

The Products and Technology Development Strategies of the Horiba Medical Group

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Abstract

Systems for medical treatment are undergoing major reconsideration, and the manufacturers of clinical testing devices are experiencing a period of great transition. Today, there is a demand for the simultaneous realization of quantity, quality and speed. With compact blood testing devices as a weapon, the Horiba Medical Group is working to develop business in the field of point of care testing. In this paper, we present an introduction to what projects the Medical Group currently has underway, and what measures the Medical Group is planning to implement, with respect to the changes taking place in the market environment of clinical testing devices.

1 Introduction

The field of clinical testing is undergoing a period of great transformation, with demand for improvement in terms of quantity and quality, as well as speed. With major advances being made in medicine, combined with a comprehensive medical insurance system, people can now expect to lead healthy lives into old age. However, these factors are driving up the overall cost of maintaining the nation's healthcare system, and have begun to strain the government's finances. Japan's Health, Labor, and Welfare Ministry is already considering the introduction of comprehensive cost-cutting methods such as DRG-PPS and Critical Path, which have been adopted by the U.S. and some countries in Europe. These methods incorporate the principles of carefully selecting which tests should be carried out, as well as insurance points systems.

With clinical testing moving in such a direction, and with big changes occurring in society and the business environment, the Horiba Medical Group is moving ahead with a wide-ranging reappraisal of its own business practices. The company's basic philosophy of offering customers the products they want, at appropriate prices, and speedily, remains unchanged, but in response to fast-changing market needs, we aim to develop products even more speedily, while at the same time acknowledging that we must adapt to the rapidly emerging global market and

ensuring that we stay focused on the needs of individual customers.

This article outlines the products and development strategies of the Horiba Medical Group, using blood-testing devices as its key example.

2 Demands for Improved Productivity and More Compact Devices for Clinical Testing

Today's trend finds medical organizations testing increasing numbers of samples and conducting increasing numbers of different types of tests. The introduction of automatic blood testing equipment and the amalgamation of testing laboratories is contributing to improved productivity in the clinical testing field. The drawbacks are that costs for introducing such new systems are increasing and that the test labs and the surgeries where medical treatment is carried out are growing farther apart.

It is a commonly heard complaint that it can take a very long time between a visit to the hospital and the time when the test results are ready. This trend is especially prevalent in smaller hospitals where computer networks, etc., are not adequate. The long wait for test results is not only bad for patients, but is also a cause of stress for the medical staff who want to diagnose patients and start treating them as soon as possible.

In an attempt to relieve these problems, some larger medical institutions are trying to improve the productivity of clinical testing by introducing automatic testing devices and FMS/ branch labs, and by installing advanced computer networks. Smaller surgeries and clinics that cannot afford such large capital investments are increasingly cutting costs by outsourcing testing to specialist test centers. However, hand in hand with improved productivity, there is still the problem that the surgery where the doctor meets patients and the place where testing is carried out are becoming more distant from each other.

The ideal arrangement would be that the necessary testing is immediately done at the clinic or surgery so that an accurate diagnosis can be offered without delay. In the case of patients requiring emergency treatment, this can be a matter of life or death. There are also cases where it is necessary to continuously monitor the effects of medicines that were given to a patient. In these cases it is necessary for testing equipment to be brought into the operating theater or surgery.

In individual clinics, if a doctor can perform tests and at the same time explain to the patient, face-to-face, what he is doing, then patients' trust in their doctors should improve. Furthermore, by taking a sample of the patient's blood, testing it, and then looking at the raw data, it is possible that important or unexpected data could be obtained by the doctor in a way similar to a physical examination of the patient's body.

Although the large-scale testing systems outlined above have merits, it cannot always be said that they fit with the idea of an ideal system. It is important to build clinical testing systems and testing equipment that are speedy and can be used flexibly. The Horiba Medical Group aims to pursue dynamic change in the clinical testing market, differentiating development, production, and sales to ensure efficiency in its global operations.

3 Automatic Blood Cell Counters - the Pentra Series

The ABX-developed Pentra series are stand-alone automatic blood cell counters that allow for appropriate testing, at the appropriate time, give accurate and fast results, and are easy to use. These instruments can count the number of white blood cells in the blood and determine their type.

Makers of clinical test equipment need to supply two different types of devices: those for use in laboratories, and others for use in the surgery – so called point-of-care-testing. Skilled lab technicians and other specialists

use the former, whereas the latter are for use by the doctors and nurses and other medical staff closest to the patient.

The Pentra series caters to every segment of the market. The Pentra 60 is aimed at small private medical practices and small hospitals and clinics and the Pentra 120 is designed for use in testing laboratories. In addition to being able to count five types of white blood cells, the devices in the series can also form smears which are essential in examining the state of blood.

All blood testing devices must be accurate, reliable, and suitable for a wide range of different applications. Horiba's Pentra 60 is special in targeting a segment not covered by the products of other makers – an automatic blood cell counter designed specifically for smaller hospitals and clinics. (For more details, see pages 24-28 of this issue.) The features and functions demanded vary depending on the region or country in which the devices are to be used. For example, in the U.S. and Europe, where doctors, lab technicians, and equipment operators all have clearly defined roles, ease of operation is a priority. However, in Japan, where different kinds of people use equipment, there is more demand for better performance and accuracy.

The Horiba Medical Group has split the world into three main sales regions – Japan (Horiba), Europe (ABX S.A.) and the U.S. (ABX Inc.) – and has production, sales, and service operations in many different countries. This makes it possible for the company to best suit the needs of each individual market.

