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Lessons learned while building an integrated ICU workstation

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Abstract

The project LUCY (Linked Ulm Care sYstem) is described. The goal of this project was to build a research workstation in an Intensive Care Unit which enables evaluation of data/information processing and presentation concepts. Also evaluation of new devices and functions considering not only one device but the workplace as an entirety was an aim of the project. We describe the complete process of building from the stage of design until its testing in clinical routine. LUCY includes a patient monitor, a ventilator, 4 infusion pumps and 8 syringe pumps. All devices are connected to a preprocessing computer via serial interfaces. A high performance graphic workstation is used for central display of physiological and therapeutic variables. A versatile user interface provides touch screen, keyboard and mouse interaction. For fluid administration a bar code based control and documentation facility was included.

While our scheduled development efforts were below 4 man-years, the overall man-power needed until the first routine test amounts to 8 man-years. Costs of devices and software sum up to 160,000 US$. First experiences in clinical routine show good general acceptance of the workplace concept. Analysing the recorded data we found 90% of the items to be redundant: individual filtering algorithms are necessary for each of nowaday's devices.

The flexibility of the system concerning the implementation of new features is far from our expectations. Technical maintenance of the system during clinical operation requires continuous effort which we cannot afford in the current situation.

Introduction

Four years ago, when we started the described project of constructing an Integrated Intensive Care workplace, the situation of workstations on our ICU could have been characterized as follows:

- Most devices offer an interface for data exchange and control, but usually neither a standard protocol is used nor is an adequate program or even support offered by manufacturers.
- No commercial vendor offers a complete, easily adaptable data management system.
- Extended use of devices for monitoring and therapy leads to an increased workload upon the staff of the ICU because of documentation and device-related tasks.
- Purchasing a data management system necessitated a substitution of most of the existing bedside devices.
- None of these data management systems is based on a real integral concept that collects and filters all available data and information, performing purpose adapted documentation and presentation [1–5].

To our knowledge this situation has not changed considerably since then. This contrasts with the hope expressed by Blum in 1986 [6] concerning the use of computers in HDE in this decade. The reasons for this are probably manifold; some aspects such as lack of technical and medical standards were discussed in a recent editorial by Gardner [7].

Our main field of research is focused on interactions between staff and devices in the clinical environment. For evaluating new approaches a flexible integrated data management system would be of great help. Such a system should enable both the evaluation of new individual devices as elements of an integrated workplace as well as the evaluation of the workplace as an entirety.

Therefore we decided to build an integrated ICU workstation. In close cooperation with three medical device manufacturers, B. Braun Medical, Melsungen, Germany, Dräger Werke, Läbeck, Germany and PPG Hellige, Freiburg, Germany, we designed and developed our Linked Ulm Care sYstem (LUCY). This article gives a review of this project. We describe our design principles, intentions and expectations and resume the used methods and necessary efforts to build up this system.

Basic concept of LUCY

LUCY was intended to be used in our surgical ICU. This unit is run by the department of anaesthesiology. Eight physicians and some 60 nurses care for about 1000 patients each year (general surgery, trauma, vascular and heart surgery). Due to a shortage of nursing staff, the number of beds has been reduced from 18 to 12 (grouped in 4 rooms).

The choice of the medical devices integrated in LUCY was guided by the following principles: The integrated devices should already be in use in our ICU to minimize staff training. Each device had to provide a standalone function guaranteeing continuity in patient care in case of system breakdown. The integrated devices as a whole should provide a workplace suitable for the majority of patients treated in our ICU. The composition of devices was based on a former workplace design [8, 9] and included:

- four infusion pumps 'Infusomat secura' (B. Braun Medical, BBM), providing a serial (RS232C) interface,
- eight syringe pumps 'Perfusor secura FT' (BBM), offering a serial (RS232C) interface via an interface system called Dianet [10], which allows 6 pumps to be connected to one port (an RS485 is also provided),
- one ventilator 'Evita' (Dräger, Lübeck, Germany), providing a RS232C interface,
- one intensive care, module-based patient monitor 'SERVOMED' (PPG Hellige, Freiburg, Germany), offering a RS232C serial link via a 'HELBUS'-Converter.

