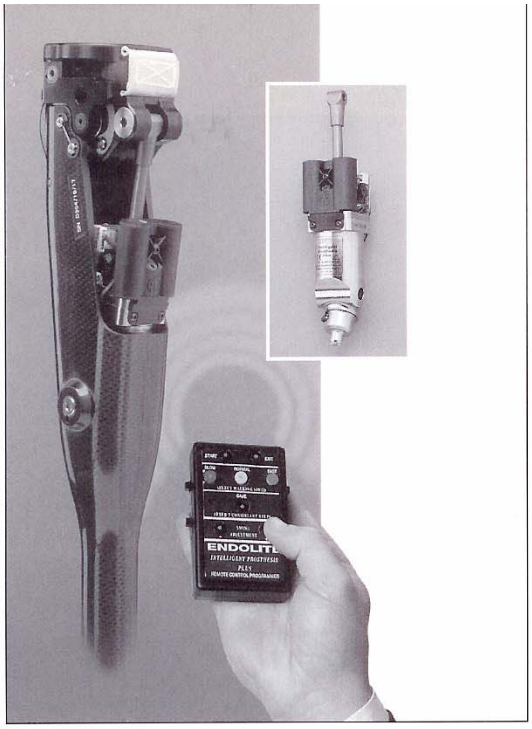

The Intelligent Prosthesis *Plus*

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1996
THE QUEEN'S AWARD FOR TECHNOLOGICAL ACHIEVEMENT

THE PRINCE OF WALES AWARD
For Innovation
Winner 1996

From its very beginning the Intelligent Prosthesis Plus received praise from amputees whose life had been transformed by it. On the first anniversary of its launch the IP+ won the 1996 Prince of Wales Award for Innovation and was granted the Queens Award for Technological Achievement.

The concept of a microprocessor controlled lower limb prosthesis was first described by Nakagawa et al of Hyogo Assistech in 1986. In 1990 Blatchford obtained the licence for this technology and the fruition of their work was the Endolite Intelligent Prosthesis (IP), the first commercial application of microprocessor technology in a lower limb prosthesis.

The first generation of commercial devices which utilised the computer controlled swing phase mechanism was launched in 1993. This commercial unit was founded on the extensive prosthetic experience of Blatchford and the electronic control expertise of NABCO. By mid 1995 nearly 1,000 IP's had been fitted world-wide. Over the following 12 months a further 1,000 amputees were fitted with the second generation award winning IP Plus.

Despite the considerable cost of developing this product, its long term benefits were significant enough to outweigh short term economic objections. The application of micro electronic control has now been accepted as indicating the future type of artificial limbs.

Blatchford is renowned for it's innovations, showing the way for future developments. To this end the requirements for the research into future artificial limbs has been identified. The world of prosthetics has now recognised that the benefit for the amputee surpasses all other pressures. The way forward therefore is to provide a limb system with more control, requiring less effort by the user to walk, easy to adjust and maintain by the prosthetist and readily available for prescription by the clinicians. Since mid 1993 there have been many indications by major prosthetic manufacturers that they are now convinced that the experience of the Endolite IP has paved the way for them to invest with a greater degree of certainty, in this line of development. Already several patents have been drawn on the limb systems of the future and several research departments are now progressing the work. With this in mind it has been a priority for Blatchford to refine the performance, price, availability, interchangeability, size, ease of use, power and production methods for microprocessor controlled prosthesis.

By addressing these main issues and taking the lead, a new design specification for future devices has been established. Application of high level technology to lower limb prosthetics ensures greater control, ease of use and reduction of effort by amputees during walking activities. Other considerations include full interchangeability and modularity for ease and flexibility of prescription. An adjustment procedure requiring no special skills is imperative and the final device should be made available within a moderate pricing structure for all countries and categories of above knee amputee.

Development of the IP+

The specification of IP+ was based on the areas of improvement highlighted from field experiences of the first generation Endolite IP. It was important to use as many parts of the original system as possible as they are now regarded as proven technology in the light of the success of the Endolite IP. Improvements in the reliability of the complete prosthesis is achieved by a reduction in the forces generated in the mechanism during walking at high speed. The system is designed to adjust itself automatically for different walking speeds, hence, there is no need for amputees to kick their leg to ensure full extension. As a result, secondary components such as the ESK knee stabiliser, pivot pins and so on enjoy an even greater degree of reliability.

