Promising industrial products from research in the field of biomedical technology

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**CONTENTS**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>2</td>
</tr>
<tr>
<td>2. The researchers</td>
<td>3</td>
</tr>
<tr>
<td>3. Scientific research</td>
<td>4</td>
</tr>
<tr>
<td>4. Total picture</td>
<td>7</td>
</tr>
<tr>
<td>5. Status of suggestions for promising products</td>
<td>9</td>
</tr>
<tr>
<td>6. Image-forming and image-processing units and accessories (FC 03.00.00)</td>
<td>11</td>
</tr>
<tr>
<td>7. Equipment and accessories for function research (FC 06.00.00)</td>
<td>12</td>
</tr>
<tr>
<td>8. Laboratory equipment and accessories (FC 09.00.00)</td>
<td>13</td>
</tr>
<tr>
<td>9. Surgical instruments and accessories (FC 15.00.00)</td>
<td>14</td>
</tr>
<tr>
<td>10. Equipment and accessories for support of organic function (FC 18.00.00); artificial tissues and artificial organs</td>
<td>14</td>
</tr>
<tr>
<td>11. Aids for the handicapped (FC 21.00.00)</td>
<td>15</td>
</tr>
<tr>
<td>12. Therapeutic equipment and accessories (FC 24.00.00)</td>
<td>16</td>
</tr>
<tr>
<td>13. Other areas of interest</td>
<td>16</td>
</tr>
<tr>
<td>14. List of contact persons with reference to the suggestions put forward</td>
<td>17</td>
</tr>
<tr>
<td>15. References</td>
<td>18</td>
</tr>
<tr>
<td>16. List of technical terms and abbreviations</td>
<td>19</td>
</tr>
</tbody>
</table>
1. Introduction

This report puts forward a number of suggestions for promising industrial products in the field of biomedical technology (BMT). It was commissioned by the Ministry of Economic Affairs (EA). These suggestions are in part based on the research survey made by the Interuniversity Consultation on Research and Education in biomedical technology (IUO-BMT) (ref. 1). It was carried out in the framework of a long-term dialogue between the national BMT consultation process and members of EA (summarised in ref. 2).

The suggestions in this report were made by BMT researchers on a personal basis as stated in section 14. The authors express their thanks for the cooperation of the persons concerned. One university made reference to a communication of its own to EA and expressed the wish that the points of view put forward on that field should not be ventilated afresh in the present report. In a relatively large number of cases it was stated that concrete ideas were available but that it was desired not to disclose them as they were intended for possible initiatives that might be taken in the direction of industry. Naturally this has to be respected by us. We only state it as a matter of fact.

The ideas in this report are presented in brief form by researchers from university institutions. It has been found when there is insufficient experience in this field the suggestions put forward are open, not only to overestimation but also to the opposite. In sections 2 and 3 we outline the world in which the researcher lives in order to make clear what can be expected from these ideas for industrial innovation and what can not.

In section 4 we sketch a total picture of the interconnections between university institutions, industry and the health-care system. We feel that it is right and proper to give consideration to policy formation in this framework in such a wide context. Section 5 summarises afresh everything that we have considered of interest as regards the status of the suggestions made in the present report. Here are also expressed a number of personal standpoints with regard to further progress on the basis of these ideas. Where the suggestions have been personal ones on the part of the researchers already mentioned, the context of the first five sections is wholly attributable to the authors of the present report.

As regards the suggestions received, we have chosen the same brief formulation as that used in the IUO-BMT survey (ref. 1). In order to make this somewhat more accessible to a wider readership we have added a list of technical terms and abbreviations.
2. **The researchers**

A researcher in a given branch of science is oriented to a specific field of data. He is concerned with searching out, identifying and verifying these data. He seeks to systematise and classify them and to obtain scientific insight into the target field in so doing.

The acquisition of scientific insight is the aim and justification on the part of the researcher. The standards for his activities he obtains from science itself. So to speak, these standards are autonomously laid down for him.

Professor John Ziman (ref. 3) described the scientist as an extremely individualist and introverted person who works intensely on an extremely difficult and highly specialised subject, seeking to achieve a reputation for excellence in that subject. The academic manner in the pursuit of science, as Professor Ziman says, will even cause people who do not have a natural aptitude for the job, to persist and, in many cases, to succeed.

