



Is All CompactFlash® Really Created Equal?

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Using CompactFlash Cards With Portable Medical Devices

The portable medical device industry is inherently driven by the unique requirements and expectations from two very different markets: consumer electronics and defense/military. Requirements such as high quality and reliability, shorter development cycles, a well-defined and documented supply chain and extended product lifecycles are being combined with expectations such as an easy-to-use interface and simple data acquisition and transfer. It is important to look at these drivers in context to fully understand the challenges that portable medical device manufacturers face, primarily those developing products for use by physicians within clinical settings as well as their patients at home.

To leverage the consumer electronics market's pricing and availability, certain portable medical devices are utilizing memory cards such as CompactFlash (CF) to achieve reliable and simple data acquisition and transfer for a variety of patient monitoring applications. Can the same CF card that is used in digital cameras provide the level of reliability, performance and functionality needed for the acquisition of critical medical data?

For any components used in these applications there are unique requirements and expectations relating to reliability and operating conditions that may not be addressed completely by standard commodity CF cards. Because these commodity commercial cards are driven so heavily by price and volume, manufacturers continuously shop the cheapest components. When you buy to a commodity part number, it is often tied to some rudimentary electrical performance criteria and not the CF card's reliability or the components that make up that CF card. Because of the effort and the time that it takes to get a portable medical device designed, developed and approved, things like critical component control, lifespan, and overall electrical robustness of these storage devices should be carefully reviewed during the design and development stage. To reduce surprises that are found later in the lifecycle, the electronic components, such as CF cards, used within a particular device must be selected to ensure the desired functionality, performance and operability now and in the future.

One such portable medical device is the Holter™ recorder. A Holter recorder acquires, digitizes and stores electrocardiogram (ECG) data for a patient. It is equipped with leads that are attached to the patient to record a pre-determined time segment of cardiac events on a series of different channels. Holter recorders are designed to be used repeatedly to record individual patient data. The industry standard is 24 to 48 hours of continuous full-disclosure operation¹.

¹ <http://www.americanheart.org/presenter.jhtml?identifier=2117>



Holter Recorder



The acquired patient ECG data is stored on a CF card that is inserted into the Holter recorder. This ECG data is the critical information that trained medical personnel use to help determine whether the patient has regular or irregular cardiac rhythmic patterns.

One of the basic formulas to determine the capacity needed per channel is: $(256 \text{ samples/second/channel}) \times (60 \text{ seconds} \times 60 \text{ minutes} \times 24 \text{ hours})$. Based on that formula and a typical sample size of two bytes, a 512MB CF card can provide sufficient capacity to store up to 48 hours of three-channel, uncompressed patient data including space for voice annotations.

One Type Does Not Always Fit All

Key considerations for using a CF card with a Holter recorder for data acquisition and transfer include performance, wear leveling, error correction and data protection. In this application the loss of data or the corruption of such data would disrupt the patient care protocol, create a reduced confidence in the data, as well as potentially product downtime and maintenance.

Let us look at the composition of a standard 512MB CF card in relation to the above reliability, performance and functionality considerations.

Performance

A CF card's construction typically contains one or more NAND flash devices. NAND flash is currently available in single-level cell (SLC) and multi-level cell (MLC) configurations. In general, the SLC technology has an industry benchmark of 100,000 write/erase cycles per cell, which means that once you write to any physical cell 100,000 times, that cell's life is limited and failures become possible with future writes. With the MLC NAND technology, the same physical cell can store more than one bit of information. This configuration enables the device manufacturer to achieve a denser flash chip. The MLC technology was developed in response to the ever increasing demand for larger memory density in the consumer marketplace and is now the standard for commercial CF cards.

This increased density per cell does come at a price in terms of the write/erase cycles per cell and read disturbance. The typical wear-out for an MLC cell is 10,000 writes or 10 times shorter than the SLC NAND cell. This shorter write/erase cycle directly translates to lower endurance and shorter CF card life with all other factors being equal. The stored bits of an MLC device are also more susceptible to what is known as read disturbances. This is a phenomenon that affects cells in proximity to those being read and the cells tendency to flip or corrupt. Although this should be managed by the controller's error correction capability, if the failures exceed the controller's capability to correct during data acquisition the result is bad data stored. For these reasons, only CF cards that are constructed with top-grade SLC NAND devices should be considered for medical applications. To ensure that the CF card is constructed with the same technical SLC components, it is important to understand the supplier's revision control policies and procedures.

Wear Leveling

Wear leveling is basically a way of controlling which cell or cells get written to, ensuring that the writes are evenly distributed over the entire array of the CF card's flash memory. Wear leveling techniques range in both complexity and effectiveness, and can have tremendous implications on the endurance and disk life performance of a card. Most CF cards are formatted to utilize a File Allocation Table (FAT) file system. Each time a new write is performed, the FAT gets updated to refresh the table's record. Because the FAT table resides in a specific assigned address field, each update rewrites the same cell locations over and over.

Without any type of wear leveling, worst-case conditions could cause the card to begin failing after as soon as four months for an SLC flash and as soon as 12 days for an MLC technology CF card. Truly superior wear leveling techniques utilize methods by which both the cells on a chip-by-chip basis as well as across multiple chips are leveled. A CF card that includes both of these aspects of wear leveling optimizes its disk life through maximizing its endurance. Many commercial CF card controllers are centered on an 8-bit microprocessor core, which can rob the card of the kind of processing power required for most effective wear leveling routines. To that end, it is important also to ensure that the controller within the CF card is powerful enough to support the dual wear-leveling technique without impacting its read or write performance.