Except for the patient monitor, all staff were familiar with all included devices. The selected patient monitor provided digital display of all essential data at its modules. This gave us the possibility of omitting the original separate screen. Curves and figures are part of our centralized and integrated display concept.

The following aspects were considered in our selection of computers, operating systems and development software: For the evaluation of our presentation concepts we required a central display with high graphical resolution and the appropriate hardware [11]. To minimize implementation efforts we used rapid prototyping tools and a well established development environment. Concerning the integration of other/further devices, hard- and software was built up in modules.

LUCY was implemented using two computer subsystems: a high performance graphics workstation 'Personal Iris' (Silicon Graphics) running under UNIX and an industrial process computing system based on 'Eurocom 6' (Eltec elektronik GmbH, Mainz, Germany), running under the real time operating system OS9. The 'OS9-system' had to handle communication with medical devices, processing the individual protocols and transcribing them to standards. It also controlled the user interface of the infusion subsystem (see below).

The graphics workstation fulfilled the following tasks:

- gathering online data from the 'OS9-system',
- reformating data for storage in a data base (Informix),
- looking up thresholds, limits, priorities and screen layout values in the database,
- providing a versatile user interface including touch-screen, mouse, keyboard, and sound modules,
- administering a decision support data base,
- graphics presentation of all data/information on the central screen.

Relying on rapid prototyping, a real time data presentation tool was selected – 'DataViews' (V.I. Corportation, Amherst, MA 01002, USA) – which was supposed to facilitate the development by offering predefined display elements and design tools, as well as establishing straightforward relations between display elements and data sources. We started with the version 5.0. Each half year a new release followed. The tool did not fulfill our requirements concerning dynamic display of our 'Smart profiles' [1] presentation concept.

Development efforts

A development team was established, consisting of several engineers and physiscists from our department

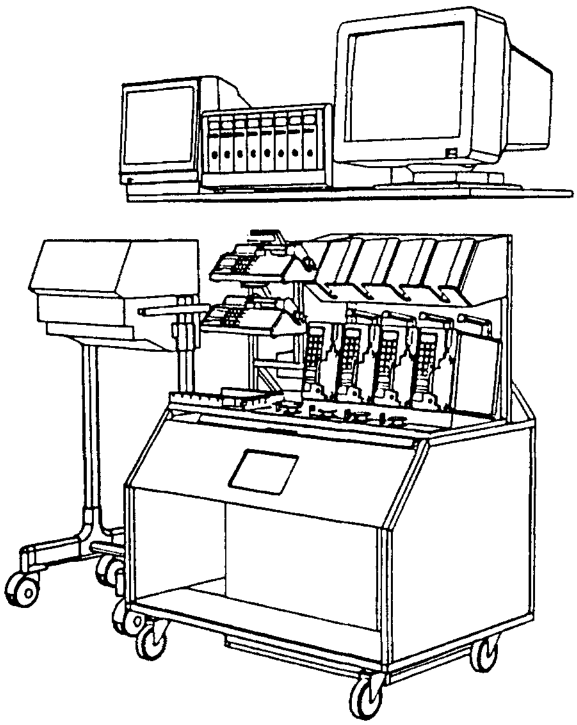

Fig. 1. The physical arrangement of the intensive care workplace LUCY. The shelf, on which both screens are placed, limited us in height. The inclined surface underneath the 4 infusion pumps is the front side of the drawer carrying 6 additional syringe pumps. Most left is the ventilator (*Evita*) resting on wheels as does our rack.

and from the industrial partners. They received clinical input from consultant anaesthetists and an experienced research nurse. The project was divided into small work packages and a time schedule was set up based on generous estimations. Basic contents of this schedule together with our real efforts are shown in Table 1.