The development of science is moreover characterised by a rapid increase in the number of specialisms and an increasing dynamism in all those fields of research. Excellence in a given branch of science requires long-term training, intensively keeping abreast of numerous developments in the field of interest, and makes a great deal of concentration, creativity and hard work essential.
A scientific career thus needs a great deal of time and dedication, so that there is practically none left for anything outside. The great restlessness caused in recent years by cut-backs, changes in scientific education and the restructuration of research has negatively affected the situation still further.

All the suggestions considered significant in the present report on industrial developments have to be looked at against the background of the reality sketched out above. These suggestions have been made by researchers. They have not been based on market analyses. Only in a small number of cases is there mention of anything like a first prototype. As a rule, no test production run has been made and further surveyed by means of field research. Production-technology aspects are scarcely considered or not at all. Well considered costs/profit analyses are in no way to be expected in the present report. The domain of a specialised researcher in any BMT field has no place for such aspects.

BMT researchers arrive at these suggestions thanks to their long years of experience with technological applications in a given field of medicine, from their knowledge of the various developments in such a field and from their feeling for the most promising trends in these fields. Such suggestions are the result of what one might call scientific marketing. They indicate what is expected in their fields with regard to medicine in the immediate future. In application-oriented BMT research account is often taken of equipment available on the market for given medical functions. Suggestions from this "angle of incidence" are then partly based on considerations that better equipment is possible or that, in some cases, could be marketed more cheaply. All these suggestions can be evaluated as such and it is worthwhile making use of them in a policy which is oriented to strengthening Dutch industry in this market.

3. **Scientific research**

Between a new product on the market and the scientific research on which it is based there is a certain interval. This interval or distance can be described as time required, manpower, provisions available. One can distinguish between various forms of science. The distance between these forms of science and such a new product is variable. A common distinction is shown in figure 2.

It is practical empirical science which stands closest to a new product. Here we find the realisation of new products, methods, systems or processes. It is also described as applied research. Theoretical empirical science stands further away from a new product. Here research is oriented to the acquisition of more fundamental insight in the form of a theory or a given model of reality. The distance to a new product is still greater in the case of non-empirical science. Here analytical tools are developed. For instance, mathematics is considered as belonging to this branch of science. The position of prototypes and test-production runs in this framework is discussed in section 4.
BMT research occurs in all these forms of science. A BMT research project often has elements from all these manifestations of science. As a rule the accent in that case lies, however, in one particular manifestation or other. BMT research is either strongly application-oriented or dominantly structured in the direction of basic insight.

It will be clear that, in interpreting the suggestions of BMT researchers in the body of this report, it is important also to consider the scientific starting point from which they have come into being. From the standpoint of application-oriented research a new product can be developed in a shorter period of time than would be possible by way of suggestions from more basic research. From successful basic research new insight can lead to more thoroughly considered specifications for a new product, with greater promise for successful development, but as a rule a great deal more has to be done before that is the case.
BMT research is multidisciplinary in nature. Figure 3 provides an impression of this. Such a research development commences with the statement of the medical problem and its translation in terms of a technological problem. The formulation of such a problem in both branches of science mostly takes place in an interactive process between experts in these various disciplines. Then follows the selection of theories and the formulation of working hypotheses. They are tested in calculations and experiments, which again leads to adjustments to theory and working hypotheses. As a rule these empirical cycles are gone through several times. In the development of the experiments, different technological disciplines are often applied. In animal experiments and in clinical evaluation, various medical disciplines have their role to play. A BMT project will in most cases require the attention of a complete multidisciplinary team of researchers.

Figure 3:
Process followed in research and product development in the field of biomedical and health-care technology
Should such a BMT project give rise to a new product which is promising for industry, then the same amount of dedicated attention is required for the design cycle. From the environment of research and often, too, from the standpoint of an industry, such a product development is estimated in fact as a bit too simple. Of course, all the partial processes shown in figure 3 will not always be of significance for a new product. Experience has shown that careful estimation of all aspects concerned in the development of a product is anything but simple and certainly very necessary. It has also taught that there can be cases in which the initial "push" by research must give way to a "pull" from industry. There is moreover a great deal of management concern required for such a process of innovation, and it is known, again from experience, that industry can provide for this much better.

4. **Total picture**

In figure 4 below we sketch a rough picture of the interconnection between university institutions, industry and the health-care system as seen from the standpoint of industrial innovation. By university institutions we understand traditional universities as well as technological ones. Sections 2 and 3 discuss some aspects of this.

