

GRIEVANCE

On April 5, 2006, R46 was dispatched to a medical call. During the call, the LifePak 12 encountered problems. This was then relayed to the Fire Medic Lieutenant. After the call, R46 crew consisting of Fire Medic Chris Vaughan and Fire Fighter Jeff Wallace, were ordered to report to Fire Station 49 by Chief of EMS J.P. Medani. The crew swapped the monitor, batteries and charger as was told them by the Fire Medic Lieutenant. The crew was then told that Chief Medani wanted to question them. This took place somewhere between 0100-0200 at Fire Station 49, where Chief Medani resides at least four times per week. Fire Medic Vaughan and Fire Fighter Wallace were separated and interrogated without Union or legal representation. After illegal interrogation took place, the crew returned to Station 46 to restock their vehicle and was questioned by a police detective, again, without Union or legal representation. The crew finally went to bed around 0500.

The 2nd shift following the incident, Fire Medic Vaughan and Fire Fighter Wallace were informed that they would once again be subjected to an investigation, this time at Fire Station 45. This took place after normal business hours, again illegally and in violation of the Agreement. When the Union representative complained that this was in violation of the Firefighter Bill of Rights, Chief Medani ignored that and continued with the investigation. Afterwards, the request was made for a copy of the tape and transcript, but Chief Medani refused. Again, this is a violation of the Firefighter Bill of Rights.

Fire Medic Vaughan then had several shifts off on vacation and upon returning home, noted that there were several phone messages from Chief Jamie Geer. Chief Geer stated on the messages that Fire Medic Vaughan was being investigated further and that his paramedic license was suspended. When Fire Medic Vaughan returned to work on April 28th, he was told to report to Chief Weiss for a 40-hour week assignment. Fire Medic Vaughan asked Chief Weiss for copies of the paperwork concerning this, but was told he didn't know where it was. Several calls to Chief Medani were placed for the paperwork, but the calls were never returned. Fire Medic Vaughan then called Chief Howell, who told him that nobody knew where the paperwork was. The Fire Medic Lieutenant was then contacted and told Fire Medic Vaughan that Chiefs Geer and Medani were out of town and only they knew where the paperwork was. The following Friday, Fire Medic Vaughan talked to Chief Medani at the mechanics' shop and then was driven to the post office to retrieve the paperwork.

Subsequent conversations with Chief Medani took place and Fire Medic Vaughan explained that the stress of that call, as well as the time of morning, might have had a bearing on the EMS report. Chief Medani seemed relieved by this. One sticking point was the alleged destruction of the LifePak 12 rhythm tape. The Fire Medic Lieutenant has told the paramedics not to place the whole code summary on the report, as it will not fit in the file. As has been past practice, only the portions showing rhythm changes due to, but not limited to, medications that were administered, changes for other reasons, etc, were attached to the report. At no time did Fire Medic Vaughan attempt to falsify the

report by attaching only portions of the tape to the report. This was backed up by Fire Lieutenant Tellone, a former Fire Rescue Lieutenant.

As far as the problems with the LifePak 12 or its batteries, this was noted and relayed through the proper channels at shift change. One problem battery was only four days old, noted by the off-going shift, which was removed from Fire Station 46 by Chief Medani and the Fire Medic Lieutenant. LifePak 12 and its batteries have been having problems nationwide, as noted in the supporting evidence of this grievance.

All of this was unnecessary. Fire Medic Vaughan is an excellent paramedic and has been decorated and acknowledged many times over. His career is exemplary as he typically receives Outstanding and Highly Successful marks on his yearly evaluation. Fire Medic Vaughan has served the Clearwater Fire Department faithfully for over twenty-three years and has never been disciplined. Had the EMS report followed the normal chain-of-command, the Fire Medic Lieutenant would have noted any errors or irregularities on the report and returned it to Fire Medic Vaughan for any needed correction and/or gone over the report with him. However, this was not done and things have progressed way out of proportion and without merit. It is felt that this was yet another seek-and-destroy ploy by the fire chiefs involved because of prior grievances filed by Fire Medic Vaughan, as well as his membership in IAFF Local 1158, Inc. Fire Medic Vaughan is also a senior gentleman, nearing fifty years old, and has been denied the promotional process and promotion itself by chief Geers' statement that he wants lieutenants who would be here for quite awhile. This resulted in a grievance filed by Fire Medic Vaughan and may also have been the impetus to retaliate against him by trumping up these charges. Fire Medic Vaughan is also grandfathered in as one who may give up his Paramedic and EMT licenses and demote to a regular fire fighter. This has been a past practice and even recognized by the chief in subsequent testimony. The chief denied Fire Medic Vaughan this right as well. Fire Medic Vaughan was terminated without just cause and due process.

