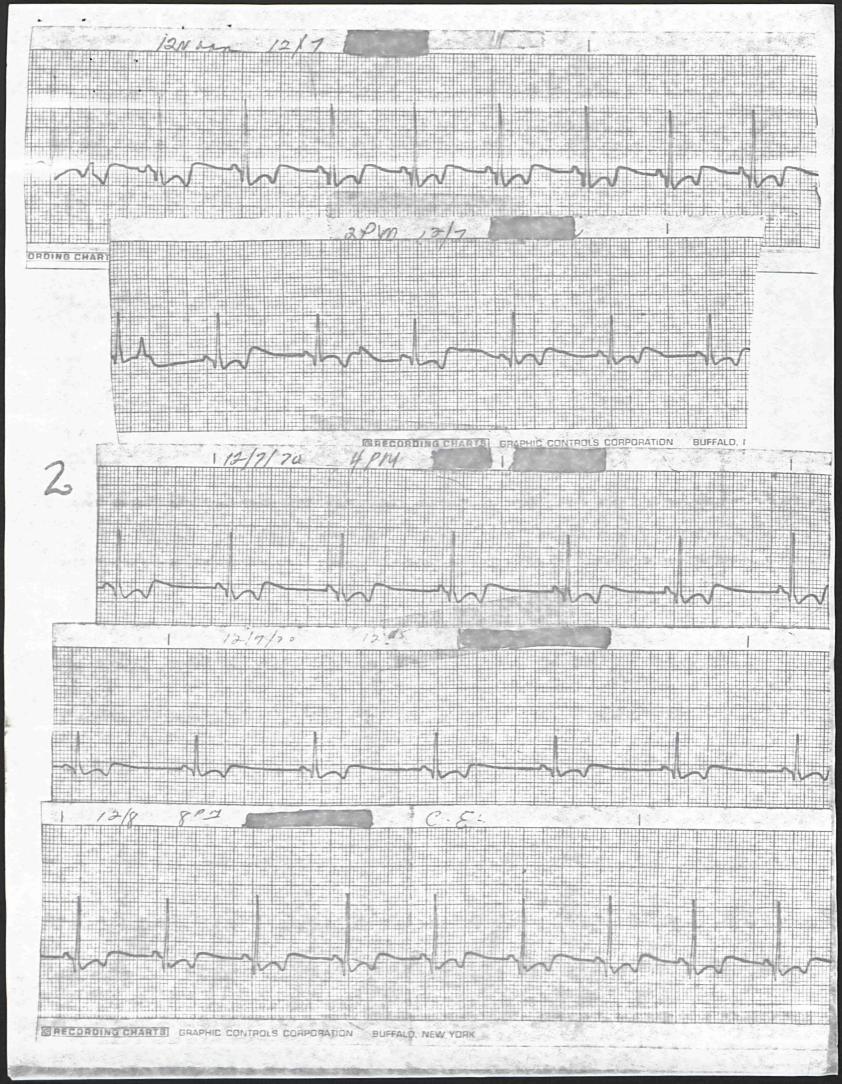
Temp. Range 10°C - 40°C

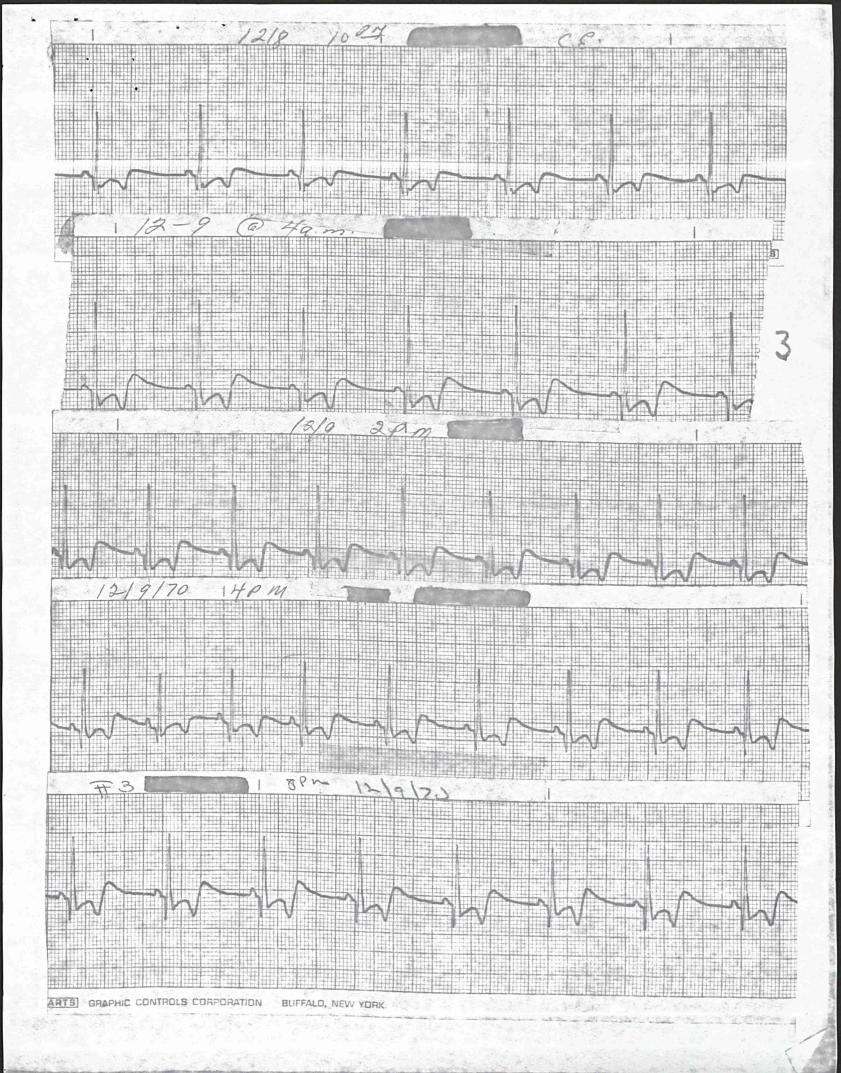
Cardiac Electronics, Inc.

4915 RANSOM ROAD CLARENCE, NEW YORK 14031 AREA CODE 716-759-6167 or 759-8304

Sample EKG chart recordings of a C.C.U. patient wearing Cardiac Electronics' disposable transmitter wireless electrode; recordings made over a continuous four (4) day period.







VOL. II NO. 24

Hospital Hazards More Patients Hurt As Electronic Devices Come Into Greater Use

Improperly Trained Workers, Faulty Equipment Blamed; New Federal Rules Urged

Queasy About Defibrillators

By JOHN E. COONEY

Staff Reporter of THE WALL STREET JOURNAL

When the Melvin Weisbergs took their three-year-old daughter, Elizabeth, to a Miami hospital last year, she was to undergo routine surgery for a middle-ear infection. Several hours later, however, the Weisbergs learned that their only child had almost died on the operating table.

The next-tragedy had nothing to do with any undersean surgical complications. Rather, the little girl had received a severe shock when a common piece of operating-room equipment, a heart monitor, short-circuited.

Each year such faulty or improperly operated electrical devices are idling several hundred patients and injuring thousands of others. The rising number of such accidents is bringing cries of alarm from consumer, advocates and proposals for regulation from the Federal Government.

"We're making medical-electronics safety our No. 1 cause this year." says Michael Miller, director of the Association for the Advancement of Medical Instrumentation, a nonprofit group of bosuital and industry personnel seeking safer patient care.

A Bizarre Accident

Underlying the concern is the rapidly expanding use of electronic equipment in hospital procedures. Sales of X-ray and other equipment are expected to reach \$560 million this year, up sharply from the \$382 million of 1968. And the growth is just beginning. Some analysts estimate that by 1980 medical electronics will be a \$1.5 billion-a-year market. Already, the field has attracted more than 200 manufacturers, including such major companies as General Electric and Westinghouse.

The mushrooming use of electronics is unquestionably a boon to the medical profession and is responsible for saving many lives. But problems have developed because some of the equipment, turned out in a hurry, is faulty and because many hospitals hire untrained people to use the devices.

