

Bath Institute of Medical Engineering LIMITED

433932

President

Sir Andrew Huxley, OM, FRS

Past Presidents

Sir Barnes Wallis, CBE, FRS
Sir George Godber, GCB, DM, FRCP
Sir Ludwig Guttman, CBE, FRS, MD, FRCP, FRCS
Professor Lord Zuckerman, OM, KCB, FRS, DSc, MD

COUNCIL (Year ended 31 March 1999)

Chair

Dr P. Lawes, PhD, CEng
*Vice President, Scientific Strategy and Intellectual Property,
Pfizer Medical Technology Group Limited*

Vice Chair

Dr D. T. Protheroe, FRCA
Consultant Anaesthetist
Dr A. K. Clarke, BSc, MB, BS, FRCP(UK)
Consultant Rheumatologist
Mr W. Crossland, OBE, CEng, MIEE
Director, Portex Ltd.
Dr P. Magee, FRCA
Consultant Anaesthetist
Dr N. R. Nutt, BA, PhD, MB, BS, MRCS, LRCP, DRCOG, MRCGP
General Practitioner, Keynsham
Mr R. J. Oldale, BA, HDD (from 2.10.98)
Design Consultant
Professor J. R. Quayle, MA, PhD, FRS
Retired Vice-Chancellor
Professor D. W. Robinson, BSc, DPhil, FRSC, FRSM
Consultant, Engineering and Physical Sciences Research Council
Mr M. F. Scarffe, MSc (from 2.10.98)
Technical Director, Saw Technologies Ltd
Mr B. R. Sugg, BSc(Eng), ACGI (to 2.10.98)
Retired Consultant Engineer
Mr K. Lloyd Williams, MA, MD, MChir, FRCS
Retired Consultant Surgeon

South and West Health Authority (West)

Mr J. A. Garrett, CEng, FIEE, FIPSM, DMS
*Director of the Medical Equipment Management Organisation,
Bristol Royal Infirmary*

South and West Health Authority (South)

Dr J. C. Robertson, MB, BS, FRCP(UK), DCH
*Consultant in Rheumatology and Rehabilitation, Salisbury
Healthcare*

University of Bath

Professor V. D. VandeLinde, BS, MS, PhD
Vice-Chancellor
Mr J. A. Bursey, BA, MSc
Registrar
Dr S. E. Clift, BSc, PhD, MInstP, MBES
Senior Lecturer in the Department of Mechanical Engineering
Professor J. F. Eastham, PhD, DSc, FIEE, FEng, FRSE
(to 1.9.98)
Professor of Power Engineering
Mr R. M. Mawditt, OBE, MSc, FCCA, FBIM, FRSA
*Director of the International Centre for Higher Education
Management*
Mr A. W. Miles, BSc, MSc, MBES
Reader in the Department of Mechanical Engineering
Dr I. G. Turner, BSc, PhD, MBES
*Lecturer in the Department of Materials Science and
Engineering*

Director

Professor S. C. Lillicrap, DSc, PhD, FInstP, DIC, ARCS
Professor of Medical Physics, University of Bath

Honorary Secretary

Mr J. A. Bursey, BA, MSc
Registrar, University of Bath

Honorary Assistant Secretary

Ms M. C. Henderson, MA, ACIS, AIL, DipRSA
Assistant Registrar, University of Bath

PROJECTS COMMITTEE

Dr A. K. Clarke
(Chair)
Professor S. C. Lillicrap
Mr K. Lloyd Williams
Dr P. Lawes
Mr C. Jones
Consultant Orthopaedic Surgeon
Dr W. Hubbard
Consultant Cardiologist
Dr T. Hutchinson
Consultant Paediatrician
Professor D. W. Robinson
Mr A. C. Ross
Consultant Orthopaedic Surgeon
Dr S. Medworth
General Practitioner, Bath
Dr S. E. Clift
Mr R. Oldale
Consultant Engineer
Mr M. F. Scarffe
Consultant Engineer
Dr M. R. Hillman
(Secretary)

ENGINEERING, TECHNICAL AND SUPPORT STAFF

Professor S. C. Lillicrap, *Director*
Dr R. Orpwood, BSc, BEng, PhD, *Head of Engineering*
Dr M. R. Hillman, BA, PhD, CEng, MIMechE, *Senior Engineer*
Mrs K. Hagan, BEng, MSc, *Engineer*
Mr R. Aley, MA, *Designer (to 14.8.98)*
Mr S. Hagan, BSc, *Engineer*
Ms T. Dunn, MSc, *Engineer*
Mrs A. Hill, MSc, *Engineer*
Mr T. Adlam, BEng, MSc, *Engineer*
Mr L. Taylor, BA *Designer (from 15.2.99)*
Mr M. Rouse, *Technician*
Mr M. Breakwell, *Technician*
Mr S. Gale, *Technician*
Mr D. Whatley, *Technician*
Mr S. Adams, BSc, *Technician (part-time)*
Mrs J. Jepson, DipCOT, *Occupational Therapist (part-time)*
Mrs R. Hooper, *Secretary*
Mrs J. Whatley, *Domestic (part-time)*

Bath Institute of Medical Engineering Limited
The Wolfson Centre
Royal United Hospital
Bath BA1 3NG

Registered National Charity No. 256335



A26
COMPANIES HOUSE

A35JTLU4

0009
29/11/99

B I M E

What it does

The Bath Institute of Medical Engineering fills a role in medical research in a way that is unusual in this country. It uses the multidisciplinary approach of medicine, engineering and science to identify needs of disabled people and hospital patients not being met elsewhere and to provide solutions. The research of the Institute is always directed towards a practical outcome.

The Institute is an independent body. It was founded, and continues to be maintained, by charitable grants and donations. The offices and laboratories are in the grounds of the Royal United Hospital, Bath. There is a close working collaboration with this hospital and also with other hospitals throughout the country. The Institute is managed by the University of Bath and has strong technical links with Schools of the University. All these connections are of great importance to the activities of the Institute.

The Institute designs and tests prototypes and arranges clinical trials of new equipment for hospitals and special aids for sick and disabled people. When these are satisfactorily completed, the Institute collaborates with manufacturers, where it can, for the production and marketing to be undertaken. If a suitable manufacturer cannot be found the Institute produces the aid "in-house" and distributes it on a non-profit basis, often in collaboration with specialist marketing companies. The Institute also provides an information and advice service to the disabled community and manufacturers in the field, and undertakes work to help solve specific aids design problems.

The full-time engineering and technical staff of the Institute's laboratories are guided by an honorary group of medical consultants, university staff, scientists, engineers and industrialists.

Why it began

The Institute came into being in June 1968, launched by its first President, Sir Barnes Wallis, to provide the environment and facilities which enable all disciplines to work together for the advancement of medical treatment and care.

Its foundation had the support of the (then) Ministry of Health, the Board of Trade, and the regional and local hospital authorities, and it was given national charitable status by the Charity Commissioners.

Many of the project ideas originate within the Institute. Others may be brought to the laboratories by those who have not the resources or facilities to complete their own development of a worthwhile aid or apparatus.

In summary, the aims of BIME are to promote the design, development and manufacture of appliances to help sick and disabled people by collaboration between the staff of the Institute, the medical and dental professions and other professions allied to medicine and industry, whilst maintaining close contact with the patients for whom the appliances are intended.

Chairman's Message

Starting its 4th decade, BIME completes another notable year. Many good projects, the BBC TV programme, but the sad departure of Bevan Horstmann. More on all these are to be found in the Director's report.

As I write this Chairman's Statement my early thoughts are about the very word 'Statement', and what expectations it conjures up in your mind. How much more inviting a chairman's message, thoughts, views, opinion or even welcome might be. If the heading has been changed when this gets to print, you will know that someone took notice!

I have another axe to grind which I hope you will find more significant. Healthcare is a vital industry in two senses. The vitality of patients is at the core of healthcare. For BIME it is those minority groups among the lesser-abled population who form our focus of attention. But there is also the economic vitality both of healthcare and many other industries. However, unlike most others, healthcare sadly suffers from a cost minimising culture.

Hospitals, pharmaceutical manufacturers, medical device companies, general practitioners, therapists and the associated research and development functions, whether university-based or elsewhere, collectively form a vital mosaic. Healthcare offers employment, education and training, imports and exports, investment, profits and taxes, technology and advancement. This is the stuff of real and valuable economic activity.

Contrast this with, for instance, motor cars. Governments want the economic activity and are prepared to offer large cash incentives to keep component supply and car assembly. On the other hand they do not want the associated traffic and pollution, and neither does society. With healthcare we want both product and activity and yet this industry is penalised by economic constraint which is arguably artificial.

Defence of the status quo usually differentiates between these industries on the basis of either "free market supply and demand" or "non payment at the point of use". There is no absolute law of nature which states that an industry, which is so valuable regardless of how it is evaluated, should be so restricted.

If motor cars are dismissed as a relevant comparison, then try housing, heating, clothes, and food, all of which are essentials to life. Or consider life assurance which not only separates payment and receipt but each event usually involves different individuals.

Users of BIME products are usually not paying customers. The charitable funding it receives enables it to do much valuable work. It could do a lot more and, heaven knows, the demand is there. Scarce resources cause projects to be rejected. Furthermore, the products of successfully completed projects could reach a larger population.

BIME's output is a well developed, well engineered product. To describe them as prototypes would be to sell them short. But BIME's resources do not usually permit the level of design for production, maintenance, after sales service, marketing and promotion which BIME staff would wish.

We need to explore additional sources of funding so that BIME can reach more of those who can benefit from its services, if only they knew what was on offer and how to obtain it: users, manufacturers and distributors. The list of charities contained in this report is impressive. They form the lion's share of BIME funding. Our thanks go to them all. BIME would not be what it is but for them.

Thanks, as always, also go to the BIME Director and Staff, to patients and medical practitioners, to suppliers and customers, the University of Bath and the Royal United Hospital, to all contributors, friends and members.

I would also like to single out Sir Andrew Huxley for offering to continue as BIME President for a further term and for accompanying me to visit BIME in October '98 and again in January '99. We were made very welcome by all. Sir Andrew's sharpness at analysing projects and products and offering very pertinent suggestions is notable.

I do hope you agree that this was no "statement".

April 1999

Peter Lawes, Ph.D., C.Eng.
Chairman

Director's Report

Introduction

In the year under review in this report the Institute celebrated its 30th Anniversary since it began its work of developing new devices to help disabled people back in 1968. As part of the celebration we were grateful to the BBC for featuring our work twice during July in their "Lifeline" broadcasts. Peter Snow kindly agreed to present the programme and two days were spent with the BBC team both at the Institute and visiting users of BIME's products as far afield as London and Cheltenham. The television coverage produced many donations to support the work, amounting to almost £20,000, and also many enquiries from disabled people themselves and friends of those who need such help as we can provide.

A founder of the Institute 30 years ago, and its chairman for the first seven years was Mr Bevan Horstmann, a leading industrialist in Bath, and we were sad to learn of his death in May. Bevan had maintained his support and enthusiasm for the Institute and often came in or telephoned to share ideas for new devices and demonstrate his prototypes. We extend our sympathies to his wife Deidre and family. Without the vision of Bevan and the other founders at the time the Institute would not have been created.

At the AGM in October we were very pleased to learn that our President, Sir Andrew Huxley, had agreed to serve as President for another term. We have benefited much from Sir Andrew's leadership and from his support for and keen interest in all our projects, which is much valued by the engineering team.

In this report the financial and forward planning aspects are presented first, followed by a description of our projects for disabled people undertaken during the year and the work of our production unit, finishing with a review of more general matters.