4 The Idea of Medical Plus

Horiba's LC-270 CRP automatic blood cell counter first appeared in 1998. It is easy to operate: it requires only that a blood sample be set in its sample holder, and it then simultaneously tests for eight basic properties (WBC, RBC, Hgb, Hct, PLT, MCV, MCH, MCHC) and an immune serum, C-reactive protein (CRP). It is the world's first compact-size hematology analyzer.

In blood testing, a white blood cell count is widely used as the primary test for inflammation. CRP, on the other hand, is a useful test for diagnosing acute tissue damage or infections. By being able to perform these two tests simultaneously, a more accurate diagnosis can be obtained. Patients also benefit, thanks to the fact that only a small amount of blood needs to be drawn.

The LC-270 CRP analyzer performs these two important tests, which use using very different testing principles, in a device having a very compact design. In

fact, in conventional blood testing, the two tests are sometimes carried out in different sections of the lab – the blood testing section for white blood cell count, and the biochemistry and immunology sections for CRP. In particular, the device has garnered high approval for the speedy way it can test for inflammation from the many small clinics and hospitals that use it for emergency testing.

The reason for Horiba's lead over other makers, despite its later entrance to the market, and its continued strong position in the market for blood testing equipment, is that the LC-270 CRP is based on the idea of “medical plus.”

For diagnosis of inflammation, CRP testing is firmly established in the Japanese medical services market. In the U.S. and Europe, sedimentation testing (ESR) is still used, but this technique will eventually be replaced by CRP. ABX is starting to market the MICROS CRP (which can test for three types of white blood cells) in Europe and the U.S. to establish Horiba's hematology analyzers as global products.

5 External Quality Control System - QCSP

Horiba provides an external quality control service—quality control support program (QCSP) – to users of its blood analyzers. In order to ensure that accurate results are obtained from its analyzers when testing living tissues, a strict quality assurance regimen is indispensable. In large laboratories and testing centers specialist technicians analyze test results on a daily basis to ensure that equipment is in good working order and being used properly – so-called in-house quality control. These large centers also participate in control surveys organized by medical councils so that they can compare their performance with that of other similar institutions. However, at medium and small-sized institutions, tests are performed and equipment is maintained by busy doctors and nurses. For this reason, it can be difficult for smaller hospitals to ensure they have an adequate level of quality control. These customers want some kind of backup support service.

Horiba believes it should offer its customers full quality control support, not only for its equipment, but also for the whole testing process. The QCSP is Horiba's system for carrying out external quality control monitoring by analyzing test results sent in by participating centers to ensure that equipment is functioning as it should. Users of Horiba devices can feel confident that with QCSP and our on-call service, they are receiving full support.

6 Developments in the Twenty-First Century

The roots of the Horiba Medical Group lie in basic technologies such as the pH meters and infrared gas analyzers that were the basis of the SERA series of electrolyte analyzers and exhaled gas analyzers, and which have been a part of Horiba's product lineup since the firm was first established. Since 1996, with the addition of specialist blood testing equipment maker ABX, the Medical Group's business has developed dramatically. The driving force for this development is demand for stand-alone devices—both in Japan and around the world—a case of “Think Global Act Local.”

The environment surrounding the clinical testing equipment market is changing drastically. Improvements in both quantity and quality, as well as in speed, are now demanded. Horiba intends to more fully develop the existing market, as well as to create new products for related fields, in order to continue to develop its business. Research and development based on Horiba's core technologies will allow us to overcome existing boundaries. One of the ABX clinical testing department's medium-long term strategies is to introduce new technologies into its hematology testing devices. The Horiba Group's technological strengths, along with careful assessment of user needs and superb cost-effective manufacturing processes, will continue to differentiate the company from its rivals.

In Europe, ABX is working jointly with universities to develop a groundbreaking new large-scale device that should be ready in the near future. Horiba is continuing to develop smaller devices, with the main emphasis on quality, in order to pursue its strategy for penetrating the global market. Furthermore, new sensors are being developed, based on new micro-processing technologies, and these may also end up being used in the clinical testing equipment field.

In this article I have introduced the products and technology development strategies of the Horiba Medical Group. These products and developments are all made possible by the customers that use our devices. We hope to receive their continued support and feedback.

References

1) DRG-PPS (Diagnostic Related Group-Prospective Payment System)

The idea of a fixed fee being stipulated for treating a group of related or similar medical problems.

Whatever tests or treatments are carried out, the patient is charged the fixed fee. It was introduced in the U.S. in 1983 and is currently under consideration in Japan.

2) Critical Path

A schedule of a series of medical steps-from hospitalization, testing, and treatment to discharge from the hospital. It is expected to help both medical institutions and patients understand the process better.

3) FMS - Branch Labs

The practice, usually by larger hospitals, of outsourcing clinical testing. With FMS (Facility Managed System), the hospital supplies the test technicians and buildings for a testing center that carries out the testing. For a branch lab, the hospital rents out the lab space to the test center (branch lab), which is responsible for all testing and management of tests.

4) Point Of Care Testing (POCT)

All clinical testing performed away from specialist testing centers. It includes bedside testing (by hospital staff), self-testing (by the patient testing him or herself), and testing inside small clinics, etc.

5) Control Survey

A quality control system in which identical samples are tested by a number of different test centers and their results are analyzed and compared independently.



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