Use of Flash Storage in Medical Equipment

Introduction

Modern medical equipment typically incorporates one or more computing devices which in turn rely on semiconductor Flash storage devices such as SD's, SSD's, and USB drives. Since the Flash storage devices require initial programming as well as long term faultless operation, it is imperative that they be purchased and programmed in a way that insures their short and long term error free operation.

For many years, International Microsystems Inc ("IMI") has sold a number of different Flash testers and duplicators to medical equipment manufacturers. And Supertalent Inc has manufactured and sold large quantities of Flash storage devices to many of these same medical manufacturers. One of IMI's supporting products is a supply chain procurement process called "Known Good Media" or KGM that has been used by our customers to purchase, program and use Flash media. This paper presents a summary check list for the purchasing and testing of Flash Storage products that IMI and Supertalent have learned over a number of years. We hope that the lessons we have learned will assist you the reader in producing reliable medical equipment which is dependent upon faultless operation of Flash storage.

Essential Elements of Flash Storage

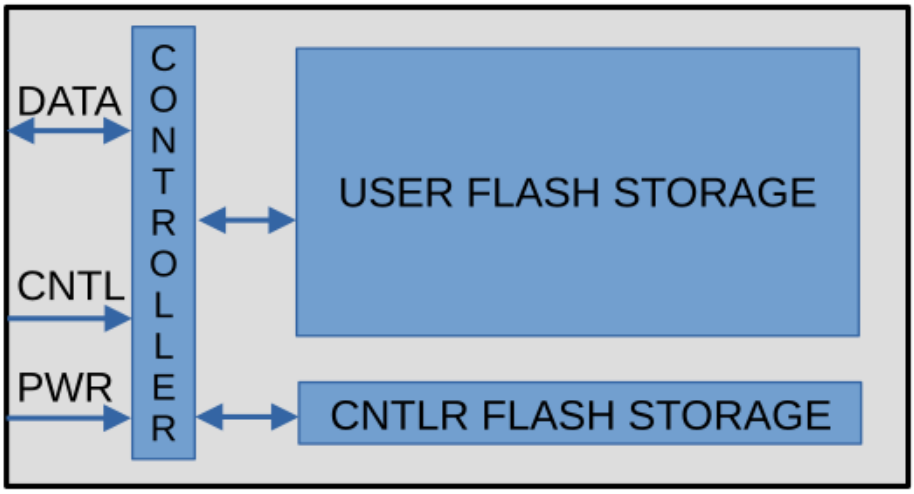

Figure 1: Flash Storage Assembly

Figure 1 shows the essential components in a Flash storage product which effect its suitability, performance, and quality. The goal of assuring that the Flash storage meets it expected performance requirements means that the user should document and test the various elements shown in Figure 1 against a given set of well documented parameters. We suggest the good way to do this is to have the following documents defined for the purchasing and testing of the Flash storage.

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Below we list the documents and optional operations we recommend in purchasing and testing the Flash storage along with an example shown in ***Italic Bold***.

I. General Document--describing the basic Flash storage requirements
   1. Flash media device type: ***USB 3.0 including USB 2.0***
   2. Commercial Size: ***8GB***
   3. Standard Interface: ***USB Connector- Type A- Blue***
   4. Standard Physical Form Factor***: Aluminum case with custom logo***
   5. List of References to other Flash Storage Control Documents

II. Fixed BOM- Bill Of Materials of all Flash storage components
   1. Detailed list of part numbers of all components in the Flash Storage assembly
   2. Exact size in bytes of the user Flash Storage (See Figure 1)
   3. Software Version # of the USB controller used on the device

III. Compliance Test Documentation
   1. ESD test definition and test results
   2. Other Country & Region Electrical & Safety Certification such as UL & CE
   3. Maximum power (VCC & ICC) requirements

IV. Optional Device Requirements Document
   1. Bar Code
   2. Storage Data Encryption
   3. Unique Device Serial Number
   4. Wear Level specification such as SD Health Status value

V. Programming and Verification Document
   1. Specification of Programming Equipment
   2. Binary, File, or Smart Programming Method
   3. Programming and Verify Job Description
   4. Program/Verify Log File Report
   5. Operator ESD Method
   6. Projected Weekly Throughput Specification including Acceptable Pass/Fail Media Percentages

VI. Packaging and Shipping Document
   1. Packaging specification for the Flash storage media
   2. Customer shipping information
   3. Customer acceptance requirements including actions to be taken for rejection of failing media.

