Abstract: The control methods used for medical devices parts have to secure the accomplishment of the special conditions required by the characteristics of the measuring (some slight measuring errors, narrow measuring field, and diminished tolerance zone). Taking into account these characteristics, as far as the medical devices industry is concerned, in this paper are analyzed so-called classical methods (with contact), as well as methods with no contact (optical).

Key words: Medical devices, dimensional inspection, automation.

1. INTRODUCTION

Medical devices have become an increasingly important health care area in relation to their impact on health and health care activities. These fields cover some 10,000 types of products, ranging from simple instruments or spectacles, through life maintaining implantable protheses, equipment to screen and diagnose disease and health conditions, to the most sophisticated diagnostic imaging and minimal invasive surgery equipment. The people involved in this industry expect that these devices meet the highest safety and complete standards of quality. In this sense, the European Commission has proposed amendments to the current legislative filed and the proposals have been developed involving extensive people and public consultation.

The most significant proposals concern conformity assessment, including design documentation and design review, clarification of the clinical evaluation requirements, assurance the quality in medical devices production, compliance of custom-made device manufacturers and the alignment of the original medical device directive 90/385/EEC. An introducing and development of a specific quality system at any medical devices production or service is necessary assumption to be flexible and dynamic in a diverse and specific market. These special attentions must be devoted to tasks of the quality of medical devices production, because an incidental use of technical poor quality medical devices can be caused different health loss or can put in danger the user’s life. All risks from using the medical devices actions must be eliminated or minimized by the producers of medical devices through a correct and constant better design, selection of the materials and manufacturing process. That why, the complex risk analyze has to be performed like an important and inseparable part of the conformity assessment procedure for medical devices production. For that, practical knowledge and experiences with introducing, development and inspection of the quality system at medical device producer are important for the manufacture company and allow to the researchers to develop and solve different practical projects.

Inspection, which is what, quality insurance usually means, is historical, since the work is done. The best way to think about quality is in process control. When modern quality techniques are applied correctly to business, engineering, manufacturing or assembly processes, all aspects of quality will be improved. The medical device industry encompasses a wide range of technologies and applications, ranging from simple hand tools to complex computer-controlled surgical machines, from
implantable screws to artificial organs, from blood-glucose test strips to diagnostic imaging systems and laboratory test equipment. These devices are manufactured by companies varying in size and structure, methods of design and development, and methods of management.

By means of the present research, we have intended a particularly modern approach of the automatic inspection systems and the implementation of the latest methods of measurement and analysis required in establishing and ensuring the quality of medical devices as essential elements for health care.

2. THEORETICAL ASPECTS

The using risk factor is the most important aspect and for that medical devices are classified according to their potential risk to a human body. The level of pre-market intervention is proportional to the level of potential risk on the human body health.

The risk category for a device is determined by taking into account the manufacturer's intended purpose for the medical device and by the application of a set of classification rules. Applying these rules can classify medical devices into one of the following classes:

- **Class I** - low risk devices including low risk devices that are sterile and/or have a measuring function
- **Class IIa** - low-medium risk devices,
- **Class IIb** - medium-high risk devices,
- **Class III** - high risk medical devices, and
- **Class AIMD** - Active Implantable Medical Devices (AIMDs). These are treated in a similar way to Class III medical devices.

N.B. The classification and the requirements of a medical devices properties may differ from this proposed classification, if the manufacturer, changes the initial purpose of using the medical device from single use to reusable, also changes other aspects of its intended use, including changing the sterility status of the product[^6].

When a manufacturing firm produces a product designated for use in the medical field, the company must supply one element regardless of part design: assurance.

Through the use of in-line product testing and final package testing, a manufacturer can document the steps taken to assure the end user that the product has been examined and has passed the standard testing procedures designated by specific organizations[^1].

A quality control department must be aware of different testing methodologies in order to gain this control and assurance over the production and packaging processes. The medical devices quality inspection objectives depend on how the task is carried out.

The basic requirements for quality objectives are quite simple: -Establish quality objectives at relevant functions and levels. -Make sure they're measurable.-Include objectives needed to meet product requirements. -During management reviews, evaluate the need for changes to quality objectives.

Quality objectives should be attacked in four basic steps: to establish the foundation for objectives; to select key measures; to base quality objectives on key measures and to analyze the data and manage the system[^1].

