

Action plan for “RESEARCH AND PRODUCTION OF MEDICAL EQUIPMENT TO 2010”

(DECISION 18/2005/QĐ-TTĐ DATED 21 JANUARY 2005 OF THE PRIME MINISTER)

1.1 PROJECT OBJECTIVE

a. Overall Objective

“To concentrate scientific and technological potentials nationwide on the formation and development of Vietnam’s medical equipment manufacturing industry, which, by 2010, will be capable of manufacturing and supplying essential and common medical equipment as well as a number of hi-tech equipments for healthcare establishments at all levels; ensuring the achievement of the targets of the national policy on medical equipment in the period of 2002 and 2010”.

b. Specific objectives

- By 2010, to ensure the satisfaction to 60% of the entire health service's demand for essential and common medical equipment.
- To focus in-depth investment in production chains of medical equipment so as to improve the quality and designs, promote new brands, thus meeting the domestic demand and step by step involving in export activities.
- To set up domestic scientific-technological institutions with full conditions and capability for research into, and manufacture of, hi-tech medical equipment including X-ray machines of all types, diagnostic ultrasonic machines, electrocardiographic equipment, high-frequency scalpels, medical lasers, bio-chemical and hematological analyzing devices, etc...
- To expand and complete the system for standardizing control of medical equipment, which shall, by 2010, be capable of controlling such medical equipment as required by the Ministry of Science and Technology.

-To develop human resources specialized in medical equipment; to build and strengthen services and repair centers of medical equipment; the first stage would be for ones in Hanoi, Danang and Ho Chi Minh city, then expanding to other provinces; to exploit potentials and bringing internal strengths into play, thereby to ensure the realization of the core objectives the National Policy on Medical Equipment.

- To use efficiently medical equipment already furnished at the current healthcare establishments and avoid inappropriate purchase of equipment for respective healthcare levels.

II. IMPLEMENTATION PROGRAM

- Based on primary principles and criteria for research and production of medical equipment (3 principles and 6 criteria), the medical equipment to be focused in research and production in the plan to 2010 have been identified in the Decision No. 18/2005/QĐ-TTg.

- Based on functions, responsibilities, directions and attention of the related ministries and agencies for research and production of medical equipment.
- Considering the realities after several years of cooperation, monitoring, assessing the potential, capabilities and experience as well as reputation of science and technology institutions and production facilities in whole country, the Ministry of Health proposes 7 sub-projects on medical equipment categories required focused research and production in the period of 2005 - 2010.
- Successful implementation of the 7 below sub-projects will greatly and decisively contribute to the success of the National Policy on Medical Equipment in the period of 2002 - 2010

2.1 SUB-PROJECTS

1. Sub-project on research and production of hospital interior devices and equipment (34 types of products)

Participants:

- State-owned enterprises
- Join-stock companies
- Private companies
- The foreign-invested enterprises

2. SUB-PROJECT ON RESEARCH AND PRODUCTION OF PHYSIOTHERAPEUTIC AND REHABILITATING EQUIPMENT

➤ **Leading Institution:**

Institute of Bio-medical physics
The Ministry of Defense

A. Manufactured equipments:

- | | |
|-----------------------------------|----------|
| 1. Therapeutic laser equipment: | 187 sets |
| 2. Therapeutic electrical device: | 66 sets |
| 3. Therapeutic magnetic device: | 274 sets |

B. Equipment to be researched and produced in 2006-2010

- | | |
|--|----------|
| 1. Therapeutic Laser machine: | 296 sets |
| 2. Therapeutic short-wave machine: | 790 sets |
| 3. Continuous and pulsed microware machine | 770 sets |
| 4. Therapeutic Ultrasound machine: | 350 sets |



- Prof. Dr. Le Ngoc Trong – Vice Minister of Health, on his visit to Laser Technology Center (Institute of Technological Application, Ministry of Science and Technology).