During LUCY's development additional work-packages came up:

- Space limitation forced us to locate 6 of the 8 syringe pumps in a drawer. Therefore a display was placed at the front of the drawer, presenting essential information about the hidden devices (Fig. 1).
- A bar-code-reader based user interface for fluid administration was developed.
- As already stated, the rapid prototyping tool did not fulfill our requirements and was substituted by a tool which we programmed using 'Silicon Graphics – C – Graphics Library'.
- The OS9 crashed several times presumably caused by noisy power supply. A watchdog system was integrated which enabled automatic reset.

A straightforward programming progress was hindered by the occurence of faults. For example, an interrupt handling failure of the 'OS9-system' multi-serial-port driver caused communication problems. This occured only under maximal load and was very difficult to identify. Finally the manufacturer was able to isolate and remove the mistake. This one fault caused a delay of at least 3 months.

Figures 2 and 3 show the final software structure of the software modules running on the 'OS9-system' and the workstation. Note the ring communication via 'Pipes' which we created as the key element of data exchange between modules. This concept has proved helpful in the development of a versatile user interface including keyboard, touch screen, mouse, and audio facilities.

To guarantee trouble-free interaction of the different software modules we developed a simulation environment where we could test the system. A patient simulator (Lionheart, Bio-Tek Instruments, Winooski, VT, USA) created a three-lead ECG pattern and blood pressure curves. A pulseoxymeter sensor was applied to one member of the development team. The ventilator was connected to a lung simulator equipped with an orifice for resistance adjustment. The fluid delivery system was controlled via the bar code reader. Using this simulation the priorities and request frequencies of the communication modules were adjusted. Two modules were developed guaranteeing communication functionality: A time-out controlled reading task prevented infinite waiting for a module in the event that communication did not work properly (not provided by OS9). A 'transfer-task' (Fig. 2) collected all messages from the modules, checked for data consistency and filtered redundant data. For these messages we used a format similar to the Medical Device Data Language (MDDL) specified by the Medical Information Bus (MIB) [12].

Electrical safety aspects must be considered if a system is to be used in the clinical environment. Three basic problems had to be addressed:

1. Off the shelf computer systems do not fulfill clinical electrical safety requirements.
2. Connecting several devices via data and/or power lines causes a summing of leakage currents.
3. Connections may transmit voltage across several devices.

Table 1. Scheduled and needed efforts of development.

Workpackage	expected effort (man-months)	needed effort (man-months)	level of training	reason for discrepancy (if known)
Rack/physical layout	4	8 engineer	mechanics	drawer
Set up OS9 system	2	6 engineer	informatics	rebuild
Set up Work Station	2	6 engineer	informatics	concept
Modules OS9 (programming)	24	38 engineer	informatics	OS fault
Work Station Modules	12	24 and engin.	team of clin.	no rap. proto.
Test/Debug System	1	12 and clinic.	informat.	inexperience
Sum	41	94		alltogether

