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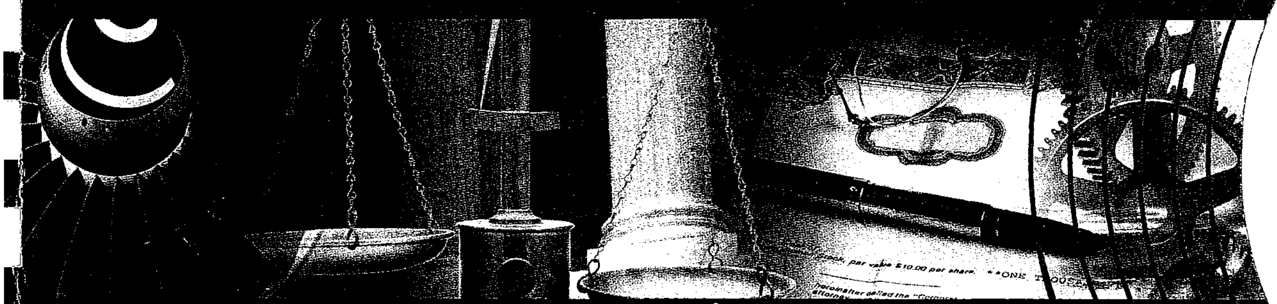

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THE ENGINEERING DESIGN OF THE MARGRON HIP PROSTHESIS

Report prepared on behalf of
Unisearch Limited

on

THE ENGINEERING DESIGN OF THE MARGRON HIP PROSTHESIS

by

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for

Portland Square Pty Ltd

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1. INTRODUCTION

The idea for the Margron Hip Prosthesis ("the hip") was born out of a recognition by Dr Ronald Sekel, Senior Orthapaedic Surgeon at The St George Hospital, Sydney, of the shortcomings of traditional-type hip prostheses, and his further recognition that these shortcomings need not persist into the future. Something much better was easily within reach, conceptually at least. The path to bring the better idea to fruition has been travelled jointly by a number of people: Ron Sekel, who has maintained overall control of the project, and guided it and nurtured it along its way; Dr Tony Farmer of the CSIRO, who has developed the hydroxyapatite coating technology which is unique to this application; and I have contributed to the development of the "architecture" of the hip and its modularisation, to the selection of manufacturing processes to be used, and have done the engineering design work. The companies who will manufacture the hip, Westray Engineering (the forgers) and MAC Instruments (the machinists and manufacturing coordinators) have each contributed much of worth to the development of the project.

The road has not always been easy, or particularly straight. Nevertheless, all of us associated with this project believe that something of worth has emerged, which will provide a sound basis for better hip prostheses and more-reliably successful implantings of these prostheses in the future than has been the case in the past.

2. THE PHILOSOPHY BEHIND THE DESIGN

Most traditional-style hip prostheses have provided curved, tapered tangs which need to be well fitted into cavities within the femur. This has necessitated the production by the installing surgeon of a cavity in the femur which is just the right size and shape to accept the tang of the prosthesis stem with just the right degree of tightness. Further, this cavity, which the surgeon must produce expeditiously during surgery, must also be in just the right position and in just the right orientation (especially in relation to anteversion) if problems of leg length, alignment and freedom from dislocation are to be avoided. This is no easy task. Not surprisingly, perfection has not always been reliably achieved.

In the past, many hip designs have relied upon acrylic bone cement to retain them in position in the femur. This has led to problems at the implanting of a prosthesis, where temperature build-up during the curing process of the bone cement can cause damage of its own. Loosening of cemented prostheses is common and usually leads to the need for revision surgery. Revision of a cemented hip prosthesis is greatly lengthened, with consequential strain on both the patient and the surgeon, by the necessity to remove every fragment of bone cement from the interior of the femur. Failure to do so carries a high risk of a persistent infection, while success in this task generally results in a degraded femur which provides a poor prospect for the successful implanting of a new prosthesis.

The idea behind the Margron Hip Prosthesis has been to provide an uncemented prosthesis which is quick and easy to install to the correct tightness in a position which is reliably correct, and which allows the surgeon to deal individually with the various considerations which arise.

A stem with a straight axis and a basically circular cross section allows the preparation of the cavity in the femur very quickly and reliably by means of a specially profiled reamer, which suits the profile shape of the stem which is to be implanted. The reaming process can be continued until the correct depth of cavity in the femur has been produced. The stem can then be screwed down into position in the femur by rotating it bodily about its own axis by means of a special tool, thereby fixing it by its external screw threads. The angular position of rotation at which this is achieved is unimportant. The stem automatically fits perfectly in the reamed cavity and a hydroxyapatite coating on the top section of the stem, together with anti-derotation slots which are axially oriented on the outer surface of the stem, together encourage bony ingrowth and secure retention of the stem in the femur.

At its top end, the stem contains a circular-conical tapered cavity (a "female taper") which provides a mounting feature for a corresponding circular-conical taper stem (a "male taper") at the base of a separate neck component. The male and female tapers together provide an arrangement whereby the neck component can be inserted into the stem component, and can then be rotated about the axis of its male taper, which is also the axis of the female taper in the top of the stem, so that the correct anteversion angle is achieved. A series of sharp but not massive strikes by a mallet on a boss feature at the top of the neck component serves to drive the taper joint into a semi-permanent state of self-locking fixation, ie into a locked-together state which requires a special wedge tool for its release.

> *It is to be noted that self-locking taper joints of this type, so-called "Morse tapers", have been used for many decades in machine tools, and especially in the spindles of drilling machines, where they are used with great success and reliability to hold, locate in alignment and drive the drill chuck and hence the drill itself in its drilling task. The taper used to fix the neck into the stem in the Margron Hip Prosthesis is essentially a Morse-type taper.*

Thereafter, a separate ball component containing a female taper within it is placed on a second male taper which is integrally part of the neck component and which is located at the top of the neck component. As the balls are proprietary items, the detailed design of the proximal taper on the neck is dictated by the stated requirements of the ball suppliers, which have been derived by them to suit the requirements of the balls and their reliable fixation. The balls are supplied in several variations, relating to the female taper within them. A nominal (or "zero") ball which locates on the male taper on the neck so that its centre comes to a nominal or "zero" position along the axis of that taper, a "+7" ball which locates 7mm further out along the male taper on the neck component, a "+4" ball, and a "-4" ball which locates 4mm further in along the male taper than does the zero ball. The selection of the ball to be installed from this set of available choices provides a measure of control of the lateral offset between the shaft of the femur and the centre of the ball. The proximal taper on the neck component is oriented at an angle to the distal male taper on the neck, and hence to the stem, which corresponds to the angle along which variations in height and offset between the head and the shaft of the natural femur will occur.

Other specific features of note are provided on both the stem and the neck. On the stem, a differential screw thread system is used, comprising two screw threads with different pitches. The distal screw thread, with a greater pitch, screws into a pre-cut screw thread in the cortical bone in the shaft of the femur. How It is designed to do so with minimal stress-concentrating effect in either the bone or the stem. The proximal screw thread, with a lesser pitch, self-threads into the cancellous bone in the top of the femur. This thread is designed to grip how well in this bone. This arrangement provides the benefit of locking a compressive axial residual stress into the bone, thereby avoiding loosening of the prosthesis caused by re-modelling of the bone. It also provides a very significant long-reach "spring washer" effect on the stem, which contributes markedly to the avoidance of movement, and particularly unwinding, of the

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stem in the femur in the early post-operative period, prior to the development of bony ingrowth into the hydroxyapetite coating.

Ref.

A hexagonal cavity, such as is found in the heads of cap head screws, is located below the base of the female taper in the stem. This provides a feature by which the stem can be screwed into position in the bone and, if necessary, by which it can be unscrewed out of the bone during revision surgery. In the event that unscrewing of the stem out of the bone should prove unsuccessful during revision, an extraction groove is provided within the female taper in the stem, just below the top extremity of the stem. The driving tool which is used to wind the stem in or out engages in both the hexagonal socket and the extraction groove, and provides a slap-hammer function for the reliable removal of the stem from the femur during revision.

The neck provides a small boss at its top aspect, above the axis of its distal taper. This boss contains a small depression which locates and guides the foot of a driving-in punch which is used in conjunction with a mallet to drive the neck into its fixed engagement with the stem. The neck also provides two pairs of lugs or projections, in which each such pair provides one lug at each side of the neck component. The two lugs which are located just above the top of the distal taper provide a means for a wedge-type extraction tool to be used to separate a neck from its stem, while the two lugs near the base of the proximal taper provide a means of removing a ball from the neck.

3. PRELIMINARY DESIGN CONSIDERATIONS

While the adoption of a prosthesis layout which embodies separable stem and neck components, which are connected by a conical taper joint, confers valuable advantages as referred to above, it does also bring with it factors which require careful consideration and management in design. One of these factors is the transition from a relatively thin-walled cup-like structure at the top of the stem, where the female taper pocket is located, to a solid lower section of the stem below the taper pocket. This requires some care in order to limit the stress-concentrating potential of that transition and to provide a design which can be manufactured to the required tolerances and finishes, in a material which is quite difficult to machine, by the use of realistic technology. The stress-concentrating effect of the transition from thin-walled cup to solid stem has been minimised by the location of the hexagon-shaped driving socket, which is used for winding the prosthesis into and out of the femur, below the base of the female taper pocket at the top of the stem, with an intervening conical transition section and with a spherical radius forming the bottom of the hexagon socket. Further, a blend radius is incorporated between the bottom of the actual taper pocket and the conical transition section and a further blend radius will be present at the junction of the bottom of the hexagon socket and its spherical bottom surface due to the production of that socket by means of electric discharge machining (EDM-"spark erosion"). As a result of this arrangement, the wall thickness of the top section of the stem which accommodates the female taper and the hexagon socket increases in several stages down the length of the stem and, simultaneously the diameter of the outer profile of the stem reduces progressively so that, at the point where the transition from hollow to solid actually occurs, the transition has been minimised.

A further aspect requiring care arises from the fact that the taper joint section of the assembled neck and stem is radially bulky due to the overlapping of the thicknesses of the male taper on the base of the neck and the walls of the top, cup-like section of the stem. This has the effect of forcing the outer profile of the stem out to a greater diameter than would otherwise be the case but, fortunately, this section of the stem is located in the top section of the femur, just below the trochanter, where there is room to accommodate it. Nevertheless, there is a design incentive to keep both the maximum diameter of the distal male taper on the neck and the wall thickness at the top of the stem as small as can reasonably and safely be achieved. In view of the presence of the proximal screw thread, just below the top of the stem, and the fact that the outside diameter of the stem below that thread must be slightly smaller than the root diameter of that thread, the wall thickness of the stem at the bottom of the taper pocket is somewhat constrained. While the overlapped section of the taper joint between the neck and the stem will inevitably be far stronger than is required, due to the their tight fixity and combined action, the stem wall at the bottom of the taper pocket and the distal male taper on the neck just above the top of the stem must each be individually strong enough to carry the loads which exist at those two sections. Care has been taken to ensure that this is the case.

The strength requirements on the neck and stem led to the selection of ASTM F799-87 cobalt-chromium-molybdenum biocompatible forging alloy for both the neck and the stem. This material provides an ultimate tensile strength of 1172MPa and a yield strength (0.2% offset) of 827MPa, both of which are conveniently high, and a reduction in area of 12% at failure in a tension test, which suggests that care in reducing the severity of stress-concentrating features would be appropriate. This latter consideration has certainly been carried through the entire design process.

In view of the selection of this material, and the shapes of the neck and stem, a decision was taken to make the stems by machining from solid from forged circular bar, for the time being at least even if forging was adopted later when production volumes would justify it, and for the necks to be forged from the outset, also using forged bar as the forging stock. This method of manufacture is very well suited to the provision of extended-length stems to suit the long osteotomies which are likely to be required in revision surgery. In addition, the taper pocket in the stem and the distal taper on the neck are finished by grinding and, as mentioned above, the hexagon socket in the stem are finished by EDM from a pre-drilled pilot hole. The proximal taper on the neck are finished with a special turning process which would give the required large peak-to-valley dimension for the surface finish, as required to suit the locking to the female taper within a ceramic ball without risk of bursting that ball when it was struck onto the taper on the neck.

The decisions referred to above in relation to material and manufacturing methods had the inevitable consequences that it would be comparatively easy and cost effective to produce a range of stem sizes using mostly standard tooling in an NC lathe and resorting to only comparatively few special form tools which could themselves be standardised across the range of stem sizes to be produced, whereas each neck size would require the production of a forging die to suit it specifically. Accordingly, it would not be easy or cost effective to produce a wide range of different neck sizes. A careful study by Dr Sekel indicated that the needs of the vast majority of the western world could be satisfied by a series of six stem sizes and three neck sizes, so arranged that each neck size could be assembled with two different stem sizes. This produced a system in which neck size A assembled to stem sizes 1 and 2, neck B to stems 3 and 4, and neck C to stems 5 and 6. All three neck sizes utilise the same proximal taper dimensions to suit a common ball size which is used throughout the range. At the time of writing of this report it appears that it may be desirable to extend the range of the system by introducing two smaller stem sizes, say 0 and 00, each of which would assemble to a smaller-than-A neck, say S, to suit the Asian requirements, and also to introduce a size 7 stem which would assemble to the size C neck

The crushing of the surface texture on the proximal taper on the neck during the striking-on of a ball, in order to provide a good seating and locking for the ball, inevitably carries with it the requirement that the striking-on of a ball is a once-only event for the proximal taper of the neck. For this reason, and also to allow a check to be made that correct height and anteversion angle have been achieved in the installation, a trial stem and a trial neck are provided in each size of each component. The trial stem provides a distal screw thread only, in order to not disrupt the cancellous bone into which the proximal thread of the final installed stem must self-tap. When the trial stem has been screwed into the position which will be occupied by the stem to be installed, by the tightening of its screw thread into the thread already tapped in the cortical bone, the trial neck can be inserted into the stem and locked into a temporary position while a trial ball is placed on the proximal taper of the trial neck. The joint can then be temporarily reduced in order to check height and anteversion angle. If these are correct, the joint is re-separated and the trial components are removed. The actual prosthesis can then be installed with confidence that its geometry will be correct.

It is to be noted that, in addition to providing the operational, procedural benefits at the time of installation of a hip which are referred to above, and which are expected to produce a much lower frequency of sub-optimal installations than is currently the case with traditional-type hips, the conical taper joint between the separable stem and neck components is also the vital connecting link which permits the modularity upon which this six-stem/three-neck system depends. Both the male and female members of this taper joint are significantly stiffer in a radial direction at the bottom of the taper than they

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are at the top of the taper. As a result, if both members had the same taper angle, the interfacial pressure between these members would be significantly higher at the bottom of the taper than at the top after the joint is driven into its assembled fixity. The friction forces available to resist rotational slip-around of the joint would thereby be highest where the radius is least, reducing the value of the applied torque required to cause joint slip. In order to avoid this, a deliberate small "mismatch" has been introduced in the angles of the two tapers.

4. PRELIMINARY ANALYSIS

A calculation was performed in the traditional manner to evaluate the endurance limit stress value in the stem component, based on the published material data in ASTM F799-87 to the effect that ultimate tensile strength Su=1127MPa and yield strength (0.2%offset) Sy=827MPa. By applying the normal factor of 0.5 to Su to obtain a specimen endurance limit Se' and then applying a size factor of 0.85 and a surface finish factor of 0.87, a component endurance limit Se of 418MPa was obtained. A Modified Goodman fatigue diagram based on these values was drawn. As the loading on a hip joint is repeated loading, ie from zero to maximum then back to zero, rather than fully-reversed loading, a plotted point on the diagram will be along a line through the origin at +45 degrees in the tension field or at –45 degrees in the compression field. Such stress locus lines intersect the fatigue failure locus lines at the points (305,305) in tension and (415,415) in compression. Accordingly, the limiting value for both mean stress Sm and alternating stress Sa to avoid an eventual fatigue failure is 305MPa in tension and 415MPa in compression. This indicates that the peak stresses which can be safely incurred are 610MPa in tension and 830MPa in compression. ?