*Figure 4:*

A picture of the interconnection centring on an industrial innovation in the field of biomedical and health-care technology.
In BMT research the relationship with health-care experts is good as a rule. In medical faculties at the universities this interlink is of course very strong. But for BMT projects at technological universities also involves cooperation in research, mostly in an inter-university framework, and sometimes with peripheral hospitals.

The Netherlands health-care system is a far from negligible market for industry. The National Hospital Council (Nationale Ziekenhuisraad) has recently estimated this market at a value of three thousand million guilders per year, 0.8 thousand million guilders per year being spent on capital goods (reference 4). The health-care system shows a number of specific market characteristics. Some of them are mentioned in reference 2. These market aspects have of course to be thoroughly investigated. Too little insight increases the chance of suffering shipwreck with a product. Knowledge of this is even considered to be important for the decision processes as to operating on this market or not. Under the auspices of the Ministry of Economic Affairs a study is being carried out on these specific aspects of the market by the Business Management group of Product Development at Delft University of Technology.

This report is primarily intended for the information of industry. It is therefore not considered advisable to discuss the aspects stated in figure 4 in this connection with reference to the industries concerned. It must be stated that cooperation between BMT research at university institutions and industry occurs relatively seldom, although it is not completely unknown.

Figure 4 therefore leaves something suspended in the air, as it were, that is the production of prototypes, the production of test series and their evaluation in market situations. Of course these aspects attract the attention of industry when they give rise to new products on the market. But as we have already stated in the introduction, the picture here sketched is based on the ambience of BMT research. Where BMT research is rounded off with a product, possibly suitable for industrial innovation, it is no simple matter to find an industry willing to take it up directly. The majority of small and medium-sized industries do not pursue so aggressive a policy. The financing system, however, allows a university institution no room for adding the above-mentioned steps to such an investigation. The present-day structure and usage at our university institutions are moreover considered by us to be hardly suited to this sort of activity. But structural solutions can certainly be found for the problem sketched out here. We restrict ourselves at the moment to drawing attention to it.

The total capacity in BMT research at our university institutions is in the order of 300 full man-years per year. It is of course important to give structure to the necessary situations for orientation towards the question as to what can be important objects for this research capacity. Based on the initiative of the Interuniversity Consultation on BMT and structured by the Eindhoven University of Technology, one or more workshops are held every year on these aspects of medical technology assessment (see also reference 6). Here, too, we feel
obliged to say that the financing system governing our university institutions scarcely envisage the scope required.

Finally, two important aspects concerning every industrial innovation in this field. Attention to the integration of all elements essential in such an innovation, and forceful innovation management based on an industry intending to market such a product. During the development period, many small and middle-sized industries are incapable of meeting such temporary management requirements. In the present report we make a plea for a structural solution to the problem, that is setting up a network of organisational consultation bureaux, manned by experts in the BMT field, who can provide such temporary specific needs in project management. We restrict ourselves here to posing the problem and putting forward this suggestion for its structural solution.

5. The status of the suggestions for promising product developments

The ideas for industrial innovations are classified in the following paragraphs in accordance with the Functional Classification System (FCS) for hospital inventories (reference 5). The reference numbers refer to the list of persons given in section 14. Of course, all these suggestions are put forward without engagement and are given on a personal basis. The figure below the column with the heading "promising", states the rating for each suggestion - from 1 (very promising) to 4 (promising) inclusive - expected by the persons concerned for the product development in question. The indications S or L indicate whether this is expected in the short or the long term.

All persons who put forward suggestions had at their disposal the recent BMT survey of the inter-university consultation (IUO) on biomedical technology (BMT) (ref. 1). The majority stated what they personally thought was a promising product development in this survey. A number of suggestions referred to matters outside this IUO compilation of BMT elements. It is important to stress once more that all these suggestions come from the ambience of BMT research. What can be expected and what not, is stated in sections 2 and 3. No commercial analyses are centred on this kind of product, but what we call scientific marketing is certainly behind all these suggestions; as a rule no ideas enabling a product to be quickly put on the market, but usually products with considerable added value, products whose development is a relatively complex matter, which require time, and above all, forceful project management.