Therefore, this Grievance is being filed for the following violations of the AGREEMENT between CITY OF CLEARWATER and INTERNATIONAL ASSOCIATION OF FIRE FIGHTERS, AFL-CIO Local 1158:

1. Preamble;
2. Article 1, Section 1;
3. Article 1; Section 3;
4. Article 2, Section 1;
5. Article 3. Section 1;
6. Article 3, Section 2;
7. Article 3, Section 4;
8. Article 5;
9. Article 7, Section 1;
10. Article 7, Section 2;
11. Article 7, Section 3;
12. Article 7, Section 8;

13. Article 7, Section 13;
14. Article 7 Section 15;
15. Article 7, Section 17;
16. Article 8, Section 3;
17. Article 11;
18. Article 15, Section 1; and
19. Article 15, Section 2.

As to the first violation:

The City has maintained that they do not violate this section of the AGREEMENT and work to maintain harmonious relations with the Union; however, breaking a signed agreement with Local 1158 is not dealing in good faith practices. The number of grievances filed to date and the manner and reasons for this grievance alone supports this stance. Fire Medic Vaughan had asked to remain on a 56-hour workweek, as has been the past practice, so that he could tend to his very sick son and the amount of much needed therapy to keep him alive. This was denied by the chief. Chief Geer also terminated Fire Medic Vaughan in a most unusual and cold-hearted maneuver, which was by leaving a message on Fire Medic Vaughan's answering service. This callousness further supports this violation of the Preamble.

As to the second violation:

The City never addressed the Union nor recognized the bargaining representative in this matter. Typically in matters such as this, it is commonplace for administrators to meet with Union representatives to discuss situations such as this, however, the administration of this city chose to conduct meetings clandestinely amongst themselves and then blindsided the Union membership.

As to the third violation:

The AGREEMENT contains and spells out how wages, benefits, etc. are to be handled. Multiple violations have occurred and are clearly spelled out. The chiefs and administrators have horribly skewed the entire processes set forth in the AGREEMENT.

As to the fourth violation:

Chief Medani, by conducting the first interrogation of Fire Medic Vaughan and Fire Fighter Wallace, failed the process and the right to Union representatives. The extreme late hour prohibited the dealing with said Union representatives.

As to the fifth violation:

This Article contains the agreed to managements rights section. While management has the right to terminate employees, they must do it for just cause. The events and violations

committed by city officials does not support termination for just cause or any other reason whatsoever.

As to the sixth violation:

As there were no civil emergency conditions existing or any other catastrophic disorders, the AGREEMENT should have been adhered to in its entirety. Had the chiefs and administrators done so, the need for this grievance would not be necessary and a very valuable employee, Fire Medic Vaughan, would not have been terminated.

As to the seventh violation:

Fire Medic Vaughan is a senior employee approaching fifty years old. He is a member in good standing of IAFF Local 1158, Inc., and has filed several grievances during the current administrations' tenure. It is felt that these are some of the reasons why Fire Medic Vaughan has been terminated in a most unjust and with prejudiced manner.

As to the eighth violation:

The chiefs and the administrators of the City have never contacted the Union to sit down as written in the AGREEMENT to invoke the Labor/Management committee. The Union has attempted this, but is always denied by the City. Had the City been cooperative, this termination, grievance, etc. may have been unnecessary.

As to the ninth violation:

Fire Medic Vaughan is a 56-hour week employee.

Work Schedule

A. Hours and Days of Work: Shifts shall start at 8:00 A.M. each workday and end at 8:00 A.M. the following morning. Total: 24 hours. Coverage shall consist of three shifts: "A", "B", and "C", which will work in the following rotation (see sample monthly work schedule below):

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1 work	2 off	3 work	4 off	5 work	6 off	7 off
8 off	9 off	10 work	11 off	12 work	13 off	14 work
15 off	16 off	17 off	18 off	19 work	20 off	21 work
22 off	23 work	24 off	25 off	26 off	27 off	28 work
29 off	30 work, etc.					