Some of the accidents are bizarre. A patient at a Midwestern hospital was crushed to death recently when a radiation sherary machine that was descending toward his cheef failed to shut off.

ber of doctors and nurses have been surjously injured by definitiators, which are used to administer shock heatments to patients suffering cardiac arrests, "I'm still queasy around a defibrillator," says Dr. Richard Soricelli, who was nearly electrocuted by one while interning at Philadelphia's Jefferson Hospital.

Such accidents are nothing new, of course. In 1929 Dr. Roger O. Egeberg, now Assistant Health, Education and Welfare Secretary, was injured when he was an intern at Chicago's Wesley Memorial Hospital. "I was holding a catheter in a patient's bladder while another intern took an X-ray of it," he remembers. "Something went wrong. I was shocked and went into convulsions." The patient was only slightly injured.

Potential for Electrocution Rises

The increase in the use of catheters—tubes implanted in the body, usually to drain fluid—generally multiplies the potential for electrocution because the instruments can be conductors of electricity. Doctors say that when a shock has an internal route to the heart, it takes only 1/1,000th as much electricity to kill a person as when the shock is transmitted through the surface of the skin.

Although authorities agree that at least several hundred electronically related deaths occur in hospitals each year, figures are difficult to document. After checking scores of articles published between 1963 and 1963, the Food and Drug Administration tallied 678 deaths and more than 10,000 injuries from medical equipment during the period.

But Dr. Carl W. Walter, professor of surgery at Harvard Medical School, says there are 1,200 deaths annually from hospital electrocutions alone. He is also hospital committee chairman of the National Fire Protection Association, which drafts safety codes for electrical devices. The 1,200 figure, however, is much in dispute by Dr. Walter's colleagues.

Whatever the correct figure, Dr. Joel J. Nobel, circular of the Emergency Care Research Institute in Philadelphia, says nearly half the accidents are caused by "electronic boobs"—people who con't know how to operate the sophisticated component or fail to recognize their potential hazards. The institute is a non-profit organization that does biomedical research.

A Problem of Wiring

One common problem is that many hospital operating rooms don't have outlets that will accept the grounded three-pronged plugs used on most electronic devices. Rather than install new outlets, hospital personnel use converter plugs that have a ground wire. But often they snip off this wire, thus making previously safe equipment hazardous.

On the other hand, defective equipment is no rarity. Seymour Ben-Zvi, director of scientific and medical instrumentation at Downstate Medical Center in Brooklyn, N.Y., says 30% to 40% of the devices his staff inspects are hazardous to the patient or the operator. Dr. Nobel, who cites similar figures, claims manufacturers tend to forget where their equipment will be used and fail to take into account the possibility that a short-circuit in an operating room can result in a patient's death.

"There must be a new technology developed to meet hospital needs," Dr. Nobel says, "Manufacturers, of course, all make noises that they're doing this. But it costs money, so unfortunately the profit motive often gets in the way." Handacturers, of course, dispute

Past talking electronics salesmen are also blamed for part of the problem. "Doctors sometimes don't know what the hell they want and can be talked into anything by fly-by-night salesmen," says Murray Altman, director of purchasing at Chicago's Michael Reese Hospital.

In defense of the industry, one Federal Government official says that on the whole the performance of hospital electronic devices is "beautiful." "Sure, problems exist," says Lester Goodman, head of the biomedical engineering and instrumentation division of the Government's National Institutes of Health. "But millions of operations are performed every year, and very few accidents happen comparatively."

An official of Hewlett-Packard, which manufactures more than 100 medical devices, says, the industry is constantly redesigning equipment to make sure potential hazards are removed. The equipment is thoroughly inspected before it is considered fit for use, adds the official, John Post, manager of marketing support for the company. He insists that most accidents are the result of the ignorance of equipment operators.

Manufacturers fear that overemphasis on product safety could hamper the development of new life-saving devices. "We don't want this hazard thing to turn into another thalidomide scare," says Hewlett-Packard's Mr. Post. The company puts out a handbook for doctors and nurses on the safe use of electronic equipment in an effort to eliminate some hazards.

Federal controls in the field were called for by both Presidents Kernedy and Johnson, but little action resulted until President Nixon included a demand for such legislation in his consumer message in the fall of 1969. A task force set up within the Health, Education and Welfare Department recommended in September that the Government be granted new authority to regulate marketing of medical devices.