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Powerful pneumatics

In this respect the main features of the original pneumatic system were to be maintained in the IP plus. In addition the new cylinder design, which is based on Endolite 160mm geometry, provides 25% more resistance (Graph One). Equally, by utilising the complete extension stroke of the cylinder and controlling the air flow, the cushion for terminal impact has been significantly improved across the entire walking speed range (Graph Three). Thus all categories of amputee walking at every speed can be accommodated. The cylinder is strong enough to take all extension loads, removing the need for secondary extension stops.

The type of motor is unchanged. However the drivers have been improved and, in conjunction with a new microprocessor, the IP+ is capable of providing half step change which means the valve adjustment can now be fine-tuned to 12 microns instead of 25 microns on the first version (Graph Two).

More finely tuned

In combination with the design of the valve arrangement the system has an effective range which now provides 46 adjustment steps compared to the original 30. This will mean that a smoother and wider range of resistances can be programmed and allowance made for the effect of the cosmetic cover. The IP+ can now be prescribed to a larger number of amputees with precise adjustment to the exact speed of swing on the finished prosthesis.

Pneumatics and hydraulics

The smooth resistance profile combined with increased power, greater cushion and damping resistance and the ability to take extension load, means that a larger number of hydraulic users can now be fitted with the IP+. These amputees can now benefit from a significant reduction in effort as well as being able to change their walking speed without any extra effort. This refined control has until now only been available with an hydraulic cylinder, particularly in slow gait. This provides a sure foot step for those amputees who can now safely walk very slowly for the first time. In addition, by using the IP+, the amputee can now walk faster as well, thus enjoying a larger range of walking speeds.

Improved controller

There are many other improvements in the controller design, such as reduced battery consumption, automatic correction of errors made in adjustment, selection of speed and valve setting sequence. By allowing the device to operate in the automatic mode during programming, the prosthetist can check how the adjustment allows an optimum gait with changes in walking speed. The final setting may be reconsidered before confirmation using a "time out" sequence which enables the system to revert back to the previous setting of the controller.

A special channel selection switch provides security for transmission, thus enabling two devices to be programmed at the same time. The programmer itself uses standard miniature low power FM transmitter and receiver modules which have already gained government approval.

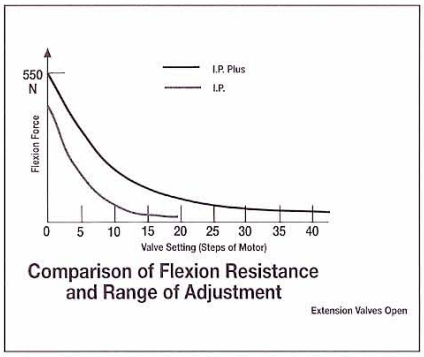
The system has undergone extensive power optimisation which allowed the use of two standard 3 volt, 1.3 Ah 2/3 A size lithium batteries. These are clipped in position, making their replacement very easy. The receiver is switched off during normal operation and is activated before programming by a special sequence of flexion and extension of the knee. A short "time out" waiting for a signal from the programmer ensures power is saved in case of activation during normal use. The overall refinement has resulted in a more efficient system in all respects with a significant reduction in the cost of manufacture.

Programming Procedure

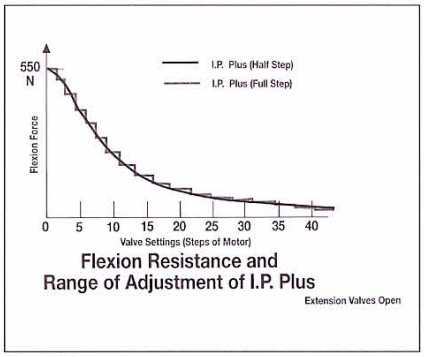
The key to the simplification of this procedure has been a radical change in speed detection software. The controller continuously averages the walking speed allowing on line processing and interaction during programming. The programming procedure is simply to select a **SPEED** of walking, then adjust the valve setting of the swing phase control by pressing a (+) / (-) key. The settings are then saved at the required speed. Repeating this sequence at two other speeds, automatically leads to the generation of five valve settings and associated speed boundary conditions.