There is nothing in the AGREEMENT that states that a fire fighter within the bargaining unit will be mandated to convert to a 40-hour workweek. Fire Medic Vaughan was placed on such a work schedule even though others before him had been placed with the District Fire Chiefs (before the position was abolished) as well as the Assistant Chiefs of

Suppression. Placing Fire Medic Vaughan on the 40-hour workweek appears to be nothing more than retaliation and possible double jeopardy form of punishment.

As to the tenth violation:

Fire Medic Vaughan did not ask to be placed on a 40-hour workweek. By being forced to do so, he was not eligible to receive FLSA in accordance with Article 7, Section 8 as a 56-hour workweek employee.

As to the eleventh violation:

Fire Medic Vaughan was placed on a 40-hour workweek. This maneuver denied him the ability to work overtime in a 56-hour workweek as spelled out in this Article of the AGREEMENT.

As to the twelfth violation:

Fire Medic Vaughan is still certified by the State of Florida as a Fire Fighter, Paramedic and EMT. He is therefore able to work as “slick sleeve fire fighter” as do others within the fire department. There are qualified paramedics within the department that are newly hired that could swap positions with him.

Fire Medic Vaughan, by being placed on a 40-hour workweek, has been denied FLSA as outlined in this Article of the AGREEMENT. His is a 112-hour biweekly setup, whereas Fire Prevention Inspectors are the only listed 40-hour workweek employees. Fire Medic Vaughan was placed in the warehouse performing duties unrelated to fire suppression whatsoever, thus denying the ability to get FLSA or overtime.

As to the thirteenth violation:

Fire Medic Vaughan was removed from his 56-hour workweek and placed on a 40-hour workweek that is not in accordance with the AGREEMENT and does not conform to the mention portion of the AGREEMENT, specifically Article 7, Section 2. Even 40-hour workweek employees shall maintain their work schedule as written in this Article.

As to the fourteenth violation:

Alternatively, Fire Medic Vaughan is allowed to demote to the classification of Fire Fighter. This Article also provides, in part, that if the City should cease operating EMS services, those in the Fire Medic position shall continue to be employed by the City. Fire Medic Vaughan is qualified to demote to Fire Fighter and should be afforded this opportunity. This would be consistent with past practice.

Fire Medic Vaughan has always complied with the standards as set forth by the fire department, as well as the City and the County. This was nothing more than a clerical

error on an EMS report and the failure of a battery on the LifePak 12, which has case histories of being a problem nationwide.

The AGREEMENT states that there is no recourse when superseded by a superior governmental agency. The Office of the Medical Director is no such entity, but rather a private corporation that functions with its own rules and subcontracts from Pinellas County, thus negating the ability to make final ruling on the employees of the fire department and allowing an arbitrator to make a final judgment ruling.

As to the fifteenth violation:

The City has never notified the Union that any change in the work schedule would take place, i.e. putting a 56-hour workweek employee into a 40-hour workweek schedule involuntarily. This was done in an arbitrary and capricious manner. Fire Medic Vaughan was regulated to filling out supply orders and delivering them to the fire stations. Fire Medic Vaughan was unable to enjoy the same rights and working conditions as did his fellow fire Brothers and Sisters.

As to the sixteenth violation:

Since Fire Medic Vaughan was dismissed unjustly and without cause, his sick time payment should stay in effect.

As to the seventeenth violation:

The termination was without just cause and due process. Alternatively the firing was too severe.

The City has never approached the Union to review the effectiveness of the PBMP. The actions of the chiefs and administration of the City are not consistent with sound personnel practices. The PBMP states that all employees are expected to conform to the standards as set forth, yet when it comes to a manager or a rank and file employee, the standards are quite different indeed. The same policy infractions that the City is claiming are just cause for terminating Fire Medic Vaughan have been proven, through recent Unfair Labor Practices and against those very individuals condemning him, having committed the same acts yet have not been punished in a like manner.

Fire Medic Vaughan is charged with multiple infractions and is addressed as follows:

Bullet 1: Fire Medic Vaughan did not violate the standards of his profession. He made a clerical error, coupled with the failure of a LifePak 12 in a highly charged and stressful situation, that had it gone through the normal channel would have been caught and corrected as has been the impressed upon standards.