Finance and Planning

At the start of each year an estimate is made of the donations required to maintain our engineering commitment to the programme of aids development put to us through our Projects Committee, who first research the various needs and ideas brought to the Institute. Again, in this our 30th anniversary year, we have been supported most generously by our sponsors who have donated at a record level helped

by the magnificent response to our BBC Lifeline appeal mentioned above. May I express our thanks to all of our sponsors including the many individuals who donated to the Lifeline appeal. We have been able to carry forward the work in a number of ways. Mr Tim Adlam was originally appointed for two years as a design engineer with a commitment also to promoting our products to disabled users, their carers and therapists. As reported later, this post has worked well and when the contract ran out in November we were able to renew it. Also we were able to increase substantially the hours of Mrs Jill Jepson, our occupational therapist, who will now lead the promotions work supported by Mr Tim Adlam for publications. Many of our devices are seen first by occupational therapists both in the community and special schools and as a fellow occupational therapist Jill can discuss problems on a professional level.

Another post we were able to proceed with because of the outstanding response to our anniversary appeal was an electrical engineer to assist Mr Sean Hagan, our senior electrical engineer. More and more of our devices to assist disabled people are electronic in nature and incorporate electronic control. This has led to increasing demands on the electronics laboratory. This new appointment, which is currently being advertised, will enable us to build more electronic control into our devices.

During the year Mr Robert Aley moved on from the Institute to join the Intermediate Technology Group in Warwick. We are very grateful for the Industrial Design skills he brought to our work. He has been replaced by Mr Lee Taylor who also comes from an Industrial Design background. Lee is primarily involved in the paediatric work undertaken by the Institute and we welcome him to the design and development team. Mrs Karen Hagan is currently on maternity leave. We would very much like to congratulate her and her husband, Mr Sean Hagan, on the birth of their daughter.

In order to assess the income and expenditure required to maintain the Institute's work over the short term, an estimate has been made of the income and expenditure levels over a three year period. This has proved most useful in showing our sponsors and members how we propose to use the income already received, and illustrates our need for a regular level of donation income to match the

Director's Report—*continued*

trend of inflation. The three-year estimate prepared for this year's report, summarised as a table, together with a fourth year projection, is given on page 31.

As in last year's estimates, the table indicates the total staff commitment to the work of the Institute and the effective cost involved. This is done because some of those working at the Institute are employees of other organisations (mainly the Royal United Hospital Trust) whose salary costs are not shown in the Annual Accounts. In addition, some of the staff employed by the Institute are partially or wholly funded by project grants from the Department of Health. This support is also shown in the table separately from that provided by our donors. Not shown are the costs of the considerable administrative assistance provided by the University of Bath, to which the Institute is greatly indebted.

As the accounts show, the major source of income for the Institute's projects are the donations it receives from its sponsors. The figures for anticipated income from both donations and grants shown in the table are estimates. The projected grant income is based on the current indications of likely funding from Government grant-awarding bodies. The figures for anticipated donations have been estimated from promises received for the future and from anticipated donations from regular contributors, with an allowance for some increase each year. The estimated figures are not assured but represent targets for income which we hope our sponsors will provide. Obviously, although the estimated income and expenditure should be fairly accurate for the current financial year, the accuracy will decrease with time and be very approximate for 2002/2003. A figure of three per cent per year has been assumed for the effect of inflation on both 1999/2000 salary and non-salary costs. An allowance for the incremental scales has also been made for the salary costs.

The future course and requirements of the Institute have been shown in the table in terms of staff commitments, rather than the individual project requirements, as this can be presented more clearly. It reflects the Institute's policy of keeping together a viable basic engineering team supplemented by short-term appointments, when our income allows, related to individual projects and where extra help is required. Because much of our

income comes from individual gifts with no promise of repetition it has been considered prudent to hold a reserve equivalent to one year's support for both the permanent engineering team and the normal running costs of the Institute to complete our project programme, and to assign any excess over this sum to fund the short-term appointments. Thus, together with the part-time occupational therapy post, we now have nine engineers and technicians budgeted for short-term appointments. These commitments are detailed under note 9 in the Accounts and leave an uncommitted reserve of approximately one year's running costs.

All the staff are involved in a number of long and short-term projects. The long-term projects are individually assessed for staff and other funding requirements. Donations given for specific projects are earmarked and recorded separately in the Accounts. Many of the short-term projects are more difficult to assess in detail and are fitted in as the programme permits. The engineering and technical staff are fully involved in the design and production of prototype aids, instruments and devices for sick and disabled people, either at home or in hospital. The table therefore gives an accurate indication of the personnel and engineering effort continuously employed on such projects. It can be seen from the table that more than half of the Institute's projects are funded by donations, and the remainder by direct employment (Royal United Hospital), and project grants from the Department of Health (DH) and other grant-giving bodies.

Projects

Every member of the engineering team contributes to this report, particularly in the descriptions which follow of the projects they are involved in. We are working on a large number of projects of different scale and type. Where possible these have been grouped under section headings. Projects described are those which have been completed during the year, those started during the year, and the state of development of some longer-term projects. The length of the description in this report should not be taken as a guide to the time commitment of the engineering team to the project. Some of our shorter projects require considerable explanation of their aims, while some projects, where there has been a major time commitment, are quite straightforward, with little background

explanation required. For each project, the stage of progress in making the aid or device generally available is indicated; this may be by collaboration with a manufacturer for production of the aid, by small scale production by BIME, or by work commissioned by manufacturers or the DH to solve specific problems concerning an aid or hospital device or improve its design.

In all our work on equipment development, we are grateful to the great range of collaborators who help us through the development process to produce aids to help with the problems of a large number of disabled people. Our collaborators include many disabled people and patients, and individual members of many professions: medical, engineering, therapy, nursing, industry and teaching of the handicapped.

Equipment for Children

A number of projects for children have been completed over the year and several others have been started. Some of these are reported under "Individual Equipment".

1. *Car Swivel Seat*

An often quoted problem for parents of disabled children is the difficulty they experience when lifting their child into a car seat. It is not too difficult while the child is still young and quite light, but once the child has reached 4 or 5 years old he or she is becoming quite hard to handle. To get the child into his or her seat the parent has to lift the child over the back seat of the car, and somehow swing them around into the disabled car seat. This becomes very difficult to do and a potential cause of severe back problems.

The Institute has been designing a car swivel seat attachment. The device supports a normal commercial disabled car seat but is able to rotate and slide over the back seat of the car. A framework supports the device and provides a secure locking once in position. When the child needs to be positioned in the car, the swivel seat is turned to face out of the car door. The child is then positioned on the seat which can then be slid sideways and swung around to lock into position. The child's security is maintained by means of the normal car support straps. Development of the device is continuing and it is hoped comprehensive evaluations will start shortly.

2. *Bicycles for Children with Restricted Growth*

These are projects which are being generously supported by the BBC "Children in Need" charity, Glaxo Wellcome plc and the Mercers Company, for "age-appropriate" bicycles and tricycles for children with achondroplasia. They are described later in this Report under "Restricted Growth Association Projects".

3. *Potty Chair for Children with Brittle Bone Disease*

The Institute has been involved with the development of a potty seat for children with brittle bone disease. The seat provides a secure support for the child whilst toileting but has all the support surfaces designed so that they can be hinged out of the way leaving the child in a supine position. From this position it is possible for carers to lift the child without the risk of breaking any bones. Any slight load on the bones of children with this condition will snap them.

The seat has been the subject of a development programme in conjunction with the national Occupational Therapist of the Brittle Bone Society (BBS), based at Great Ormond Street Children's Hospital. After modifying the chair to suit their clinical requirements, devices have been made available for an extended evaluation with children throughout the UK taking part. The evaluation has led to further refinements and is near its completion. It is hoped that a batch of these chairs can now be constructed to be made available through the BBS. This project has been generously supported by the Cleopatra Trust.

4. *Compliant Seating*

The Institute has been involved with the design of seating systems for users who are prone to extensor spasms of their whole body. In collaboration with Great Ormond Street Children's Hospital we have developed seating systems which move with the user as they spasm, and then gently return them to a resting position once the spasm is over. The technique has been applied to a local young adult with cerebral palsy to see if it could make her more comfortable in her powered wheelchair. The compliant seat technique was just used for the back of her chair, and combined with a tilt-in-space mechanism to provide her with more stability once she was in her chair. The project has been very successful.



Wheelchair fitted with a compliant seat designed to move with users who suffer from extensor spasms of their whole body.

5. Hearing Assessment Unit

Testing the hearing thresholds of very young children is routinely done by generating tones of calibrated volumes through speakers on either side of the child under test and watching for head turns towards the sound source. Accurate assessment is often difficult and time consuming as young children are easily distracted during testing, often turning their heads towards any sound or movement. A technique for improving assessment is to provide a visual reward immediately after applying a test sound. This encourages the child to turn towards the test sound source. After a short time the visual reward becomes associated with the test sound and the child will turn towards the test sound, if it is audible, expecting the visual reward.

In response to a child-health doctor's request for an easily controlled visual reinforcement audiometry system, we have designed a unit supplied by mains electricity, but operating on low voltages only, which

is controlled remotely by a hand-held switch assembly. The unit offers a choice on each side of three illuminated and animated toys, and any combination of the three can be activated. The system has proved particularly useful not only for the 'difficult-to-test child', but also in obtaining accurate hearing thresholds in the hearing impaired child.

We are receiving increasing numbers of orders for this device from audiology units around the country. Difficulties in sourcing the animated children's toys, which are an essential part of this device, still remain although we are successfully fulfilling current orders. Work on reducing the construction time for these devices is on-going and improvements to the power supply design have been necessary for CE requirements.

6. Child's Bottom Wiper

Children with short arms find it difficult to reach to clean themselves after defaecating. The Bottom Wiper means they can manage themselves at school. This design is based, in principle, on the successful BIME bottom wiper, but with a different paper gripper design and a small handle suitable for the hands of children with restricted growth. The paper gripper uses a plastic bag closer similar to those used for sealing opened cereal packets. The device is made from a single piece of aluminium tube which is split diagonally end to end. This gives the clean, discrete appearance required for social acceptability. The wiper is currently being evaluated.

7. Toilet Handles

Short arms and legs mean that children cannot reach the floor or the seat to stabilise themselves when sitting on the toilet. Falling off or in is a very real risk. The Toilet Handles, shown at the Restricted Growth Association convention, have been evaluated and found to be useful. The first prototypes were not adjustable, but it was felt that until a toilet was found that they would not fit, it was best to keep the design as simple as possible. The first prototype fitted the toilets in the hospital, and some others; however the first evaluator's own toilet was not suitable, though those they encountered on holiday were. A second prototype has been built that is adjustable and will fit many more toilet designs.

Director's Report—continued

8. Protective Helmet

Children's heads are always particularly vulnerable and many protective devices are available for those children who may fall frequently, for example because of problems with epilepsy. Getting the balance right between functionality and appearance for these protector systems can be quite tricky. The Institute was asked to provide a head protector for a child with a cochlear implant. These implants are like hearing aids but rather than amplify sounds in the outside world they pass signals directly to the inner ear for people who have severe hearing deficits. The parents and therapists working with the child were very concerned that the implant was not damaged by normal boisterous play.



Protective helmet within a baseball cap for children who frequently fall to protect areas of the head.

A protective hat has been designed which uses cup shaped composite foam pad structures over the areas needing protection. The foam cups are attached inside a normal baseball cap by means of velcro. They are shaped so as to locate against the ears. The baseball cap makes the protector more acceptable to the child and the velcro fixing allows the parents to make fine adjustments to the position of the protective pads.

9. Football Wheelchair

Powered wheelchairs provide children with the ability to get out and play with their friends, and to



The football wheelchair to enable children to play with their able-bodied friends.

improve social skills and motivation. This fact has been much underlined by our own work on the pre-school buggies that are described elsewhere in this report. However some games are quite difficult for children in electric wheelchairs. We were approached recently by a local therapist enquiring about the possibility of designing an attachment to powered chairs that would enable the children using them to play football. The idea was to have a means which would enable the child to drive around and push a football around at the same time. It would also have the facility for giving the ball an extra push to pass it to a friend. In this way the child could catch, dribble and pass the ball.