3. SUB-PROJECT ON RESEARCH AND PRODUCTION OF MEDICAL ELECTRO-MECHANIC EQUIPMENT AND PHARMACEUTICAL EQUIPMENT

Leading Institution:

Binh Dinh medical equipment and pharmaceutical Company

A. Manufactured equipments:

1. Automated Sterile Autoclave 250 – 2000 litres
2. Washing machine 50 kg
3. Sterile hand cleaning instrument
4. High rate mixer device
5. Fluid-bed Dryer
6. Double-time water distilling machine, 300-litre per hour

B. Equipment being researched and technological developed for production

1. Automatic uninterrupted infusion bottling system
2. Closed pharmaceutical processing system
3. Uninterrupted washing, drying and filling system
4. Industrial waste treatment system
5. Goods transporting belt used in GSP warehouse.

4. Sub-project on research and production of high-tech medical and therapeutic equipment

Leading Institution:

Centre of laser technology (Institute of research And application - Ministry of science and technology)

Collaborating institutions:

- Units under the Institute of Research and Application
- Institute of Materials, Institute of Electrics – Vietnam Institute of Science and Technology
- National Institute of Atomic Energy
- General Department of Quality, Measurement and Standards
- Ministry of Defense
- Hanoi University of Technology

This is a major sub-project with the objectives to:

- Produce high-tech medical equipment of substantial value to support the renovation and modernization of hospitals.
- Set up medical equipment facilities of desired size and ISO 9000-2001, in order to research and produce scientific products greatly needed for local use and for export.
- Train a force of highly-qualified scientific and technological experts in medical equipment.

5. SUB-PROJECT ON RESEARCH AND PRODUCTION OF BIOCHEMICAL, HEMATOLOGICAL ANALYZING DEVICES, LABORATORY EQUIPMENT AND SPECIALIZED DISPOSABLE MATERIALS

Leading Institution: **Vietnam Institute of Science and Technology**
(Participating institutes include those leading each item of sub-project)

No	Name of products (38 types of equipment, devices)	Technological solutions	Research , trial	Pilot sub-industrial production	Full-scale production
A. Group of materials and diagnostic devices					
1	Electro-diagram signal analyzing machine	Research	X		
2	24/24 hours CV Monitoring Holter machine	Technology completion		X	
3	Clar lights	Production			X



Pulsed magnetic therapeutic machine, 2 chanel, 2 frequencies and 5 frequencies
Model: DK-800



Magnetic therapeutic Machine
DK-1500



Vietnam institute of science and technology Institute of physics & electrics - center for physical techniques



Magnetic cups MC 35-45



Magnetic watches



Magnetic bells

6. SUB-PROJECT ON RESEARCH AND PRODUCTION OF HOSPITAL EQUIPMENT AND STERILIZATION EQUIPMENT

Leading Institution:
Informatics

Vietnam Cooperation of Electronics and

Implementing institution: Dong Da Electronic Company

Have produced 45 types of equipment and devices for medical projects,

No.	Produced Equipment	Units	Quantity
A. (Supply to World Bank projects in 2001)			
1	Autoclave, 20 litre	piece	2,135
2	Autoclave of all types	piece	4,200
3	Autoclave, 50 litre	Piece	145
4	Autoclave, 160 litre	Piece	145
5	Fluid removing machine, on troller	Piece	297
B. Epidemic control program (in 2003)			
1	Autoclave, 75 litre	piece	8