The HEW panel considered devices ranging from artificial hearts to crutches, as well as electronic equipment. It urged that the devices be placed in three categories: Those that are unquestionably safe to market, such as crutches; those that potentially could be hazardous and would require Government inspection prior to marketing; and a vast middle ground where safety standards could be drafted by manufacturers but would need Federal approval.

Hospital Hazards:
More Patients
Are Injured by
Electronic Gear

HOUSE OF REPRESENTATIVES, U.S.

WASHINGTON, D.C. 20515

PUBLIC DOCUMENT

OFFICIAL BUSINESS

Honey V. Smith ist. M.C.

House of Representatives, U.S.
WASHINGTON, D.C. 20518
PUBLIC DOCUMENT
OFFICIAL BUSINESS

Honey P. Smith 111
APR 1971 M.C

The Honorable Richard M. Nixon President of the United States The White House Washington, D.C. 20500

Control Con March 10, 1971 Honorable Dean Burch Chairman Federal Communications Commission Washington, D. C. 20554 Dear Mr. Chairman: The need for policy and administrative actions as regards communications in connection with the "Emergency Medical Service" has been called to my attention. Statistics have been quoted such as "700 lives a day could be saved" and "approximately a quarter of the 56,000 deaths due to auto accidents each year could be prevented if prompt medical attention were available." While not undertaking to verify the exactness of these claims, in replying to requests for assistance I have stated that the Administration considers the matter to be urgent and, as a matter of policy, supports the early application of communications technology for emergency medical and public safety purposes. Part of the problem, as I understand it, is the lack of agreement on the part of both users and manufacturers as to the most effective means of operating the foregoing service. I understand further that, for this reason, the Commission has authorized only a limited number of experimental licenses to permit a study of the feasibility of mobile medical telemetry and data handling systems under actual operating conditions. Due to the pressing need, and the foreseen potential requirements for Government operations of a similar nature (e.g., Veterans Administration, military, and Public Health Service). I am requesting the IRAC to look into the matter

with a view to a possible joint Government/non-Government allocation provision.

Your views on this matter would be appreciated.

Sincerely,

Clay T. Whitehead

LRRaish/dtb/mef/3/5/71 /cc: FMD/Reading/OTP/OTP Daily Reading File

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF TELECOMMUNICATIONS POLICY
WASHINGTON, C.C. 20504
March 10, 1971

DIRECTOR

Mr. John M. Waters
Executive Assistant and
Chief Operating Officer
Office of the Mayor
City Hall - 220 East Bay Street
Jacksonville, Florida 32202

Dear Mr. Waters:

The President has asked me to reply to your letter of February 23, 1971, which added your support to Dr. Nagel's letter of February 18, 1971 on Emergency Care Systems.

In my reply to Dr. Nagel I confirmed that this Administration, as a matter of policy. strongly supports the early accommodation of a medical communications service that can save so many lives. Your views, being based on your experience as a high official in a fine large city, are of particular value in assessing means for applying communications technology to meet emergency medical service requirements.

While there is no question that the actual technology is available, there appears to be, unfortunately, a lack of agreement on the part of both users and equipment manufacturers as to the most effective means for applying it on a large scale to the emergency medical service. Pending resolution of some of the key issues, primarily involving the radio frequency bands to be used and the compatibility of telemetry and voice signals in the same service, the Federal Communications Commission (FCC), as the responsible regulatory agency, has granted only a limited number of experimental and developmental licenses. These were granted to study the feasibility of mobile medical telemetering and data handling under actual operating conditions.

As a result of the correspondence from you and Dr. Nagel, I am this day writing to the Chairman of the FCC, advising him that the Administration considers this matter to be urgent and supports the early application of communications technology to emergency medical uses. I am also requesting the Interdepartment Radio Advisory Committee, which advises this Office concerning the use and management of the Government portion of the electromagnetic spectrum, to consider a joint Government/non-government allocation provision.

I appreciate the interest in this important matter demonstrated by such busy professional people as yourself and Dr. Nagel. You may be sure that your expression of concern has been heard and is being acted upon. I hope you will not hesitate to write if we can be of any further assistance.