A local child is highly motivated to help us develop such a device. A scoop-like attachment has been designed that fits onto the uprights of her chair. As well as providing a means for manipulating the ball, the scoop is in the form of a lever which the child can operate with her free hand. The lever provides the extra push to pass the ball. Initial tests of an early prototype have proved to be very promising and the device is being further developed to enable better ball control.

Director's Report—continued

Playing games is as important a part of a child's therapy as more formal treatment. It is hoped that this new development will enable children using powered wheelchairs to join in and play ball games with their able bodied friends. We are very grateful to the BBC "Children in Need" charity for their support of this work.

Department of Health - Equipment Evaluation Programme

Infusion Systems and Enteral Feeding Pumps

This is the 20th year that BIME has been funded to run a programme of evaluation of infusion pumps and enteral feeding pumps on behalf of the Medical Devices Agency (MDA). The programme underwent a complete change of staff early in 1998, with the departure of Mr Simon Morling and Ms Andrea Harry and the arrival of Miss Teresa Dunn and Mrs Ann Hill.

A major review of the project was instigated by the MDA in mid-1998, involving reassessment of all aspects of the work at the centre and associated activities in the Device Evaluation Programme at MDA. The review has given the new incumbents a valuable opportunity to assimilate all the inherited expertise, experimental techniques and general day-to-day procedures involved with the project. Equipment in the laboratory has been overhauled or replaced where required and software rewritten. In particular, four new PCs have been acquired and National Instruments Virtual Instrumentation adopted as a tool. This will allow greater flexibility in future.

The immediate stimulus for this review was the need to look again at the guidelines for use of specific types of pump. These guidelines have previously been published as MDA DB 9503 "Infusion Systems", which document was published in 1995 and freely distributed within the health service at that time. The aim of this document is to promote safer and more appropriate use of infusion devices. The need for such advice increases, as devices become more complex. Infusion devices, in particular, are involved in between 100-200 adverse incidents yearly, frequently involving deaths. The Evaluation Programme continues to assess devices for safety and to advise users on good practice.

The work of the review body is now drawing to a close and will result in an updated section of the advisory document MDA DB 9503. Some



Mrs Ann Hill in the infusion pump evaluation laboratory.

modifications in the testing protocols will also result; in particular more information is to be gathered from clinical users of particular infusion devices. These comments will form a larger part of the Evaluation reports. This mirrors the general policy of the MDA to canvas and serve the interests of users better through the already much valued evaluation programmes. MDA reviews of other centres dealing with other types of medical device will follow.

The review process has not prevented the continuation of testing. The publication of an overall review of volumetric and syringe pumps was published in January. Testing of enteral pumps has been largely completed and a report on enteral devices will shortly be produced. In addition, detailed technical and user testing on two syringe pumps has been completed. Reports on all these devices are expected early in 1999. The completion of these reports leaves the opportunity to proceed with the planned assessment of ambulatory infusion devices; a market survey has revealed all likely candidates and some pumps have already been received preparatory to testing.

The contribution of BIME to the BSI standards subcommittee on infusion devices (CH/115) continues with the co-opting of Miss Teresa Dunn. Significant changes are occurring in standards and the manner in which they are policed, as a result of CE marking. Since June 1998 all equipment sold within the UK Health Service has to bear a CE mark. This development will also have some consequences for the role of the evaluation centres. This formed a major topic of discussion at the two MDA marketing conferences, which have taken

Director's Report—continued

place in 1998. Other matters discussed were the change of emphasis towards more user assessments and the development of new and better information products including possible Internet access to the "Evaluation" reports. Representatives from all evaluation centres within the general medical segment were present at these marketing conferences and discussions were fruitful. A vigorous future is forecast for the evaluation programme.

User enquiries continue to form a significant part of the workload. The evaluation centre is also occasionally asked to assist in investigations of adverse incidents in co-operation with the Adverse Incident Centre. The database of infusion devices, developed by Ms Andrea Harry last year, has been updated and continues to be sent to the Adverse Incident Centre to assist them in their enquiries.

In November 1998 the requirement for equipment to count the number of drops in disposable drip sets generated an electronics project to build a drop detector unit. This unit was purpose built for the evaluation laboratory to detect electrical analogue signals from a flow sensor, amplify the detected signal and output the signal in a digital form for data processing later in a computer. The project has been successful and the completed unit is ready for use.

Thanks are offered to several people who have assisted greatly during the potentially difficult period of handover between outgoing and incoming evaluation teams. Mr Roy Smith who kindly returned from retirement, Mr Lindsay Grant, Medical Physics and Mr Simon Morling, now of Alaris for freely given technical advice and Dr David Protheroe who is clinical adviser to the project.

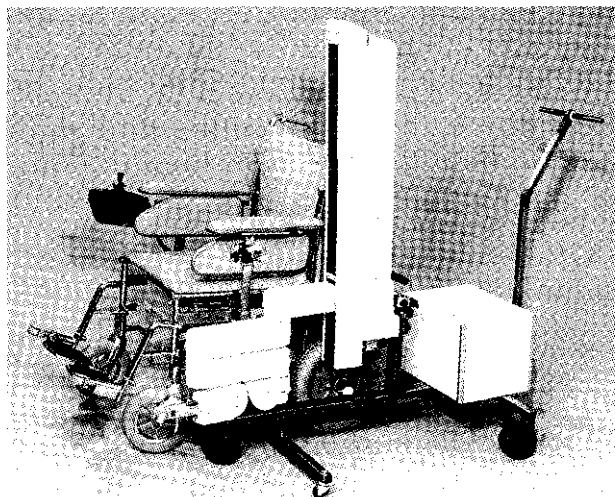
We look forward to a year of fruitful work and many reports.

Equipment for Living

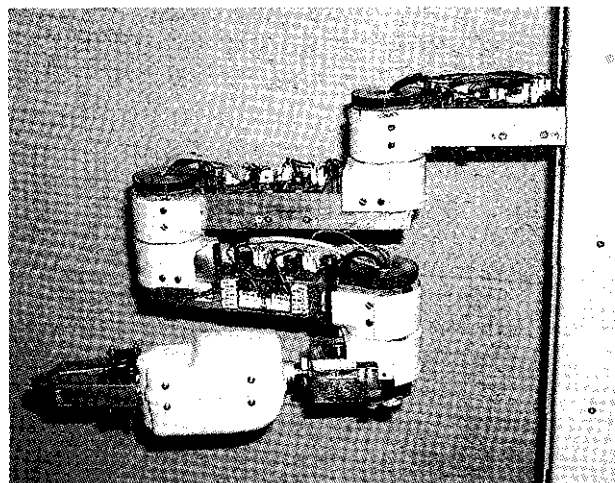
1. Assistive Robots

The Institute is designing a wheelchair mounted robotic manipulator to assist electric wheelchair users, who have limited use of their hands and arms. Construction of the prototype is nearly complete and it is hoped to start evaluations with our volunteers after Easter.

The manipulator is being initially mounted onto a "Home & Away" wheelchair which we have been loaned by Scandinavian Mobility. Mounting the



The complete wheelchair robot system mounted on a separate trolley for evaluation with a range of wheelchairs. The photograph below shows the robot arm with the covers removed to show the internal mechanism.



manipulator onto a wider range of wheelchairs is an area for further development. Since it is not easy for wheelchair users to simply transfer into a different wheelchair these initial evaluations will use a special trolley to support the robot arm, which may be wheeled up close to the user's current wheelchair. Later in the year it is intended to carry out longer term evaluations for which the manipulator will be mounted to the user's own wheelchair.

BIME's earlier trolley-mounted "Wessex" robot used a prosthetic hand gripper. This never proved totally effective as a robot gripper. A purpose made gripper has been designed specifically for the current device. It features two parallel moving jaws,

Director's Report—continued

and has a slim profile to allow good visibility of the item being gripped. It is important that when the power is removed from the gripper motor the gripping force is maintained so that the gripper does not drop the object. This is achieved by the use of a non-backdrivable gear train and compliant elements in the drive train to maintain the grip force. The compliance also allows the gripping force to be varied.

Users of electric wheelchairs are generally able to use a two-degree of freedom input, either a conventional joystick or a head or chin operated joystick. It was decided that this would be the most appropriate input for a wheelchair-mounted robot. The use of a two-degree-of-freedom joystick provides an intuitive form of control of a manipulator in real time. In the longer term we envisage the user being able to use the same joystick to control both wheelchair and manipulator.

Control of a six-degree-of-freedom device (as is the robot) with a two-degree-of-freedom input requires mode switching. The scheme used for the wheelchair-mounted robot uses the joystick movements to navigate around a map, displayed on a small LCD screen, or to switch to an alternative mode. A prototype of the interface, simulated on a lap-top computer, has been evaluated by some of our volunteers. They have generally been very positive about the approach and have made many detailed comments which are being incorporated in the interface which will be used to control the robot. We are most grateful to the Southern Trust who have generously provided the funding for this project.

2. *Sip Cup*

The sip cup allows someone with swallowing difficulties to receive only a limited volume of fluid each time they bring the cup to their lips. The current design is basically very successful and we have many potential users and therapists who would like to obtain one of the cups. Over the past year we have been exploring several manufacturers whom, we hoped, would be willing to make the necessary investment in injection moulding tooling to make the cup commercially available. Currently one of the manufacturers approached, while not wishing to take the project on themselves, has promised to supply us with some of their contacts who may be able to help.

3. *Flat Pack Commode*

The flat pack commode, intended for use when travelling away from home, was described last year. The prototype device has been extensively evaluated over the past year. Early evaluations were by volunteers in their own homes. More recently the commode has been borrowed by volunteers who have been travelling in the UK and Europe, and one lady who took it on a cruise. In all cases the commode proved valuable, and useful comments were fed back.

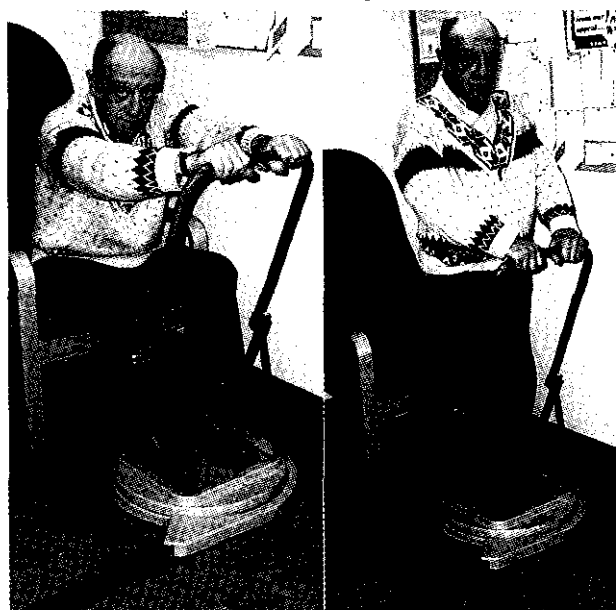
We are currently investigating the production development of the commode. This will probably be initially through in-house production, although we hope manufacturers may be interested.

4. *Flat Pack Toilet Seat*

Many people, particularly with arthritis, use a raised toilet seat in their homes. However when out, most public lavatories do not have such facilities. We have been investigating the feasibility of this project and have decided to make a version of a raised toilet seat which can easily pack into a carrying case.

5. *Standing Transfer Unit*

Many elderly and frail people have great difficulty in transferring between a chair, bed and toilet. The transfer involves them standing to their feet, rotating



The standing transfer unit to assist carers and elderly or frail people in the transfer between a chair, bed or toilet.

Director's Report—continued

around and then lowering themselves down again. There are frames that can help with standing, and turntables that can help unsteady people to be rotated by their carers. It was suggested to the Institute by an occupational therapist working for Poole social services that a combination of these two devices would have much benefit for this client group.

A standing transfer unit has been successfully developed and has undergone many clinical evaluations. Much development has taken place to improve the strength and effectiveness of the devices following these tests. The device has now evolved into a very effective piece of equipment and is about to start longer term evaluations in two centres. We are hopeful that the device will become commercially available in the not too distant future. The Trusthouse Charitable Foundation has kindly provided funding for this project.