Federation of science for high-tech material production



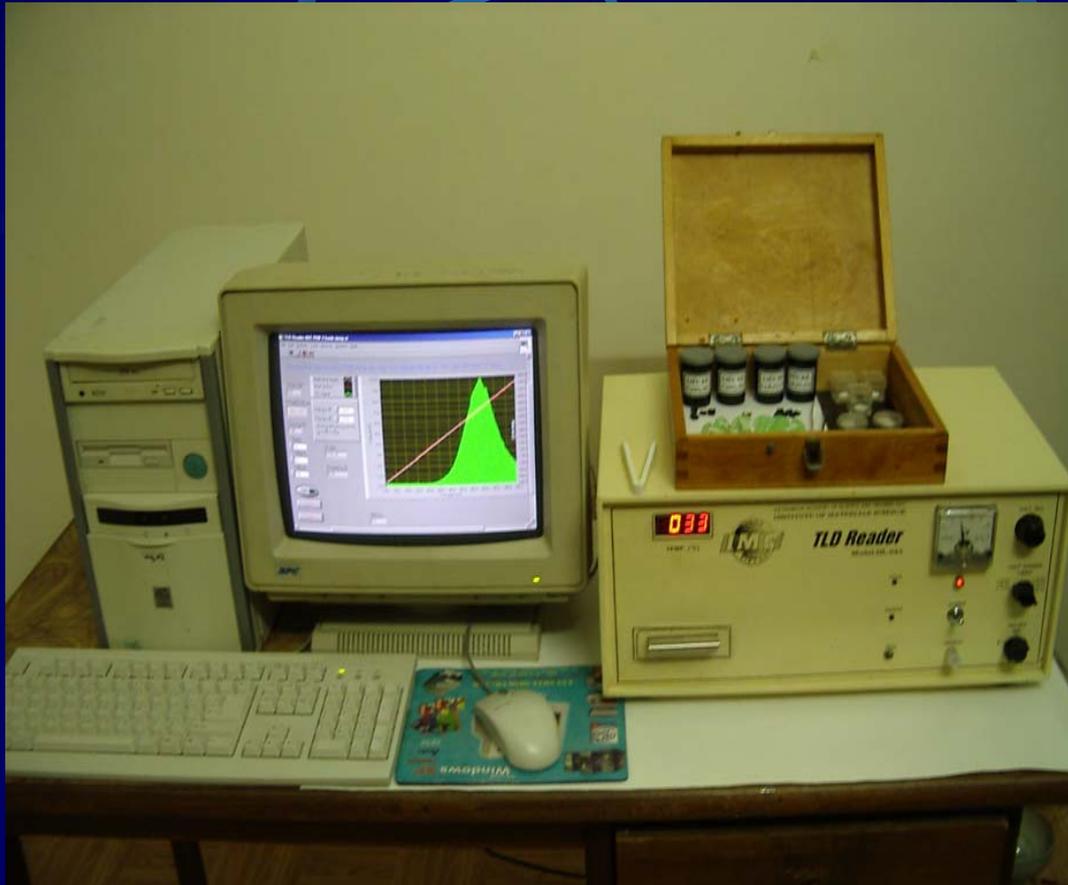
High and low frequency therapeutic machine



Therapeutic machine using electrical static ions



**Institute of material sciences
vietnam institute of sciences and technology**



**Dosing meter reader Model DL 04-1
and different types of dosing meter**



7. Sub-project on research and production of diagnostic imaging & functions detection machines

Leading institution: Vietnam Cooperation of Electrics and Informatics

Implementing institutions:
Advanced Medical Engineering Company (AMEC)
Dong Da Electronic Company
Thu Duc Electronic Company

A. Produced Equipment:

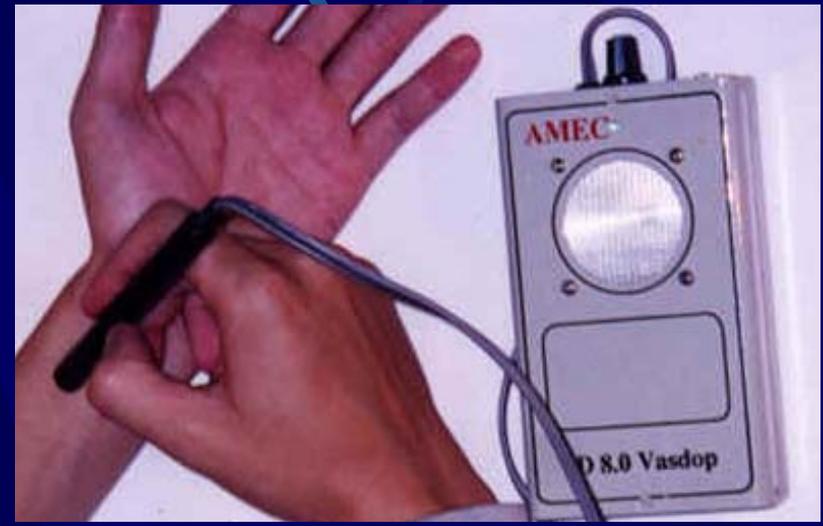
Presently this Sub-project has produced Foetus pulse doppler machine, demo electro-cardiographic machine for training purpose.