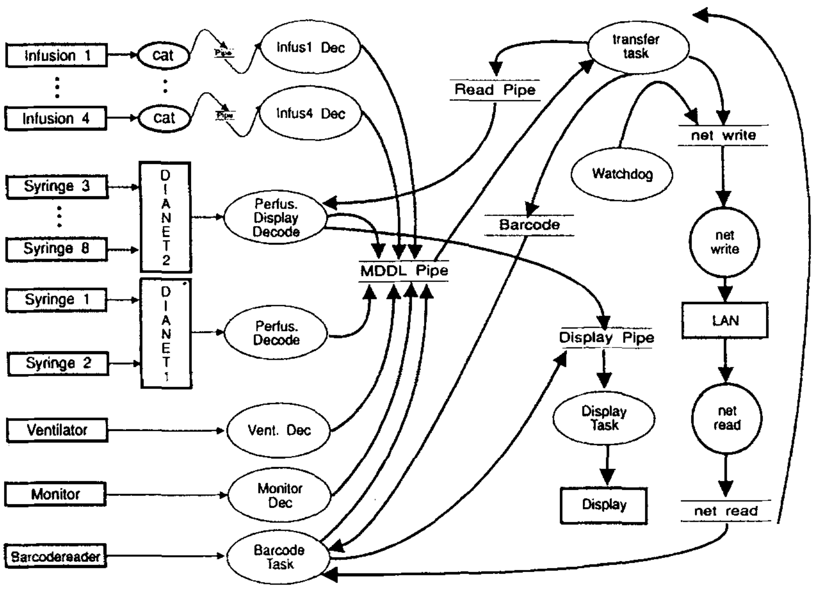

Fig. 2. Structure of software modules on the 'OS9-system' which transfers the formatted data via Ethernet to the graphics workstation. The data is gathered via 9 serial ports each of them handled by its own process.

4. Induction loops occur, causing additional faulty currents.

The first problem was solved by using an additional isolation transformer[1] in the power line of the workstation. The 'OS9-system' was placed in an additional isolating housing. The other problems were solved by using optocoupled data connections. The whole system was tested using an electrical safety tester (Bender μP Sicherheitstester, Medizintechnik Bender, Grünberg, Germany) according to the IEC 601/VDE750. The measurements showed the effectivity of the isolation

[1] This point may be criticised due to references stating that additional transformers may even increase leakage currents [13, 14]. This only applies if secondary capacitive coupling to ground is small compared to the transformer's. This topic will be addressed in a forthcoming article.

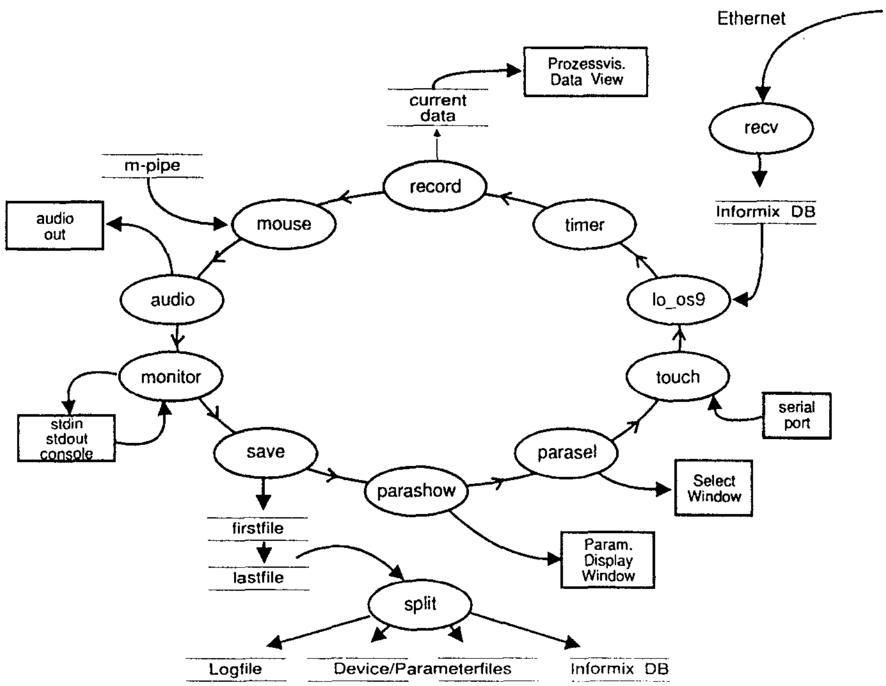

Fig. 3. Program modules on the UNIX based graphics workstation. Apparent is the ring communication via 'Pipes'.

transformer which reduced the leakage current of the work station (touch-screen) from 3 mA to 30 μA.

LUCY in clinical routine

To implement LUCY in clinical routine the environment had to be prepared. Additional rack-holders provided support for the 19 inch graphics presentation screen. Data connections for the remote supervison of LUCY had to be installed.