From this point on, this report will refer to computer spreadsheet files which are to be found on the accompanying floppy disk. Hard copies of these files are also to be found appended to this report. It is to be noted that, due to a computer upgrade during the course of the design work on this hip prosthesis, it was necessary to transfer these files from an older computer where they were in Microsoft Works format to a newer computer where they are in Microsoft Excel format. As a result of this, the filename noted near the top of each file, which is of the form [**FILENAME.WKS**], and which has been left unchanged in the hard copy, will appear as an Excel-type file with no suffix when the folder **"Hip Joints"** is opened on the floppy disk. Further, to facilitate the movement of files from one system to the other, a minor re-naming of files has occurred, to the extent that in the new system the final letter of the letter-string part of [**FILENAME**], prior to the numeral or numeral string, has been repeated, ie **HIP1** in the old system and in the appended hard copy has become **HIPP1** on the appended floppy disk.

File **HIPP1** shows some initial exploratory calculations which were undertaken in order to establish a benchmark for the relativities between the requirements of stems and the requirements of necks. They are based on the diameter of the distal taper on the neck, just above the stem, and on the cross section of the hollow part of the stem at the base of the taper pocket.

In this analysis, which was primarily a comparative study intended to explore the compatibility of the requirements of the stems and the necks, rather than to finalise actual dimensions, the procedure adopted was to assume a repeated loading of 5 x body weight for a 120kg person, with the offset between the stem axis and the ball centre taken as a value of 50.7mm, which was the maximum expected actual offset distance. For the distal taper on the neck, a range of taper diameters was examined and, for each such diameter, the bending stress SB and the direct compressive stress SC were calculated. The sum of these, SB+SC, which is the maximum value of compressive stress in the distal taper on the neck, and the difference of these two, SB-SC, which is the maximum tensile stress were also calculated. A re-proportioning was then performed to determine the body weight in kg which, with a dynamic factor of 5, would produce a maximum tensile stress of 470MPa. The value of 470MPa was selected as the allowable in-service tension stress in view of the calculation referred to above which indicated a tensile failure-boundary stress of 610MPa, together with the considerations that size and surface finish allowances had been fairly generous (conservative) and not every step involves a loading of 5x body weight even in an active person, and the opposing fact that some degree of stress-concentrating effect would inevitably remain in the prosthesis due to its required geometrical features. (470 = 610/1.3).

The calculations referred to above were followed in **HIPP1** by a stem/neck comparison based on a modular system comprising six stems and three necks (Series A) and on another modular system comprising six stems and six necks (Series B). Again, the calculations produced a body weight value in kilograms which, with a dynamic factor of 5, would produce a peak stress of 470MPa. For Series A, a neck taper diameter was selected which was suitable for use in two stem sizes and stem dimensions were adjusted so that the temporary kg "rating" for the neck fell between the two kg "ratings" for the two stem sizes associated with that neck. In each case it was found that a convenient "ratings" balance was achieved between stems and necks with useable component dimensions. For Series B, a good "ratings" balance was achieved between each stem/neck size pair, but this Series was not proceeded with. This outcome provided a sound basis for further initial design work on the curved section of the neck, once the offset dimensions for the three neck sizes had been determined.

It is to be noted that the dynamic factor of 5x referred to above was applied to body weight in all design calculations for this hip system. It is therefore included in all kg rating determinations.

The offset distances between the stem axis and the centre of the zero ball were determined by Dr Sekel to be 35.47mm for the A neck, 39.30mm for the B neck and 46.97mm for the C neck. It was obvious from the outset that the forged necks would be of a tightly curved shape, and would be produced in dies for which the parting plane would be the plane containing the axes of the two tapers, thereby providing a parting line which ran around the outside of the S-shaped curve of the neck at its mid-width and also around the inside of the curve of the neck at its mid-width. Accordingly, the cross-sectional shape of the curved section of the neck had to be configured in such a way as to facilitate the forging process in an alloy that would not be easy to forge. The small boss which was to be incorporated on the upper, outer surface of the curved section of the neck to accept and guide the foot of the punch which would be used to drive the neck into its locked state in the taper of the stem, would be across the parting plane of the dies.

Also because the neck would be a tightly curved shape, wherein the mean radius of curvature would be of the same order of magnitude as the full depth of the curved section acting as a beam, the Winkler-Bach curved-beam theory was used for the design of the curved sections of the necks. This theory accurately predicts a hyperbolic stress distribution across the depth of the beam, with higher stresses at the inner edge than at the outer edge. Fortunately, in the distal end of the curved section of the neck, close to the distal taper and furthest from the centre of the ball through which loads would be applied, the tension stresses would be on the outside of the neck, and therefore lower in value than the compressive stresses, which would be on the inside of the neck.

A basically rectangular section of suitable width and depth to provide a good transition to the distal taper, especially in respect of a smooth profile at the lateral edge which would be in the tension field, was selected for each of the three neck sizes. An appropriate draft angle and bottom corner radius to suit the forging dies was also selected. A suitable inner radius for the curve of the neck was selected to give an appropriate neck shape which would ultimately blend well to the bottom of the proximal taper.

As the compressive stresses at the inner edge of the curved section of the neck were much higher than the tension stresses at the outside edge, the design was based on the inner-edge compressive stresses. Considerations similar to those referred to above, which led to a value of allowable in-service tensile stress of 470MPa based on a fatigue failure-boundary stress level of 610MPa, led here to a value of allowable in-service compressive stress of 690MPa based on a fatigue failure-boundary stress level of 830MPa. This proportionately higher value of allowable in-service stress (690 = 830/1.2) was considered appropriate in this case, as repeated compressive loading initiates a fatigue failure much less readily than does repeated tensile loading and, apart from the hyperbolic stress distribution due to the curved-beam effect, which is already accounted for by the use on the Winkler-Bach theory, stress-concentrating features are absent from this section of the design.

Spreadsheets **NECKK1**, **NECKK2** and, **NECKK3**, which are appended to this report, were used for the preliminary estimation of the dimensions of the curved sections of necks C, A and B respectively, with distal taper diameters of 20mm, 15mm and 17.5mm respectively. In each case, the actual offset distance from the stem axis to the centre of a +5 ball (which was in consideration at that time, but which was subsequently supplanted in consideration by +4, -4 and +7 balls, see Sections 5 and 7 of this report) was used and the load, which was assumed to pass through the ball centre, was taken as 5 x body weight for a 120kg person. Each of these spreadsheets was used to determine, at a range of angles (PHI) around the bend of the neck, an appropriate outer radius (Po) and width (w) for a particular assumed inner radius (Pi). Po and w were adjusted at each value of PHI to give the best achievable kg "rating" which resulted in an inner-edge compressive stress of 690MPa. This involved intermediate calculations of section area (A), radius to the neutral surface (RNS), bending moment (M), outer-edge bending stress (So), inner-edge bending stress (Si), direct compressive stress (Sc), total outer-edge stress (Sto) and total inner-edge stress (Sti). These calculations were used to empirically derive a tapering-down of the neck cross section, as it swept up and around, away from the top of its distal taper in order to provide a good blending to the proximal taper, while simultaneously not allowing the kg "rating" of the curved section of the neck to fall any lower than was avoidable. From a plane located at approximately PHI=95 degrees, where the bending moment was already significantly reduced, and was rapidly reducing further as the base of the proximal taper was approached, the reduced rectangular section was faired down to suit the base of the proximal taper as the neck curved back in the opposite direction to meet the base of the proximal taper.

5. FURTHER DESIGN WORK

Following the success of the preliminary design work referred to in the previous section of this report, further design work was undertaken to consolidate the results achieved thus far and to refine and optimise the design wherever possible. Drawings SGHP-001 FEMORAL STEM COMPONENT and SGHP-002 FEMORAL NECK COMPONENT were prepared.

Discussions with manufacturers ensued and, as is always the case, numerous details requiring further attention were brought to light. The drawings SGHP-001 and SGHP-002 underwent several revisions, to issue C.

Also during this period, negotiations with prospective manufacturers led to both the selected forging company and the selected machining company being changed. Further negotiations with the new manufacturers ensued and yet further detail modifications to the design were made to suit the specific manufacturing convenience of the new manufacturers. This, unfortunately, is all too typical of new product development and it represented a temporary setback, not a fundamental problem. Drawings SGHP-001 and SGHP-002 were amended to issue D. Significant and frustrating delays were still thereafter experienced in negotiations with the suppliers of the surgical balls in relation to the surface finish required on the proximal taper of the neck component to suit the requirements of the ceramic balls.

The effects of the detail design changes which were made during this period were checked in new spreadsheets **STMXEKK** and **NEKXEKK**. In **NEKXEKK**, and the parts of **STMXEKK** dealing with the distal tapers, an allowable compressive stress of 640MPa was used. (640 = 830/1.3). These changes, and the use of the actual offset distance which would be incurred in each stem and neck size combination with the use of a +5 ball, rather than the use of the maximum expected offset distance for the entire range, served to bring the absolute values of the kg ratings for the size 1 stems and the A necks above the minimum threshold level of 72kg.

It was recognised that other hip prosthesis systems provided a short-offset version and a long-offset version of their prostheses. Our prosthesis system had been designed from its inception in what was, effectively, the long-offset version. It was recognised that a short-offset neck would be a valuable extension to the modular range of our prosthesis system. At the time of writing, this has yet to be designed in detail, as is the case for the smaller prostheses intended for the Asian market and the single larger stem referred in Section 3 of this report.

It was also recognised that a +7 ball was available and, despite the fact that our prosthesis system had already been designed to suit long-offset requirements, it was envisaged that a +7 ball may on some occasions be used on the necks which had already been designed for our prosthesis system. It was therefore considered imperative to perform a calculation check on the design of our system to ensure that it would perform satisfactorily if a +7 ball was used on any one of the three necks in our system, see Section 7.

6. TESTING

A size 1 stem and an A neck in accordance with what was about to become issue C of the drawings were subjected to fatigue tests in accordance with Standard ISO7206-3:88. The results of this testing were satisfactory. A copy of the test report is appended to this report.

Tests were also undertaken to determine the likely level of torque required to cause rotational slip in the taper joint between the stem and the neck, and to validate the belief that if some slip of this nature were to occur for any reason, such as in an accident scenario, which was believed to be necessary to cause such slip, the taper joint would remain firmly engaged rather than undergoing a release. Special taper plugs and sockets were made up for this test, to the same dimensions as the size B tapers on the prosthesis components, and to several different surface finishes. These plugs and sockets had flats machined on their ends which were remote from the ends which contained the taper features. Levers were able to be attached to the plug and socket bodies by means of these flats, so that a twisting moment could be applied to the joint between the plug and socket. The striking energy which would be applied to a taper joint during surgery was estimated by Dr Sekel striking nails into timber using a striking implement of the same mass and handle length as would be used in surgery, and striking with the same intensity as would be used during surgery. The sink-in distance of each nail was measured after each blow and the penetration force to drive the nails into the timber was measured in a universal testing machine. This enabled the strike energy to be determined, and a drop-weight impacter which would deliver this amount of energy to the taper plug and socket test assembly was designed and built.

In testing, the drop-weight impacter was used to impact the plug and socket test components together with either one or four impacts, as Dr Sekel envisaged that four mallet strikes would be used in surgery to lock the taper joint together. The levers were then applied to the test components and a universal testing machine was used to load the lever ends and thereby apply a twisting moment to the taper joint.

These tests showed that, as expected, a better surface finish on both tapers resulted in a higher value of slip torque. Accordingly, the best surface finish used on each of these two components in the tests, and which was the best finish which could realistically be expected in production without resorting to highly specialised finishing operations, was adopted for both the stem and neck prosthesis components.

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When the plug-and-socket combination containing both members with this best value of surface finish was tested after receiving four impacts from the drop-weight impacter, a very satisfactory level of slip torque resulted, which could only realistically occur in an accident situation. Further, the taper joint itself remained in firm connection throughout several degrees of relative slip between its two components, thereby exhibiting the capability of absorbing significant amounts of energy during a slip event. Unisearch Report 19956-01 reported on these tests, and a copy of that report is appended to this report.

7. FURTHER WORK IN THE LIGHT OF THE CLINICAL TRIALS

By late 1998 significant experience had accumulated from the clinical trials phase of this development project. These trials did not reveal any serious shortcomings with the new prosthesis system and were regarded as fully successful. Nevertheless, they did indicate several further minor changes which would be beneficial.

It became clear that the two lugs above the top of the distal taper on the neck, which were to be used to separate the neck from the stem by means of a wedge tool, were likely to be difficult to approach and engage with the tool when the prosthesis was installed. Accordingly, an extra ridge surface was provided at the lower end of the underside of the curved section of the neck, just above the wash-out radius at the top of the distal taper, facing downwardly, against which the wedge tool could abut. This extra ridge was located symmetrically about the centre-plane of the neck, and was of a shape which blended back towards the two original lugs at the sides of the neck, which were retained. It thereby provided good access for a wedge tool from either side of the prosthesis installation.

It also became clear that the anti-derotation slots in the distal shanks of all 6 stem sizes were not really necessary, and that it would be beneficial to remove them in order to avoid any possibility of difficulty in removing a stem from a femur after a significant period of installation. Reducing the diameter of the distal shank slightly in stem sizes 1 to 4 inclusive was also seen as desirable. Spreadsheets **STMXEKK2** and **NEKXEKK2** were compiled to evaluate the combined effects of a +7 ball and a reduced distal shank diameter on the stems and the effect of a +7 ball on the necks, respectively. It was found that this combination of changes was viable, and drawings were amended to issue F. As the new ridge surface referred to in the previous paragraph provided extra material in a stressed region of the neck, and as **NEKXEKK2** indicated that the neck was adequate in strength without this extra material, no further calculations to explore the additional strength arising from this extra material were undertaken at this time.

Our early expectation that extended-length stems would be useful in hip prosthesis revision surgery, and also in cases of tumor resection involving the loss of a significant length of the proximal femur, were shown during the clinical trials to be well founded. Accordingly, a system of extended-stem prostheses was configured as an addition to the modular range of components already within our prosthesis system. The extended-length stem consists of a component which is identical in all respects to a standard stem of that size, except that the top face of the stem and all the interior details within the pocket of the stem are extended upwardly by either 1cm, 2cm, and so on, in 1cm increments, to a maximum of 5cm. In addition, separate extender pieces which provide an extension of either 6, 7 or 8cm are also provided. These extender pieces provide a male taper at their bottom end which is identical with the male taper on the neck which would be used with that size stem, and a female taper and hexagon pocket in their top ends which are identical with those features on the corresponding stem. When such an extender piece is used, the installed system consists of the stem, the extender piece, the neck and the ball. In this way, each extender piece serves two stem sizes, just as each neck size does. The outside diameter of each extender piece is equal to the outside diameter of the top of the smaller of the two stems which that extender piece serves. This system provides the ability for stem extensions in 1 cm increments to a maximum of 5cm without the introduction of any extra component into the installed assembly, and for extensions to a maximum of 13cm with the addition of only one extra component into the installed assembly.

8. CONCLUSION

A modular femoral hip prosthesis system, consisting of six basic stem sizes and three necks, together with extended-length stems in each of the six basic sizes, and three extender pieces corresponding to the three neck sizes, has been successfully designed. At the time of writing of this report, standard (non-extended) components have been tested successfully in fatigue. Numerous components of various sizes have been successfully trialed in a clinical trials program.

Early experience indicates that this system will be viable and, in many instances advantageous, in normal hip replacement surgery, in hip prosthesis revision surgery, and in tumor resection surgery where the loss of a significant length of the superior end of the femur is involved.

Spreadsheet **SUMMARY** gives a tabular summary of the kg ratings of the stem and neck size combinations in the standard system when a +7 ball is used. The use of a ball with a smaller offset will not reduce kg ratings. Because of the geometry of the stem extensions and the extender pieces, the kg rating of any combination of standard components will not be reduced by the use of corresponding extended-length stems or the appropriate extender pieces. Due to the modularity in this system, the assembly of inappropriate combinations of components is not possible.

I trust that this report satisfies the needs of its readers and provides an appropriate basis for the evaluation of the design of the Margron hip prosthesis system for regulatory approval. If any clarification is required, I will be pleased to provide this upon request. At the time of writing, the intention remains to further extend the system by the inclusion of a smaller neck and two smaller stems, a larger stem, and a range of shorter-offset necks. These extensions to the system will be the subject of one or more further reports in the future.