Foetus pulse ultrasound doppler machine



Computerized electro-cardiographic machine



Pulse doppler machine

To improve quality of management, ISO 9001-2000 has been applied since 1 November 2004

TỔNG CỤC TIÊU CHUẨN
ĐO LƯỜNG CHẤT LƯỢNG
TRUNG TÂM CHỨNG NHẬN
PHÙ HỢP TIÊU CHUẨN

DIRECTORATE FOR STANDARDS AND QUALITY
STAMEQ
VIETNAM CERTIFICATION SERVICES
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GIẤY CHỨNG NHẬN CERTIFICATE

No.: HT 907.05.19

Chứng nhận hệ thống quản lý chất lượng của:
This is to certify that the Quality Management System of

CÔNG TY ĐIỆN TỬ Y TẾ KỸ THUẬT CAO- AMEC
ADVANCED MEDICAL ENGINEERING CORPORATION

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cho lĩnh vực / for the following activities:

**Kinh doanh và Cung cấp dịch vụ kỹ thuật cho Thiết bị y tế;
Thiết kế, Phát triển và Sản xuất Thiết bị chẩn đoán y tế**
**Trade and Provision of Technical Services for Medical Equipment;
Design, Development and Manufacture of Medical Diagnostic Equipment**

đã được đánh giá và phù hợp với các yêu cầu của tiêu chuẩn:
has been assessed and found to conform with the requirements of the following standard

TCVN ISO 9001 : 2000 / ISO 9001 : 2000

Giấy chứng nhận này có giá trị từ / This certificate is valid from:

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A27

CÔNG TY ĐIỆN TỬ Y TẾ KỸ THUẬT CAO - AMEC



Prof. Le Ngoc Trong, Vice-Minister of Health on his visit to the AMEC's stall at Vietnam Medical-Pharmaceutical Exhibition

III. Activities needed

1. Organize focus workshops in relation to the 7 sub-projects with participants being:
 - Scientists and technologists from leading and implementing institutions of sub-projects.
 - Medical Equipment Technical Committee of MoH
 - Specialized medical experts and specialized medical associations related to the products, will provide demand to sub-projects to identify categories and demand of medical equipment, so as to focus on research and production.
 - Progress and size of implementation of sub-projects – this depends on the demand of healthcare services by 2006 and by 2010.
 - Categories of products requiring investment for quality improvement, design improvement, marketing for subsequent export.

2. The Ministry of Health, in collaboration with Ministries of Trade, Science & Technology, Finance and Justice :

Develop and submit to the Government for approval of legal documents to ensure that the domestic medical equipment meeting quality specifications, holding marketing licenses and having affordable prices, will be used in the healthcare sector; and benefited from encouraging policies.

Import of medical equipment: Strengthen the business system (sale, import, export) to ensure that medical equipment from reputable manufacturers with their representative offices in Vietnam are imported, so that services and repair, as well as spare parts and disposables warehouses are available, and to ensure long-term services, thus avoiding risks for healthcare facilities.

3) The Ministry of Health, in collaboration with other related ministries, to direct

*** *Research and producing facilities***

- Research and production should be focused on those medical equipment identified as priority in previous section
- Have detailed plan for study and cooperation with manufacturers in preparing for technical staffs and technological facilities to meet ISO standards in order for technological transfer.

*** *Manufacturers:***

1. Establish and maintain ISO and GMP standards
2. Closely cooperate with scientific and technological centers aiming at continuous improvement of product quality, design and usage value, as well as reduction of prices

3. Pay attention to training for workers and technical staffs with skills and specialized qualifications
4. Focus on development of R&D and quality control laboratories
5. Set up and improve quality of services centers for maintenance of the products produced and sold by themselves

*** *Joint-venture facilities:***

- Implement the roadmap for localization as per the schedule outlined in the Project as approved; pay attention to training technical staffs and gradually transfer technologies to Vietnamese staffs
- Improve quality; reduce prices
- Avoid the formative joint-ventures; i.e. in practice, medical equipment is actually imported into Vietnam for sale

- ***Training for human resources in medical equipment:***

- + Upgrade and expand the Technical College of medical equipment.
- + Propose to the Ministry of Education and Training to consider and assign the task of technical training on medical equipment to Hanoi University of Technology, HCMC University of Technology and other technical schools on medical equipment which have capability as required.
 - + Continue the cooperation with the Universities of Technology in Hanoi and HCMC to train medico-biological engineer.

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thank you