Product Introduction

A New Generation of High End Instruments

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High end instruments for Hematology market is a tremendous request both from hospitals and screening platforms where high reliability and throughput are required. To address this challenging market, the Nexus product was designed and manufactured as an improvement of the existing Pentra DX120 blood analyzer. The main improvements concern hardware and software, including the use of a new laser technology, some pneumatic improvements, additional functionalities in the Pentra ML Data Management and an ergonomic evolution including a new cover integrating a color touch screen. The Pentra Nexus comes out in two versions, the Pentra DF Nexus, making cell blood count, and the Pentra DX Nexus adding the 5 diff formula, erythroblast and reticulocyte parameters to the cell blood count (Figure 1). This article sets out the major technical developments of the Pentra DX Nexus.

Aim of the Project

Before launching the teams on such a development and fixing the project planning, it was necessary to define the project framework. The main needs to make a new product were clear, but it was necessary to define details, to be sure they could be achieved within the project constraints. Three main changes were set out, improving reliability, adding new features on Data Management and changing the look & feel of the instrument.

The reliability of a product is extremely important, for our customers who use our products every day as well as to reduce field service costs. It was necessary to identify possible changes that would improve the product reliability. A study was conducted on the most common

Figure 1   Pentra DX Nexus with Pentra ML Data Management

machine failures reported from the field. Each type of failure was analyzed so as to identify its cause and find a technical solution to reduce or correct the defect. The study showed a possible gain on MTBF (Mean Time Between Failure). Seven possible improvements were identified and could be tackled within the project constraints. Some feasibilities were made to validate the solutions. The effective gain on MTBF was dependent on the efficiency of each modification, but some of those MTBF can only be observed after some use. Indeed, some failures occur after several months of use. Verification of this efficiency can only intervene at the end of the project through reliability tests on the product and then through measurement directly on the field, on installed machines.

The Pentra ML Data Management is a validation station of test results. Several high range instruments can be connected to the Data Management. The test results are automatically validated according to given rules before being transmitted to the LIS (Laboratory Information System) that centralizes all the prescription results. The validation rules exploit the patient's historical antecedents if any, to carry out a rerun or reflex (additional tests) following according to specific conditions. Finally, the results that cannot be automatically validated are manually validated through a man-machine interface that gives the biologist the necessary information to make a decision. Among the changes, it was requested to add information on the reagents used to obtain the result, such information being needed for analysis traceability. The other major change was to improve the QC management by centralizing information on Pentra ML. Detailed specifications of these new functions have been defined with the Marketing and Development.

The requested Look and Feel change resulted in major design changes. The instrument cover is a molded part of a size of the instrument, modifying its shape implies the creation of a new mold composed of two steel parts and weighing 10 tons. Replacing a screen by another implies mechanical changes but also electronics and software evolutions. In both cases, changes had to remain consistent with the target to release a new product within one year.

Design Elements

Right away, realization of a new cover was considered critical in the project. It was necessary to define a new cover shape as soon as possible. To do so, we used a designer who proposed several sketches, from classic to modern, taking into account technical constraints, such as the opening of the cover, loading or ejecting racks.

Communication and Marketing departments chose the final design among those proposed. At this point, the hardware department was able to start designing the cover and all associated changes such as incorporating a PC subset, USB ports in front and back, and upgrading the loading chimney to accept open racks, yet another expected development. These racks can be used in laboratory pre- and post-analytical systems, to automatically load or unload tubes. Once the cover design was completed and verified, a prototype was developed with FDM (Fused Deposition Modeling) technology. This prototype cover was assembled on a machine frame and it allowed checking each part of this new mechanical part in detail. Minor changes were proposed on the drawing (3D) before starting the mold design and its validation. The mold was made in China. Once completed, the first injected parts were tested again to validate the covers themselves and the injection process. Our supplier was ready to produce the first series.

The Pentra DX Nexus is an evolution of an existing product, the Pentra DX120 which was designed around 1995. Replacing the black and white LCD screen by another compatible screen or any other system was not easy since it was specified that the electronic design would not be reconsidered. This instrument has an architecture based on an MOTOROLA 68000 microprocessor electronic board and a set of dedicated electronic boards equipped, for some of them, with HC11 microcontrollers. These boards are grouped on a G96 bus, each having a specific function such as input/output management, acquisition management, stepper motor management, and communication management (RS232, parallel port). From a software perspective, the operating system is OS9 from MICROWARE, a real-time multitasking system. The software has a multi-process architecture, each process having a specific responsibility and a limited interface with other processes. Communication between processes is done through a mail. A signal system, implemented in the OS9 operating system allows to cadence actions of the analytical process and rack automation process.