Sincerely,

Člay T. Whitehead

Route Slip

2 MAR 1971

Clay T. Whitchcod
George F. Mansur
A. Scalia
Wilfrid Dean
Steve Doyle
Walt Hinchman
Charles Joyce
William Lyons
Amos Crafta

Eva Daughtrey
Timmie White
Judy Morton

REMARKS

refecommunications Policy

THE WHITE HOUSE OFFICE

REFERRAL

To: Honorable Clay T. Whitehead Date:
Director
Office of Telecommunications Policy

Date: February 26, 1971

ACTION R	EQUESTED
Draft reply for: President's signature. Undersigned's signature. Memorandum for use as enclosure to reply. Direct reply. Furnish information copy. X Suitable acknowledgment or other appropriate handling. Furnish copy of reply, if any. For your information.	Prompt action is essential. If more than 48 hours' delay is encountered, please telephone the undersigned immediately, Code 1450. Basic correspondence should be returned when draft reply, memorandum, or comment is requested.
For comment. REMARKS: The letter from Dr. Eugene	L. Nagel was forwarded
to you on February 24th. Description:	
X_ Letter: Telegram: Other: To: The President From: John M. Waters, Executive Assista	Say Street, Jacksonville, Florida r. Nagel re communication problem in who suffer accidents; have obtained radi

By direction of the President:

Noble M. Melencamp Staff Assistant to the President

rah

THE WHITE HOUSE OFFICE

REFERRAL

Honorable Clay T. Whitehead Date: February 26, 1971 Director Office of Telecommunications Policy ACTION REQUESTED ____ Draft reply for: President's signature. _____Undersigned's signature. NOTE Memorandum for use as enclosure to reply. Prompt action is essential. If more than 43 hours' delay is encountered, _ Direct reply. please telephone the undersigned immediately, _ Furnish information copy. Code 1450. X Suitable acknowledgment or other appropriate handling. Basic correspondence should be returned when ___ Furnish copy of reply, if any. draft reply, memorandum, or comment is requested. For your information. For comment. REMARKS: The letter from Dr. Eugene L. Nagel was forwarded to you on February 24th. Description: X Letter: Telegram; Other: To: The President From: John M. Waters, Executive Assistant and Chief Operating Officer, Office of the Mayor, 220 E. Bay Street, Jacksonville, Florida Subject: Supports letter to President from Dr. Nagel re communication problem in rendering emergency medical care to citizens who suffer accidents; have obtained radio

By direction of the President:

Noble M. Melencamp Staff Assistant to the President

frequencies and have shown dramatic results; asks assistance expedite similar action in

OFFICE OF THE MAYOR
John M. Waters
Executive Assistant and

Chief Operating Officer

February 23, 1971



Honorable Richard M. Nixon The White House Washington, D. C.

Dear President Nixon:

I would like to add my strongest possible support to the letter to you from Eugene L. Nagel, M.D., dated February 18, 1971, concerning the communication problem in rendering emergency medical care to our citizens who suffer accident and acute illnesses outside the hospital.

I cannot emphasize too strongly the urgency of this problem which every single citizen of this country will face during his lifetime. Tens of thousands of our citizens are dying needlessly of cardiac arrest and of fatal arrythmia when they are in fact salvable. In Jacksonville, Florida, we have been fortunate in obtaining the necessary radio frequencies and have shown dramatic results in saving our citizens who become acutely ill or suffer accidents. A number of leading physicians have termed Jacksonville to be the safest place in the country in which to have a heart attack.

Being a top official in a large city I am acutely and daily aware of the many pressing priorities. However, I can think of no priority higher than that of saving human life. Every day that we procrastinate in augmenting this system nationally will cost us another 700 victims, many in the prime of life who are our most productive citizens and heads of families. We have the know-how to save many of these today. Our failure to proceed in an expeditious manner is resulting in thousands of our citizens dying outside the hospital without any medical relief or aid.

As a member of the Committee on Emergency Medical Services of the National Academy of Science/National Research Council, I wish to convey to you our frustration at what seems to be excessive red-tape in making available to the medical profession and the governmental agencies of our country the lifesaving tools that are already available and awaiting implementation. I am willing to volunteer my services at any time, and I speak for many other busy professionals,



Honorable Richard M. Nixon -2- February 23, 1971

in assisting your office in any way possible to expedite this matter.