Bullet 2: Fire Medic Vaughan did not falsify any City record or personnel record. The record in question is a Pinellas County record; it was not falsified.

Bullet 3: Fire Medic Vaughan followed the Standard Operating Procedures concerning patient care in light of a highly charged and very stressful emergency call. The acts in question were of a clerical and mechanical nature and did not warrant the charges brought forth by the City or the County. This is supported below.

Bullet 4: Fire Medic Vaughan is one of the most honest, trustworthy, fair, ethical, courteous, positive and open-minded employees. His numerous awards, acknowledgements, and yearly high marks attest to this. He truly stands on his own merits.

Bullet 5: Fire Medic Vaughan maintains his professionalism at all times. His cooperation with the chiefs and city administrators concerning this situation is also testament to this.

Bullet 6: Fire Medic Vaughan does support and exhibit the organization's expectations and standards as reflected in his yearly evaluations. He has continually been rated with outstanding and highly successful marks year after year.

Bullet 7: Fire Medic Vaughan commits to the highest standards of personal and professional integrity by being himself. Those who work with him know him to be of the highest caliber of individual. His skills, both fire fighting and EMS, are second to none.

Bullet 8: Fire Medic Vaughan has never committed any action that is viewed as negative or offensive by his coworkers, other City employees or the public whatsoever. There is no documentation to support this. He also did not commit any flagrant offense, other than a clerical error that would have been corrected. He did not commit or participate in any activity or action that undermines anything or anyone. He also has not participated in conduct unbecoming a City employee, other than making a clerical error. If this act was so egregious, then why did it take almost two weeks to have him put on clinical suspension? Fire Medic Vaughan also has not endangered the health and welfare of anyone whatsoever. In fact, he should be commended for being able to facilitate the intubation of a person with an alleged crushed trachea in the heat of the moment. He has not committed any negative, illegal, immoral or unethical act, etc. or lied in an attempted to cover up any matter whatsoever.

Bullet 9: Fire Medic Vaughan has not attempted to falsify or inappropriately alter any EMS record. Again, it was a matter of clerical errors that occurred in the heat of stressful EMS call.

The following are violations of Fire Medic Vaughan's Firefighter Bill of Rights and are thus explained:

F.S. 112.81 (6): Fire Medic Vaughan, as well as Fire Fighter Wallace, were ordered to report to Station 49 at approximately 0100-0200hrs. They were then separated and interrogated by Chief Medani. The next meeting was a formal investigation that took

place on April 12, 2006, thus proving that it was an interrogation after the call because it was not pursuant to an informal inquiry.

F.S. 112.82: The interrogation was not conducted pursuant to the terms of this section.

F.S. 112.82 (1): The interrogation did not take place at the investigating officer's assigned facility, which is in Fire Administration, but at the place where Chief Medani was living. Chief Medani lives several counties north of Clearwater and lives at the fire stations at least four nights a week and has been doing so since his hiring. The second meeting, which was a formal investigation, took place after normal business hours. The Union representative complained to Chief Medani, but the chief ignored him and continued with the questioning anyway.

F.S. 112.82 (2): Neither Fire Medic Vaughan nor Fire Fighter Wallace received any written notice of interrogation nor were they informed of beforehand of the names of who would be conducting the interrogation.

F.S. 112.82 (3): The interrogation took place sometime after 0100hrs., which is not a reasonable time of the day. Since no action took place for almost two weeks, this act was in violation of this section.

F.S. 112.82 (4): Neither Fire Medic Vaughan nor Fire Fighter Wallace received any notice of the names, rank, unit, or command of any other persons present who would be participating in the interrogation.

F.S. 112.82 (5): Neither Fire Medic Vaughan nor Fire Fighter Wallace was afforded any rest prior to the interrogation.

F.S. 112.82 (8): The current collective bargaining agreement provides that a Union representative may be present during the interrogation, but due to the extremely early hour of the morning, it was unfeasible to allow this.

As to the eighteenth violation:

The AGREEMENT has never been amended at any time by written mutual consent of the Union or the City. Therefore, the AGREEMENT should stand as written and all of the rights and benefits afforded to all should have been so with Fire Medic Vaughan. This has not been the case as evidenced.

As to the nineteenth violation:

While some of the supporting Article violations have not been acted upon in previous grievances, they are pertinent to this grievance and are not deemed to be waived for non-exercise.