Richard B Frost, BE, FIEAust., CPEng.(Mech. & Biomed.), FRSA

APPENDIX

HIP PROSTHESIS INITIAL DESIGN WORKSHEET
Filename: HIP1.WKS

Max BM caused by (5*120=600)kg =	5886	N
acting at	50.7	mm
is	298420.2	Nmm

DISTAL TAPER ON NECK:
Neck forged in Co-Cr alloy F799; Sall=470MPa

DIA mm	SB MPa	SC MPa	SB+SC	SB-SC	kg max
24.00	219.9	13.0	232.9	206.9	272.63
23.00	249.8	14.2	264.0	235.7	239.32
22.00	285.5	15.5	301.0	270.0	208.9[illegible]
21.00	328.2	17.0	345.2	311.2	181.22
20.00	380.0	18.7	398.7	361.2	156.14
19.00	443.2	20.8	463.9	422.4	133.52
18.00	521.2	23.1	544.3	498.1	113.24
17.00	618.7	25.9	644.6	592.8	95.15
16.00	742.1	29.3	771.4	712.8	79.12
15.00	900.6	33.3	934.0	867.3	65.03
14.00	1107.8	38.2	1146.0	1069.5	52.73
13.00	1383.6	44.3	1427.9	1339.2	42.11

STEM/NECK MODULAR SIZE COMBINATIONS:
Stem and neck both forged in Co-Cr alloy F799; Sall=470MPa
Neck based on tension due to (Max BM - compression),
stem based on tension due to (0.9 * Max BM), as
- compression assumed pulled out by screw threads,
- worst bending stresses at base of taper pocket, and
  BM reduces linearly down socket length.

Series A:
6 stem sizes, 3 neck sizes, each neck serves 2 stems:

D taper / 45mm = 6 Unthreaded head length mm = 25
C taper / 45mm = 5

SIZE No	1	2	3	4	5	6
A mm	to be finalised					
B mm	to be finalised					
Dtop mm	21.00	23.00	25.00	27.00	29.00	31.00
Ctop mm	15.00	15.00	19.00	19.00	22.00	22.00
Ttop mm	3.00	4.00	3.00	4.00	3.50	4.50
NECK kg	65.03	65.03	133.52	133.52	208.90	208.90
Dbot mm	15.00	17.00	19.00	21.00	23.00	25.00
Cbot mm	10.00	10.00	14.00	14.00	17.00	17.00
Tbot mm	2.50	3.50	2.50	3.50	3.00	4.00
Tmid mm	2.056	3.056	2.056	3.056	2.556	3.556
STEM kg	55.84	89.16	99.72	153.21	175.97	253.25
NECK kg	65.03	65.03	133.52	133.52	208.90	208.90
STEM kg	55.84	89.16	99.72	153.21	175.97	253.25
SIZE kg	55.84	65.03	99.72	133.52	175.97	208.90

Series B:

6 stem sizes, 6 neck sizes, capacities balanced:

D taper / 45mm = 6 Unthreaded head length mm = 25
C taper / 45mm = 5

SIZE No	1	2	3	4	5	6
A mm	to be finalised					
B mm	to be finalised					
Dtop mm	21.00	23.00	25.00	27.00	29.00	31.00
Ctop mm	14.50	16.20	17.90	19.60	21.25	22.90
Ttop mm	3.25	3.40	3.55	3.70	3.88	4.05
NECK kg	58.66	82.17	111.33	146.80	187.89	236.15
Dbot mm	15.00	17.00	19.00	21.00	23.00	25.00
Cbot mm	9.50	11.20	12.90	14.60	16.25	17.90
Tbot mm	2.75	2.90	3.05	3.20	3.38	3.55
Tmid mm	2.306	2.456	2.606	2.756	2.931	3.106
STEM kg	58.38	82.20	111.36	146.32	188.34	237.47
NECK kg	58.66	82.17	111.33	146.80	187.89	236.15
STEM kg	58.38	82.20	111.36	146.32	188.34	237.47
SIZE kg	58.38	82.17	111.33	146.32	187.89	236.15

R.B.Frost
19 Oct 1991

HIP JOINT NECK DESIGN WORKSHEET
Filename: NECK1.WKS
Neck forged in Co-Cr alloy F799; Sall=690MPa
+5 ball limit

DISTAL CURVE:
Distal taper diameter = 20
Flare-out radius = 2

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	25.0	3.0	22.0	462.0	10.7	250544	94.8	-428.5	-12.7	82.1	-441.2	187.7
10	24.6	3.0	21.7	447.0	10.6	248917	99.5	-445.0	-13.0	86.6	-457.9	180.8
20	24.2	3.0	21.4	432.3	10.5	245458	103.8	-459.1	-12.8	91.0	-471.9	175.5
30	23.7	3.0	21.1	415.7	10.4	240163	108.8	-474.2	-12.3	96.5	-486.4	170.2
40	23.3	3.0	20.8	401.4	10.2	233540	112.2	-483.3	-11.2	100.9	-494.6	167.4
50	22.5	3.0	20.5	379.3	10.0	225220	120.3	-506.2	-10.0	110.3	-516.2	160.4
60	22.0	3.0	20.0	360.0	9.9	216373	125.7	-520.9	-8.2	117.5	-529.1	156.5
70	21.0	3.0	19.6	333.2	9.6	206603	138.6	-556.6	-6.0	132.5	-562.7	147.2
80	20.0	3.0	19.2	307.2	9.3	196817	153.7	-597.3	-3.3	150.3	-600.6	137.9
90	19.0	3.0	19.1	286.5	9.0	187351	169.1	-634.9	0.0	169.1	-634.9	130.4
100	18.5	3.0	19.1	277.0	8.8	178356	173.2	-639.0	3.7	176.9	-635.3	130.3
110	18.0	3.0	19.1	267.4	8.6	169947	178.1	-644.9	7.5	185.6	-637.4	129.9
120	21.0	3.0	17.2	292.4	9.6	159207	121.7	-488.8	10.1	131.7	-478.7	173.0
130	20.6	3.0	16.8	278.9	9.4	151625	124.9	-495.3	13.6	138.5	-481.8	171.9
140	20.2	3.0	16.4	265.7	9.3	145320	129.3	-506.0	17.0	146.3	-489.0	169.3
												129.9

R.B.Frost. 31 Jan 1992

HIP JOINT NECK DESIGN WORKSHEET
Filename: NECK2.WKS
Neck forged in Co-Cr alloy F799; Sall=690MPa
+5 ball limit

DISTAL CURVE:
Distal taper diameter = 15
Flare-out radius = 2

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	20.5	3.5	16.0	256.0	9.9	257365	247.1	-872.6	-23.0	224.1	-895.5	92.5
10	20.3	3.5	16.0	252.8	9.8	256117	252.7	-886.5	-22.9	229.7	-909.4	91.0
20	20.1	3.5	16.0	249.6	9.8	253160	256.7	-894.9	-22.2	234.6	-917.0	90.3
30	19.9	3.5	16.0	246.4	9.7	248603	259.3	-897.7	-20.7	238.6	-918.3	90.2
40	19.7	3.5	16.0	243.2	9.6	242606	260.3	-895.1	-18.5	241.8	-913.7	90.6
50	19.4	3.5	16.0	238.4	9.5	235251	263.6	-897.1	-15.9	247.7	-912.9	90.7
60	19.0	3.5	16.0	232.0	9.4	226852	269.6	-904.9	-12.7	256.9	-917.6	90.2
70	18.5	3.5	16.0	224.0	9.3	217769	279.3	-920.8	-9.0	270.3	-929.8	89.1
80	18.0	3.5	16.0	216.0	9.1	208425	289.3	-936.3	-4.7	284.5	-941.1	88.0
90	17.5	3.5	16.0	208.0	8.9	199123	300.0	-952.7	0.0	300.0	-952.7	86.9
100	17.5	3.5	16.0	208.0	8.9	189987	286.2	-909.0	4.9	291.1	-904.1	91.6
110	17.5	3.5	16.0	208.0	8.9	181129	272.9	-866.6	9.7	282.5	-857.0	96.6
120	17.5	3.5	16.0	208.0	8.9	172817	260.3	-826.9	14.1	274.5	-812.7	101.9
130	17.5	3.5	16.0	208.0	8.9	165305	249.0	-790.9	18.2	267.2	-772.7	107.2
140	17.5	3.5	16.0	208.0	8.9	158820	239.2	-759.9	21.7	260.9	-738.2	112.2
												86.9

R.B.Frost. 31 Jan 1992

HIP JOINT NECK DESIGN WORKSHEET
Filename: NECK3.WKS
Neck forged in Co-Cr alloy F799; Sall=690MPa
+5 ball limit

DISTAL CURVE:
Distal taper diameter = 17.5
Flare-out radius = 2

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	23.0	4.0	17.0	306.0	11.1	254409	181.8	-629.8	-19.2	162.6	-649.0	127.6
10	22.8	4.0	16.9	300.8	11.1	253050	186.4	-641.9	-19.3	167.1	-661.1	125.2
20	22.7	4.0	16.8	297.4	11.0	249935	187.5	-643.7	-18.6	168.9	-662.3	125.0
30	22.5	4.0	16.7	292.3	11.0	244824	189.4	-646.3	-17.4	171.9	-663.7	124.8
40	22.2	4.0	16.6	285.5	10.9	237933	192.2	-650.2	-15.8	176.4	-666.0	124.3
50	21.9	4.0	16.5	278.9	10.8	229673	193.9	-650.1	-13.6	180.4	-663.6	124.8
60	21.4	4.0	16.4	269.0	10.6	220131	199.6	-658.8	-10.9	188.7	-669.8	123.6
70	20.9	4.0	16.3	259.2	10.5	209918	204.9	-665.5	-7.8	197.1	-673.2	123.0
80	20.4	4.0	16.2	249.5	10.3	199369	209.9	-670.7	-4.1	205.8	-674.8	122.7
90	19.9	4.0	16.1	239.9	10.2	188823	214.9	-675.4	0.0	214.9	-675.4	122.6
100	19.4	4.0	16.0	230.4	10.0	178609	220.3	-680.6	4.4	224.7	-676.2	122.4
110	19.0	4.0	15.9	222.6	9.9	168969	222.9	-679.3	9.0	232.0	-670.3	123.5
120	18.5	4.0	15.8	213.3	9.7	160283	230.3	-689.4	13.8	244.1	-675.6	122.6
130	18.2	4.0	15.7	207.2	9.6	152510	231.6	-685.6	18.3	249.8	-667.4	124.1
140	17.8	4.0	15.6	199.7	9.5	146148	238.8	-696.5	22.6	261.3	-674.0	122.9
												122.4

R.B.Frost. 31 Jan 1992

HIP PROSTHESIS DESIGN CHECK: STEMS
Filename: STMXEK.WKS

Stems forged in CO-Cr F799 forging alloy;
Sall=470MPa in tension,640Mpa in compression.
Dimensions as per drg SGHP-001/D (PROTOTYPE)

stem size no	1	2	3	4	5	6
load, N	5886	5886	5886	5886	5886	5886
tilt, deg	10	10	10	10	10	10
ball shift, mm	5	5	5	5	5	5
Etot, mm	39.300	39.300	43.130	43.130	50.800	50.800
Ftot, mm	27.504	27.504	30.704	30.704	33.144	33.144
B dia, mm	15	15	17.5	17.5	20	20
At taper bottom:						
J, mm	30	30	35	35	40	40
below ball, mm	58.504	58.504	66.704	66.704	74.144	74.144
BM, Nmm	168010	168010	181830	181830	218685	218685
AA+AB, mm	22.5	22.5	22.5	22.5	22.5	22.5
AC, mm	60	60	60	60	60	60
C dia, mm	17.8	19.8	21.8	23.8	25.8	27.8
D dia, mm	17	19	21	22	24	26
Dout, mm	17.640	19.640	21.533	23.200	24.960	26.960
Din, mm	13.481	13.481	15.719	15.719	17.957	17.957
A, mm^2	101.7	160.2	170.1	228.7	236.0	317.6
I, mm^4	3131.6	5682.2	7556.8	11223.6	13947.8	20828.3
Sb, MPa	473.2	290.4	259.1	187.9	195.7	141.5
Sc, MPa	-57.0	-36.2	-34.1	-25.3	-24.6	-18.3
Smedial, MPa	-530.2	-326.5	-293.1	-213.3	-220.2	-159.8
Slateral, MPa	416.2	254.2	225.0	162.6	171.1	123.3
At socket bottom:						
J+K, mm	40	40	47	47	55	55
below ball, mm	68.504	68.504	78.704	78.704	89.144	89.144
BM, Nmm	157789	157789	169565	169565	203354	203354
AA+AB, mm	22.5	22.5	22.5	22.5	22.5	22.5
AC, mm	60	60	60	60	60	60
C dia, mm	17.8	19.8	21.8	23.8	25.8	27.8
D dia, mm	17	19	21	22	24	26
Dout, mm	17.427	19.427	21.277	22.624	24.240	26.240
I (OD), mm^4	4527.2	6991.4	10060.9	12860.2	16947.3	23271.5
nslot	6	6	6	8	8	8
wslot, mm	4	4	4	4	4	4
dslot, mm	1.5	1.5	1.5	1.5	1.5	1.5
rmeanslot, mm	7.963	8.963	9.889	10.562	11.370	12.370
I (slots), mm^4	1168.8	1473.5	1787.5	2713.8	3139.1	3708.9
AFhex, mm	8	8	10	10	12	12
I (hex), mm^4	246.3	246.3	601.4	601.4	1247.1	1247.1
A, mm^2	91.7	149.6	146.4	180.8	164.1	243.4
Itot, mm^4	3112.0	5271.5	7672.0	9544.9	12561.1	18315.6
Sb, MPa	441.8	290.7	235.1	201.0	196.2	145.7
Sc, MPa	-63.2	-38.8	-39.6	-32.1	-35.3	-23.8
Smedial, MPa	-492.8	-341.7	-286.1	-252.0	-247.2	-196.7
Slateral, MPa	378.6	252.0	195.5	168.9	160.9	121.8
At top of thread Q:						
AC+AD, mm	70	70	70	70	70	70
below ball, mm	98.5	98.5	101.7	101.7	104.1	104.1
F dia, mm	11	12.5	14	14.5	15	15
L, mm	130	135	140	145	150	150
depth, mm	73.00	77.25	84.70	89.45	96.64	96.64
force conc top, N	978.3	868.3	964.1	858.7	1178.8	1178.8

BM, Nmm	109023.5	111059.9	125131.6	127420.6	159562.5	159562.5
E dia, mm	14.5	16	18	19	21	23
OD, mm	11.5	13	15	16	18	20
A, mm^2	103.9	132.7	176.7	201.1	254.5	314.2
I, mm^4	858.5	1402.0	2485.0	3217.0	5153.0	7854.0
Sb, MPa	730.2	514.9	377.7	316.9	278.7	203.2
Sc, MPa	-55.8	-43.7	-32.8	-28.8	-22.8	-18.5
Smedial, MPa	-786.0	-558.6	-410.5	-345.7	-301.5	-221.6
Slateral, MPa	674.4	471.2	344.9	288.0	255.9	184.7

At top of lower shank:

AC+AD+AE, mm	85	85	85	85	85	85
below ball, mm	113.5	113.5	116.7	116.7	119.1	119.1
F dia, mm	11	12.5	14	14.5	15	15
L, mm	130	135	140	145	150	150
depth, mm	73.00	77.25	84.70	89.45	96.64	96.64
force conc top, N	978.3	868.3	964.1	858.7	1178.8	1178.8
BM, Nmm	79017.0	82704.2	95338.3	99209.4	126549.6	126549.6
A, mm^2	95.0	122.7	153.9	165.1	176.7	176.7
I, mm^4	718.7	1198.4	1885.7	2169.9	2485.0	2485.0
Sb, MPa	604.7	431.3	353.9	331.5	381.9	381.9
Sc, MPa	-61.0	-47.2	-37.7	-35.1	-32.8	-32.8
Smedial, MPa	-665.7	-478.6	-391.6	-366.6	-414.7	-414.7
Slateral, MPa	543.7	384.1	316.2	296.4	349.1	349.1
kg medial	97.7	137.5	187.1	209.5	185.2	185.2
kg lateral	83.6	119.7	163.5	190.3	161.5	161.5
kg stem	83.6	119.7	163.5	190.3	161.5	161.5

Richard B. Frost, 5 December, 1994.

HIP PROSTHESIS DESIGN CHECK: NECK BENDS & DISTAL TAPERS
Filename: NEKXEK.WKS
Neck forged in Co-Cr alloy F799
Sall = 690Mpa in compression in bend;
Sall = 470Mpa in tension in distal taper;
Sall = 640MPa in compression in distal taper.