Yours very truly,

Executive Assistant and Chief Operating Officer

:dt

cc: Eugene L. Nagel, M. D. Senator Edward Gurney

OFFICE OF THE PRESIDENT
OFFICE OF TELECOMMUNICATIONS POLICY
WASHINGTON, D.C. 20504

DIRECTOR

extra con

March 10, 1971

Eugene L. Nagel, M.D. Associate Professor University of Miami Miami, Florida 33152

Dear Dr. Nagel:

The President has asked me to reply to your letter of February 18, 1971, on Emergency Care Systems.

The application of communications technology to meet emergency medical and public safety requirements, articulated so well in your letter, is strongly supported by this Administration as a matter of policy.

While there is no question that the technology is available to conduct mobile telemetry, there is, apparently and unfortunately, a lack of agreement on the part of both users and equipment manufacturers as to the most effective means for applying the technology on a large scale to the medical service. For this reason, the Federal Communications Commission, as the responsible regulatory agency, has granted only a limited number of experimental and developmental licenses to study the feasibility of mobile medical telemetering and data handling under actual operating conditions.

The complications appear to center around the radio frequency bands to be used and problems that may be caused by mixing telemetry and voice signals in the land mobile frequency bands. There are indications that separate dedicated channels may be required for the telemetry function to

assure its interference-tree operation during an actual emergency. Because of such questions, the FCC has thus far discouraged other than experimental operations in the emergency medical service.

Unquestionably emergency medical communications is a type of service that must be accommodated. As a direct result of your letter, I am this day writing to the Chairman of the FCC, advising him that the Administration considers this matter to be urgent and supports the early application of communications technology to emergency medical uses. I am also requesting the Interdepartment Radio Advisory Committee, which advises this Office concerning the use and management of the Government portion of the electromagnetic spectrum, to consider a joint Government/non-Government allocation provision.

Thank you for bringing this important matter to our attention and if I can assist further in this or any other matter, please do not hesitate to ask.

Sincerely,

Clay T. Whitehead

Office of Telecommunications Policy Route Slip

2 6 FEB 1971		To
601	Clay T. Whitehead	
	Goorge F. Mansur	
	A. Scalia	
	Wilfrid Dean .	
	Steve Doyle	1
	Walt Hinchman	
	Charles Joyce	
	William Lyons	

	Eva Daughtrey	
	Timmie White	
	Judy Morton	

REMARKS

Nino
Tuthis shop, the deepest well-spring of information on this subject is Bob Raish. I recommend consulting when prior to any answer drafting.

Stere.

THE WHITE HOUSE OFFICE

REFERRAL

Honorable Clay T. Whitehead Director Office of Telecommunications Policy

February 24, 1971

	ACTION R	EQUESTED
=	Draft reply for: President's signature. Undersigned's signature.	NOTE
	Memorandum for use as enclosure to reply.	Prompt action is essential.
=	Direct reply. Furnish information copy.	If more than 48 hours' delay is encountered, please telephone the undersigned immediately, Code 1450.
_ X	Suitable acknowledgment or other appropriate handling. Furnish copy of reply, if any. For your information.	Basic correspondence should be returned when draft reply, memorandum, or comment is requested.
	For comment.	
MARKS:		

RE

Description:

X Letter: ____ Telegram; Other:

The President To:

Eugene L. Nagel, M.D., Associate Professor, University of Miami, Fla. From:

Date:

Re Emergency Care Systems -- Federal Communications Commission -telemetry systems for transmitting electrocardiogram by voice radio channel essential and the key to perpetuation of present techniques.

By direction of the President:

Noble M. Melencamp Staff Assistant to the President

UNIVERSITY OF MIAMI MIAMI, FLORIDA 33152

Mailing Address:
DEPARTMENT OF ANESTHESIOLOGY
SCHOOL OF MEDICINE
P. O. BOX 875, BISCAYNE ANNEX

Location: CENTRAL BUILDING JACKSON MEMORIAL HOSPITAL

February 18, 1971

Honorable Richard M. Nixon The White House Washington, D.C.