REMEDY

The solutions are very simple. First, stop violating the contract. Reviewing the AGREEMENT from time to time can remedy this. Second, rehire Fire Medic Vaughan and make him whole including but not limited to paying him back pay, holiday pay, medical insurance premiums, medical co-payments, out of pocket medical expenses, seniority, expenses relating to this unjust termination including any legal fees, fuel costs, etc. with interest. Third, a written apology to be posted in all firehouses for this unjust termination. Fourth, hold those accountable for instigating this unjust termination. Fifth, rescind the termination, or in the alternative reduce it.

Respectfully submitted,

Dwayne C. Vaughan, Fire Medic
Clearwater Fire & Rescue
City of Clearwater, Florida
Box 4748
Clearwater, Florida 33758-4748

SUPPORTING EVIDENCE

Below is evidence supporting the claim of mechanical breakdowns of the LifePak 12 along with the websites where the information was gleaned:

1. A Paramedic journal excerpt: I was able to get some other work done although it did point out a significant problem with our LifePak 12 monitors. I should say a problem with the batteries, not the monitors themselves. The monitors have performed very well for us. Last year we replaced all of our batteries when they started to fail and since then the new batteries have been failing at an alarming rate with less than a year in service. Medtronic-Physio Control knows about it and is replacing them at no charge but it is annoying as anything. Right now I have 9 batteries that are unusable, which is making me reallocate batteries from one station to another just to make minimum requirements. I am not happy with this whole thing and, after talking with Biomedical Engineering and my boss, when it comes time to replace the monitors in a year or two I have serious doubts if Medtronic will be getting the contract unless they can do a better job solving this problem. Anyone else having this problem with LP batteries?

http://www.themacmedic.us/archives/2004_10.html

2.



Rechargeable nickel-cadmium battery with 1.2 amp hours capacity.

The FASTPAK battery may be recharged with the Battery Support System 2 or the Battery Support System.

NiCd batteries are best suited for high use, transport environments where the batteries are cycled frequently.

Details

Price: **\$60.00**

Options

Quantity

Add to cart

<http://www.defibcentral.com/FastPak-Battery-p-16213.html>

3. Environmental

IPX4 per IEC 529

Altitude, Operating: To 4545m (15,000 ft)

Altitude, Non-operating: To 5455m (18,000 ft)

Humidity: 5 to 95% non-condensing

Temperature, Operating: 0° to 50°C (32° to 122°F)

Temperature, Storage: -20° to 65°C

(-4° to 150°F) (followed by one hour temperature stabilization in operating temperature range)

http://www.defibcentral.com/aed_spec_pdf_files/LifePak12.pdf

4. FDA letter warns Medtronic of legal and civil penalties over its failure to correct problems and investigate complaints in its defibrillators, including one death - 6/23/05

In a letter made public June 21, 2005, the U.S. Food and Drug Administration warned Medtronic Emergency Response System, a unit of Medtronic, Inc., that its failure to correct manufacturing problems or investigate complaints regarding its LifePak 12 external defibrillators may force the company to face civil and legal penalties. External defibrillators deliver powerful electrical shocks to the chest in order to restore the heart's natural rhythm.

The letter highlighted a problem with the LifePak 12 involving broken or bent pins in therapy cables connected to the device, which is used to treat patients experiencing sudden cardiac arrest. The damaged cables in some of the LifePak 12 defibrillators caused them to deliver inappropriate energy levels while in use, resulting in numerous complaints.

The FDA inspected Medtronic's plant in Redmond, WA, in February and March, 2005, on several occasions after Medtronic recalled about 87,000 units of another implantable defibrillator after the discovery of battery failures. At that time Medtronic promised to remedy manufacturing problems despite citing an "internal analysis" of the LifePak 12, which they claimed revealed no issues with the device. The recently published letter by the FDA states that Medtronic has failed to adequately correct manufacturing problems related to its defibrillators. The company also violated its own internal safety procedures when it did not open an investigation on a defibrillator complaint involving a patient death. The letter stated, "There have been continued complaints of broken pins in the therapy cables used with the new redacted connector" intended to remedy the flaw. The FDA pointed to inadequate inspection procedures as one possible source of the problem.