6. *Mug Holder*

Carrying items around with you when using a wheelchair can be quite tricky. Both hands are occupied with propelling the chair so that most items have to be carried on one's lap. Carrying drinks is a particular problem, because of the ease of spillage. A survey of wheelchair users carried out by the Institute using the newsletter of the Spinal Injuries Association has shown the problem to be a widely experienced one.

The Institute is designing a mug/glass holder that will fit onto a wide range of wheelchairs. The programme is particularly aiming at reducing the risk of spilling drinks. Various support mounts have been explored and current work is focussing on a gimbaled mug support system which keeps the mug pointing in the direction of forces acting on it so that the liquid is prevented from "sloshing". We are looking forward to the day when one of our volunteers can carry a glass of beer back from the bar on a wheelchair without any spillage!

7. *Saliva Pump*

There are a number of conditions which give poor control over saliva and therefore may lead to drooling. This can be both uncomfortable and embarrassing. The Institute is developing a hand held pump which may be used to drain saliva from the mouth. Although initially aimed at sufferers from motor neurone disease the device is also seen as

being appropriate for other disability groups. Evaluation of a batch of pumps last year indicated that for many users stronger suction may be required. A change in power supply should overcome this problem and the necessary redesign is booked into our schedules for later in the year. Other necessary modifications have been identified, in particular making the design easier to clean to prevent infection.

Mobility Equipment

1. *Wheelchair Baby Carrier*

An organisation known as "Equipped" was set up a few years ago to provide support for parents with disabilities. One of their aims was to promote the development of equipment that would benefit this group. The Institute has been involved closely with the organisation. A survey of needs was carried out and one of the main requirements that was highlighted was the need for devices to enable parents who used a wheelchair to carry their children around with them. Recently the Institute was approached by a social services occupational therapist who asked if just such a device could be developed for one of her clients, and with the support and guidance of this user a development programme has been underway.

The first device developed was a baby carrier that fitted onto a wheelchair so that the baby could either face forward or look back at the parent. The device was very successful and enabled the family to go for walks together, and for the disabled parent to interact with the baby in a way that would have been impossible without the device. The baby carrier featured strongly in BIME's appeal film which was shown on BBC television during the summer. As is discussed elsewhere in this report the appeal was very successful, but as well as receiving many donations the Institute also received many requests for help. One of the most common was for baby and toddler carrying devices similar to the one viewers had seen on the television. Consequently a programme of further development was instigated.

The baby carrier is almost complete and only really requires further work on the wheelchair mounting. In addition to this device a separate toddler carrier has been developed. The device has to cater for young children up to about 4 years of age. To take the weight, and to keep the wheelchair stable, the toddler carrier has a separate wheel



The wheelchair toddler carrier in use designed to carry young children up to four years old.

added at the front to take the bulk of the child's weight. The child faces forward and the frame carrying the child is hinged relative to the wheelchair to ease the problem of going up and down kerbs and other obstacles. It has been fitted with a rain hood to keep the child dry when it is raining. The prototype device has again been very effective and has nearly completed development. It is hoped the response obtained by Equipped and that received by ourselves can be satisfied with these new designs.

2. Lever Operated Wheelchair

People with poor hand function often find the normal handrim propulsion of a wheelchair to be difficult. Forward propulsion, steering, braking and reverse operations all require the user to grip the rim securely as well as providing propulsive forces. Such users will often have to resort to using a powered chair. The Institute has had a programme running to develop lever operated propulsion systems to enable such users to maintain their use of a manual chair.

The work has concentrated on providing units that can be added on to standard wheelchairs. Several designs have been explored and the system has evolved to a device that clamps onto the wheelchair frame just behind the drive wheels. The unit uses a friction coupling between the handrim and the lever, and tests have shown it to be very effective and intuitive in use.

Several variations on the theme of the basic design have been explored. A version of the device for standard NHS wheelchairs has been developed. Several devices have been provided in response to referrals from wheelchair centres. A version has also been developed for a user who had a congenital loss of her upper limbs but who had vestigial fingers at her shoulders. The lever system was modified to enable her to use the device from her shoulders. The work entailed developing a system that enabled a variable mechanical advantage to be used and provided a friction drive onto a separate disc attached to the wheel rather than the handrim. Possible variations of the design to enable hemiplegics to more easily operate a manual chair have also been explored.

The work has shown that manual wheelchair operation could be made available to many more possible users than is possible by just using a hand rim. The Institute is currently exploring ways in which the design can be made available to whoever could benefit from it.

3. Foot Operated Wheelchair

There are many wheelchair users who propel themselves around by pushing or pulling with their feet on the ground. Surveys of adults with cerebral palsy have shown that one-fifth of wheelchair users employ this method of propulsion. The method is far from ideal. The user either has to push backwards and twist around to see where they are going, or they have to try and pull forwards with their feet on the ground, which is not easy to do. A feasibility study has been completed by the Institute to see if simple mechanisms could be developed which would enable such users to propel with their feet more easily. A mechanism was identified which allowed controlled forward movement and braking of the chair by pushing with the user's feet on a footplate.

Several test mechanisms have been constructed which fitted onto the front of standard wheelchairs



The prototype foot operated wheelchair designed specifically for people with cerebral palsy who can control their foot movements.

but did not drive them. The aim of the mechanisms was to explore how easily the user could operate the footplate drive. Following completion of this work a complete wheelchair design has been constructed employing the most promising features from the mechanism tests. This wheelchair has completed basic testing and appears to be quite promising. The design has been developed to try to reduce the resistance of the drive and to make the propulsion easier to carry out. A biomechanics exercise to optimise the efficiency of the drive has also been started in conjunction with the Department of Mechanical Engineering at Bath University.

There is no doubt that there are large numbers of wheelchair users who could benefit from a successfully developed foot propulsion system and we are very hopeful that the approach being followed by the Institute will provide the solution needed. We are most grateful to Remedi who have generously supported this project.

4. Lifter for people with Muscular Dystrophy

The lifter has been designed in collaboration with the national Muscular Dystrophy Group to address a common problem faced by people with this disease – an inability to get up again after a fall. The lifter was exhibited at the South-West Regional Conference of the Muscular Dystrophy Group last June where it was examined by people with Muscular Dystrophy and professional health care workers. The feedback received was very encouraging. People who have tried using the device have reported that it feels stable during use, the speed of the lifting seat is good, it is easy to manoeuvre over a variety of floor surfaces (when it is folded) and although the device looks big it is not unattractive.

The following improvements have been suggested from these trials and have been addressed: smoother action on stopping and starting, user control switches with better tactile response and an easier-to-operate locking system for the front supports. The control switches have been redesigned to give a better tactile response and work is presently underway to give the movement of the seat a smoother action on starting and stopping. It is anticipated that the evaluations will be able to recommence shortly to test the improved system. After that the plan is to make a batch of lifters available to the Regional Care Officers of the Muscular Dystrophy Group for them to place in homes as the need arises for them. We gratefully acknowledge the generous support of the Southern Trust and the assistance of our volunteers.

5. Omni-directional Wheelchair

Users of wheelchairs are not able to move around their homes as easily as someone on foot. To move sideways, perhaps along a kitchen work surface, normally just requires a step to left or right. Someone in a wheelchair however must shuffle their wheelchair forwards and backwards several times. The more restricted the space available, the more difficult this is. A solution to this is to use an omni-directional wheelchair, which can move left or right and rotate on the spot as well as the more conventional movements.

Several projects have addressed this problem in the past but have been complex and expensive and haven't worked on all floor surfaces. The Institute has developed concepts for a simpler and more

Director's Report—continued

robust omni-directional base and plans to integrate this into a wheelchair design. Current funding will take this through to the stage of a first demonstrator prototype and work has started on this stage. Questionnaires have been distributed to clients of various mobility centres, and engineering design work has begun. We are most grateful for the generosity of the Headley Trust who have kindly provided funding for the prototype design.

6. Rural Mobility Equipment

Most wheelchairs, crutches, and other mobility aids are designed for an urban environment, to which they are well suited. The situation for disabled people living in a rural environment is not so good. We have begun to look at the feasibility of providing help in a number of areas. These projects are at an early stage.

Manual Wheelchair

One of the primary projects is a manual wheelchair suitable for use on rural roads and footpaths. The Disabled Drivers Association Countryside Access Group (DDACAG) have given us valuable information about the practicalities of rural transport. In cooperation with the DDACAG, we are currently studying a number of projects which will result in a wheelchair design that is suitable for outdoor use in a rural environment.

Crutches

Conventional elbow crutches are not well suited to a rural environment for several reasons. The ferrules on their ends do not grip well on rocks or wet grass, and sink into mud. Their length adjustment mechanism is prone to being jammed by the ingress of grit and dirt, and they are not strong enough or rigid enough for heavy outdoor use. We are investigating the feasibility of building an off-road crutch that will be light, strong, and grip well on outdoor surfaces. Several approaches are being investigated, including one based on the trekking poles commonly found in outdoor shops.

Scooter Adaptations

Many people use electric pavement scooters for transport around town and the shops. They are also used by disabled people in the countryside. Many of the scooter designs available at present are suitable for use off the road and will cope well with uneven

and soft terrain. However, their quoted maximum ranges, sometimes as much as 30 miles, can be drastically reduced by hills, soft ground, and worn out batteries to as little as 2 miles. We are investigating an auxiliary power-pack that, by using an alternative fuel source such as petrol or propane, will be able to continuously charge the battery and greatly, if not indefinitely extend the range of the scooter.

Restricted Growth Association (RGA) Projects

In 1996 BIME began a programme of work with the Restricted Growth Association (RGA). Following a survey of members of the RGA, a 'wish list' of projects was drawn up. Design work began with the appointment of a new engineer in October 1996. 1998 has seen the RGA projects develop considerably. We now have three products close to the pre-production phase - the ReachStick, and the large and small bicycles. Development of the other projects continues. The main focus of the year's work on the RGA projects was the annual convention of the RGA at Weston-super-Mare in October. We organised the exhibition, exhibited our products, and presented a seminar on how we develop an idea into a product.

1. *Reaching Sticks*

Many people with restricted growth find that they cannot reach light switches, lift buttons, and clothes rails when they are out and about. When shopping or at home, reaching a high shelf can be a great challenge. We have developed two collapsible sticks that can be used to retrieve items otherwise out of reach. The ReachStick is a lightweight telescopic stick that can be stored in a pocket or handbag. It is of a simple design with a 'prodger' and hook on its end. The ShopStick is a larger more substantial stick that folds and features a noose type gripper at its end for retrieving many different objects from shelves.

The small ReachStick has reached the production development phase following extensive evaluation with RGA members in the South West region. A locking mechanism has been selected though at the time of printing, we are investigating a novel locking mechanism that allows the stick to be locked at any length.

The larger ShopStick has progressed further with a cable locking mechanism being selected, prototyped, and needing final development. The

Director's Report—continued

gripper design of the stick is essentially complete, but needs some small modifications following the introduction of a steel cable to replace the original plastic strapping. For the gripper to grip reliably, some compliance is needed in the cable between the gripper and the cable grip. This has been achieved with the insertion of a tension spring in the cable line. Both devices will be made available this year through the Production Unit.

2. *Lightweight Stool*

Another of the high scoring projects in the survey was a lightweight stool that could be carried in a schoolbag or when shopping to provide the extra height needed for many activities in a world designed for people of average height. Examples of activities that present problems are using a toilet, operating lift buttons, reaching light switches, and so on.

Following extensive evaluation, the LightStep design has settled to two fixed height folding steps at 150mm (6") and 230mm (9") high. The LightStep is suitable for people up to 95kg (15st) weight. The step folds to a package 220mm x 240mm x 100mm and weighs 1.4kg (3 lb.).