This initially well-thought architecture allowed many Pentra DX120 product changes since its launch, and it will facilitate replacement of the screen. Besides this change of look and feel and user interface, we had to solve problems of electronic component obsolescence. This was the case with the LCD screen. The first solution was to replace the reference by an equivalent. Unfortunately, there was no component strictly equivalent without changing the display controller. Hardware changes to this LCD controller would have led to mandatory changes of

Product Introduction   A New Generation of High End Instruments

its embedded software. The strong time constraint did not allow imagining a long and complex software development. We had to limit software development workload and the associated validation tests.

In the software architecture of this product, a process (A) is dedicated to management of the user interface and its behavior. It manages menus, organization of the user interface, keyboard inputs and interfaces with other processes. Graphic display is managed by another process (B). Its role is quite simple, it receives requests displaying high-level, like opening a window, writing a string to an X, Y coordinates, displaying a bitmap ... This displaying process addresses the LCD through its controller in order to draw on the screen each request sent by the management process (A) of the man-machine interface. The number of requests is quite low, about 20 display queries. The function of each query is easily transferable to another software environment.

Thanks to the software modular architecture, and the theoretical study performed, it became possible to redirect the graphical management of postings on another system with a standard screen.

A software feasibility was required to validate this principle. Display queries normally received by the process (B) could be sent to another process (B') installed on a PC via a serial RS232. From PC side, a program (process B') functionally equivalent to the process (B) side view OS9, receives display queries and redraws them on the PC screen (Figure 2). This software mockup also allowed verifying that the flow of information sent by RS232 had performances consistent with a display process. The reactivity of the display had to be similar to that existing on the Pentra DX120.
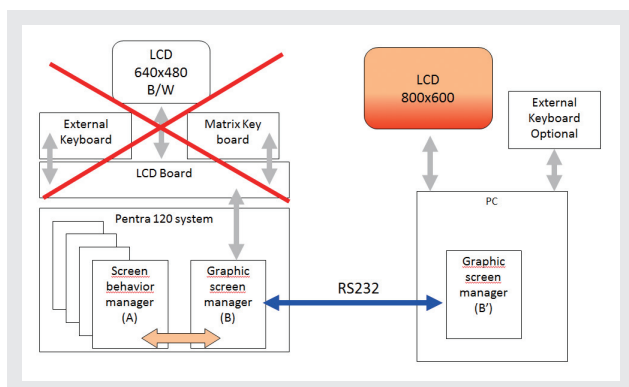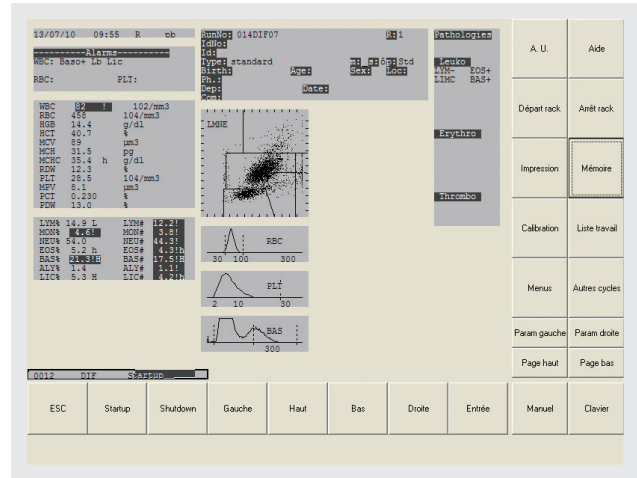

Figure 3   First Software Mockup

The first software mockup (Figure 3) confirmed that this new hardware architecture, although a little more expensive, allowed management of a new color screen. A touch screen was easy to integrate from a mechanical point of view and allowed to improve the software ergonomics. This new color "touch screen" provides an innovative solution to the Pentra DX Nexus.Choosing a PC platform allowed the use of standard electronic components, already used on other products, without having to make a new electronic design. Only the mechanics part of this subset would have to be designed so that it could be integrated into the new cover.