In section 4 we put forward a plea for the promotion of organisational consultation bureaux for the temporary provision of specific management requirements in the various phases of such a process of innovation. It is our belief that the interval between a suggestion stated in this report and the marketing of such a product would have to be bridged over in this structural manner.

We feel obliged to take up a firm position against the expectation that by way of some general operations, part of the said suggestions can in some simple manner be identified as the most promising for Netherlands industry. For instance, we do not believe that it can be achieved.
simply just by means of a delphi survey involving all those persons who contributed the suggestions put forward in the present report. We should consider this as a grave underestimation of the volume and complexity of the health-care system and research oriented towards it. All suggestions in this report come from researchers who are active on a relatively small area in this whole field. They have good insight into that narrow area and as a rule scarcely any into the whole medical-technical field of developments outside of it. In addition to the problem of the large number of subsectors in the health-care system, there is also the variation in the form of BMT research and the inherent differences in distance to the reality of a new product. We have already discussed this in section 3. We shall make reference once again to the inadequate availability of commercial market insight concerning new products. No single operation on the part of such a group of experts can do anything directly to change this situation. The corpus of suggestions given in this report forms a summation of many fragmentary points of view. They have been collected by specialists on a limited area and here and there by generalists over a somewhat wider one. The diversity to be found among all these experts and in all the suggestions put forward by them is too great to expect much realism in their judgement on suggestions by other persons active in a completely different area of the health-care system.

However, we do not wish to leave any doubt as to the value of all these suggestions. What we do plead for is that, as a follow-up, every single suggestion is considered with the necessary care. From experience we feel it is our duty to point out that the care and attention required is of an extremely high order and that it successfully can come most from an interested industry. A product development and a decision process with regard to it is usually largely determined by the strengths and weaknesses of a given industrial enterprise and by the strategic perspectives of such an enterprise. And this is different for each and every one.

Finally we should like to refer to opinion formation as met with in an "innovation-oriented research programme" on the subject of biomedical technology. The appendices 3 and 4 of reference 2 provide more details. It is our opinion that very many suggestions given in the following pages can in fact result in new products by way of such a financing system. In the structuration of such a programme for the purposes of BMT, however, account has to be taken as far as possible of the wide-ranging reality described in the foregoing pages.
short (s) or long (l) - term
very promising (1) - promising (4)
reference suggestion, see section 14

6. **Image-forming and image-processing equipment (FC 03.00.00)**

| a. Ultrasound Doppler equipment ("vascular laboratory") | 18 | 3 | s |
| b. Ultrasonic medical diagnostics: | 15 | 1 | s |
| improvement in resolution; development of sensors | 2 | 4 | 1 |
| c. Imaging technique with ultrasound | 3 | 1 | l,s |
| d. Multichannel-pulsed Doppler system | 1,2,9 | 1 | s |
| e. Identification of tissue by echo | 5 | 4 | 1 |
| f. Cardiac echo imaging | 5 | 2 | s |
| g. Automated image recognition | 8 | 1 | s |
| h. Software for pattern recognition | 15 | 1 | s |
| i. Image analysis system (automatic) | 5 | 1 | s |
| j. Methods for image storing and image reproduction | 5 | 2 | 1 |
| k. Image processing in medicine | 13 | 2 | 1 |
| l. Quantitative analysis of angiograms and scintigrams | 15 | 1 | s |
| m. Collimators and software in nuclear medicine | 15 | 1 | s |
| n. Helium-saving superconductive magnet for the purposes of MRI | 15 | 2 | 1 |
| o. Positron Emission Tomography (PET) | 8 |  |  |
| p. Building compact cyclotrons for production of very-short-lived isotopes | 2,7,12 | 2 | 1 |
| q. Manufacture of automated labelling machine for PET | 2,7,12 | 3 | 1 |
| r. Medical database systems | 5 | 2 | 1 |
| s. Clinically oriented medical and management subsystems, communication networks | 8 | 2 | s |
| t. Software development for first-line health care | 8 | 4 | 1 |
| u. Universal microcomputer for obtaining and processing biological signals | 16,19 | 4 | l,s |
short (s) or long (l) - term

very promising (1) - promising (4)