Dimensions as per drg SGHP-002/D (PROTOTYPE)

force = 5886 tilt= 10 Ball shift = 5

BENDS

Neck size no. 1:
Distal taper diameter = 15 Etot = 39.3
Flare-out radius = 2 Ftot = 27.504

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	20.5	3.5	16.0	256.0	9.9	183740	176.4	-622.9	-22.6	153.7	-645.6	128.3
10	20.1	3.5	16.0	249.6	9.8	183888	186.5	-650.0	-23.6	162.9	-673.6	122.9
20	19.7	3.5	16.0	243.2	9.6	182285	195.6	-672.6	-23.8	171.7	-696.4	118.9
30	19.3	3.5	16.0	236.8	9.5	179024	203.5	-690.3	-23.4	180.2	-713.7	116.0
40	18.9	3.5	16.0	230.4	9.4	174248	210.2	-703.1	-22.1	188.1	-725.2	114.2
50	18.4	3.5	15.9	221.0	9.2	168001	220.2	-723.4	-20.4	199.8	-743.8	111.3
60	17.8	3.5	15.7	208.8	9.0	160572	234.6	-753.7	-18.1	216.5	-771.8	107.3
70	17.2	3.5	15.5	196.9	8.8	152402	249.3	-782.7	-15.0	234.3	-797.7	103.8
80	16.6	3.5	15.3	185.1	8.6	143784	264.7	-811.4	-10.9	253.8	-822.3	100.7
90	16.0	3.5	15.1	173.7	8.4	135015	281.2	-841.0	-5.9	275.3	-846.9	97.8
100	15.6	3.5	15.0	166.5	8.3	126384	286.1	-841.3	0.0	286.1	-841.3	98.4
												97.8

Neck size no. 2:
Distal taper diameter = 17.5 Etot = 43.13
Flare-out radius = 2 Ftot = 30.704

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	23.5	4.0	17.0	314.5	11.3	200662	135.1	-474.9	-18.4	116.7	-493.3	167.8
10	23.1	4.0	17.0	307.7	11.2	200940	141.9	-492.9	-19.1	122.8	-512.1	161.7
20	22.7	4.0	17.0	300.9	11.0	199216	147.7	-507.0	-19.3	128.4	-526.3	157.3
30	22.3	4.0	17.0	294.1	10.9	195587	152.4	-516.9	-18.8	133.6	-535.7	154.6
40	21.9	4.0	17.0	287.3	10.8	190207	155.9	-522.5	-17.7	138.2	-540.3	153.3
50	21.5	4.0	16.8	277.2	10.7	183281	160.1	-530.1	-16.3	143.9	-546.4	151.5
60	21.1	4.0	16.6	267.3	10.5	175058	163.3	-533.7	-14.2	149.1	-547.9	151.1
70	20.7	4.0	16.4	257.5	10.4	165820	165.3	-533.6	-11.4	153.9	-545.0	151.9
80	20.3	4.0	16.2	247.9	10.3	155877	166.4	-530.1	-8.1	158.3	-538.2	153.8
90	19.9	4.0	16.0	238.4	10.2	145551	166.7	-523.9	-4.3	162.4	-528.1	156.8
100	19.5	4.0	15.8	229.1	10.0	135170	166.3	-515.6	0.0	166.3	-515.6	160.6

Neck size no. 3: 151.1

Distal taper diameter = 20 Etot = 50.8
Flare-out radius = 2 Ftot = 33.144

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	26.5	4.5	20.2	424.2	12.7	240610	105.5	-369.2	-13.7	91.8	-382.9	216.3
10	25.9	4.5	20.2	412.1	12.5	240651	112.4	-387.2	-14.3	98.1	-401.5	206.2
20	25.3	4.5	20.0	396.0	12.3	238446	120.0	-407.0	-14.6	105.4	-421.7	196.4
30	24.7	4.5	19.7	378.2	12.1	234131	127.9	-426.9	-14.6	113.3	-441.5	187.5
40	24.1	4.5	19.4	360.8	11.9	227901	135.5	-444.7	-14.1	121.3	-458.8	180.5
50	23.5	4.5	19.1	343.8	11.8	220009	142.6	-460.4	-13.1	129.5	-473.5	174.9
60	22.9	4.5	18.8	327.1	11.6	210752	149.4	-474.1	-11.6	137.9	-485.6	170.5
70	22.3	4.5	18.5	310.8	11.4	200461	155.9	-485.9	-9.5	146.4	-495.3	167.2
80	21.7	4.5	18.3	296.5	11.2	189494	161.2	-493.4	-6.8	154.4	-500.2	165.5
90	21.1	4.5	18.1	282.4	11.0	178216	166.4	-499.9	-3.6	162.8	-503.5	164.4
100	19.9	4.5	17.9	257.8	10.6	166992	187.7	-542.1	0.0	187.7	-542.1	152.7

DISTAL TAPERS

SIZE	A	B	C
load, N	5886	5886	5886
d, mm	15	17.5	20
Etot, mm	39.3	43.1302	50.8002
Ftot, mm	27.504	30.7039	33.1439
BM, Nmm	199695	218625	260591
Sb, Mpa	602.69	415.515	331.795
Sc, Mpa	-32.8	-24.099	-18.451
Smedial	-635.5	-439.61	-350.25
Slateral	569.89	391.416	313.344
kg medial	120.85	174.699	219.274
kg lateral	98.967	144.092	179.994
kg taper	98.967	144.092	179.994

R.B.Frost, 2 December, 1994.

HIP PROSTHESIS DESIGN CHECK: STEMS
Filename: STMXEKK2.XLS

Stems forged in CO-Cr F799 forging alloy;
Sall=470MPa in tension, 640Mpa in compression.
Dimensions as per drg SGHP-001/F

stem size no	1	2	3	4	5	6
load, N	5886	5886	5886	5886	5886	5886
tilt, deg	10	10	10	10	10	10
ball shift, mm	7	7	7	7	7	7
Etot, mm	40.832	40.832	44.662	44.662	52.332	52.332
Ftot, mm	28.790	28.790	31.990	31.990	34.430	34.430
B dia, mm	15	15	17.5	17.5	20	20
At taper bottom:						
J, mm	30	30	35	35	40	40
below ball, mm	59.790	59.790	67.990	67.990	75.430	75.430
BM, Nmm	175577	175577	189397	189397	226252	226252
AA+AB, mm	22.5	22.5	22.5	22.5	22.5	22.5
AC, mm	60	60	60	60	60	60
C dia, mm	17.8	19.8	21.8	23.8	25.8	27.8
D dia, mm	17	19	21	22	24	26
Dout, mm	17.640	19.640	21.533	23.200	24.960	26.960
Din, mm	13.481	13.481	15.719	15.719	17.957	17.957
A, mm^2	101.7	160.2	170.1	228.7	236.0	317.6
I, mm^4	3131.6	5682.2	7556.8	11223.6	13947.8	20828.3
Sb, MPa	494.5	303.4	269.8	195.7	202.4	146.4
Sc, MPa	-57.0	-36.2	-34.1	-25.3	-24.6	-18.3
Smedial, MPa	-551.5	-339.6	-303.9	-221.1	-227.0	-164.7
Slateral, MPa	437.5	267.3	235.8	170.4	177.9	128.2
At socket bottom:						
J+K, mm	40	40	47	47	55	55
below ball, mm	69.790	69.790	79.990	79.990	90.430	90.430
BM, Nmm	165356	165356	177132	177132	210921	210921
AA+AB, mm	22.5	22.5	22.5	22.5	22.5	22.5
AC, mm	60	60	60	60	60	60
C dia, mm	17.8	19.8	21.8	23.8	25.8	27.8
D dia, mm	17	19	21	22	24	26
Dout, mm	17.427	19.427	21.277	22.624	24.240	26.240
I (OD), mm^4	4527.2	6991.4	10060.9	12860.2	16947.3	23271.5
nslot	6	6	6	8	8	8
wslot, mm	4	4	4	4	4	4
dslot, mm	1.5	1.5	1.5	1.5	1.5	1.5
rmeanslot, mm	7.963	8.963	9.889	10.562	11.370	12.370
I (slots), mm^4	1168.8	1473.5	1787.5	2713.8	3139.1	3708.9
AFhex, mm	8	8	10	10	12	12
I (hex), mm^4	246.3	246.3	601.4	601.4	1247.1	1247.1
A, mm^2	91.7	149.6	146.4	180.8	164.1	243.4
Itot, mm^4	3112.0	5271.5	7672.0	9544.9	12561.1	18315.6
Sb, MPa	463.0	304.7	245.6	209.9	203.5	151.1
Sc, MPa	-63.2	-38.8	-39.6	-32.1	-35.3	-23.8
Smedial, MPa	-514.0	-355.7	-296.6	-260.9	-254.5	-202.1
Slateral, MPa	399.7	265.9	206.0	177.9	168.2	127.3
At top of thread Q:						
AC+AD, mm	70	70	70	70	70	70
below ball, mm	99.8	99.8	103.0	103.0	105.4	105.4
F dia, mm	10	11	12.5	13	15	15
L, mm	130	135	140	145	150	150
depth, mm	74.79	79.29	86.74	91.49	97.93	97.93
force conc top, N	1049.3	931.8	1019.9	913.9	1240.6	1240.6

BM, Nmm	113927.9	116254.4	130176.8	132614.1	164042.6	164042.6
E dia, mm	14.5	16	18	19	21	23
OD, mm	11.5	13	15	16	18	20
A, mm^2	103.9	132.7	176.7	201.1	254.5	314.2
I, mm^4	858.5	1402.0	2485.0	3217.0	5153.0	7854.0
Sb, MPa	763.0	539.0	392.9	329.8	286.5	208.9
Sc, MPa	-55.8	-43.7	-32.8	-28.8	-22.8	-18.5
Smedial, MPa	-818.8	-582.7	-425.7	-358.6	-309.3	-227.3
Slateral, MPa	707.2	495.3	360.1	301.0	263.7	190.4

At top of lower shank:

AC+AD+AE, mm	85	85	85	85	85	85
below ball, mm	114.8	114.8	118.0	118.0	120.4	120.4
F dia, mm	10	11	12.5	13	15	15
L, mm	130	135	140	145	150	150
depth, mm	74.79	79.29	86.74	91.49	97.93	97.93
force conc top, N	1049.3	931.8	1019.9	913.9	1240.6	1240.6
BM, Nmm	82856.7	86946.6	99547.0	103574.5	130102.8	130102.8
A, mm^2	78.5	95.0	122.7	132.7	176.7	176.7
I, mm^4	490.9	718.7	1198.4	1402.0	2485.0	2485.0
Sb, MPa	844.0	665.4	519.2	480.2	392.7	392.7
Sc, MPa	-73.8	-61.0	-47.2	-43.7	-32.8	-32.8
Smedial, MPa	-917.8	-726.4	-566.4	-523.9	-425.5	-425.5
Slateral, MPa	770.2	604.4	471.9	436.5	359.9	359.9

kg medial	83.7	105.7	135.6	146.6	180.5	180.5
kg lateral	73.2	93.3	119.5	129.2	156.7	156.7
kg stem	73.2	93.3	119.5	129.2	156.7	156.7

Richard B. Frost, 16 December, 1998.

HIP PROSTHESIS DESIGN CHECK: NECK BENDS & DISTAL TAPERS
Filename: NEKXEKK2.XLS
Neck forged in Co-Cr alloy F799
Sall = 690Mpa in compression in bend;
Sall =470Mpa in tension in distal taper;
Sall = 640MPa in compression in distal taper.

Dimensions as per drg SGHP-002/F

force = 5886 tilt= 10 Ball shift = 7

BENDS

Neck size no. 1:
Distal taper diameter = 15 Etot = 40.832
Flare-out radius = 2 Ftot = 28.79

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	20.5	3.5	16.0	256.0	9.9	191307	183.6	-648.6	-22.6	161.0	-671.2	123.4
10	20.1	3.5	16.0	249.6	9.8	191455	194.2	-676.7	-23.6	170.6	-700.3	118.2
20	19.7	3.5	16.0	243.2	9.6	189852	203.7	-700.5	-23.8	179.9	-724.3	114.3
30	19.3	3.5	16.0	236.8	9.5	186591	212.1	-719.5	-23.4	188.8	-742.8	111.5
40	18.9	3.5	16.0	230.4	9.4	181815	219.4	-733.6	-22.1	197.2	-755.8	109.6
50	18.4	3.5	15.9	221.0	9.2	175567	230.2	-756.0	-20.4	209.8	-776.4	106.6
60	17.8	3.5	15.7	208.8	9.0	168139	245.7	-789.2	-18.1	227.5	-807.3	102.6
70	17.2	3.5	15.5	196.9	8.8	159969	261.7	-821.6	-15.0	246.7	-836.5	99.0
80	16.6	3.5	15.3	185.1	8.6	151351	278.6	-854.1	-10.9	267.7	-865.0	95.7
90	16.0	3.5	15.1	173.7	8.4	142581	296.9	-888.2	-5.9	291.0	-894.1	92.6
100	15.6	3.5	15.0	166.5	8.3	133951	303.2	-891.7	0.0	303.2	-891.7	92.9

92.6

Neck size no. 2:
Distal taper diameter = 17.5 Etot = 44.662
Flare-out radius = 2 Ftot = 31.99

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	23.5	4.0	17.0	314.5	11.3	208229	140.2	-492.8	-18.4	121.8	-511.2	162.0
10	23.1	4.0	17.0	307.7	11.2	208507	147.2	-511.5	-19.1	128.1	-530.6	156.0
20	22.7	4.0	17.0	300.9	11.0	206783	153.3	-526.3	-19.3	134.0	-545.5	151.8
30	22.3	4.0	17.0	294.1	10.9	203154	158.3	-536.9	-18.8	139.5	-555.7	149.0
40	21.9	4.0	17.0	287.3	10.8	197774	162.1	-543.3	-17.7	144.4	-561.0	147.6
50	21.5	4.0	16.8	277.2	10.7	190848	166.7	-552.0	-16.3	150.5	-568.3	145.7
60	21.1	4.0	16.6	267.3	10.5	182625	170.3	-556.8	-14.2	156.2	-571.0	145.0
70	20.7	4.0	16.4	257.5	10.4	173387	172.9	-557.9	-11.4	161.4	-569.4	145.4
80	20.3	4.0	16.2	247.9	10.3	163444	174.5	-555.8	-8.1	166.4	-564.0	146.8
90	19.9	4.0	16.0	238.4	10.2	153118	175.3	-551.1	-4.3	171.0	-555.4	149.1
100	19.5	4.0	15.8	229.1	10.0	142737	175.6	-544.5	0.0	175.6	-544.5	152.1

145.0

Neck size no. 3:
Distal taper diameter = 20 Etot = 52.332
Flare-out radius = 2 Ftot = 34.43

PHI	Po	Pi	w	A	RNS	M	So	Si	Sc	Sto	Sti	kg
0	26.5	4.5	20.2	424.2	12.7	248177	108.8	-380.8	-13.7	95.2	-394.5	209.9
10	25.9	4.5	20.2	412.1	12.5	248218	115.9	-399.4	-14.3	101.6	-413.7	200.1
20	25.3	4.5	20.0	396.0	12.3	246013	123.8	-420.0	-14.6	109.2	-434.6	190.5
30	24.7	4.5	19.7	378.2	12.1	241698	132.0	-440.7	-14.6	117.4	-455.3	181.9
40	24.1	4.5	19.4	360.8	11.9	235468	139.9	-459.5	-14.1	125.8	-473.6	174.8
50	23.5	4.5	19.1	343.8	11.8	227576	147.5	-476.3	-13.1	134.4	-489.4	169.2
60	22.9	4.5	18.8	327.1	11.6	218318	154.8	-491.1	-11.6	143.2	-502.7	164.7
70	22.3	4.5	18.5	310.8	11.4	208028	161.8	-504.2	-9.5	152.3	-513.7	161.2
80	21.7	4.5	18.3	296.5	11.2	197061	167.7	-513.1	-6.8	160.9	-519.9	159.3
90	21.1	4.5	18.1	282.4	11.0	185783	173.5	-521.1	-3.6	169.9	-524.7	157.8

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100	19.9	4.5	17.9	257.8	10.6	174559	196.2	-566.6	0.0	196.2	-566.6	146.1
												146.1

DISTAL TAPERS

SIZE	A	B	C
load, N	5886	5886	5886
d, mm	15	17.5	20
Etot, mm	40.832	44.6623	52.3323
Ftot, mm	28.79	31.9895	34.4295
BM, Nmm	207262	226192	268158
Sb, Mpa	625.53	429.896	341.43
Sc, Mpa	-32.8	-24.099	-18.451
Smedial	-658.3	-454	-359.88
Slateral	592.73	405.797	322.979
kg medial	116.66	169.165	213.404
kg lateral	95.154	138.986	174.625
kg taper	95.154	138.986	174.625

R.B.Frost, 16 December, 1998.