3. *Bicycles*

The highest scoring child's project in the survey was a bicycle. Children with restricted growth find that a conventionally proportioned bicycle frame is not appropriate. The first prototype built was very adjustable and allowed us to find an appropriate riding position. We have developed two bicycles and built prototypes for evaluation. The larger bicycle is for teenagers and adults, and the smaller is for younger children up to the age of about seven years.

Adult/Teenage Bicycle

The adult bicycle has been designed to be attractive to look at - this is very important when it is aimed at a fashion conscious population. Details like the design of the brake levers and the position of the handlebars have been carefully attended to.

During 1998 we have seen the completion of development of the first prototype bicycle. The proportions of the bicycle and the degree of adjustability have been determined. Eugene, our primary volunteer, continues to use the bicycle on a daily basis around Bath.

We built a second prototype for the 1998 RGA convention. This was of a simpler, less adjustable design, and is close to the frame design expected to be used for production. We are investigating production techniques at present to provide the bicycle from the Production Unit. We are most grateful to the Hayward Foundation who have generously supported this project.

Child's Bicycle

The child's bicycle is a much simpler design than the adult version, and is of a robust, but lightweight construction appropriate for the heavy use that any adventurous child will give it. Again, it is extensively adjustable as not all children with restricted growth are affected to the same degree.



Child's bicycle for children with restricted growth with a young user.

The child's bicycle has progressed to the point of building a pre-production prototype. Evaluation of the first prototype has been very successful, with no functional modifications being introduced into the second bicycle that was built for a child in time for Christmas. It was very well received. We are currently finding sub-contractors to manufacture the frame for a pre-production prototype and subsequent production models. We are very grateful to Glaxo Wellcome plc and the Mercers Company for their generous support of this project.

Equipment for Developing Countries

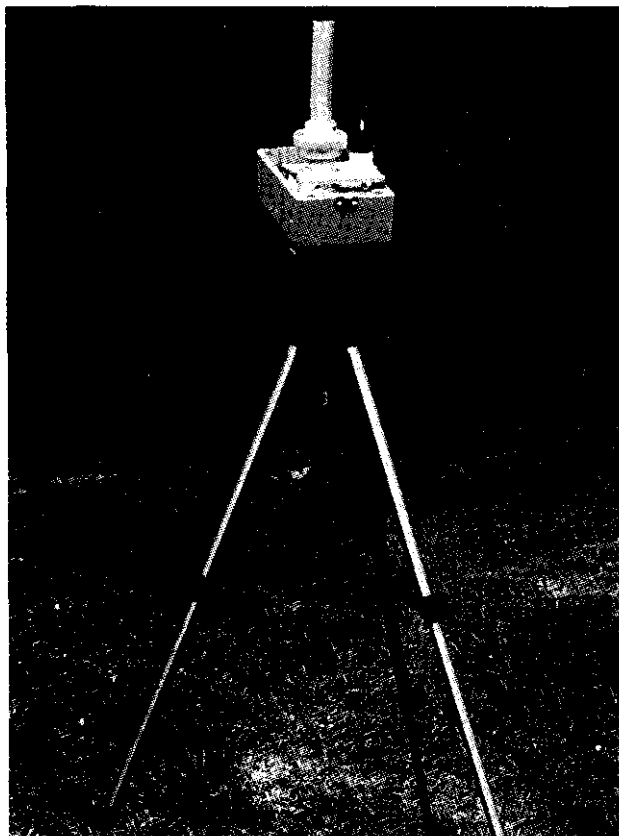
The Institute has been approached by Primary Diagnostics, an organisation run by people with

Director's Report—continued

many years experience of working at the primary healthcare level in developing countries. They had identified several pieces of diagnostic equipment that they felt would markedly improve the ability of clinicians to make diagnoses in primitive field situations. Two items in particular were felt to be much needed: a field microscope that had sufficient power to enable malarial parasite damage to be seen and a haemoglobinometer to provide basic indications of levels of anaemia. Both these devices have been developed to an advanced stage.

1. *Microscope*

The microscope was felt to be a key piece of diagnostic equipment but it would only be successful if it was designed down to a price that was affordable for healthcare budgets in developing countries, and a target of £150 was aimed at. The device also had to be very robust and able to withstand fairly harsh handling and severe environmental conditions. It also needed to be



The low cost field microscope for use in developing countries. It has sufficient power to enable malarial parasite damage to be seen.

maintainable using local technology and such that it could run from a wide variety of power sources.

The prototype devices used bought-in optical components and the mechanics of the microscope were designed around them. The only focus used was a very fine thread on the barrel of the instrument to provide reasonable adjustment. The slide manipulation was provided through a novel joystick system. The instrument used one of the new white light LEDs that have become available. These light sources use very low currents and are very robust whilst providing bright light and are very inexpensive.

The prototype instrument has been tested in the haematology department at North Devon District Hospital, Barnstaple and performed well. Several modifications were incorporated as a result of these tests. The focus was provided with an anti-backlash device to improve its operation. The barrel of the microscope was fitted with a bayonet fitting so that it could be easily removed to change the objective. The instrument was also built into a box which enabled the whole instrument to be folded down into the enclosure with a lid that provided a hermetically sealed space when closed. This instrument has undergone initial field testing in Indonesia for a 5 week period with help from MERLIN, a disaster relief organisation based in the UK. It was very well received and only minor modifications were needed as a result.

An excellent source of inexpensive optics have been sourced and the Institute is now in a position to prepare for more extended field trials before advertising the availability of the instrument. It is hoped that it may provide a much needed boost to the provision of basic healthcare in many developing countries throughout the world.

2. *Haemoglobinometer (BIME HaemoScan)*

In many developing countries anaemia is a major problem and is a common and important cause of morbidity in tropical climates. It has many causes such as blood loss, malnutrition, and a wide range of communicable diseases - notably malaria and hookworm and is a good general indicator of sickness and of the degree of urgency of the need for treatment. Anaemia is also very common in pregnant women, nursing mothers and young children in these countries. Primary healthcare in remote rural communities is often poor due to the

Director's Report—continued

lack of appropriate and affordable medical diagnostic tools. Rural health clinics are often basic, with no electricity or proper water supply and treatment is often given without confirmed diagnosis which can be wasteful of drugs (which are usually in short supply and expensive) and may be dangerous. Besides identifying many people who are acutely or chronically ill, the accurate measurement of blood haemoglobin levels will also identify those for whom blood transfusion may be an urgent or life-saving necessity. In regions where average haemoglobin levels may be lower than the acceptable minimum for use in transfusions, their accurate measurement, in blood samples from potential donors, is vital.

There exists a real need to produce a simple, low-cost blood haemoglobin meter which can be used anywhere from any available power source including solar power in a rural health care environment. Currently available portable haemoglobin meters are either too heavy, too complicated, only use specific types of batteries (which are normally unobtainable) or, more usually, far too expensive.

BIME has developed a robust and inexpensive instrument for the *in vitro* measurement of blood haemoglobin levels in a rural primary health care setting. The instrument is capable of operating from variable mains supplies and 12V sources such as car batteries and solar cells while charging its own internal rechargeable batteries. It is accurate and simple to use requiring the absolute minimum of maintenance. The initial development prototype has recently returned from evaluation at the Haematology Department of North Devon District Hospital. It has been found to be easy to use and very accurate, provided accurate blood samples are taken. Further work on incorporating the latest monochromatic light emitting diodes into the instrument is currently underway. This should reduce the final price by eliminating a costly optical component. Final modification will be assessed before a small batch of instruments is built specifically for developing country evaluation. The African Medical and Research Foundation (AMREF) based in Nairobi, Kenya has offered to test a batch of instruments.

BIME is developing the instrument jointly with Primary Diagnostics with co-operation from North Devon Healthcare haematology department.

Vibration Diagnosis – Vibrotec

The "Vibrotec" is a device designed to help screen diabetic patients for susceptibility of developing foot ulcers. It is being developed in collaboration with the Department of Vascular Medicine at the University of Exeter. Such a measuring device, if it is to be clinically tested and then made commercially available, must be able to be easily set up and calibrated. We are currently developing the device to ensure that it meets these requirements, and also to provide a more robust power supply. It is intended to supply a batch of devices to Exeter University for trial.

Ankylosing Spondylitis Measurement Device

Ankylosing spondylitis is a rheumatic disease of the spine, suffered by young adults; often men. It leads to increasing stiffness of the spine but may be treated by physiotherapy and anti-inflammatory



Head goniometer in use designed to assess available movement in patients with ankylosing spondylitis.

drugs. Physiotherapists need to measure the severity of the condition to determine how different drug and exercise regimes are working. Physiotherapists at Bath's Royal National Hospital for Rheumatic Diseases have developed the BASMI (Bath Ankylosing Spondylitis Metrology Index) Index which requires several measurements of the range of spinal motion. The Institute is working with the physiotherapists to develop a range of three instruments to assist in taking these measurements. It is hoped that the devices can then be sold to other hospitals using the BASMI index.

Individual Equipment

Although BIME tries to concentrate on devices which benefit large numbers of people, we are often

Director's Report—continued

requested to help individuals with specific problems. As well as providing a service for these disabled people, such help also recognises the fact that solutions to one-off problems can turn out to have wider applications. The majority of the following projects, which have been undertaken this year, are for children.

1. *Head Switch Support*

We designed adaptable supports for a pair of head switches. A child at a local school uses them to control his communication aid, as he is unable to talk. The switches enable him to scan through a selection of messages or words on the communicator, which then speaks the chosen phrase. This solution will be applicable to many children.

2. *Scoot Mobility Toy*

A child in the local hospital's Children's Unit has cerebral palsy. He is unable to walk, but has better control of his legs than his arms. At home, he used a small child's ride-on toy, propelling it with his feet. He has now grown out of this, so we have developed the 'Scoot' mobility toy. He sits on the Scoot in a reclined position with head support and a lap belt. As it has a front castor, it is easily steered. The Scoot project was begun last year and has seen further development. A steering system with handlebars was evaluated, but found not to be suitable; however the handle bars were retained as they provided a secure point for him to hold on to. Evaluation of this device continues at the child's home.

3. *Wheelchair Trays*

We have built several wheelchair trays for children this year offering mountings for joysticks, communication aids, and other equipment. One was transparent, to enable a child to see to drive his electric wheelchair in school. His wheelchair joystick was mounted flush with the top of the tray so that it was easily accessible.

4. *Backrest*

We have designed a backrest for a child with achondroplasia (which causes growth restriction). Achondroplasia is an inherited disorder that restricts the growth of the arms, legs, hands, and feet. School chairs are designed for people of normal

proportions, and even then they are not very comfortable. The child needs the backrest, in conjunction with a footrest to make the school chairs of the appropriate proportions for someone with short legs and lower back problems. The work with the children's centre continues to be very rewarding, and of value to BIME and the centre. The therapists and teachers are very much appreciated for their help and cooperation with BIME in the referral work, and in evaluating other BIME paediatric projects in progress.

Student Projects

Three comprehensive projects have been started with students of Bath University. As was mentioned above under the description of the footpowered wheelchair, a major undergraduate project has been started to provide some biomechanical analysis of the mechanism used in the wheelchair design. This is mostly an analytical study but will also include some simple measurement work on the forces involved. Four students studying for MBA degrees are exploring products designed at the Institute with a view to drawing up a marketing and promotions plan for them. They are particularly interested in the lever operated wheelchair which has reached an advanced stage of development and is ripe for exploitation. And finally a PhD student has just started in Mechanical Engineering supervised by Dr Sally Clift, a member of BIME's Council, looking at the modelling of human performance with the aim of providing a design tool for the design of disability equipment. The Institute is providing guidance for her on the particular ergonomic problems that arise with the design of such aids. It is hoped that her work will culminate in a demonstrator of the potential of the design tool that she is developing.