Error Correction

An error-correcting code (ECC) is a code in which each data signal conforms to specific rules of construction so that departures from this construction in the received signal can generally be automatically detected and corrected. Most CF cards come standard with on-board error detection and correction algorithms with 4-bit ECC. When combining ECC with dynamic wear leveling techniques and the

SLC grade NAND memory, the CF card can deliver more than two million program/erase cycles for most applications. With the anticipated 100,000 segments of ECG data that would be written to the CF card within a 24-hour period, the ability to have even greater error detection and correction with higher read/write endurance is preferable.

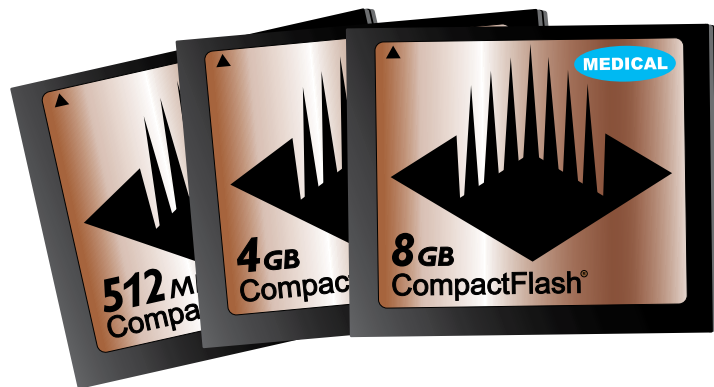
Data Protection

In a power-down situation, there may be data corruption in many CF cards. With a power loss, some CF cards lose data and/or functionality. They may require reformatting at the original card manufacturers facility, which would completely erase all pre-existing data. Using a CF card that provides data protection during power cycling can offer field-proven risk mitigation.

Medical Series CF Cards

Though using commodity/commercially available cards may be a quicker option, they are not designed and manufactured to the same standards and controls as the devices in which they are used, nor are the components within them. By using CF cards that have been specially designed to meet stringent design requirements and specifications, a high level of quality and reliability is maintained throughout.

Medical Series CF Cards



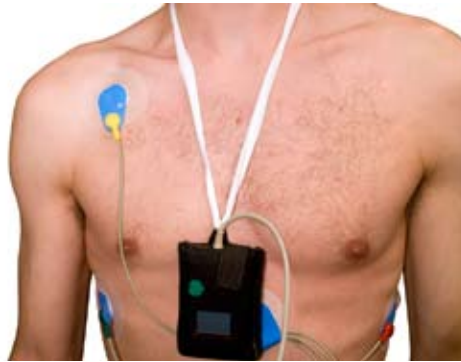
Leveraging industry knowledge and existing standards, White Electronic Designs (WEDC) designed a family of CF cards to meet the particular needs of the market's emerging diagnostic and patient monitoring devices. WEDC's history as a defense industry supplier created the foundation and understanding to appropriately support the growing medical electronics market.

Specially Designed and Manufactured for the Portable Medical Device Market

To provide a CF card with better endurance, WEDC focused on the most critical factors. WEDC provides customers with notification when a part changes, using processes developed for stringent defense manufacturing requirements. The

rigorous source and revision control processes, combined with a strictly controlled and locked bill of material (to component level) and firmware procedures, ensure WEDC customers consistent access to high-quality products with the correct density, memory, controller and firmware configuration.

Portable monitoring device



The controller utilized is constructed around a 32-bit microprocessor core that has tremendous processing power. In simple terms, the WEDC Medical Series CF card controller monitors the number of erases on each memory cell. A buffering routine acts as an address pointer that creates the ability to assign each address location to a physical cell location. This routine essentially creates a virtual address list which points to a corresponding physical address list.

As cells reach a specific write/erase threshold, they are remapped and their contents swapped to a different location with less usage on record. During this process, cell usage is evenly distributed, and CF card life is prolonged. In addition, a routine is utilized to assure leveling is consistent across all flash devices in the card. This complete process is executed across all flash cells, and therefore even user-defined blocks are leveled. Because of the extra processing power available with the 32-bit core, all this is accomplished without impacting the CF cards' operating performance. This thorough leveling routine provides superior endurance value for high-performance applications.

WEDC Medical Series CompactFlash also employs a host of sophisticated error checking and flash management utilities. Industry-leading 6-bit ECC protection, which is capable of detecting and correcting up to six bytes in every 512-byte sector without performance degradation, ensures data reliability through user data transfers and background wear-leveling operations. ECC protection combined with a proprietary static wear leveling technology provides up to four million read/write cycles per card, one of the highest read/write endurance available. For more information on CF card endurance, you can download our technical flyer "Understanding CompactFlash Endurance" from our web site at www.whiteedc.com/tech_flyers.html.



WEDC's Medical Series CF cards are available with options for an environmentally resistant conformal coating. The coating protects the CF cards from potentially harsh chemical environments associated with various medical applications.

All CompactFlash Is Not Created Equal

Innovations in medical technology require memory products that effectively incorporate protection and performance. The increased demand for high-performance and cost-effective portable medical devices created a need for an industry-specific CF card. White Electronic Designs Medical Series CompactFlash is the first such card designed specifically to meet the stringent requirements and advanced performance needs of the medical device and instrumentation market segment by leveraging the commonly accepted testing, materials and processes from our defense and aerospace heritage.

CompactFlash® is a registered trademark of SanDisk Corporation.



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