SUMMARY OF kg RATINGS FOR MARGRON HIP PROSTHESIS SYSTEM
Filename: SUMMARY.XLS

All ratings are for the use of a +7 ball

STEMS

SIZE	1	2	3	4	5	6
kg RATING	73.2	93.3	119.5	129.2	156.7	156.7

ratings are in tension at the lateral side at the top of the distal shank

NECKS

SIZE	A	B	C
BENDS	92.6	145	146.1
DISTAL TAPERS	95.1	139	174.6
OVER ALL	92.6	139	146.1

ratings are at the inside of the bend, taper ratings at the lateral side

ASSEMBLIES

STEM	1	2	3	4	5	6
NECK	A	A	B	B	C	C
RATING kg	73.2	92.6	119.5	129.2	146.1	146.1
CRITICAL	STEM	NECK	STEM	STEM	NECK	NECK

Richard B. Frost, 16 December , 1998

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Report prepared on behalf of
Unisearch Limited

on

SLIP TORQUE TESTING OF THE DISTAL TAPER JOINT OF THE ST GEORGE FEMORAL HIP PROSTHESIS

by

Associate Professor Richard B Frost
The School of Mechanical & Manufacturing Engineering
The University of New South Wales

for

Portland Square Pty Ltd

26 September, 1997

19956-01

COMMERCIAL-IN-CONFIDENCE

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1.0 INTRODUCTION

As part of the design and development work associated with the St George Femoral Hip Prosthesis, it was necessary to evaluate the torque at which the distal taper joint in the prosthesis assembly would slip after it had been driven into engagement by one or more hammer blows which were representative of the driving into engagement which it would receive during its surgical installation.

In June and July 1993 tests were carried out with a view to evaluating the level of torque which the distal taper joint in this prosthesis could sustain without slipping and also what the characteristic behaviour of this taper joint would be after some slip had initiated.

2.0 METHODOLOGY OF THE TESTING

The first stage of the testing consisted of determining the impact energy which was available to drive the conical tapered joint into its frictional engagement. This was accomplished by first driving several nails into a piece of pine softwood, which had been carefully selected for its uniformity of grain structure, so that these nails projected above the surface of the piece of wood by a measured amount. Each nail was then given one strike with either a lighter hammer or a heavier hammer and the remaining projection of the nail above the timber surface was re-measured. The drive-in distance of the nail into the timber, under the action of a hammer strike which was representative of what would occur during the surgical installation of the prosthesis, was thereby determined.

Other identical nails were then driven into the same piece of timber by means of force which was applied and measured by means of a universal testing machine.

By combining the results of these two steps, an energy quantum was determined which was representative of a typical hammer strike which would be expected during the surgical installation of the prosthesis.

A drop-weight impacter was then designed and built which would provide an impact energy equal to that which had been derived from the nail tests using the small hammer. This was conservatively done, using the data obtained from the nail which drove in most easily on the universal testing machine. Details of the nail drive-in tests and of the design of the impacter are given in the Appendix.

Two series of tests were then undertaken, each of which used male and female taper pairs of the same dimensions as the B size distal taper as used in the St George Hip Prosthesis size series. The taper components used in these tests were manufactured in the F799 chrome cobalt material from which the stem and neck components of the prosthesis would be made. The test samples were made as plain plugs, however, each of which had a pair of flats at its end remote from the end which contained the taper feature. A pair of loading arms was made to fit to the flats at the ends of the taper plug components. Each arm had at its end remote from the test piece a steel roller which was in contact with either the top or the bottom platen of a testing machine.

The taper tests were conducted by firstly cleaning the taper test plug components with spirits on clean cotton wool, assembling the taper pair loosely together with the flats at their ends in an appropriate relative angular relationship, driving the taper components together using the drop-weight impacter, fitting the loading arms to the ends of the assembled taper joint, mounting the assembly in a test machine, measuring the offset between the line joining the points of contact of the rollers at the ends of the arms and the axis of the taper joint, applying load progressively to the assembly via the testing machine, and noting the load at which slip started to occur, which was indicated by the shape of the resulting trace obtained from the testing machine.

The first series of taper testing involved the use of three male taper plugs of differing surface finish and three female taper plugs, also of differing surface finish, so that there was a smooth, a medium and a rough male plug and a smooth, a medium and a rough female plug. These were paired smooth/smooth, medium/medium, rough/rough, smooth/rough and rough/smooth. Each pairing received one impact from the drop-weight impacter to drive it into its frictional engagement prior to the test. Results of these tests are given in Table 2 in the Appendix. Chart recordings from these tests are given in Figures 1 to 5.

Another series of taper tests was conducted with both the male and female taper plugs having a surface finish corresponding to the smooth finish of the previous series of tests. This series of tests was intended to study the variability which may arise in slip torque under controlled test conditions. For this series of tests, the drop height of the drop-weight impacter was reduced somewhat. A series of five tests were conducted using a single impact of the impacter, and a further

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series of three tests were conducted using four impacts from the impacter. The results of these tests are given in Table 3 in the Appendix. Chart recordings from these tests are given in Figures 6 to 13.

3.0 DISCUSSION OF RESULTS

It is seen from Table 2 that, as would be expected, a significant benefit in terms of an increase in the slip torque accompanies a finer finish on the mating surfaces of the taper components. This increase amounts to an 86% increase in measured slip torque, ie from 172Nm to 320Nm when two smooth taper components are mated together as against the situation where two rough taper components are mated together. A rough/smooth or a smooth/rough mating of taper components provides slip torque values which do not approach that of the smooth/smooth mating.

Table 3 shows two expressions of slip load, ie the directly measured load from the testing machine in column 3 and, in column 5, the "weight" expressed in kg which would be required to cause slip of the taper if it were acting at an offset of 43mm, which is the offset from the taper axis of the centre of the zero ball head on the B size neck component of the St George Hip Prosthesis System. For the tests carried out on taper joints which were assembled with only one impact from the drop-weight impacter, the values of this force vary between 259kg and 408kg, with a mean of 348.5kg and a standard deviation of 54.5kg, which represents 15.6% of the mean value. The value of this weight load corresponding to 3 standard deviations below the mean is calculated to be 185kg. For the tests carried out on taper joints which were assembled with four impacts from the impacter, the values of the slip load at 43mm offset vary

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between 590kg and 738kg, with a mean of 647.8kg and a standard deviation of 64.3kg, which is 9.9% of the mean value. The value of this weight load at 3 standard deviations below the mean is calculated to be 455kg.

It was noticed throughout the tests, and borne out by the shapes of the curves which were produced by the testing machine, that once slip initiated, the actual slip load and hence the slip torque rose somewhat, even if only slightly, and that the taper joint did not immediately disengage but, rather, remained resistive to torque throughout several degrees of relative rotation of the joint. This is quite advantageous, as it gives the joint a significant energy absorbing capability in relation to torsional slip. While this varied somewhat, and an attempt was not made to measure this accurately at the time of the test, as the aim in practice would be to avoid slip, a value of approximately 8 joules of slip energy has been achieved by the joint which is reported in the top line of Table 3 and shown in Figure 6.

4.0 CONCLUSIONS

The taper joints associated with the St George Hip Prosthesis System appear to have a slip torque level which is higher than that to which they might be expected to be subjected in service provided they are assembled in a clean state and driven into engagement with sufficient impact energy.

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Richard B Frost, BE, FIEAust., CPEng.(Mech. & Biomed.) FRSA.

APPENDIX

TABLE 1

NAIL HAMMER-IN TESTS
USING SMALL HAMMER (610g HEAD)

NAIL NO	**1**	**2**	**3**
INITIAL HEIGHT (mm)	65.0	65.0	65.0
FINAL HEIGHT (mm)	54.0	55.0	54.5
DISPLACEMENT (mm)	11.0	10.0	10.5
MEAN DISPLACEMENT (mm)		10.5	
STANDARD DEVIATION (mm)		0.5	
RUN 2			
NAIL NO	**1**	**2**	**3**
INITIAL HEIGHT (mm)	40.0	40.0	40.0
FINAL HEIGHT (mm)	28.0	27.0	27.5
DISPLACEMENT (mm)	12.0	13.0	13.5
MEAN DISPLACEMENT (mm)		12.5	
STANDARD DEVIATION (mm)		0.5	

NAIL DRIVE-IN TESTS
ON UNIVERSAL TESTING MACHINE

NAIL 1 500-1000N
NAIL 2 1350-1700N
NAIL 3 1750-2000N

HAMMER STRIKE ENERGY TAKEN TO BE 10.5mm AT 770N, ie 8.1J

DROP-WEIGHT IMPACTER
WEIGHT: STEEL BAR 38mm DIA 435mm LONG
MASS: 3.85kg
DROP HEIGHT: 214mm

TABLE 2
ROUGHNESS EFFECT ON SLIP TORQUE

TEST NO	MALE PLUG uRA	FEMALE PLUG uRa	OFFSET DISTANCE mm	SLIP LOAD N	SLIP TORQUE Nm
1	0.5	0.5	183	1748	320
2	1.0	1.0	183	1140	208
3	1.5	1.5	183	940	172
4	0.5	1.5	183	820	150
5	1.5	0.5	183	1135	207

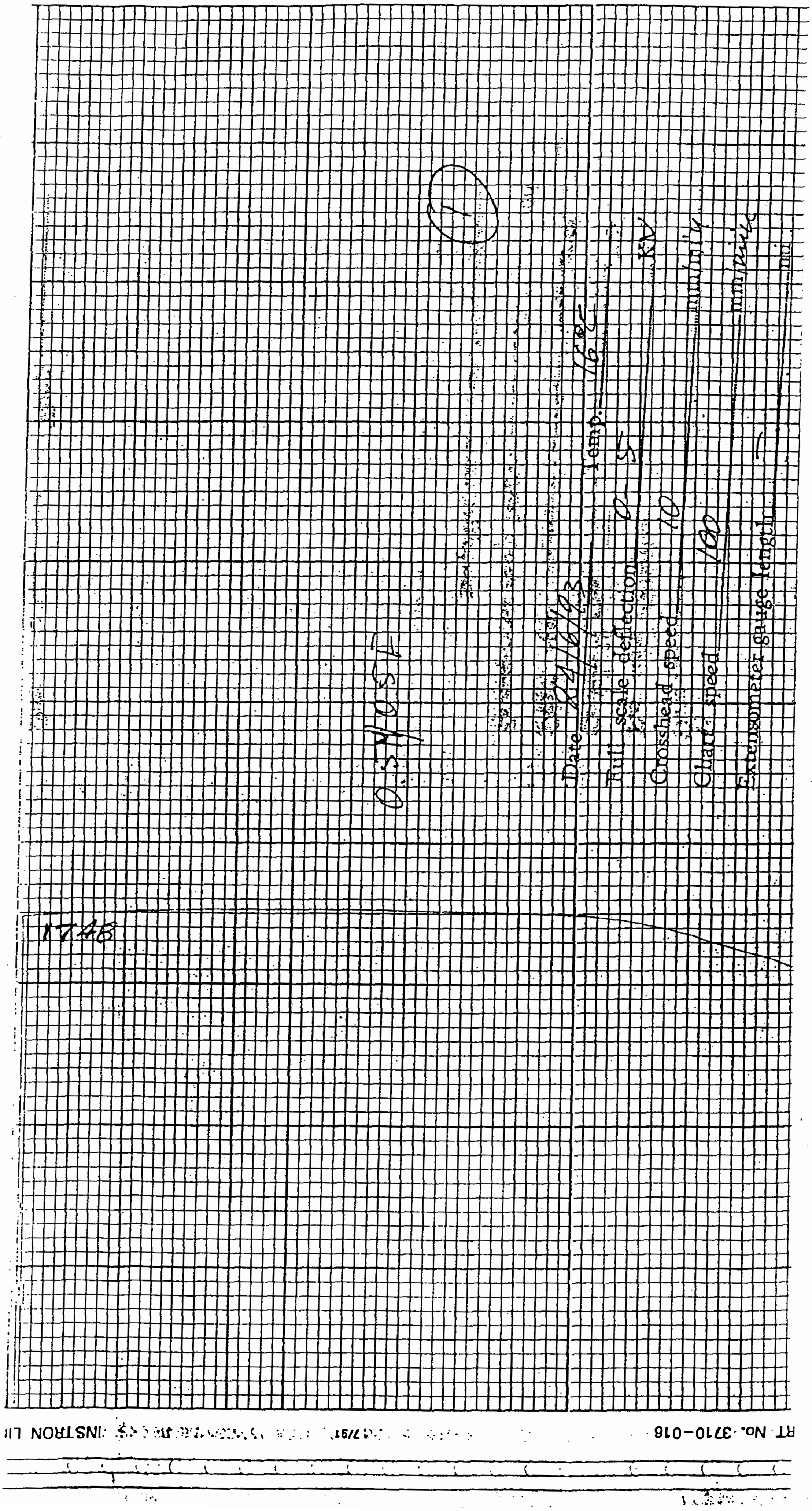
TABLE 3
VARIABILITY WITH CONSTANT IMPACT ENERGY AND ROUGHNESS

MALE AND FEMALE TAPER FINISHES BOTH 0.5uRa
IMPACTER DROP HEIGHT 140mm
IMPACT ENERGY 5.3J
OFFSET 183mm

TEST NO	NO OF IMPACTS	SLIP LOAD N	SLIP TORQUE Nm	SLIP WT AT 43mm OFFSET kg	MEAN kg	STD DEV kg
1	1	780	143	338		
2	1	597	109	259		
3	1	930	170	403	348.5	54.5
4	1	940	172	408		
5	1	770	141	334		
6	4	1420	260	616		
7	4	1700	311	738	647.8	64.3
8	4	1360	249	590		

FIGURES

FIG 1



Date 24/6/93
Temp. 16°C
Full scale deflection 0.5 KN
Crosshead speed 10 mm/min
Chart speed 100 mm/min
Extensometer gauge length — mm
1745
RT No. 3710-018
INSTRON LI