Past experience of previous generations showed that having access to a quantified value of valve settings and

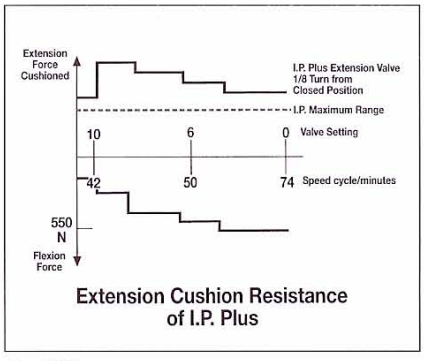
Hand held programmer.



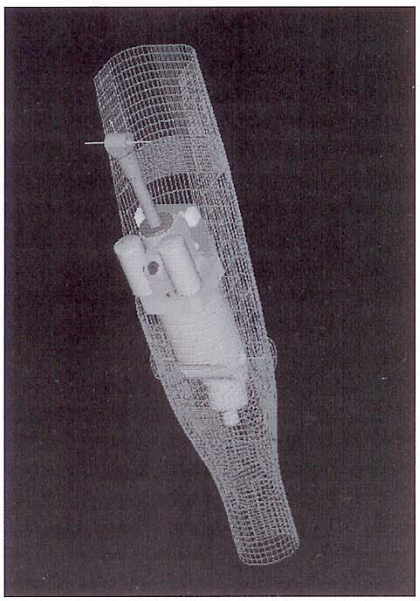
Graph One.



Graph Two.

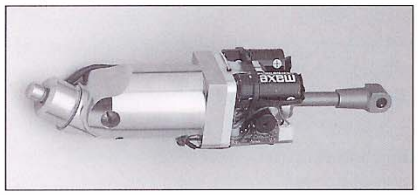


Graph Three.

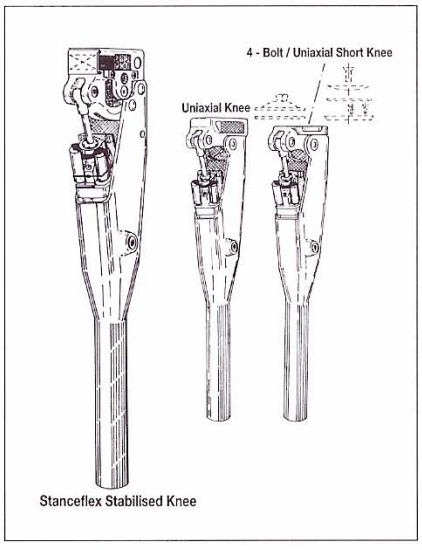


CAD model of cylinder interchangeability.

The Blatchford IP+ core research development team, Left to right; Saeed Zahedi, Senior Research Engineer, Stephen Lang, Pneumatic & Hydraulic Designer, and Andy Sykes, Electronic Design Engineer.



The new IP+ cylinder.



ESK and EUK IP+ modules.

speeds was useful. However it was difficult to teach prosthetists quickly and also manipulation of the numbers was time consuming. Five stage settings provide an adequate number of steps to cover the entire walking speed range. A larger number of stages causes delay in changing speeds.

Remote control

The remote control receiver is activated by a sequence of flexion and extension at 12 second intervals. On pressing **START**, an audible sound confirms receipt of signal. The flashing LED's switch to selection of speed, inviting the user to select one of the speeds or **EXIT**. After selection of a speed, the amputee is asked to walk at that speed while the prosthetist can observe the gait from any angle at a distance of up to 45 metres inside or outside a clinical environment. The increase (+) or decrease (-) of resistance to flexion controls how fast or slow the limb should be extending. An audible sound confirms each resistance change with the additional feature that at maximum resistance no sound is emitted for subsequent increase (+) key presses and at minimum resistance no sound is emitted for further decrease (-) key presses. Once satisfied with the swing phase performance on any step after seven consecutive consistent steps, the **SAVE** key is pressed. This stores the selected valve settings as well as the average speed at the time of pressing the key. This averaging is weighted towards the last step, hence it is important that the amputee is encouraged to walk at the specified speed. The sequence is repeated for another two speed selections and this will complete the programming procedure.