reference suggestion, see section 14

7. **Equipment and accessories for function research (FC 06.00.00)**

7.1 **Heart and circulation (FC 06.05.00)**

- a. Improvement and automation of diagnostics 13 1 s
- b. Impedance catheter for evaluation of the pumping function of the normal and abnormal heart 13 3 l
- c. Atherosclerosis: measuring methods for early detection of slight constrictions in veins 10,13 2 l
- d. Detection of the His’s-bundle activity at the thorax wall 13 3 l
- e. Software for variability in heart rhythm 15 2 s
- f. Systems for cardiography during effort 17 s
- g. Electrocardiogram 17 s
- h. Mini laser-Doppler blood flow meter 17 s
- i. Medical database systems 5 2 l
- j. Medical transducers for diagnostics and examinations in cardiology 5 1 s
- k. Cardiac echo imaging 5 2 s
- l. Multichannel pulsed Doppler system 1,2,9 1 s
- m. Velocity measuring system for micro-circulation 1,9 4 s
- n. 200-channel ECG recording system 1,9 3 l
- o. Measuring system for mechanical deformation 1,9 4 l

7.2 **Nerves, muscles, brains (FC 06.10.00 and 06.12.00)**

- a. Measuring and recording methods for movements of the eye, and the equipment required 14
- b. Automatic measuring arrangement for single fibre EMG 2 4 s
short (s) or long (l) - term
very promising (1) - promising (4)

reference suggestion, see section 14

c. Equipment for measuring very slight quantities of neuropeptides in body liquids 11 1 1

d. Development of a squid with several sensors for brain examination 11 1

7.3 Lung (FC 06.15.00)

a. Lung function - gas transport technology (various measuring systems) 13 3 s
   b. Early diagnosis of lung abnormalities 13 3 l
   c. Impedance plethysmography (determination of liquids in the thorax) 14

7.4 Sundry

a. Recording and correlation of vital parameters obtained non-invasively 13 1 1
   b. Devices dealing with incontinence 18 3 s
   c. System for measuring the flow of urine (Universities of Leiden and Amsterdam) 2 4 s

8. Laboratory equipment and accessories (FC 09.00.00)

a. Non-radioactive labelled immunological laboratory kits, e.g. on the basis of monoclonal antibodies 18 2 s
   b. Mass spectrometry 13 2 l
   c. Tracer element analysis and analysis of the function of proteins in metal metabolism 15 1 s
   d. Cyto-flow meter 17 s
   e. Computer program cytophotometry 2 3 s
short (s) or long (l) - term
very promising (1) - promising (4)

reference suggestion, see section 14

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<tr>
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<tbody>
<tr>
<td>f.</td>
<td>Compact Raman microprobe</td>
<td>17</td>
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<td>g.</td>
<td>Disposable diagnostic kits (devices for testing gradient systems)</td>
<td>8</td>
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<tr>
<td>h.</td>
<td>Specific biosensors (including therapeutic drug monitoring)</td>
<td>8</td>
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<tr>
<td>i.</td>
<td>Intelligent biosensors</td>
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9. **Surgical equipment and accessories**
(FC 15.00.00)

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<tr>
<td>a.</td>
<td>Surgical laser unit combined with fibre optics</td>
<td>18</td>
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<tr>
<td>b.</td>
<td>Laser technology in surgery</td>
<td>8</td>
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10. **Equipment and accessories for support of organ functions**
(FC 18.00.00): artificial tissues and artificial organs

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<tr>
<td>a.</td>
<td>Materials for synthetic vessels (truly biocompatible)</td>
<td>18</td>
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<tr>
<td>b.</td>
<td>Myoelectrical breathing prosthesis</td>
<td>13</td>
</tr>
<tr>
<td>c.</td>
<td>Artificial tissues and artificial organs</td>
<td>13</td>
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<tr>
<td>d.</td>
<td>Treatment of tumours</td>
<td>13</td>
</tr>
<tr>
<td>e.</td>
<td>Biomedical materials technology</td>
<td>13</td>
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<tr>
<td>f.</td>
<td>Development of neuroprostheses</td>
<td>17</td>
</tr>
<tr>
<td>g.</td>
<td>Externally adjustable thigh-bone prosthesis (growth prosthesis)</td>
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<td>h.</td>
<td>Infection-resistant urinary tract catheter</td>
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<tr>
<td>i.</td>
<td>Bio-degradable materials with controlled decay speed</td>
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<td>j.</td>
<td>Development of bloodvessel prostheses</td>
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<tr>
<td>k.</td>
<td>Development of catheter with blood-compatible surface</td>
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<tr>
<td>short (s) or long (l) - term</td>
<td>very promising (1) - promising (4)</td>
<td>reference suggestion, see section 14</td>
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1. Haemo-filtration artificial kidneys with regeneration
   m. CAPD systems
   n. Heart valve prosthesis
   o. Haemo-perfusion columns (active carbon, resins)
   p. Immuno-adsorption columns (amino acids, antibodies)
   q. Bio-reactors
   r. Bypass prosthesis
   s. Bio-degradable artificial materials