The first clinical evaluation was focused on the fluid-subsystem. A special interdisciplinary team set up a bar code based user interface providing the following noteworthy features:

- All possibilities of fluid administration were covered: syringe and infusion pumps, gravity fed infusions and bolus applications. This was done by attaching a specific bar code to each device. Additional bar codes were provided for bolus and gravity fed applications, placed at the front of the drawer.
- The most often used drugs and mixtures were listed including their bar codes. The top 30 were placed directly on a plate above the drawer, the rest (some 500) in a folder; if a drug was not found in the current list a 'meddummy' code was to be used, and our team completed the list later.
- A sticker was provided for each drug, on which the drug name was both printed and represented as a bar code. It was attached directly on the corresponding syringe, bottle or bag. Clinical routine showed that they were also used as reminders or for documentation.

The complete procedure of drug entering consisted of the following steps:

1. Activate fluid administration screen,
2. give name/volume/concentration of drug/mixture,
3. chose desired device by bar code,
4. confirm.

At each step it was possible to correct the last input. We had to ensure that all clinical personnel that would use LUCY were briefed. In a short course 28 nurses and 4 physicians were taught in the basic functions.

Additionally we provided a supervisor who was continuously on call. During the day one member of our staff was present in the ward. We had installed an Ethernet connection between LUCY and the development system in our laboratory enabling remote login.

Results of building up and testing LUCY

It took about 20 man-months to construct LUCY, including hardware installation. A further 62 man-months were needed for software development. Clinical specification by physicians and nurses took roughly 9 man-months including implementation of the drug database, user interface and algorithms for symbolic presentation of data according to the 'Smart Profiles' [1] concept. A briefing had to be worked out (3 man-months) with which clinical personnel were trained.

The monetary expenses for Hardware and Software are summed in Table 2 below. We included a rough estimate of the costs corresponding to the man power. Most of the programming was done by two informaticians as part of their doctoral thesis (12 man-months each), receiving half a salary (gross costs: 3500,– DM/month each), and five graduate students (2 physicists, 2 electrical engineers, 1 machining engineer, all with programming education, average 8 man-months each, gross costs: 800,– DM/month). One informatics engineer from industry, one biomedical engineer and one senior physicist each contributed approximately 8 man-months (average gross costs: 7000,– DM/month). An experienced research nurse contributed roughly 3 man-months (gross costs: 5000,– DM/months) and two senior anesthesiologists/intensivists each contributed 3 man-months (gross costs: 8000,– DM/month).

Finally LUCY offered:

- An integrated, ergonomically oriented, physical arrangement of all basic devices in a standard ICU workplace (Fig. 1).
- Facilities to sort and guide infusion lines (clamps, color coding).
- Data capture of all integrated devices.
- Storage of filtered data in a data base (Informix).
- A bar code reader-based user interface for fluid and drug application.
- A versatile user interface at the central data presentation screen, allowing mouse, touchscreen and/or keyboard to be used.
- An organ-related drug data base including standards of application and side effects.
- A data base containing standard values and thresholds for all physiologic variables.
- A set of presentation screens focusing variables, organ systems, and processes.
- A first approach to an integrated alarm system.

The goal of LUCY's first run in clinical routine was to check its performance and stability. LUCY was placed at the bedside of an 81 year old patient who had undergone coronary artery surgery, admitted 20 days previously to the ICU, and who was being mechanically ventilated. Five syringe pumps and 3 infusion pumps were being used. Monitoring consisted of a 3-lead ECG, central venous and invasive arterial pressures. This posed a reasonable load concerning data transmission and handling of the user interface.

The following problems occured: The 'OS9 system' went down several times, probably because of a noisy power line. During restart all recent data were transmitted, overloading the Unix machine during the first few minutes. This caused delays of user interaction, data presentation and storage.

The overall performance was not satisfactory – a typical response time to touchscreen input was about 3 seconds. At this time data presentation was based on the rapid prototyping tool 'Data Views'.

After analyzing the findings we decided to make following changes: The rapid prototyping tool was replaced by C-routines. Priorities and update frequencies of the OS9 communication tasks were readjusted and the TCP/IP Ethernet connection was changed to an UDP protocol [15].