43

FIG 2

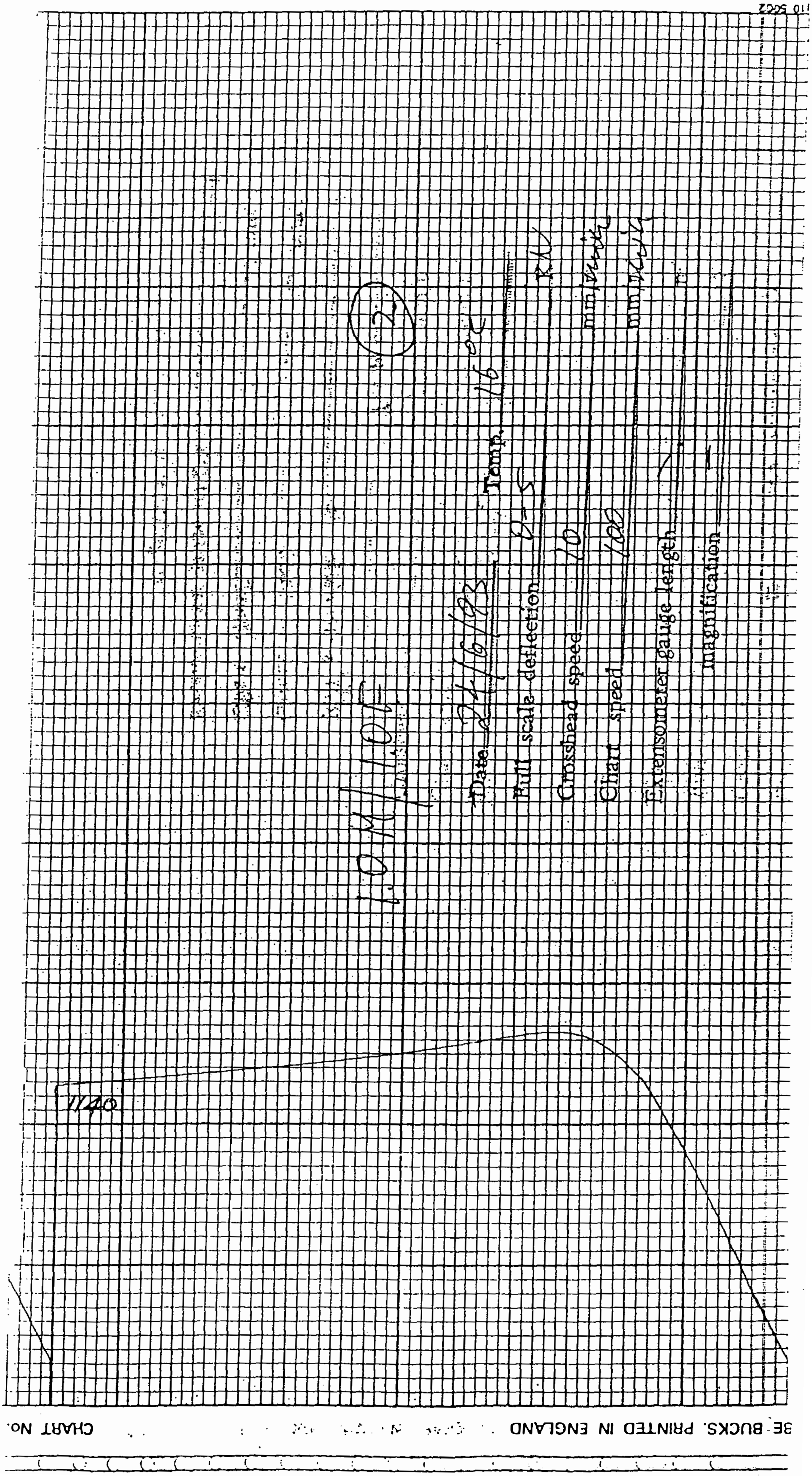
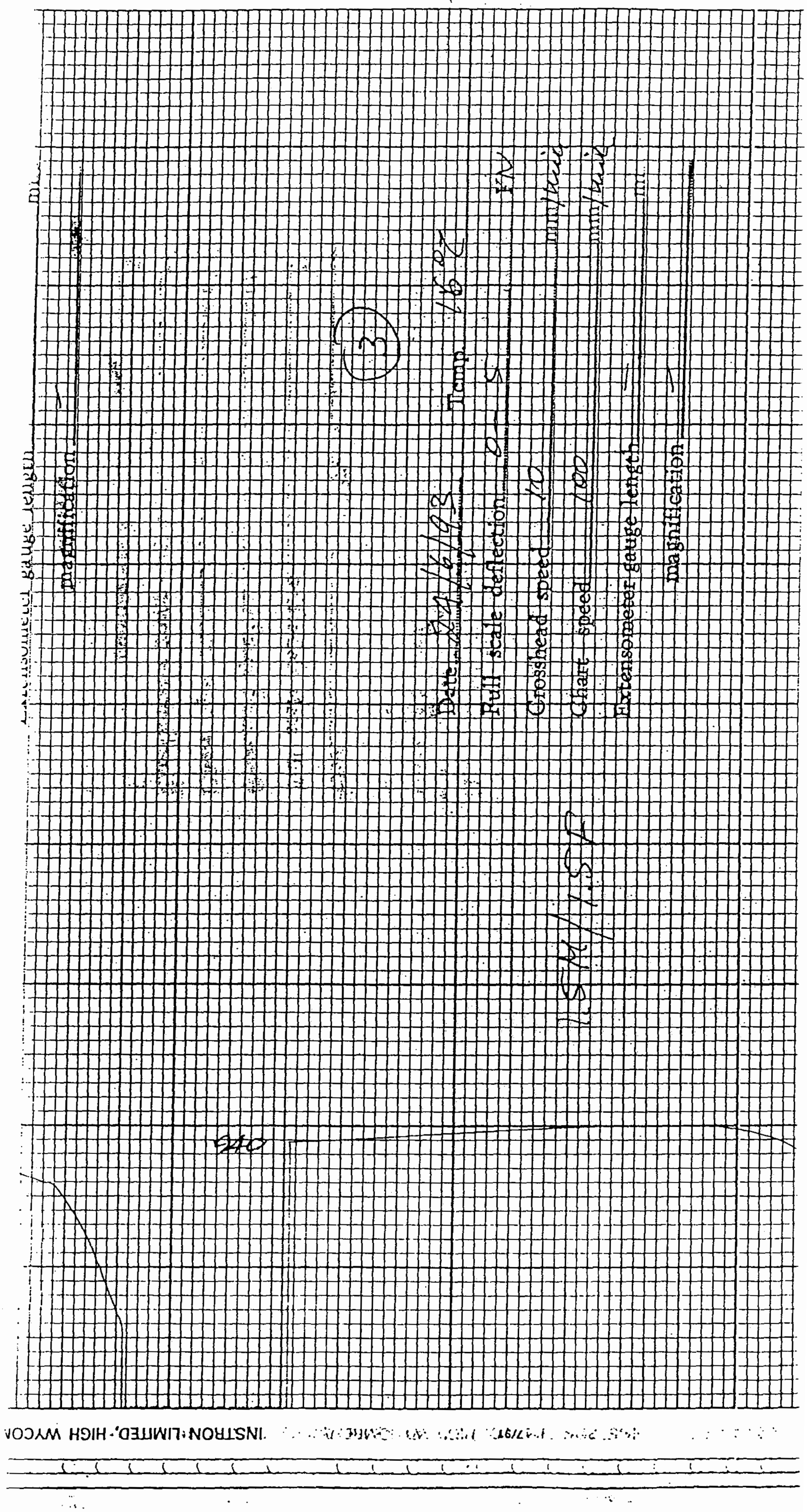

Date
Temp.
Full scale deflection
Crosshead speed
Chart speed
Extensometer gauge length
magnification
1140
CHART NO.
BUCKS. PRINTED IN ENGLAND

FIG 3



Extensometer gauge length
magnification
3
Date 22/6/93
Temp. 16°C
Full scale deflection 0 - 5 kN
Crosshead speed 10 mm/min
Chart speed 100 mm/min
Extensometer gauge length mm
magnification
240
INSTRON LIMITED, HIGH WYCOM

FIG 4

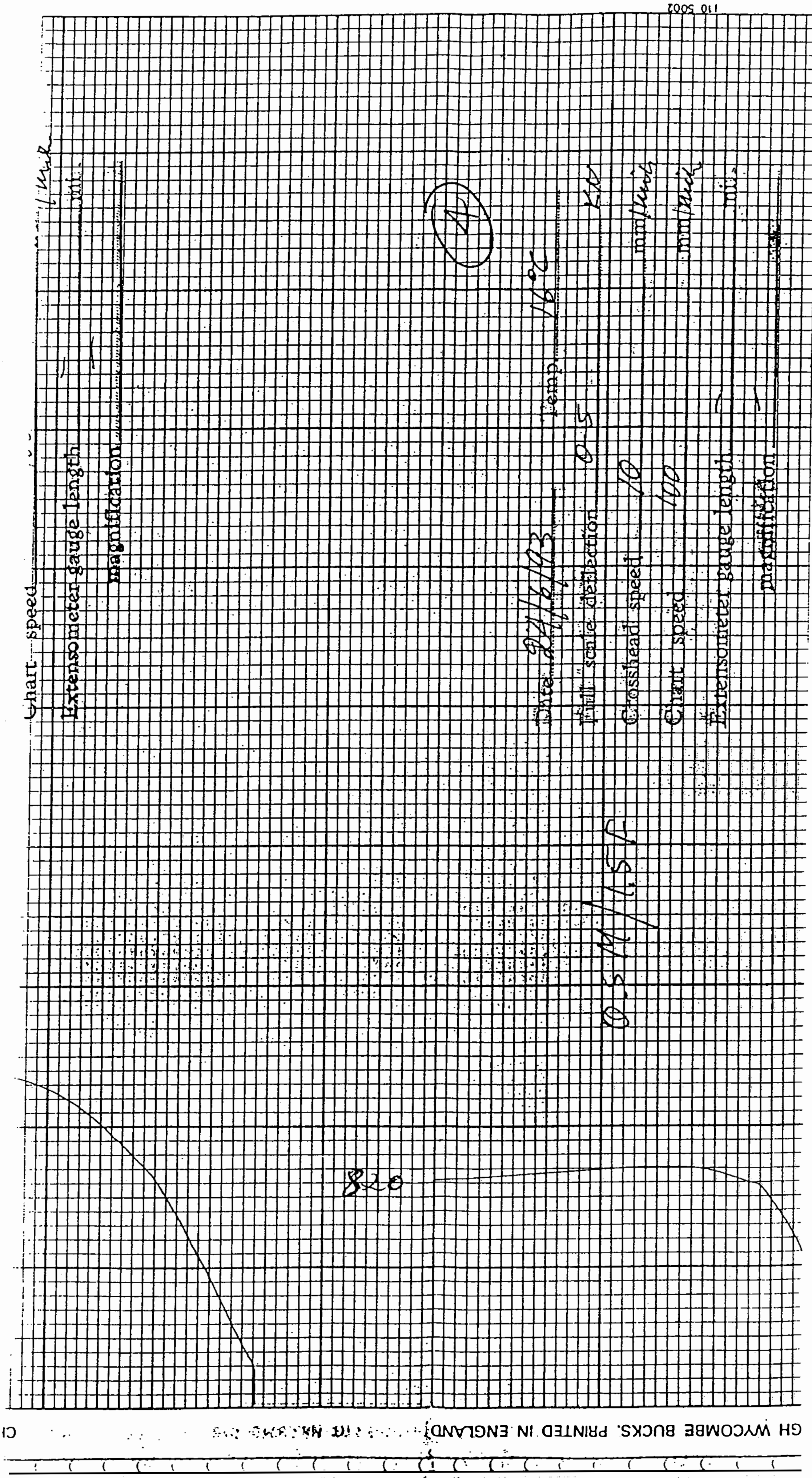


Chart speed
Extensometer gauge length
mm
magnification
A
Date 24/6/93
Temp 16°C
Full scale deflection 0.5 kN
Crosshead speed 10 mm/min
Chart speed 100 mm/min
Extensometer gauge length
mm
magnification
0.5M/1ST
820
GH WYCOMBE BUCKS. PRINTED IN ENGLAND

FIG 5

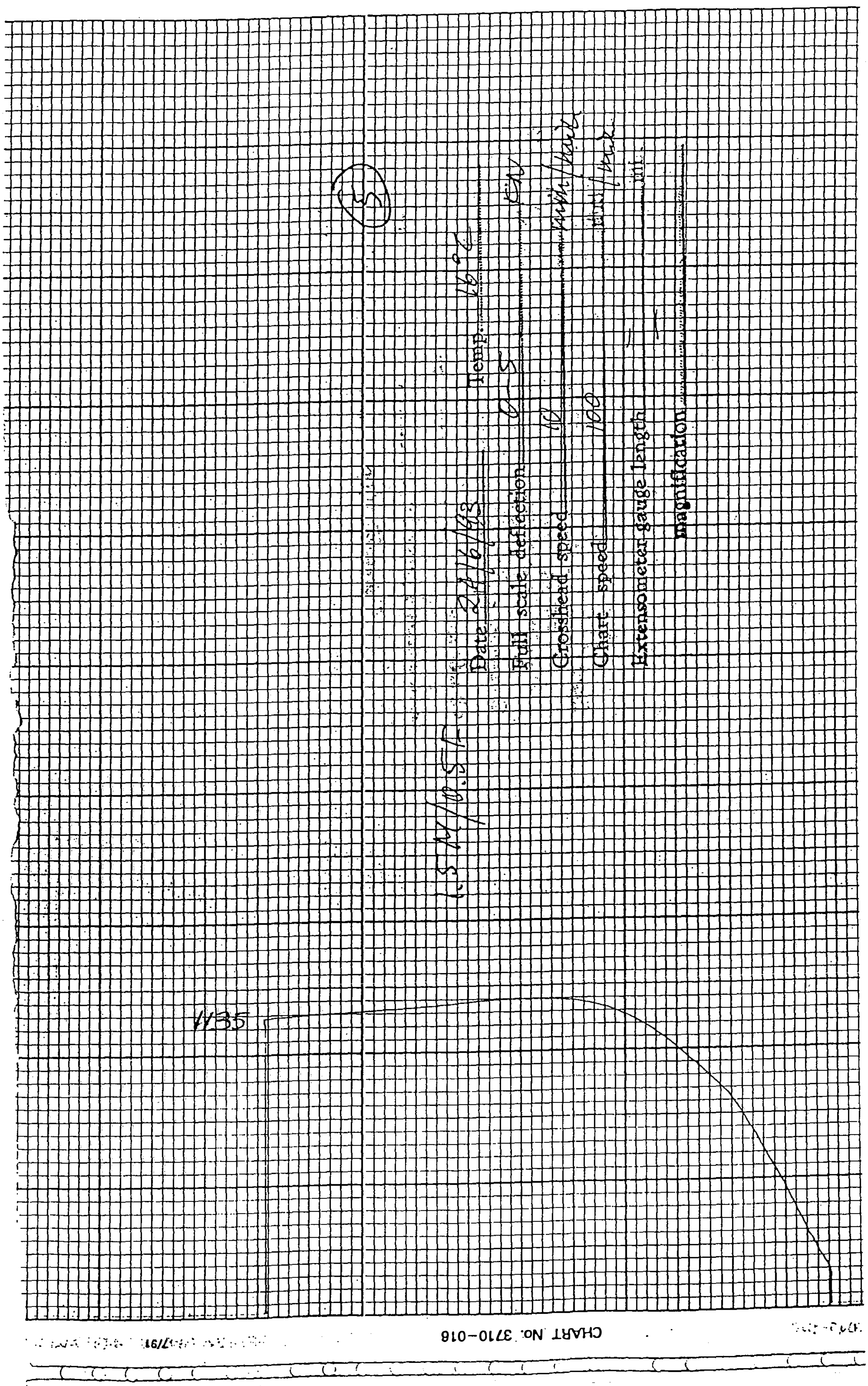

5
LSM/0.5F
Date 22/6/93 Temp. 16°C
Full scale deflection 0.5 kN
Crosshead speed 10 mm/min
Chart speed 100 mm/min
Extensometer gauge length —
Magnification —
W35
CHART No. 3710-018