Subject: Emergency Care Systems - Federal Communications Commission

Dear President Nixon:

Several years ago the National Highway Safety Bureau began a sustained drive to upgrade emergency care in the United States. A popular slogan at that time was that in Viet Nam care on the battlefield for the wounded GI was immeasurably better than care for the victim of a highway traffic accident in the United States. that time, millions of dollars have been spent for investigations in the efficacy of new types of ambulances, special training for ambulance attendants, involvement of rotary wing aircraft in these systems, and the use of telemetry-communications systems to connect doctors in the hospital to rescue workers in the field. latter activity has occupied my attention as well as that of similar workers in New York (Dr. William Grace, St. Vincent's Hospital), Seattle (Dr. Leonard Cobb, King's Hospital), Los Angeles, Oklahoma City, Indianapolis, Jacksonville, etc. The concept is a simple one, namely, that more physicians are needed in emergency rooms and in special care areas of hospitals, that it will be years before the demand for these specially trained physicians experienced in acute or emergency medicine is met in sufficient supply, and ' that there are not nearly enough physicians to even consider having them outside of the hospital in existing emergency care systems.

The alternative to physicians riding ambulances throughout the United States is a new type of emergency medical technician who is thoroughly trained in special lifesaving techniques such as defibrillation (for heart attacks), intravenous fluid therapy (for trauma and shock), giving of drugs (such as adrenaline for the

stopped heart), and intubation techniques (so that patients can be breathed and protected from vomiting and aspiration during transportation). . Pilot programs in training these new types of paramedics are under way in many parts of the country, including our own. The key to these programs is a means of legally permitting the introduction of these new treatment modalities into the emergency care procedures. This critical key has been the connection (by radiotelemetry communication channels) of the in-hospital doctor with the field paramedic. These programs have been under way in Miami and elsewhere around the country for several years and have proven that they can save lives by a factor of ten to twenty times that previously known before the introduction of these advanced treatment techniques. We, in Miami, have been in operation since 1969, and we find that more than 10% of persons who have arrested hearts can be saved to live useful lives for years thereafter. Dr. Leonard Cobb in Seattle is experiencing an even larger salvage rate, approaching 20%. When you consider that there are potentially 250,000 victims of this one manifestation of heart disease who die outside the hospital each year, you can see the potential inherent in these systems to save life.

Why, then, am I writing to you? It is because the telemetry systems for transmitting the electrocardiogram by voice radio channel are essential and are the key to the perpetuation of these techniques. The Federal Communications Commission has given temporary license (one year only) to certain cities around the United States in order to study "the feasibility of the system". There are now many cities wishing to utilize available frequencies or requesting new frequencies in order to utilize these techniques. The FCC has stated unequivocally that no new licensing will be carried out for transmission of electrocardiograms in the United States anywhere. They have stated further that the system has proven to be feasible, but that studies will have to be continued and certain procedures written for the establishment of these techniques on a permanent basis.

My question to you is, have there been any problems or difficulties experienced in the few programs that have been licensed thus far? If not, why then cannot other cities around the country start their own systems and begin saving lives now, rather than in the distant future? The issuing of temporary licenses now could be done with

the proviso that changes will be made to conform with whatever regulations may be published in the future. If problems are found, these can be handled in the same manner as with any other technical communication problem. The point is that hundreds and even thousands of lives are being wasted while this agency literally studies the problem to death. I ask your offices to please investigate this matter and to discuss the problem with officials such as Dr. Theodore Cooper (National Institutes of Health) or Dr. Eliot Corday (American College of Cardiology), or other knowledgeable experts in this field. I must be honest and admit that the most frustrating part of this problem is that if the broadcast industry with its hundreds of lawyers and consulting engineers were to approach this same agency (Federal Communications Commission), then the action taken by that agency would be measured in days, not in years. I am hopeful that through your offices the matter can at least be investigated for its merit or lack thereof, and appropriate action taken.

Yours very truly,

Eugene L. Nagel, M.D. Associate Professor

Cc: Dr. Theodore Cooper, National Institutes of Health
Dr. Eliot Corday, American College of Cardiology
Senator Claude Pepper
Senator Edward Gurney
Captain William Parker, National Highway Safe'ty Bureau
Dr. Fred Vogt, Professor Bio-Medical Engineering, University of Texas
Captain John Waters, Office of the Mayor, Jacksonville, Florida
Dr. Leonard Cobb, Director, Division of Cardiology, University
of Washington School of Medicine, Seattle, Wash.