3. EXPERIMENTAL ASPECTS

An automatic dimensional inspection system for medical devices combines the core aspects of mechatronics (system modeling, simulation, sensors, actuation, real-time computer interfacing, and control) with specific practical aspects of medical devices production.

An important problem in Mechatronic design of automatic inspection devices for medical applications is to combine precision mechanics, optics, electro-mechanics, electronics, data processing and applied computer science with very high standards of precision, reliability, accuracy miniaturization, quality and special using conditions[^2].

A modular automatic system has been designed for special applications used in medical devices productions (fig. 1).

In this system, performance qualification testing should include performance testing under conditions that simulate the real use of inspected parts.

From the general structure of an automatic system for dimensional inspection, the authors have passed to the analysis of the possible realization of such a system for applications in medical devices production.
For the system taken into consideration, we have maintained the basic modules, specific to the automata for dimensional inspection, modules for which we have established the elements specific to medical using conditions.

Roughly speaking, in designing automata for dimensional inspection, it is the measurement modulus, which raises special problems. As far as the systems for special medical parts are concerned, beside the special conditions for measurement, there arise problems in manipulating, transporting and dosing the medical parts or their elements. According to the required application, the measurement modulus can materialize methods with contact and with no contact (fig. 2).

The processing modulus consists in a central computer, which controls all the component parts of the system. Beside this one, the command and control modulus must also comprise: a computer for processing the image, a block for the control of the manipulation, a block for tracking the measuring in motion [4].

The manipulation and transport modulus raises special problems regarding the dimension range, materials and surface quality. We are compelled to state that we may not always adapt the conventional methods of manipulation to the demands of the bio and micro-world.

The micro-objects may not be handled so easily as a tool of regular size. In order to accomplish these operations we need adequate gripping elements, such as micro-pliers, and gripping nozzles.

The micro-pliers play an important part as they exercise a direct influence upon the manipulator’s handling ability. They may clasp, realize hitching by abrasion or adhere to the material, according to the physical or geometrical properties of the measuring.

Within the framework of the manipulation and transport modulus, it is compulsory, in the detriment of flexibility, to resort to some sets of grippers (pliers) adapted to the form and size of the pieces, which have to be manipulated (fig. 3).

An important problem consists in correlating the gripping forces to the characteristics of the manipulated pieces, forces, which have to ensure the gripping, but not modify the dimension and quality parameters of the surfaces.

The systems of automatic dimensional inspection used for medical applications raise another important problem, the correlation of the special quality condition and technical and economical aspects.
The solution of this problem can be found in the visual supervision of the processes, associated to a sensory system of high performance and to a processing modulus in good time.

For an optimal process control, in the dimensional inspection system structure was included a special programming modulus, which assure the possibilities to adapt and to reconfigure the dimensional inspection system to the specific working and quality conditions for medical applications.

The processing modulus consists in a central computer, which controls all the component parts of the system.

Beside this one, the command and control modulus must also comprise: a computer for processing the image, a block for the control of the manipulation, a block for tracking the measuring in motion.

The sorting device is controlled through the controlling system and sorts the pieces in three classes: suitable pieces, redeemably inadequate and unredeemable inadequate.

Because of its structure and the PC aided processing device, the measuring and control device ensures a continuous analysis of the parts.

**4. CONCLUSION**

In the circumstance we attach great importance to ensuring the product quality, as far as the dimensional inspection is concerned, there have been prefigured the trends for applying and generalizing the modern methods of quality analysis and control, for the dynamic orientation towards re-technologization with immediate and important effects upon the growth of the production precision, the dispersion reduction, the decrease of the labor and energy consumption and the fundamental shift of the control attribute, out of notable to preventive, laying a particular stress upon ensuring an optimum among the performance, the needs and the costs.

By means of the present research, we have intended the implementation of the latest methods of measurement and analysis required in establishing and ensuring the quality of medical devices production, as essential conditions for bio-medical systems quality assurance.

If the flexible automation line is well-designed and flexible modulated it can achieve in using significant and major cost reduction results, with increased control of products in process.

One of the best ways to raise and to sustain the quality is represented by standardized manufacturing procedures.

It is important that each manufacturing procedure could be performed in the exact same way, to achieve complete and performances results.

In the same time it is also imperative and very important that the operator must be authorized and best trained for the manufacturing operation for medical devices.

These actions could be done through modular and interconnected procedures, and the operator must be trained and work with the qualification in medical device productions.

**5. REFERENCES**


6. ADDITIONAL DATA ABOUT AUTHORS

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