It is useful to note that the system goes to automatic mode whenever the **SAVE** key is pressed. This means that the valve position automatically changes with speed. It is possible to go back to the programme and simply adjust the valve setting at one speed or change the walking speed selection at a particular valve setting.

The values stored in permanent memory can only be over written by a new programming sequence. This is first registered into temporary memory by pressing **SAVE** and the final confirmation is carried out by pressing **EXIT** key which transfers the settings into permanent memory.

The four minute time out facility which acts as a cancel for all adjustments is activated if no key is pressed within the time period. This causes the data stored in temporary memory to be wiped out, reverting to previous settings.

Conclusion

The development of this second generation Intelligent Prosthesis is based on several years experience in the development and commercialisation of the first microprocessor swing phase control. The areas of improvement include simplification of adjustment, rationalisation of cylinder and its carrier with regard to interchangeability and manufacturing cost. The experience so far has demonstrated that, in combination with the enhanced Endolite Stanceflex Stabilised knee, the IP plus provides a very powerful solution in the selection of correct componentry for lower limb prosthetic devices. A wider range of adjustment, in addition to increased power in providing resistance and cushioning of terminal impact, allows a pneumatic cylinder to be considered for many hydraulic users. The reduction in manufacturing costs and subsequent economies in volume of production would indicate that all other swing phase devices could perhaps be replaced by a microprocessor knee control.

The IP+ provides functional advantage of adjusting to any speed whilst reducing the effort in walking. A large number of technical barriers have been overcome in this design, resulting in a user friendly system where the principles of mechatronics in combining electronic controls with mechanical design have been usefully exploited. The rapid adjustment facility, especially when carried out on the finished prosthesis, allowing walking on any terrain outside a clinical environment, has provided the most realistic conditions for normal daily use.

Leading the way

This innovation has facilitated an increase in general awareness by society of amputee limitations and aspirations and how the latest technology is employed in meeting their needs. The IP + leads the way for the 21st Century generation of prosthetics where cybernetics will be the standard technology.

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Plus points

This second generation Intelligent Prosthesis known as IP+ provides superior performance compared to the first version. The improvements are

- Better and more precise function
- Simpler adjustment
- Reduction in time needed for programming
- Increased power of IP+ cylinder enables prescription for some hydraulic users
- Increased level of cushion for terminal impact catering for very active amputees
- Reduction in length and size of cylinder enables fitting amputee with shorter, smaller calf segments
- In-built sensor for easy replacement and exchange
- IP+ can be interchanged by undoing three bolts only
- Rationalised shin housing and fitting kit for interchangeability with other swing phase controls
- Easily accessible cushion valves
- Two standard batteries for easy replacement after several months of use
- Uses low power radio transmission for cordless remote programming
- 45 metre range of remote control enabling the prosthetist to look at gait from any distance and view
- Programming of completed limb with cosmetic cover enables adjustment to be carried outside of a clinical environment
- Half step adjustment for finer setting provides 46 intervals in the range of adjustment
- Select Channel enables two devices to be programmed at the same time
- Wider range of adjustment to suit larger range of amputee activities and categories
- Audio feedback facility for ensuring receipt of transmission signal
- Visual guidance system helps prosthetist while programming
- Cylinder can take all extension loads generated during stance phase
- Pocket size programmer with simple short operating instructions
- Coded receiver activation with use of limb movement
- Coded transmission signal for safety purposes
- Automatic programmer "time out" reverts to the previously programmed value
- Permanent memory enabling battery replacement without loss of programmed values
- Low battery power detection for emergency valve setting to normal speed
- Special routine for beginning of walking from standing / sitting position
- Automatic check of valve and speed
- Use of microprocessor technology in an open design facilitating future upgrades and development
- Simple check in the unlikely event of any problems and isolation of possible faults in a short time
- Complete technical support, service and maintenance for life of product
- Reduction in cost of manufacture
- Maintains all features of first generation IP

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