The Pentra DX120 software ergonomics is based on its black and white LCD screen, a front panel keyboard positioned on the instrument and a standard keyboard. Navigation in the man-machine interface is done through these two keyboards.

Replacing 640×480 pixels black and white screen and two keyboards with an 800×600 pixels bigger screen and "touch screen" allowed modern ergonomics. Unfortunately, software usability is linked to hardware interfaces such as screen and keyboard but also mainly to the functional behavior which defines that of the user interface, access to the menus and software functions.

The time constraint limited the opportunities for major changes in the functional organization of software and menus. To help us in this task, we contacted an outside company, specialist in ergonomics. After a training on how to use the Pentra DX120 product, the consultant led a user survey, and took into account technical constraints. At the end of this first study, several areas for

Figure 2   Software Architecture

improvement were proposed with regard to the technical constraints: Enlarging interline menus, creating a path of menus, creating a virtual keyboard, using standardized icons.

The second step was to propose a functional mockup to represent the operating principles of the new man-machine interface. This type of mockup does not take into account graphical aspects (Figure 4). A new model was then proposed with a graphical design in conjunction with our marketing and communication departments. The reuse of icon libraries allows standardizing man-machine interfaces for our products.

Several user tests were performed with this new interface and proved to be easy to use. The latest mockup (Figure 5) was validated and used to define graphic specifications needed to develop the final software (Figure 6).

The positive test results of this new hardware and software architecture were encouraging, but we had to verify that adding a PC subset in the cover of the new product would not degrade the analytical performance of the product, and that this new design would comply with the EMC (Electro Magnetic Compatibility) standards. A Pentra DX Nexus mockup was built and showed through clinical tests that there was no disturbance due to addition of a PC measured performances met product specifications. In addition, EMC testing performed showed the precautions to be taken in the final design.

At this stage, with the studies conducted since the beginning of the project, the scope was defined, hardware and software architecture were defined and validated, key feasibilities were performed and gave a good level of reliability. It remained to organize the rest of the project so that all necessary activities to achieve it are established, and resources reserved.

Project Management

To carry out product development, it is necessary to follow up a method that ensures that all activities necessary to achieve a goal like the one proposed here, are effectively implemented and monitored at each milestone.HORIBA Medical has its own development process based on the PMI (Project Management Institute). This process is based on five distinct phases (Figure 7).

Each phase has a clear objective. Phase 0 is the study of the concept, it is to define essential requirements of the product, ask for a business strategy and assess the project's potential.
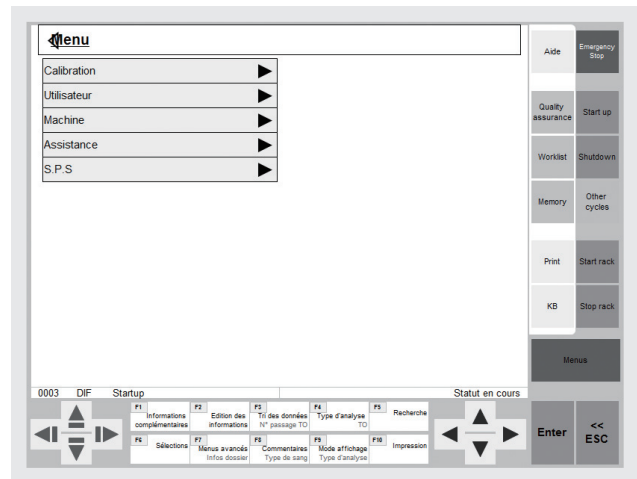
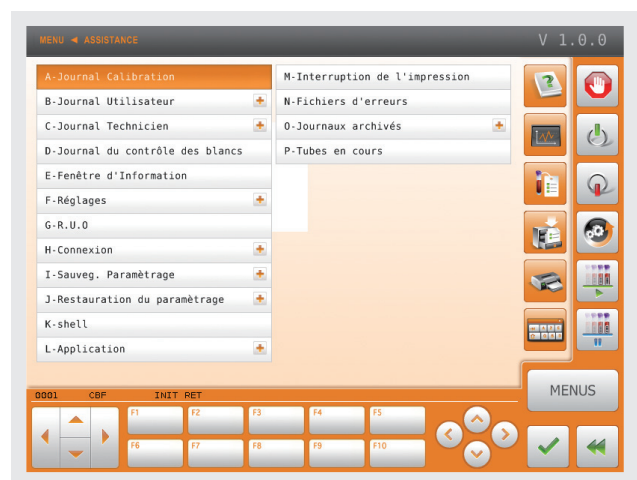