11. Aids for the handicapped (FC 21.00.00)
   a. Aids for the handicapped
   b. Movement control and adjustments for artificial limbs
   c. Eye-controlled aids for the handicapped
   d. Language-input and output applications
   e. Development of direction-sensitive hearing aid
   f. Communication aids for the handicapped
   g. Typophone: aid for typists who are blind or have very poor sight (equipment which, when connected to an electric typewriter, makes the typed characters audible in synthetic speech)
   h. Endoprostheses
   i. Number of low-tech developments: adjusted technology for the elderly, educational games for handicapped children
   j. Robot on wheelchair MANUS IRV/TNO
12. **Therapeutic equipment and accessories (FC 24.00.00)**

a. Systems for administration of medicine  
   (intelligent infusion)  
   - short (s) or long (l) - term  
   - very promising (1) - promising (4)  
   - reference suggestion, see section 14

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<tr>
<td>18</td>
<td>1</td>
<td>s</td>
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b. Controlled internal release of medicines  
   - 17 | s |

c. Drug delivery systems  
   - 8 | 1 | l |

d. Treatment of tumours  
   - 13 | 1 | s |

e. Rehabilitation aids, greater acceptance thanks to design  
   - 15 | 2 | l |

f. Infusion liquids  
   - 4 | 1 | s |

13. **Other areas of interest**

a. Mobile equipment (modified vehicles) for expensive diagnostic equipment such as CT, nuclear medicine  
   - 18 | 2 | l |

b. Automated systems for purchasing/stock control  
   - 18 | 1 | s |

c. Analysis of clinical data  
   - 13 | 1 | s |

d. Provision of advice and development criteria on medical equipment (MTS-TNO)  
   - 13 | 1 | s |

e. Universal microcomputer for obtaining and processing biological signals  
   - 16,19 | 4 | l,s |

f. Overall screening and analysis equipment  
   (epidemiology)  
   - 8 | 2 | s |

g. BMT products based on know-how from alternative medicine  
   - 8 | 3 | l |

h. Diagnostic support for undefined complaints  
   - 8 | 2 | s |
i. Continuous production of high-quality protein  
   (including monitoring and analysis equipment)  
   - 8 | 1 | l |

j. Number of high-tech developments: biotechnology (gen manipulation), co-drugs  
   - 8 | 3 | s |
14. List of contact persons for suggestions put forward

1. Arts, Dr.Ir. M.G.J., Rijksuniversiteit Limburg, Biomedisch Centrum, Postbus 616, 6200 MD Maastricht
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16. List of technical terms and abbreviations

angiography the X-ray imaging of blood and other vessels after the
injection a contrast medium
BMT biomedical technology
His's bundle bundle of prickle-conducting fibres between the
arterioventricular node and the papillary muscles of
the heart chambers
CAPD Continuous Ambulant Peritoneal Dialysis
cardio referring to heart or stomach cardia
CT Computer Tomography
cyto cell
ECG electrocardiogram; the curve obtained by recording
variations in potential caused at diverse places in the
body by the activity of the cardiac muscle
echogram recording of reflected ultrasonic vibration
EMG electromyogram; the curve obtained on the recording of
potential differences in the muscles during
contraction
endo in, within
haemo blood
catheter rigid or supple tube inserted into one of the body
channels for the purpose of dissolving liquids
prevented from flowing
MRI Magnetic Resonance Imaging
myo muscle
neuro nerve
PET Positron Emission Tomography
plethysmography determining the changes in volume of a part of the
body, particularly in order to determine the blood flow
in limbs or extremities
prosthesis artificial product for replacement of a lost part of a
body
scintigraphy scanning of an organ or part of a body for the
intensity of emitted gamma rays with the aid of a
scanner
thorax chest
ultrasound inaudible "soundwaves" having a frequency of more that
15,000/sec.
uro urine