FIG 6

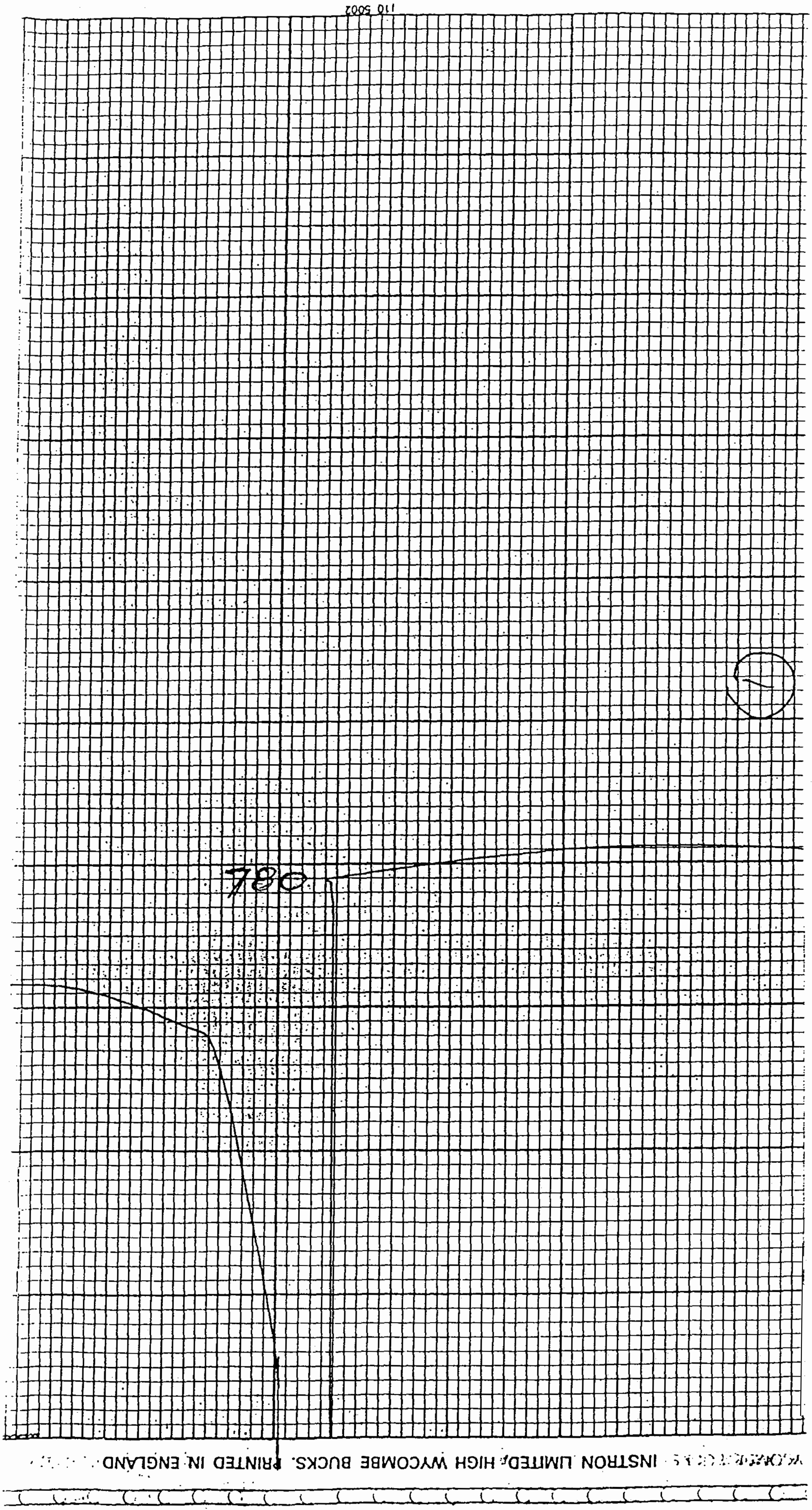

110 5002
780
INSTRON LIMITED, HIGH WYCOMBE BUCKS. PRINTED IN ENGLAND

FIG 7

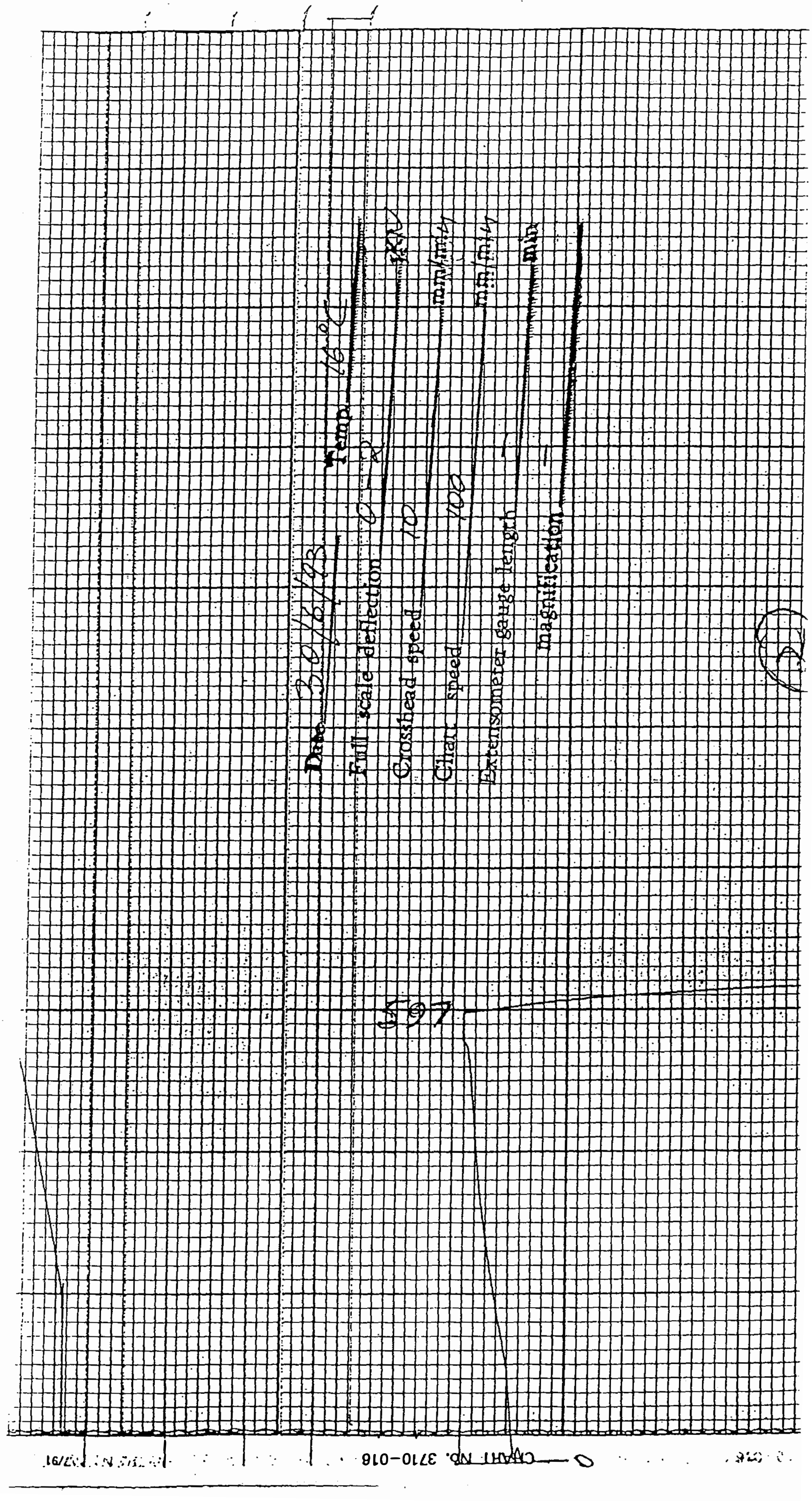

Date 30/6/93
Temp 16°C
Full scale deflection 0-2 KN
Crosshead speed 10 mm/min
Chart speed 100 mm/min
Extensometer gauge length
magnification
507
CHART NO. 3710-018