Typical Problems to be Avoided-Purchasing

Error #1 Gray Market Flash Purchasing

Flash memory IC's and Flash storage products are worldwide commodity products. Due to the way Flash IC's are made, standard Flash memory IC's have a known percentage variance of failing storage cells. Thus the Flash IC manufacturer will typically sell various grades of Flash IC's which vary in quality depending upon use temperature, speed, endurance, packaging, volume, etc. This wide variation in Flash quality means

that the Flash IC market is highly complex especially for the user who wishes to buy high quality Flash storage products.

Given the above facts, purchase from suppliers that you trust and require that the supplier provide the specific information that related to the Flash product that will insure reliable operation for your intended production.

Error #2 Exact Flash Memory Size is Not Specified

Typically, the size of Flash storage devices is specified in round numbers such as 1GB, 250GB, and !TB. However rarely is the actual storage size exactly equal to the number advertised, There are two main reasons for this discrepancy.

A. The Flash IC's used typically has variable bad blocks of memory.
B. The Flash storage used is divided up between the user Flash and the device controller Flash (see Figure 1).

The Flash used for the device controller is particularly problematic since for any specific device part number, it size may grow with time due to software changes introduced by the manufacturer. The programming of the device controller storage is called the device low level format. This occurs during the initial manufacture of the device and includes a value for the exact size of the user Flash. Below is an example for a recently purchased 16GB USB device.

1GB = 1,073,741,824 Bytes
16GB= 16 x 1073,741,824 = 17,179,869,184 Bytes
Fixed capacity Specified in the device fixed BOM specification
16GB User Flash = 15,806,234,624 Bytes

16GB Flash Label – Actual User Flash = 17,073,741,824 – 15,806,234,624
= 1,373,634,560 Bytes

Figure 2: Calculation of 16 GB USB Drive Controller Flash + Bad Block Flash

The large difference in Figure 2 above between the Flash part description size and the actual user Flash size Is a warning to the reader to be particularly careful in making sure that the actual user Flash size is specified in the Flash storage purchase agreement.

Another important reason in specifying the exact user Flash size in bytes is related to the Flash device duplication process. Typically a master device or master image that needs to be duplicated. If the target Flash

devices are not exactly the same size as this master image, it can cause significant duplication and use problems.

Error #2 Not Requiring a Fixed BOM for the Flash Storage Device

If a Flash storage device is to be used in a medical instrument, we strongly recommend that the purchase agreement include a fixed BOM ("Bill of materials") for the Flash device. Having a fixed BOM will provide the basic required information of the Flash storage device and allow easy tracking of any changes going forward.

Error #3 Not Fully Testing or Allowing for ESD Problems

Because Flash storage devices need to be handled after they are purchased but need to be programmed before use,, they are susceptible to be damaged during by high voltage ESD discharge. Typical storage IC's are manufactured with 4 KV clamp protection. However, when packaged in plastic housings high voltages are easily generated. This is especially true of USB devices. We highly recommend that as part of acceptance that the Flash storage device be formally tested for ESD acceptance and that during programming, ESD protection be employed during handling.

Typical Problems to be Avoided-Duplication

Error #4 Master Exact Size exactly Equal Target device Size

This is the same as the earlier Error #2 for purchasing above. We repeat this because it is often overlooked and affects whether the duplication process is easy or complicated.

Error #5 Master Exact Copy Requirement

Master Flash storage devices typically hold their data in formatted file systems. This means the data resides in files stored with various partitions with associated metadata. In addition, the data may be further encrypted and the total amount of data may vary be between 5% to 95% of the total storage available. Also the master Flash storage device must have large amounts of unused storage for future use. Because of these size and data variances, the default method of master copying is a binary copy which copies every byte of the master to the target copy devices.

However, many times using an intelligent ("smart") method of copying the master many significantly speed up the copy and verify process. As an example, IMI's duplicators ship with 1TB Flash drives. But the IMI duplicator software including Linux typically use only 20GB of storage. And since duplication consists of a program cycle and verify cycle, the actual IMI duplicator percentage of used data to storage data is 40GB/2048GB = 2%. Thus using smart copying can greatly increase the speed and lower the cost of the

duplication. A good benchmark in deciding whether to use a smart copy method is to use smart copy if the percentage data used divided by the total data space available is less than 60%.

Error #6 Incomplete Recording of Duplication Operations

1. There are many parameters besides master verification that are required for correct operation of the duplicated Flash devices. These include the following: maximum and minimum device current and power voltage, speed requirements, serialization, and other meta data requirements.
2. Every duplication cycle should be logged in a data base to allow tracking of the duplication process for every device so that correct ISO root cause analysis can be applied to any failures.

Summary

Medical equipment requires rigorous supply chain management techniques to insure reliable long lasting operation. Modern Flash storage devices present a challenge to use due to their critical use in running the medical computing functions as well as their ever changing availability and parametric changes. However, with intelligent purchasing, good documentation, and quality test equipment, the Flash storage devices can be used with high reliability.