The second routine test lasted five days. LUCY was used with two patients (pancreas resection and coronary surgery).

During this run LUCY proved to be stable and the response time of the user interface was acceptable (typically less than 0.25 sec). Nursing staff could define the variables which were displayed on the central data presentation screen in bargraph and digital form. Up to nine variables could be selected from a square matrix displayed on the screen which contained 42 available variables.

Amount of data

As described above filtering of redundant data was programmed in the communication modules of the 'OS9 system'. We did not store data in fixed time intervals; instead storage was triggered by a change of a measured value. Table 3 lists the file sizes recorded by the UNIX workstation in 115 h during routine clinical use. Each file corresponds to a specific device or variable.

The large size of some files was due to inclusion of irrelevant changes (e.g. body temperature changes of less than 0.1°C). Another cause for unreasonably large data files were the monitor modules and the ventilator which transmitted up to 30 times per minute an ON/OFF or STANDBY/RUNNING message albeit no corresponding control was performed. We found that

Table 2. Expenses for hardware and software needed for building up LUCY. Exchange rates applied were 1 US$ = 1.6 DM and 1 £= 2.5 DM (9'93).

Device/Software	Price/DM	Price/US$	Price/£	Remark
Graphic Workstation 1	80,000	50,000	32,000	for development
Graphic Workstation 2	80,000	50,000	32,000	to build in system
Software maintenance	3,600	2,250	1,440	each year
Processing Rack 1	18,000	11,250	7,200	for development
Processing Rack 2	22,000	13,750	8,800	to build in system
Rapid Prototyping Tool	25,000	16,625	10,000	process visualization
Maintenance contract	8,000	5,000	3,200	each year
Rack building	12,000	7,500	4,800	
Other	8,000	5,000	3,200	printer, . . .
Labour cost (approx.)	347,000	215,000	140,000	rough estimate
Sum (rounded)	600,000	375,000	240,000	

Table 3. Number of items collected during the second routine test lasting 115 h (= 6900 min). We used one line of ASCII text for each item (typically 100 bytes).

Device-Parameter	Items stored	Comment	filtered
Monitor/All	500,000	mainly not relevant	16,000
Mon./BP	420,000	off/stdb/run	9,600
Mon./HR	30,000	minor changes	5,000
Mon./SaO2	12,000	minor changes	4,500
Mon./Body Temp	3,000	run/off	0,660
Ventilator	65,000	mainly not relevant	12,000
4 Infusion Pumps	1,500	many alarms	1,500
5 Syringe Pumps	0,180	mainly control	0,180
LogFile	4,500	control steps	4,500

an overflow related to device internal processing was the reason for these messages. This behaviour had not any relevance for the clinical functioning of the device. For each of these data-garbage problems an adapted filtering algorithm was programmed enabling a reduction of up to 95%.

Syringe pumps transferred considerably less data than infusion pumps. Most of the infusion pump messages were related to 'drip' and 'air' alarms. The high rate is probably due to the inclined position of the infusion bottles exceeding the recommended angle.

Acceptance of user interface

Compared with physicians, nursing staff are the main user of bedside devices. Their assessment was the following:

- tidying up the ICU workplace was appreciated – especially the fluid subsystem including line sorting and guiding utilities,
- more fixing points for infusion bags and bottles were needed,
- the bar code based fluid administration user interface was well accepted,
- cleaning was difficult,
- the position of the screen at the front of the drawer was too low,
- the touchscreen was located too high,
- LUCY took too much space.

The reason for the required space was due to the fixed wall installations (shelfs, power and gas supply) which limited the height of LUCY causing a 'flat' arrangement.

The central data presentation screen was used primarily to support manual documentation. The nurses selected the variables according to the set which had to be documented. Adding a confirming function would enable a first step to automatic documentation.