The BIME Production Unit

Introduction

Many items developed at BIME provide much needed support for disabled people but are unlikely to sell in very large numbers. This situation makes it difficult for manufacturers to take on such products because it would take an unacceptable amount of time for them to get back their initial investment in production development, tooling and marketing. The profit to be made is just not large enough. It was decided that in order to make these successful but

Director's Report—continued

low volume products available the Institute would set up its own production unit. It was agreed with some of our major sponsors that some of our charitable income could be used to cover incidental costs, such as tooling costs etc, so that the Institute only had to sell items for the actual cost of manufacture. In this way even if only one item was sold we would have covered our costs. This policy can only be used, of course, if the product being sold is not competing with another commercial product, because of its unfair pricing advantage.

The production unit has been a great success. Its operation means that any successful design work at the Institute can be made available to whoever might benefit even if a manufacturer cannot be found who was prepared to take on the new device. We are most grateful to the Emmandjay Trust for their generous funding of the production unit technician. The accompanying table shows the range of devices currently being manufactured and some particular products are highlighted for comment below.

Device	Production Development	Being sold	Total sales
1. Bottom wiper		*	31,338
2. Folding bottom wiper		*	8,304
3. Noisy playball		*	487
4. Light action switch		*	50
5. Vaginal dilators		*	513
6. Infant and Junior buggy		*	53
7. Wedge straps		*	51
8. Adult walker		*	29
9. Selection box		*	36
10. Car restraint		*	20
11. Hearing assessment unit		*	12
12. Swallowing reminder		*	22
13. ETRAN frame		*	9
14. Food warmer		*	9
15. 'A' frame		*	4
16. Movement reminder		*	27
17. Toilet trainer		*	55
18. Wheelchair exerciser		*	7
19. Ankylosing Spond. Rig		*	3
20. Chin support		*	
21. Small RGA bike	*		2
22. Other RGA items	*		
23. Trace box	*		
24. OT bed lifter	*		

Bottom Wipers

Sales continue at an excellent level, with well over 30,000 devices having been sold to date.

Chin support

The main aim of the BIME chin support is to provide a limit to the amount of head movement that is possible so that the user's head does not fall so far forward that they cannot lift it back up again. The device is now being marketed as the "HeadUp" to place emphasis on the movement limitation it provides rather than as a device that supports the weight of the head.

Movement Reminder

Following an original request by therapists at the Royal National Hospital for Rheumatic Diseases, Bath to produce a device that vibrates at regular intervals, BIME designed the 'Movement Reminder'. This would provide a discreet reminder to people suffering from back pain to change their posture at regular intervals, thus preventing the onset of severe pain. This is known as the 'pacing' method of pain control. As the device is now a BIME production item an increasing number of the re-designed digital reminder units are currently in use at several national sites and one international site and feedback on suitability and reliability has been very favourable. The reminder unit will have other applications in addition to the area of back pain, for instance elderly people taking medicine, another form of swallow reminder or as a reminder to change posture in people susceptible to pressure sores such as paraplegics in wheelchairs. A medical equipment company has recently approached us expressing an interest in marketing the Movement Reminder after modification to add a low battery warning and CE marking. A redesign for ease of production is currently under way.

Swallowing Aid

Excessive drooling makes social contact difficult and special clothes are sometimes necessary. If someone can be encouraged to learn to swallow regularly they will be able to keep themselves dry without recourse to more invasive procedures. BIME has designed a device to assist in the accepted therapeutic practice of the use of body-worn swallow reminders. Clients are encouraged to swallow as the aid beeps, in the hope that a swallowing reflex will develop.

The swallowing aid has been available for some time now as a production item, but has recently undergone a re-design to improve the overall

Director's Report—continued

packaging of the device. The device has now been packaged into a small two part vacuum-formed moulding in the shape of a thin, round badge. The new moulding has sufficient space on the flat top surface to enable the therapist or carer to decorate the device with adhesive decals to improve the appeal of the aid to the user. As a result of further feedback from users of the aid, the controls have been improved to allow easier adjustment of the time interval and volume. The accessibility of the on-off switch has been greatly improved and the range of the volume control has been improved. Further work on this device to improve its environmental seal is required as a result of feedback from current users of the device.

Buggies

A lot of work has been completed during the year to upgrade the buggy design. The main impetus came from the need to use different motors and the changes that the motors introduced into the electronic controller. The new controller behaves very well, and the design incorporates several additional features. There is a variable speed control which has been very much welcomed by users. Appropriate alarms have also been added to prevent users from draining the battery too far. Damaged batteries have been the main cause of units being returned in the past. Various minor changes to other parts of the buggy were also incorporated during this redevelopment. A range of add-on devices has also been explored. We are already selling head controls and an extended head rest, and the new buggy includes a socket for the wiring loom so that a range of different control options can be plugged in. Several other add-on devices are being explored. A hand switch control system has been developed and prototype units are currently being evaluated with very promising results so far. We are hopeful of having these on sale by about May. Remote control devices have also been developed. An umbilical remote control has been available for some time and this has now been augmented by a radio remote control. The remote control operates in a similar fashion to a TV remote control, and provides the user with a kind of dual control option whilst a child is learning to drive the buggy. It is designed to be gripped so that it effectively provides a dead-man's handle. The buggy can be stopped dead in its tracks if the carer



Social interaction enabled by the children's mobility buggies.

relaxes their grip on the handle. We are most grateful to the BBC Children in Need Appeal, Railtrack PLC and the Viscount Nuffield Auxiliary Fund who have enabled us to undertake the above work particularly the dual and remote controls.

The buggy has been the subject of a lot of work to enable it to be CE marked. To meet the essential requirements needed for CE marking the buggy had to be subjected to many structural, performance and electrical tests. A portfolio of information relating to the buggies development history, design and production had to be compiled. The CE mark was finally realised just before Christmas. Buggy orders were held up whilst the CE mark work was taking place but despite this hold up the sales have been quite good. A major promotion plan was carried out towards the end of the year with several exhibitions being used and with adverts in *Therapy Weekly*. Many enquiries and a number of sales have resulted from this promotion. Following the concern expressed last year about the attitude of Occupational Therapists to using powered mobility equipment for pre-school children, most of the promotion work of late has focused on the importance of early mobility to a child's development.

Hearing assessment unit

The hearing assessment units enable accurate assessment of the hearing of babies and the work done this year is described under "Equipment for Children". They are a major product for BIME, selling as they do for over £1,000. There has been a lot of interest in the device over the year, mostly through word-of-mouth recommendation from a

Director's Report—continued

Bath-based clinician. We have experienced some difficulties obtaining the electric toys needed for the device but nevertheless several units have been sold and several are currently on order.

Ankylosing Spondylitis Jig

This device is a measurement aid for physiotherapists treating patients with ankylosing spondylitis. Although only promoted by word of mouth so far it has received a lot of interest. Various other similar products are currently being developed as part of a range of such aids.

RGA small bicycle and other items

The Institute has been involved in a programme of design and development work in conjunction with the Restricted Growth Association (RGA). A survey of needs amongst their membership led to a "wish list" of devices and most of these have now completed their development programmes. Work is underway to productionise these devices with a view to promoting them through the newsletter of the RGA. One item, a small bicycle, has already been sold as an urgently needed Christmas present. All the devices were those selected by the RGA membership as being needed, and by using their newsletter BIME can promote successful developments very easily. It is hoped that we should have many sales with the RGA products during the year.

Quality control and CE marking

From 14 June last year all medical equipment placed on the market must have a CE mark to show that it meets the requirements laid down by the European Directive managed by the Medical Devices Agency in the UK. The directive has led to a lot of work on Dr Hillman's part to coordinate the activities needed to meet the requirements. All our rehabilitation products which are within the definition of a "medical device" are classified as class 1 devices, which means that we can self-certificate as long as we have made sure that the products meet the requirements. The current BIME products requiring CE marking have now either been CE marked or are close to receiving it.

Outside contractors

We continue to use several outside companies for manufacturing components for our production

work. Mr Adams, the production unit supervisor, now has companies which can cope with all our component manufacture such that the production work in-house is mostly assembly. It was mentioned in the last report on the production unit that we have been using a different local workshop for our machined components. They have been providing an excellent service. During the year the loading on BIME's mechanical workshop became quite high and the relationship with the contractor proved to be very beneficial as we were able to put prototype work out to him as well. Sub-contracting in this way is a much cheaper way of dealing with peaks of activity compared to hiring short term labour, and the links we had with the contractor proved to be very useful.

Staffing and facilities

The Institute employs a technician whose role is to manufacture components for the production work and to assemble devices. As with previous years we have in addition been able to use staff from our local sheltered workshop to cover peaks of demand. The sheltered workshop has been happy for one of their staff to come into BIME for two weeks at a time to cover these periods.

Conclusions

We continue to be very pleased with the production activity of the Institute and the way that it integrates with our design and development work. The main focus for next year is to put further effort into our promotion and marketing. Our experience puts us in a very good position to know where promotional work needs to be concentrated. Overall the production activity continues to be a key part of the way that the Institute operates and of the way in which we are able to address the problems faced by disabled people and to put successful engineering solutions into their hands.

Promotion and Marketing Work

Some of the home produced devices are sold through marketing companies who include our devices in their catalogues. This is a very effective way of promoting these products. For those devices which have not been able to attract marketing organisations they are sold directly from the Institute. This work requires staff to be involved with product promotion. A promotions sub-committee is

Director's Report—continued

used to coordinate the promotion and marketing activity. Loose leaf information sheets have now been completed for the product range and their availability has enabled us to respond more effectively to enquirers. Mr Adlam, who looks after the promotions work, has also instigated a web page for BIME with information included on all our product range.



Peter Snow discussing the wheelchair robot during the filming of the BBC Lifeline programme.

During the summer we were lucky enough to attract a place on the BBC's Lifeline charity appeals programme. The BBC production team spent two days with BIME staff and some of the people we have helped, and took several hours of video. As well as editing the video into the final programme they have also made available to the Institute all the footage that they took. They are happy for us to edit any of this film into promotional videos focusing on specific products. The audio-visual unit at the University has the appropriate facilities for doing this editing and we plan to explore this option.

Our entries in the Disabled Living Foundation's lists have been kept up to date and lead to many enquiries. As in previous years we have also taken part in several exhibitions of disability equipment, with care to make sure they are appropriate to our specific devices.

It was planned that the Institute should review its promotions and marketing activities at the end of 1998. The promotions committee discussed progress to date and reported on its findings. The main conclusions are as below.

1. The promotions and marketing work is essential to BIME's production activities and should continue.
2. Much more effort should be put into trying to get marketing companies to include our products in their ranges.
3. More emphasis should be put on demonstrating devices to potential customers, particularly therapists.

To meet conclusion 2 it is planned to incorporate liaison work with potential companies within the work programmes for each of the design staff for the designs that they are involved with. To meet conclusion 3 it is planned for Mrs Jepson, our occupational therapist, to spend 16 hours a week responding to enquiries and arranging such visits. She has been involved in several exhibitions in the past and is keen to do this work. We will also explore the possibility of acquiring a van to enable demonstrations to be carried out more easily. Mr Adlam, who is currently looking after the promotions work, will continue to spend 1 day a week keeping all the promotion and exhibition material up to date.

General

1. Council

As mentioned in the introduction to this Report, at the AGM in October we were very pleased to learn that our President, Sir Andrew Huxley, had agreed to serve another term. We were very pleased to learn that Dr D T Protheroe had agreed to continue to serve as Vice-Chair and that Professor J R Quayle and Professor D W Robinson had agreed to serve further terms of office and were re-elected. We also welcomed Mr R Oldale and Mr M F Scarffe who had both served for many years on the Projects Committee and were elected to Council. We said farewell to and thanked Mr B R Sugg who had served on Council since 1983. The assistance and loyalty to the Institute for many years of all our Council members and officers is greatly appreciated.

2. Projects Committee

Under the Chairmanship of Dr A K Clarke, the Committee kept all the above projects under active review and contributed their individual experience and expertise in their different fields to the various projects. I would like to record the thanks of the Institute to the members of the Projects Committee for their valuable time and advice given to this work.