Earlier this year, Medtronic recalled 1,924 LifePak 500 external defibrillators due to 54 incident reports about a malfunction in the model that caused the units to display a "connect electrodes" message even when the device was properly connected. This flaw prevented patients from being properly defibrillated. The Redmond facility in which they were manufactured was previously owned by Physio-Control, a Washington company that first commercialized the defibrillator. Manufacturing in the facility was shut down for an entire year in 1992 after an FDA inspection raised questions about its quality-control procedures.

Medtronic's cardiac-rhythm management business, which also includes pacemakers, accounted for approximately 46% of the company's reported \$2.78 billion in sales in the quarter ending April 29, 2005. An estimated 60,000 LifePak 12 defibrillators are used worldwide.

Sources: Janet Moore, "FDA: Medtronic didn't fix defibrillator flaws," Star Tribune, June 22, 2005; "Medtronic gets FDA warning on defibrillators," Bloomberg News, June 22, 2005.

<http://www.farrin.com/legal-news/drug-recall-alerts/medtronic-fails-to-fix-LifePak12-flaws.php>

5. Self-Discharge Rate

Batteries self-discharge when not used. A new NiCd battery self-discharges approximately 1% of its capacity each day when stored at room temperature. In 10 days a new NiCd battery not installed in the defibrillator loses approximately 10% of its capacity.

Use the Battery Support System 2 to evaluate the self-discharge rate of a FASTPAK or LIFEPAK

NiCd battery by performing a shelf life test.

The actual battery self-discharge rate depends on:

- Battery age
- Temperature
- Frequency of use
- Length of time in storage
- Physical battery condition

These factors can combine to significantly increase the battery discharge rate.

For example, an older battery stored in higher temperatures may have an accelerated self-discharge rate much greater than 1% a day.

The self-discharge rate increases as the battery ages.

CAUTION!

Possible battery damage.

Charging a battery at temperatures below 5°C (41°F) or above 35°C (95°F) prevents the battery from reaching its full capacity and may lead to irreversible cell damage.

http://www.aedhelp.com/op_instructions/3010012-017.pdf

- **6. PRODUCT: LifePak 12 defibrillator/monitor** - a portable battery operated, complete acute cardiac care response system with both manual and semi-automatic defibrillation operation. Recall # Z-0542-03.

This is a Class II recall - a situation in which use of or exposure to a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CODE

All LIFEPAK 12 units are affected.

RECALLING FIRM/MANUFACTURER

Medtronic Physio Control Corp., Redmond, WA, by letter, on January 27, 2003. Firm initiated recall is ongoing.

REASON

Impact and damage to the high voltage connectors results in poor or no electrical contact from the cable to the LifePak 12 unit.

VOLUME OF PRODUCT IN COMMERCE

46,042.

DISTRIBUTION

Nationwide and Internationally.

<http://www.renalweb.com/ubb/Forum14/HTML/000173.html>

7. PRODUCT

LifePak 12 defibrillator/monitor, Recall # Z-0710-06

CODE

Domestic Serial Numbers

RECALLING FIRM/MANUFACTURER

Medtronic Emergency Response Systems, Inc., Redmond, WA, by letters dated March 2006, firm initiated recall is ongoing.

REASON

Therapy connectors may have connector sockets that do not meet design specs - short drill depth. Interruption of the connections may cause unexpected, intermittent or complete loss of pacing and defibrillation functions.

VOLUME OF PRODUCT IN COMMERCE

942 LifePak 12 devices; 2678 LifePak 20 devices

DISTRIBUTION

Nationwide and Internationally

<http://www.fda.gov/bbs/topics/enforce/2006/ENF00947.html>

8. PRODUCT

DC Power Adapter for use with the LIFEPAK 12 defibrillator/monitor. Part numbers: VLP12-09-000031 through VLP12-09-000047. Recall # Z-0971-04.

CODE

Serial numbers: 1563 through 5232 (non-contiguous).

RECALLING FIRM/MANUFACTURER

Medtronic Physio Control Corp., Redmond, WA, by letter on May 5, 2004. Firm initiated recall is ongoing.

REASON

The DC Power Adapter may fail to charge LIFEPAK NiCd 2.4 AH batteries used with the LIFEPAK 12 defibrillator/monitor.

VOLUME OF PRODUCT IN COMMERCE

1,689.

DISTRIBUTION

Nationwide.

<http://www.fda.gov/bbs/topics/enforce/2004/ENF00849.html>

9.