Figure 4   Functional Mockup

Figure 5   Graphics Mockup

Figure 6   Final Graphic User Interface

Phase 1 sets up feasibility and planning, it reduces the unknowns by technical feasibility, and verifies that the project is viable within identified constraints. It also helps define the regulatory requirements applicable to the product (21 CFR 820, CMDCAS, UL, TUV, IVD…). Finally, this phase permits to plan all activities of the various phases. In the Nexus project, given the nature of modifications and project risk level, it was decided from the beginning to provide comprehensive planning only at

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- ♦ Phase 0: Product concept definition & Business planning
- ♦ Phase 1: Feasibility study and project planning
- ♦ Phase 2: Design of the Product (HW/SW)
- ♦ Phase 3: Integration and Verification
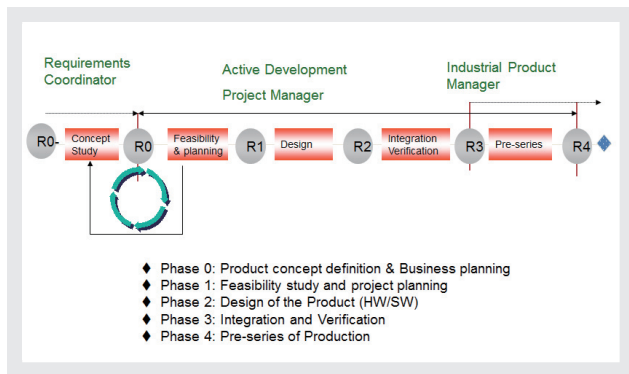- ♦ Phase 4: Pre-series of Production

Figure 7   Development Process

the end of phase 2. This choice allowed increasing confidence level of project planning, thanks to feasibility results and to definition of the initial design elements.

Phase 2 is the design that defines all elements of the new product, 3D files, drawings, schemes of electronic charts, technology. These drawings or files will enable production of prototypes and series parts. At this stage, the expected functions are reflected in the design, taking into account constraints of the project especially expected cost of the product. This phase allows design validation through the prototype that will be realized in phase 3.

Phase 3 allows integration of one or more prototypes, which will allow verifying the prototype compliance with the specifications of the expected product. At this stage, design is completed and validated, production must be prepared through a pre-production.

Phase 4 is the last phase, it is dedicated to verify the possibility to mass produce within the cost limits, and that the product of the pre-series meets these specifications. The product requirements are validated, in particular through one or more beta sites, allowing the use of the product in customer conditions. At the end of phase 4, product liability is transferred to operations.

Each phase is sanctioned by a phase review that evaluates discrepancies that may exist and determines action plans to reduce them. Depending on the nature of differences, a phase is closed with or without limitations, and sometimes it can be extended to find a solution to a major problem. It is difficult to launch a pre-production if the design is not completed or verified. Phase closure is decided by the Steering Committee. The development process provides a list of documents needed to define the project, its specification, planning, and control activities. These

deliverables are documentary or physical. Each phase defines its specific deliverables. They are expected and approved at the end of each phase at the latest. Stating here an exhaustive list of deliverables would be too long, a project like Nexus gathers approximately 350 deliverables for all five phases.

Conclusion

The Pentra DX Nexus is an example of product evolution developed from an existing product. The expected needs in the project were clear and limited. A detailed specification was established, taking into account technical constraints. The initial hardware and software architecture of the Pentra DX120 was modular enough to implement the requested changes without deeply challenging initial design of the instrument. Feasibilities were needed to confirm possible technical solutions and raise technical uncertainties.

The project management set up an organization and some follow-up activities, this allowed achieving the expected goal. This project involves several departments of the company, with different skills and organizations. Despite daily difficulties, problems to be solved, solutions to be imagined, a project is a great teamwork. At their respective levels, with their skills and work, each team member contributes to the project. About 120 people have worked on implementation of this new product. When the first Pentra DX Nexus will come out of production, everyone should be proud.

We are drafting the next evolution of the Nexus which will integrate additional functionalities, new analytical features fully compliant with extended regulations.

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