Director's Report—continued

3. Annual Lecture

Our 30th Annual Lecture was presented in October by Professor Peter Rolfe, Founder Fellow, International Academy for Medical and Biological Engineering and Director, Science and Technology, Oxford Bioengineering Consultants Ltd. His subject was "Biologically Inspired Sensors, Tissues and Organs." Professor Rolfe described the work of scientists and engineers from many disciplines in the study, manipulation and use of the biological cell both to improve understanding of disease processes and also to create engineered systems to improve health care. It was a very interesting lecture to mark our 30th anniversary and much appreciated by the audience. We are most grateful to Professor Rolfe.

The Annual Lecture for 1999 will be given at the University of Bath on Friday 15 October by Professor D Dawson, Emeritus Research Professor, Department of Mechanical Engineering, University of Leeds. Professor Dawson's field of interest is the use on new materials and articulation technologies to advance the development and research of joint replacement. We can look forward to another most interesting lecture.

4. Presentations and Publications

The work of the Institute has been presented during the year at a number of meetings and through publications.

Presentations

Hagan S and Orpwood R, "The design of primary care diagnostic equipment for developing countries", Research Forum of School of Postgraduate Medicine, University of Bath, March 1999

Hagan S and Orpwood R, "Haemoglobinometer for Rural Primary Health Care in Developing Countries", Poster Presentation at the 'Developing World Health Exhibition', Institute of Child Health, London, January 1999

Hillman M, "Mobile assistive robot systems", 29th International Symposium on Robotics, Birmingham, April 1998

Hillman M, Hagan K, Hagan S, "A wheelchair mounted robot", Institute of Physics and Engineering in Medicine Annual Conference, University of Sussex, Brighton, September 1998

Hillman M, "Assistive robotics - the way forward", School of Postgraduate Medicine Research Seminar, Bath University, December 1998

Hillman M, "Assistive robotics - the way forward" Institute of Physics and Engineering in Medicine meeting "Good practice in electronic assistive technology", Birmingham, March 1999

Jepson J, Hillman M, Hagan K, Hagan S and Orpwood R, "Rehabilitation robotics: an overview". College of Occupational Therapy Annual Conference, Belfast, June, 1998.

Orpwood R, "Introduction to the Bath Institute of Medical Engineering". Workshop at the Annual Conference of the Restricted Growth Association, Weston super Mare, October 1998

Orpwood R, "The work of BIME". Workshop at the Disablement Services Centre, Bristol, October 1998.

Publications

Dunn T, Goodman A, Harry A, Hill A and Morling S, "Product Review of Infusion Pumps" Evaluation (DH/MDA) 373, 1-200, December 1998

Orpwood R, "The dynamic response of a cerebral cortical model in response to input patterns". Procs 1st Biennial Meeting of the European Neuroscience Association, Berlin, 1998

Orpwood R, "Numerical modeling of neocortical pyramidal cells", in "Modeling in the Neurosciences: from ionic channels to neural networks", Chap 13, (R R Poznanski, ed), Harwood Academic: Amsterdam, pp 333-367, 1999

Rickman R, Orpwood R and Hagan S "More appropriate and affordable diagnostic aids for tropical primary healthcare: 1. The BIME/PDL 'Diascan' mini-microscope", Appropriate Technology, 1999 (in press)

5. Educational and Training Activities

Although the Institute is primarily a design and development organisation it is important that the expertise available amongst its staff is made available to students wishing to train as engineers and particularly medical engineers. As in previous years many requests for student projects have been received and the Institute's staff have provided guidance if at all possible. This work has included having students visit the Institute to discuss their projects with design staff. Three comprehensive projects have been started with students in other departments of Bath University and these have been described earlier under "student projects".

Director's Report—*continued*

Each year the Institute receives a number of requests for work placements. Once again this year we have had school students spend a day with us involving themselves in the typical activities of design engineering. All these educational activities take up some time on the part of the design staff but it is felt important that we encourage the next generation of creative people to use their skills for the benefit of society through medical engineering.

Another important activity that is provided is career advice. We receive many telephone calls about careers in medical engineering and again invite some of the enquirers to drop in for a discussion of their particular situation. Careers talks are also given at local schools when we are invited. Mrs Hagan is also involved in the Neighbourhood Engineers scheme run by the Engineering Council. She is seconded to a local secondary school and provides guidance on technology projects and career advice. Much of this activity is done in staff's own time and does not detract from the main activities of the Institute.

As with any organisation in a specialised field we also get a number of visitors from other organisations wishing to learn from our experience. Such visitors include people from overseas and included a party of visitors from Japan this year who were all involved in the establishment of a design and development organisation for elderly people in Japan.

6. *Professional Activities*

The Institute's staff are involved in several professional organisations. The main umbrella organisation for engineers and physicists working in the medical field is the Institute of Physics and Engineering in Medicine (IPEM). Dr Hillman is secretary of the Engineering panel of IPEM and Dr Orpwood is a member of the International Editorial board of one of IPEM's journals, *Engineering and Physics in Medicine*. Through his involvement in rehabilitation robotics Dr Hillman has also been invited to join the editorial board of the Journal, *Robotica*.

Several members of staff are chartered through the engineering institutions and Dr Hillman is a member of the Medical Engineering Division Board of the Institution of Mechanical Engineers (IMechE). Mr Adlam has just had his interview to become

chartered through the same Institution. Dr Hillman and Dr Cliff organised and chaired the IMechE's 10th Biomedical Engineering Undergraduate Student Competition held at their London headquarters in September.

Members of staff are also involved in various advisory committees. Miss Dunn sits on the British Standards Institution Technical Committee considering infusion pumps and controllers, and Dr Orpwood has just completed a term of office as a member of one of the advisory panels of the medical charity Action Research. He is also an adviser to the EU project Telemate, which is examining training within the European Union for people working at the interface between engineering, clinical practice and administration.

Conclusions

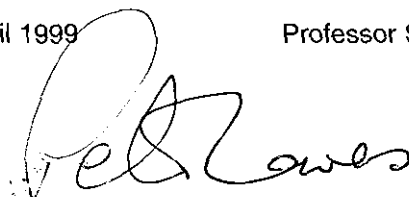
This year we have celebrated thirty years of engineering design applied to the problems of disabled people and patients in hospital. Our thirtieth year has been a most encouraging one in continuing this work, in terms of projects completed, projects advanced, and in the increasing output of our Production Unit, as described in this report.

We are greatly indebted to our many sponsors who have supported us throughout our 30 years, and for those who responded so generously to our anniversary appeal and allowed us to increase the number of projects we are undertaking for disabled children and adults. We look forward now to maintaining this increased commitment to aids and instruments development work, and to increasing the number of aids being produced and made available to the disabled community. We appeal to our regular sponsors to please continue their support to enable us to do this. For other or new supporters of the Institute's aims and work, we would request that they consider providing assistance for our work, perhaps on a regular basis.

Finally, may I express our thanks again to our many members, donors and other visitors who showed us their support and interest throughout our thirtieth anniversary year. They have given us a fruitful and most encouraging one.

April 1999

Professor S. C. Lillicrap
Director



BATH INSTITUTE OF MEDICAL ENGINEERING LIMITED

REPORT OF THE COUNCIL FOR THE YEAR ENDED 31 MARCH 1999

The Council submits its report together with the audited financial statements for the year ended 31 March 1999.

Principal activity

The company uses the multidisciplinary approach of medicine, engineering and science to identify needs of disabled people and hospital patients not being met elsewhere and to provide solutions.

Council's responsibilities in respect of the accounts

Company law requires the Council to prepare accounts for each financial year which give a true and fair view of the state of affairs of the company and of the surplus or deficit of the company for that period. In preparing those accounts, the Council is required to:

- select suitable accounting policies and then apply them consistently
- make judgements and estimates that are reasonable and prudent
- follow applicable accounting standards, subject to any material departures disclosed and explained in the accounts
- prepare the accounts on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The Council is responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the company and to enable it to ensure that the accounts comply with the Companies Act 1985. It is also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Auditors

R. S. Porter & Co. have expressed their willingness to continue in office and a resolution to re-appoint them will be proposed at the annual general meeting.

By order of the Council

J. A. Bursey
Honorary Secretary

17 May 1999

REPORT OF THE AUDITORS TO THE MEMBERS

We have audited the accounts on pages 27 to 30 which have been prepared under the historical cost convention and the accounting policies set out on page 27.

Respective responsibilities of the Council and Auditors

As described on this page the Council is responsible for the preparation of accounts. It is our responsibility to form an independent opinion, based on our audit, on those accounts and to report our opinion to you.

Basis of opinion

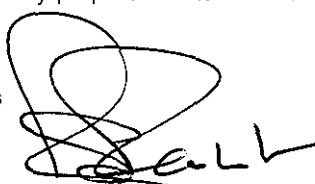
We conducted our audit in accordance with Auditing Standards issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts and disclosures in the accounts. It also includes an assessment of the significant estimates and judgements made by the Council in the preparation of the accounts, and of whether the accounting policies are appropriate to the company's circumstances, consistently applied and adequately disclosed.

We planned and performed our audit so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the accounts are free from material misstatement, whether caused by fraud or other irregularity or error. In forming our opinion we also evaluated the overall adequacy of the presentation of information in the accounts.

Opinion

In our opinion the accounts give a true and fair view of the state of the company's affairs as at 31 March 1999 and of its surplus for the year then ended and have been properly prepared in accordance with the provisions of the Companies Act 1985 applicable to small companies.

R. S. Porter & Co.
Chartered Accountants and Registered Auditors
77/81 Alma Road
Clifton
Bristol BS8 2DP



17 May 1999

STATEMENT OF ACCOUNTING POLICIES

This statement of accounting policies forms part of the accounts.

(a) *Accounting convention*

The accounts have been prepared in accordance with the historical cost basis of accounting and in accordance with Statement of Recommended Practice No. 2 "Accounting by Charities".

(b) *Taxation*

No provision for taxation, deferred or otherwise, has been provided in these accounts as the Institute is a registered charity (registered number 256335) and is therefore exempt from taxation (other than Value Added Tax) under Section 505 of the Income and Corporation Taxes Act, 1988.

(c) *Assets received as donations*

No monetary value has been incorporated in the accounts in respect of assets donated to the Institute, other than those comprising cash and securities.

(d) *Cash flow statement*

No cash flow statement has been prepared as it is considered that no material benefit would be derived from such a statement.

(e) *Sponsored research*

Income from sponsored research is included only to the extent of direct expenditure incurred during the year and overheads relevant to that year.

(f) *Replacement of fixed assets*

Land and buildings are shown in the Balance Sheet at a written-down value and the original cost to the Institute is shown in the Notes to the Accounts. Other fixed assets are excluded from the Balance Sheet and their replacement is met from general income or specific grants made for the purpose of replacement.

(g) *Investments*

Dividends and interest from investments are credited to income on receipt and include the associated income tax credits.

Investments are shown in the Balance Sheet at the mid-market price quoted by the London Stock Exchange. Gains and losses on the revaluation and realisation of investments are credited to the Investment Fund in the Statement of Financial Activities.

(h) *Reserves*

The Council of the Institute exercises its discretion in the creation of reserves to meet future expenditure and in the utilisation of those reserves. The annual surplus on the Statement of Financial Activities transferred to the Accumulated fund is shown after making transfers to and from reserves.

(i) *Stocks*

No account is taken of stocks held by the Institute as these are immaterial.