**Medical Device Recalls
Class 2 Recall
LIFEPAK 12**



Date Recall Initiated	January 27, 2003
Date Posted	February 05, 2003
Recall Number	Z-0542-03
Product	LIFEPAK 12 defibrillator/monitor is a portable, battery operated, complete acute cardiac care response system with both manual and semi-automatic defibrillation operation. It has the ability to externally pace, manually defibrillate, or automatically analyze and if necessary, defibrillate a patient through therapy cables with disposable electrodes, standard paddles, or internal handle cables. Product is labeled with "Medtronic Physio-Control, Redmond, WA"

Code Information	Each unit is given a unique serial number. All LIFEPAK 12 units are affected.
Recalling Firm/ Manufacturer	Medtronic Physio Control Corp 11811 Willows Rd NE Redmond , Washington 98073
Reason For Recall	Impact and damage to the high voltage connectors results in poor or no electrical contact from the cable to the LIFEPAK 12 unit.
Action	Firm Initiated recall is ongoing.
Quantity in Commerce	domestic: 30,575 foreign: 15,467
Distribution	Worldwide distribution, including government/military accounts.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=25538>

10. MANUFACTURER: Medtronic Physio Control Corp., Redmond, WA, by telephone and letter dated May 2004. Firm initiated recall is ongoing.

PRODUCT: LIFEPAK 12 defibrillator/monitor Part Numbers: VLP12-02-000000 through VLP12-02-005003, AVLP12-02-000000 through AVLP12-02-005003, DVLP12-02-000000 through DVLP12-02-005003, EVLP12-02-000000 through EVLP12-02-005003, FVLP12-02-000000 through FVLP12-02-005003, LVLP12-02-000000 through LVLP12-02-005003, PVLP12-02-000000 through PVLP12-02-005003, UVLP12-02-000000 through UVLP12-02-005003. Recall # Z-1107-04.

REASON: Therapy cable doesn't meet firm's standards/may not maintain connections sufficient to support ECG monitoring, external pacing or defibrillation; ECG connector with higher than normal connection resistance resulting in intermittent ECG signal; therapy connector has potential for impact damage

http://mdiconsultants.com/Section_NI/FDA_Recalls/recallarchive15.htm

11. [washingtonpost.com](http://www.washingtonpost.com)

FDA Warns Medtronic Over External Defibrillators

By Geraldine Ryerson-Cruz
Bloomberg News
Wednesday, June 22, 2005; D03

Medtronic Inc., the world's biggest maker of devices that help maintain a normal heartbeat, failed to correct manufacturing problems and investigate complaints about its LifePak 12 external defibrillators, regulators said.

The Food and Drug Administration in a June 9 letter cited damaged cable connectors and failures to follow through with preventive action. The agency posted on its Web site its letter to the Minneapolis company yesterday, after inspections of Medtronic's Redmond, Wash., plant.

Medtronic's LifePak 12 external defibrillators, used in hospitals to shock the heart back to a normal rhythm, are similar to the LifePak 500 devices the company recalled in February. Medtronic's cardiac rhythm management business, which also includes pacemakers and implantable defibrillators, accounted for 46 percent of its \$2.78 billion in sales in its latest quarter.

"We have been working with the FDA for several months on these issues and believe we are close to getting this resolved," Medtronic spokesman Rob Clark said. The company will meet with agency officials this week to present an update, he said.

About 60,000 LifePak 12 external defibrillators are in use worldwide, Clark said.

In the warning letter, the FDA said Medtronic also did not investigate some complaints about defibrillator malfunctions, including one involving a patient's death. Problems were linked to broken or bent pins in the cable connectors, possibly because the company did not have adequate inspection procedures, the agency said. Failure to correct the problems may result in legal and civil penalties, the FDA said.

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http://www.washingtonpost.com/wp-dyn/content/article/2005/06/21/AR2005062101700_pf.html

12.

ALERT DETAILS FOR #2004050294 (RELEASED 5/24/2004 15:52 EDT)	
Description:	UPDATED ALERT: LIFEPAK 12 defibrillator/monitor.
Manufacturer:	Medtronic Physio Control Corp, Redmond, WA
Reason:	Potential for display to go blank due to an electrical component that may fail due to mechanical shock of vibration of the defibrillator.
Analyst Comments:	This recall is an update of RASMAS alert #2004040147 .

<http://info.rasmas.mitretek.org/AED2004050294.html>