Discussion

In the following we want to discuss the question: *Is LUCY the system we wanted to build?*

LUCY should enable rapid implementation and clinical evaluation of information/data integration concepts. Some forty man-months were expected, actually it took almost 100 to construct a first version of LUCY. We believed too much in modern computer tools and underestimated debugging efforts.

The software includes roughly 700 kBytes of generic source code, written by a team of 12 cooperators under two distinct operating systems. Including the libraries some 50 MBytes of program have to be maintained. On a realistic estimate any new function would require at least 3 man-months of implementation time. Our needs for evaluating new functions in clinical routine are not met by such an inflexible system. In its current form LUCY is not the system we wanted to build.

The second question we want to discuss is: *Can we afford to use LUCY in clinical routine?*

Running LUCY in clinical routine yielded valuable basic results. The bar code-based user interface of the fluid subsystem has proved successful. The general physical structure of LUCY, especially sorting and guiding infusion lines, was appreciated. We learned about data filtering; realizing that each device protocol has specific problems of its very own, and cannot be handled with a standard communication software.

Up to now we have not obtained any answers to our primary questions concerning 'Smart Profiles' and other integrated data and information presentation concepts. We also found that high efforts would be necessary to perform research: Standardized testing conditions can hardly be achieved in an environment which is characterized by an infinite variability and a large number of uncontrollable influences. Running LUCY in clinical routine requires – even if the systems are stable – high permanent working capacity of our research team. Considering our limited resources we have to accept that we cannot afford to use LUCY in clinical routine.

Also we have to take into account *further aspects*: Based both in university and industry the LUCY-project has been a fascinating enterprise from the beginning. The combined expectations from our industrial partners, interested preferently in new concepts for their products, and of ourselves, who wanted to have a flexible tool for basic research, enabled a budget exceeding the usual frame. All team members learned a lot during the development phase: engineers became familiar with the clinical mode of thinking, clinicians learned to analyse their working processes. We all concentrated solely on the final product, the development itself was not seen as a research or learning phase but rather as a necessary burdensome obligation. This stressed motivation and led to a fatigue of the team, resulting in several members to leave the group increasing the load to the continuing ones. In this sense the project did not fail completely but also it did not succeed in the original goals.

Conclusions

LUCY taught us the following lessons:

- Costs and time effort are usually considerably underestimated. You must be willing and capable to spend much more money and time than scheduled. University research projects in general do not have this flexibility.
- During development of complex computing systems, hidden problems occur which were never foreseen.
- On the one hand, software tools have become more and more sophisticated (and powerful); on the other hand, it has become much more complicated to adapt and combine these tools to specific needs.
- Often introduction of complex software tools into daily use takes more time than the improvement of the tool itself offered as a new software release.
- Albeit communication standards have been under development for many years (MIB, HL7, Medix [16]) today's device interfaces have to be treated individually. Any new medical device or software update causes additional programmer's work (even medical devices' software is updated frequently).
- Running a research workplace in clinical routine requires very much effort of highly qualified personnel (physicians, nurses and computer special-

ists) to guarantee patients' safety and avoid additional workload of clinical staff.

What are our conclusions?

Financial restrictions forced us to stop the LUCY-project. Therefore we decided to focus on a part of our original goals, the development and evaluation of intelligent data and information presentation. For this purpose we will develop a laboratory environment, in which we can simulate workplace conditions. This facilitates studies considerably, but we have to accept that these studies can never really substitute studies performed in the Intensive Care Unit.

We have to drop – at least in the current situation – the goal of constructing and running a realistic research workplace in which we could evaluate new device concepts and functions, their physical and logical integration and the evaluation of workplaces as an entirety. This is a pity if we consider all development which does not meet clinical requirements (especially in the field of data management).

Together with our three industrial partners B. Braun Medical, Melsungen, Drägerwerk AG, Lübeck and PPG-Hellige, Freiburg we have applied in the past and are still applying very much effort to research and development in anaesthesia and intensive care. Many scientific questions have arisen which must be answered by basic research, which cannot be afforded by this cooperation.

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