BATH INSTITUTE OF MEDICAL ENGINEERING LIMITED

STATEMENT OF FINANCIAL ACTIVITIES Year Ended 31 March 1999

INCOME AND EXPENDITURE	Note	Unrestricted Funds £	Restricted Funds £	Reserve Funds £	Total Funds 1999 £	Total Funds 1998 £
INCOMING RESOURCES						
Donations		153,855			153,855	138,550
BBC 'Lifeline' appeal		19,927			19,927	
Grants for sponsored research			107,962		107,962	86,481
Subscriptions		372			372	298
Interest	4	53,814			53,814	68,871
Consultancies, sales and royalties		58,091			58,091	46,243
Total Incoming Resources		286,059	107,962	0	394,021	£340,443
RESOURCES EXPENDED						
<i>Direct expenditure on general activities:</i>						
Salaries and wages	5	157,653			157,653	142,740
Materials and equipment		39,395			39,395	44,180
<i>Direct expenditure on sponsored research:</i>						
Salaries and wages			98,611		98,611	78,658
Materials and equipment			6,227		6,227	1,987
Other			3,124		3,124	5,836
<i>Indirect expenses:</i>						
Rent	6	180			180	180
Premises		4,509			4,509	4,568
Administration, exhibitions and professional fees	7	20,300			20,300	13,409
Travelling and conferences		2,266			2,266	(937)
Total Resources Expended		224,303	107,962	0	332,265	£290,621
NET INCOMING (OUTGOING) RESOURCES		61,756			61,756	49,822
For the year from continuing operations						
Gains / (Losses) on Investments						
<i>Realised</i>						
Write-back previous years' unrealised gains						
<i>Unrealised</i>		(4,000)			(4,000)	8,085
<i>Transfer to Reserve for short-term appointments</i>						
		(88,400)		88,400		
Net Movement in Funds		(30,644)		88,400	57,756	57,907
BALANCE BROUGHT FORWARD AT						
31 March 1998		252,504		667,900	920,404	862,497
BALANCE CARRIED FORWARD AT						
31 March 1999		£221,860	0	£756,300	£978,160	£920,404

The notes on page 30 form part of these accounts

BATH INSTITUTE OF MEDICAL ENGINEERING LIMITED

BALANCE SHEET 31 March 1999

	Note	Unrestricted Funds £	Restricted Funds £	Reserve Funds £	Total Funds 1999 £	Total Funds 1998 £
FIXED ASSETS						
Quoted Investments	9	0	0	325,333	325,333	229,333
		0	0	325,333	325,333	229,333
Current Assets:						
Debtors Sundry		1,795			1,795	1,281
Pre-payments		186			186	30
Accrued income		24,420	12,301		36,721	18,302
University of Bath	10	84,259			84,259	152,408
Money market deposits		139,541		430,967	570,508	532,245
Bank balances		204			204	1,718
		250,405	12,301	430,967	693,673	705,984
Current Liabilities:						
Creditors Accruals		(17,985)	(24,183)	0	(42,168)	(14,913)
Net current assets		£232,420	(£11,882)	£430,967	£651,505	£691,071
Total assets, less current liabilities		£232,420	(£11,882)	£756,300	£976,838	£920,404
Represented by:						
Accumulated fund		232,420	(£11,882)	0	220,538	252,504
Reserve for short-term appointments	11			756,300	756,300	667,900
		£232,420	(£11,882)	£756,300	£976,838	£920,404

The notes on page 30 form an integral part of these accounts.

P. LAWES
D. T. PROTHCROE

Chairman
Vice-Chairman



17 May 1999

BATH INSTITUTE OF MEDICAL ENGINEERING LIMITED

NOTES TO THE ACCOUNTS

Year Ended 31 March 1999

1. LIMITATION BY GUARANTEE

The Company is limited by guarantee and as such has no share capital.

2. CHARITABLE STATUS

The Company is a registered charity (no. 256335).

3. COUNCIL

No remuneration is payable to the members of the Council of the Institute.

4. INTEREST

	£
Quoted Investments.....	19,673
University of Bath.....	-4123
C.O.I.F.....	38,175
Abbey National.....	88
	<u>53,813</u>

5. EMPLOYEES

The average number of employees during the year was as follows:

1999	1998
14	14

No employee earns more than £40,000 per year

6. LEASEHOLD PROPERTY AND FIXED ASSETS

A lease of the property at the Medical Sciences Centre, was entered into on 26 May 1995.

By the terms of the lease, the annual rent is set at £180. The lease expires on 28 September 2067.

The other fixed assets of the Company have been written down to a nil value in the accounts.

7. AUDIT FEES

Audit fees of £235.00 are included under the heading of Administration, exhibitions and professional fees.

8. DIRECTORS AND OFFICERS LIABILITY INSURANCE

The Institute has effected directors' and officers' liability insurance cover. The annual premium is £468.

9. QUOTED INVESTMENTS

	£
Value @ 31/03/98.....	229,333
Purchased in Year.....	100,000
Unrealised Gains/(Losses).....	-4,000
	<u>325,333</u>

The investments are shown in the Balance Sheet at market value.

10. UNIVERSITY OF BATH

The University of Bath administers the financial affairs of the Company. The balance on the current account with the University attracts interest at the current market rate, as determined by the average rate obtained by the University on its deposits and investments.

11. RESERVE FOR SHORT-TERM APPOINTMENTS

The Institute has assigned funds for short-term engineering appointments for specific projects.

Funds for short-term engineering appointments

	£	£
Graduate Engineer in post: 1 year and replacement.....	109,500	
Graduate Engineer in post: 3 years.....	82,000	
Graduate Engineer in post: 2 years and replacement.....	82,000	
Graduate Engineer in post: 3 years.....	82,000	
Graduate Electrical Engineer in post: 2 years and replacement.....	93,300	
Graduate Electrical Engineer, new: 3 years.....	75,500	
Workshop Technician in post: 1 year and replacement.....	71,800	
Electronics Technician in post: 3 years.....	64,300	
Production Technician in post: 2 years, replacement and costs.....	61,300	
Occupational Therapist (part-time): 2 years and replacement.....	34,600	
		<u>756,300</u>

Balance on reserve: 31 March 1998

Transfer from Income and Expenditure Account

£667,900
88,400

Balance on reserve: 31 March 1999

£756,300

Estimate of Future Income and Expenditure

Introduction to Table

The estimates in this table are for three years with a tentative projection to the fourth year. An annual rate of inflation of 3% is assumed. Please refer to the Director's Report under 'Planning' for a further discussion of the implications.

	1999/2000		2000/2001		2001/2002		(2002/2003)	
	Income	Expenditure	Income	Expenditure	Income	Expenditure	Income	Expenditure
	£	£	£	£	£	£	£	£
Estimated Income								
Subscriptions, Sales, Consultancies, Royalties	55,000		55,000		55,000		(55,000)	
Donations from regular sponsors (see Note 1)	140,000		145,000		150,000		(150,000)	
Interest	50,000		50,000		50,000		(50,000)	
Estimated Effective Expenditure & Offsetting Support (see Note 2)								
Salary commitment for staff working at BIME								
(a) Director (part-time) and 2 permanent engineers		85,200		87,800		90,400		(90,400)
Salary support provided by direct employment and project grants from the Health Authority and DH	67,400		69,400		71,500		(41,000)	
(b) Short-term appointments of 6 engineers and 1 physicist		166,400		171,400		176,500		(76,000)
Salary support provided by project grants	53,300		54,900		56,500			
(c) 5.5 Technicians and Therapists		107,700		110,900		114,200		(57,000)
Salary support provided by direct employment and project grants	22,800		23,500		24,200		(11,000)	
(d) Secretarial		13,800		14,200		14,600		(14,600)
Salary support provided by direct employment and project grants	7,000		7,200		7,400			
(e) Cleaning		2,200		2,300		2,400		(2,600)
Salary support from DH grants	1,100		1,200		1,200			
Materials & Equipment		50,000		50,000		50,000		(50,000)
Support from DH grants	3,000		3,000		3,000			
Premises		4,500		4,500		4,500		(4,500)
Administration, exhibitions etc		20,000		20,000		20,000		(20,000)
Support from DH grants	10,000		10,000		10,000			
Travelling		2,000		2,000		2,000		(2,000)
Support from DH grants	1,000		1,000		1,000			
Fees and Service charges		200		200		200		(200)
	<u>£410,600</u>	<u>£452,000</u>	<u>£420,200</u>	<u>£463,300</u>	<u>£429,800</u>	<u>£474,800</u>	<u>(£307,000)</u>	<u>(£317,300)</u>
Balance on year		-£41,400		-£43,100		-£45,000		(£10,300)

Notes

- The estimates of donations from regular sponsors have been based on promised support and experience of the level recently received. They represent target figures for donated income which we hope our sponsors will provide.
- The effective expenditure is the cost of running the Institute. Some of the staff working at the Institute are employees of other organisations (Royal United Hospital NHS Trust, University of Bath) and their salary costs are not recorded in the Annual Accounts. The offsetting support under 'income' includes this salary contribution and also the salary contribution provided by the DH grants. Not included in this table is an estimate of the cost of the administrative support provided by the University.

BATH INSTITUTE OF MEDICAL ENGINEERING LIMITED

DONATIONS RECEIVED

Year Ended 31 March 1999

Under £200 : 30 donors

The following were exceptionally generous in their donations:

The Headley Trust	Abbott Mead Vickers Plc
The Southern Trust	The Arnold Foundation
BBC Lifeline Appeal	Barclays Bank Plc
Charity of Henry Smith (Kensington Estate)	Bath Area Rag
The Hayward Foundation	George Henry Collins Charity
Railtrack Plc	The A.M. Fenton Trust
Emmandjay Trust	General Accident Fire & Life Assurance Corp. Plc
The H.B. Allen Charitable Trust	Col. W.W. Pilkington Will Trust
The Paul Balint Charitable Trust	Racal Charitable Trust
The Dunhill Medical Trust	Albert Reckitt Charitable Trust
The John Ellerman Foundation	Renishaw Plc
The late Mrs. Eileen Gross	Smiths Industries Plc
Carrie Rudolf Will Trust	Jessie Spencer Trust
Steel Charitable Trust	Ti Group Plc
Viscount Nuffield Auxiliary Fund	Benham Charitable Trust
Pilkington Charitable Trust	Fine Art Developments Plc
Trusthouse Charitable Foundation	Henderson Administration Ltd
Jenour Foundation	Pall Medical
Cleopatra Trust	Rolls-Royce Plc
The Alchemy Foundation	IMI Plc
Lazard Brothers & Co. Ltd.	Mr. P.G. Davis
The Dowager Countess Eleanor Peel Trust	Dr. J.D. Garnish
Zeneca Group Plc	Mars U.K. Ltd.
Inman Charity Trustees Ltd.	Fosseway Townswomen's Guild
The Inverforth Charitable Trust	Fox Memorial Trust
Friarsgate Trust	Miki Travel Ltd.
Remedi	The Ashby Charitable Trust
BBC Children in Need	Mr. & Mrs. C. Leslie Bibby
Sir James Reckitt Charity	Miss J.M. Bisgood
The Mason Bibby 1981 Trust	Mrs. A.L.K. Cadbury
Chapman Charitable Trust	Fenwick Ltd.
Cooper Charitable Trust	Robert Fleming Holdings Ltd.
Lady Hind Trust	KPMG
The Jane Hodge Foundation	Lewis Family Charitable Trust
Robert Kiln Charitable Trust	London Forfeiting Company Plc
Oakley Charitable Trust	Midland Bank Plc
P.F. Charitable Trust	The Sobell Foundation
John Pryor Charitable Trust	Andrew Anderson Trust
Mr. & Mrs. J.A. Pye's Charitable Settlement	Bertie Black Foundation
Charles & Elsie Sykes Trust	The Fitton Trust
Dame Violet Wills Will Trust	Glynwed Charitable Trust
In memory of Mr. Bevan Horstmann	R. Hickson-Collis Charitable Trust
Matthews Wrightson Charity	The Higgs Charitable Trust
The Freemasons' Grand Charity	Imperial Tobacco Ltd
The Norman Family Charitable Trust	Stella Symons Charitable Trust
Christopher Rowbotham Charitable Trust	Waitrose Ltd
G.M. Morrison Charitable Trust	Wessex Water Plc
Pilkington General Charitable Trust	
Ravensdale Trust	
Mrs. R.A. Brinton	

One Donor wished to remain anonymous