FIG 8

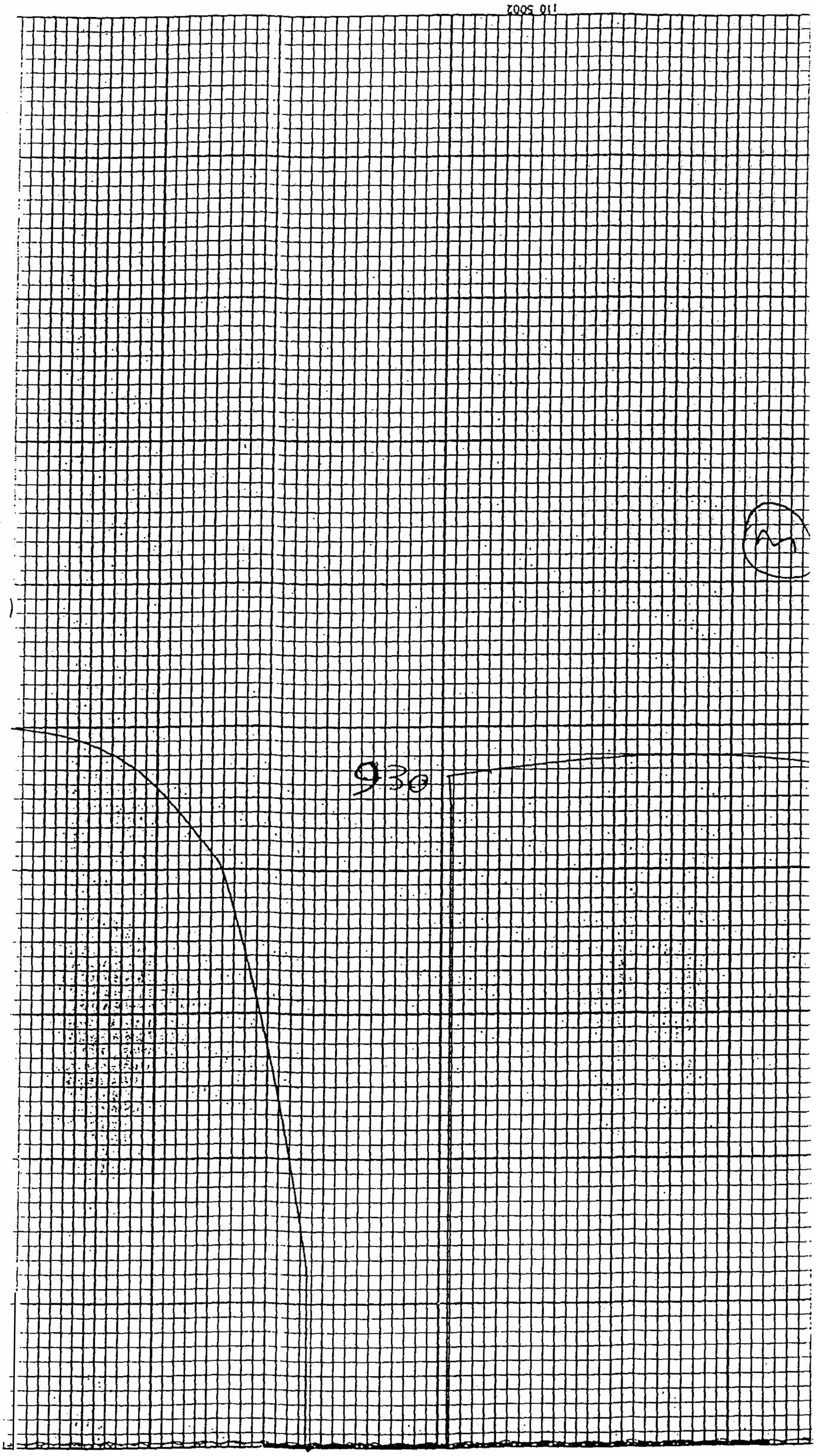


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FIG 9

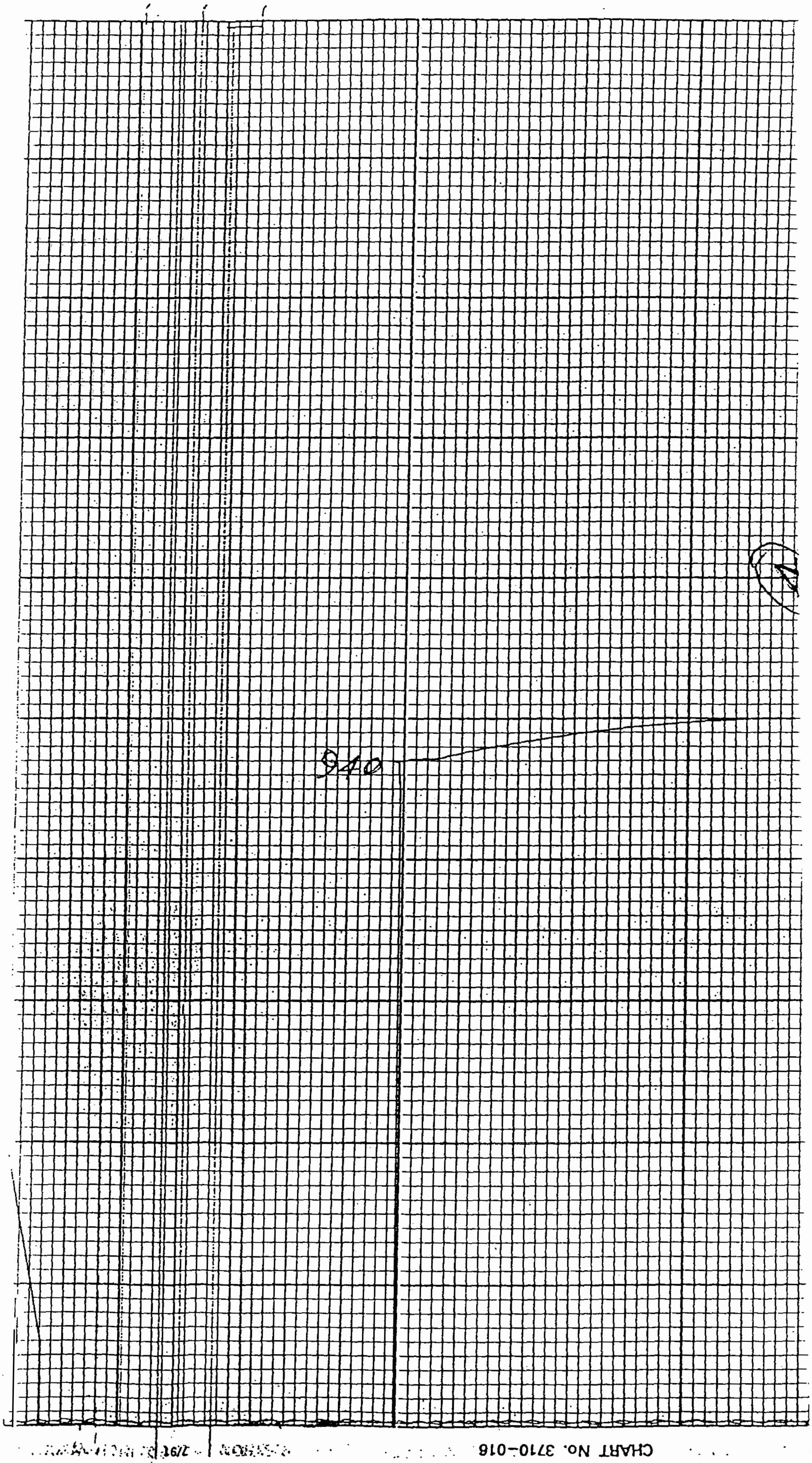


FIG 10

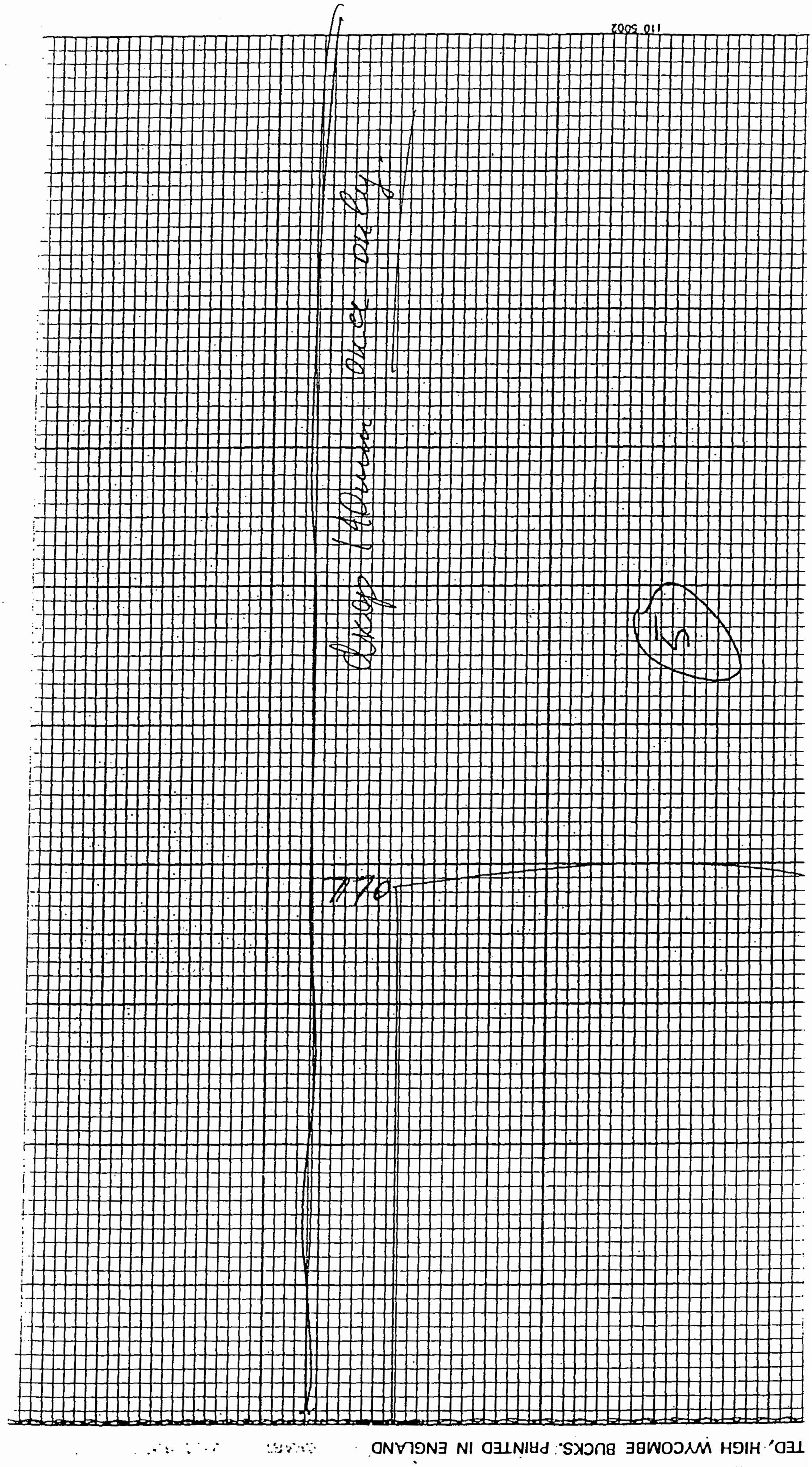

110 5002
Drop 140mm one only
770
5
TED, HIGH WYCOMBE BUCKS. PRINTED IN ENGLAND

FIG 11

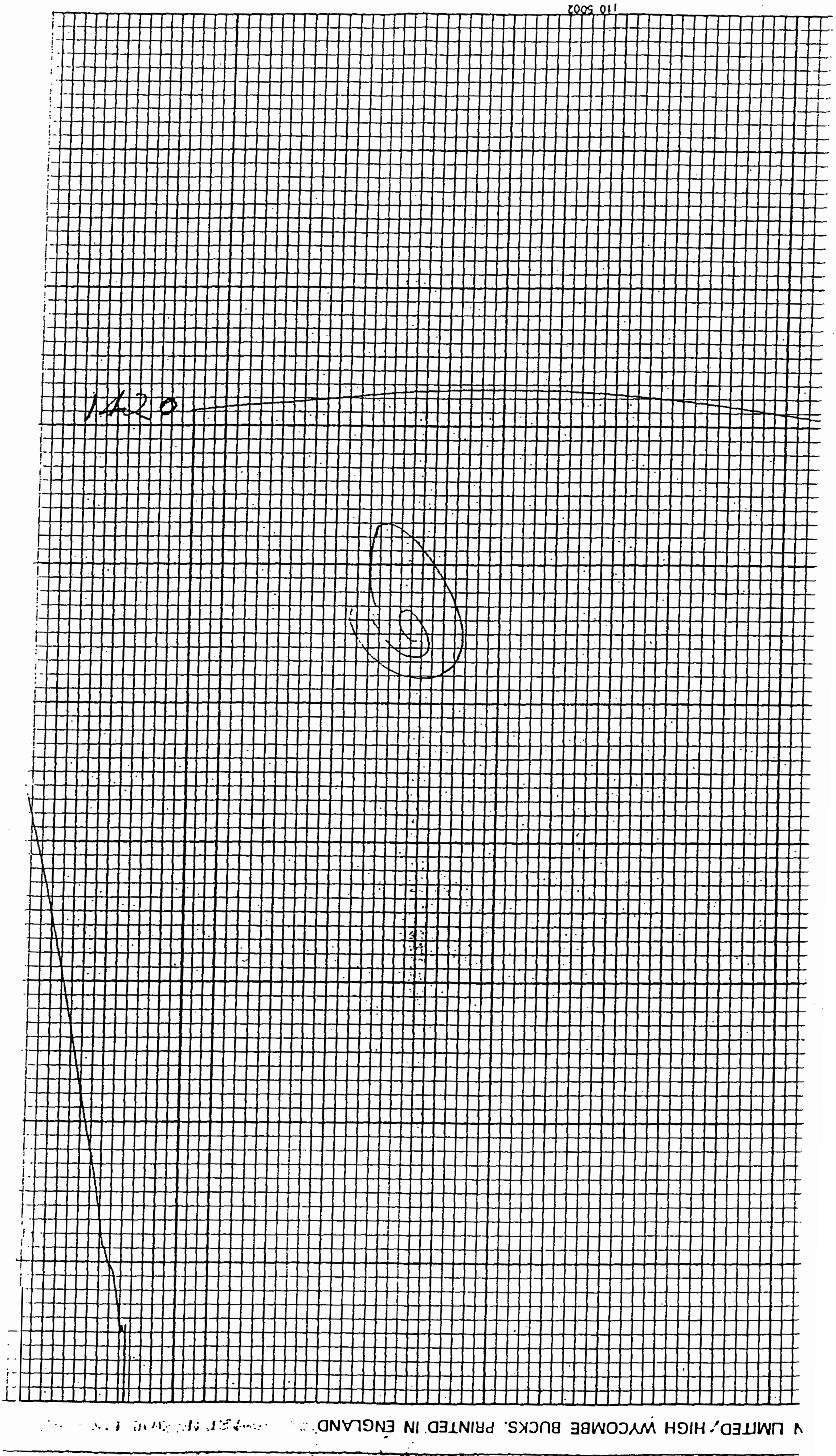


FIG 12

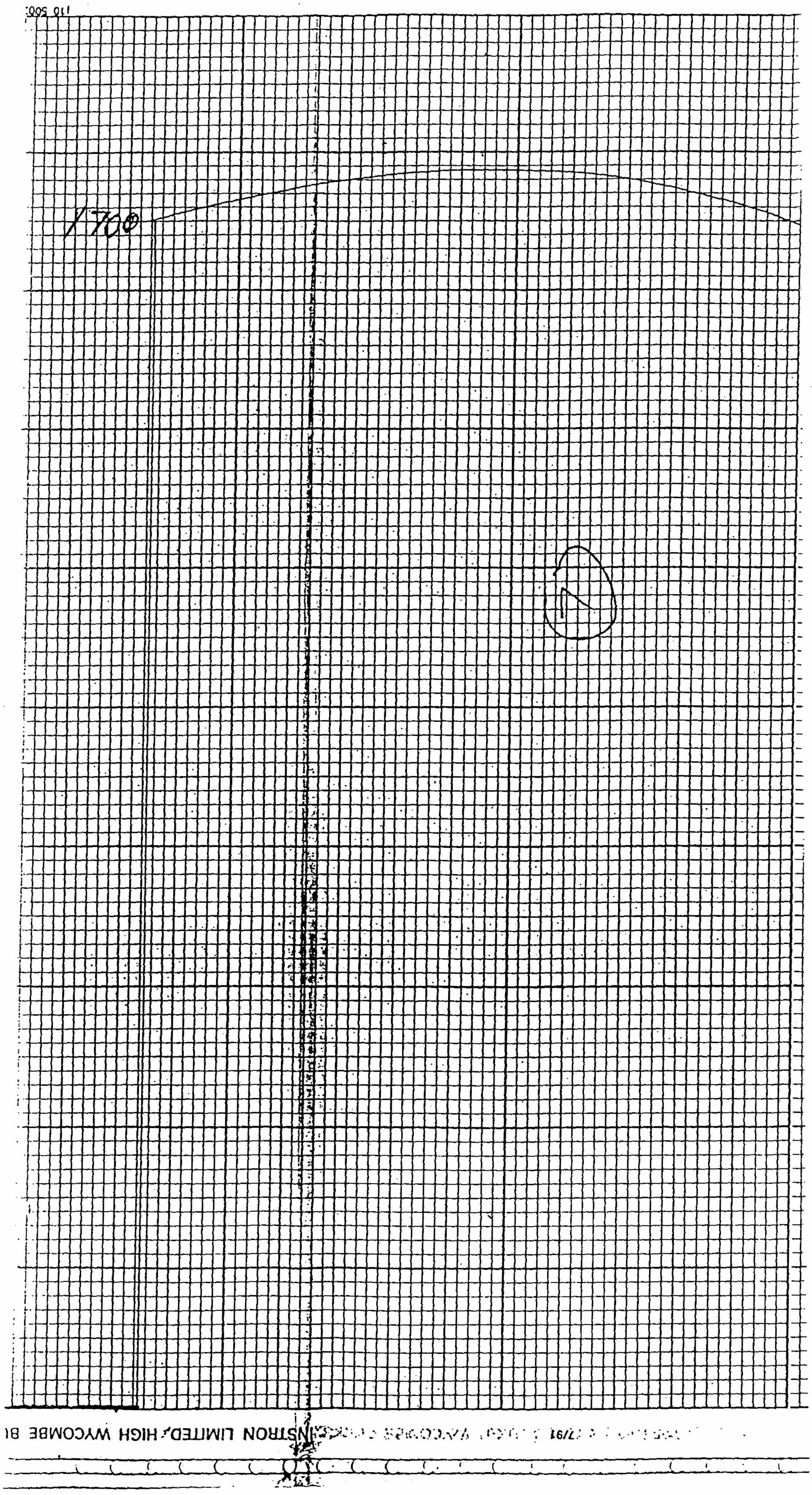
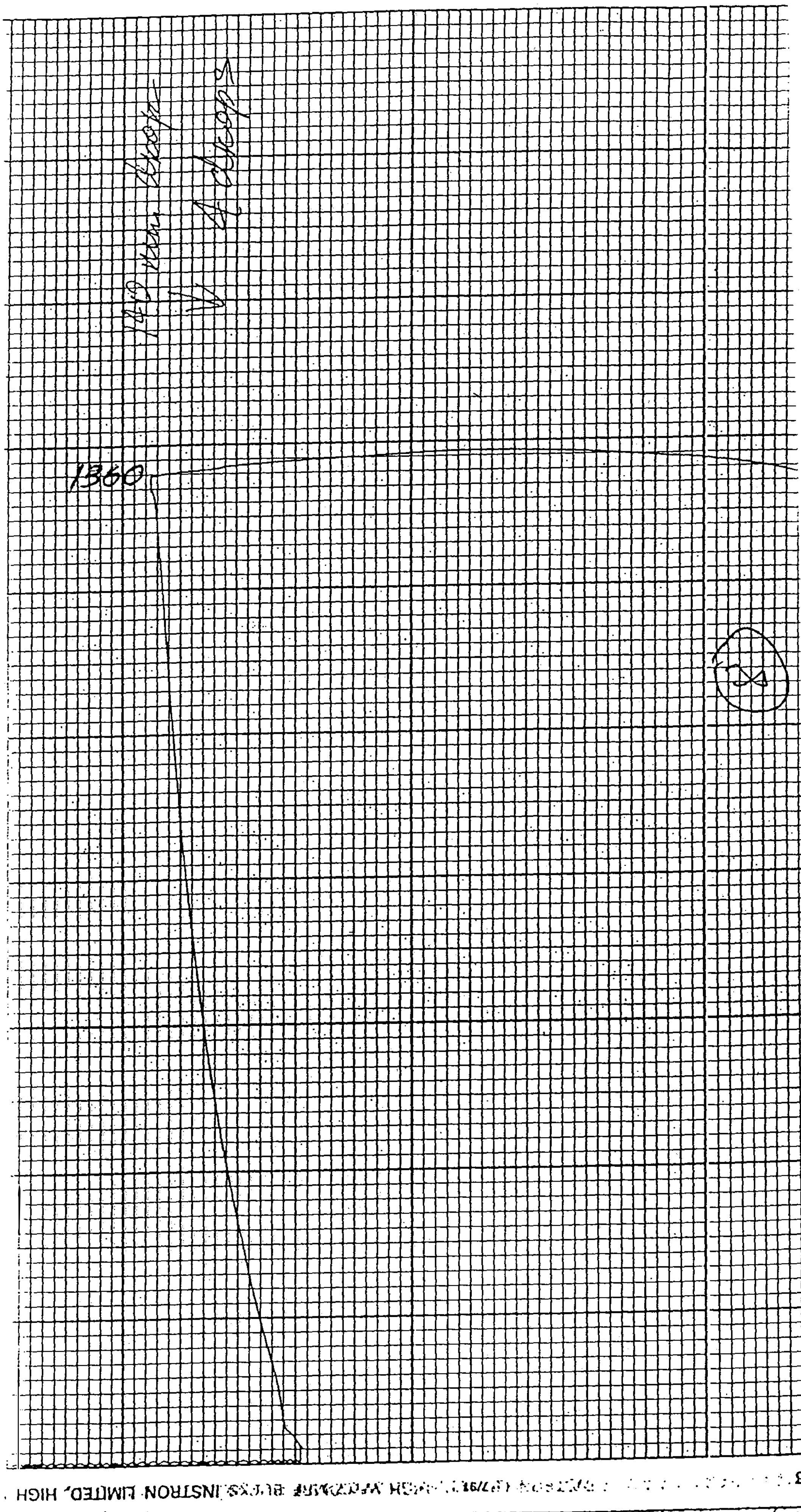


FIG 13



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Report No: WC93-671
Client: Portland Square Pty Ltd
Attention: Mr R. Sekel
Date: 05 November 1993
Subject: Endurance Testing of Femoral Prothesis -

1.0 INTRODUCTION

A modular design femoral prothesis known as the "St George Hip" was evaluated for endurance properties in accordance with ISO 7206 Part 3.

ISO 7206 Part 3 requires that the prothesis is loaded to apply a bending load, without torsion, to the head, neck and upper stem region. This is achieved by embedding the lower region of the component in a suitable potting material. To achieve the required bending the device is loaded at a 10° angle to the major axis of the stem.

A cyclic compression load is then applied while the prothesis is exposed to fluid at 37°C. ISO 7206 does not specify the load requirements, however a frequency of 10Hz is recommended for metallic devices.

Following completion of 10 million load cycles at 10Hz, the prothesis was removed from the rig and subjected to dye penetrant inspection. The device was considered to have passed the test if fatigue or other cracking was absent.

2.0 PROCEDURE

2.1 Identification

The prothesis was marked:-

Stem	NFI No. 3 O/S
Neck	NFI No. 6
Ball	COCr Mo - SL
	32 - M12/14
	OSTEO
	E02696

Should test be conduct to all combination ?

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2.2 Encapsulation

The femoral prothesis was held by the head, and the angle of the stem adjusted. An epoxy casting resin was then poured into a mould around the stem and allowed to set. The setting of the epoxy was monitored using a shore 'D' durometer. Sufficient hardness to proceed to testing was achieved after 6 days.

Specific details of this stage of the procedure were:-

Stem Axis:	10° and 0° angle to vertical
Casting Medium:	Resin - Araldite LC 177 Hardener - LC 177 Mix Ratio - 5:1 by weight Hardness - 80 Shore 'D'
Stem Cleaning:	Ultrasonic cleaning in detergent and water, rinse in distilled water and rinse with acetone, dry.
Depth of Insertion of Stem:	80mm from centreline of head as per ISO 7206 Part 3.

2.2 Endurance Testing

The prothesis and mounting block was installed into the immersion bath of a servohydraulic test machine. The bath was filled to the centreline of the head with fluid and the fluid then heated. A cyclic load at 10Hz was applied to the top of the head via a PTFE block. The load was cycled between 6 times average body weight, and 10% of this figure. During the test the bath was constantly stirred and aerated.

Specific details of the endurance testing were:-

Test Machine:	Shimadzu Servo Pulser Type EHF-ED30 Serial No. 87792
Immersion Fluid:	Distilled waster with 9gm/ℓ analytical grade sodium chloride (NaCℓ).
Temperature:	37°C ± 1°C
Condition:	Constantly stirred and aerated
Load:	Major 4.10kN Minor 0.41kN
Frequency:	10Hz

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3.0 RESULTS

3.1 Endurance Testing

During cyclic loading a typical deflection range of 0.2mm was experienced. As the test progressed the prothesis moved down, however this was due to creep in the potting medium.

At 3,613,181 cycles the test stopped due to an external power failure. The opportunity was taken to visually examine the prothesis for cracking with none being found.

The test was restarted and ran to a total of 10 million cycles without incident. The temperature of the fluid was maintained at 37°C ± 1°C at all times with the actual temperature range being -3°C + 2°C of the required 37°C.

3.2 Dye Penetrant Inspection

The neck area of the prothesis was sprayed with a high sensitivity fluorescent dye and allowed to penetrate. Following cleaning the neck was sprayed with developer and after a delay time was examined for crack indications under a fluorescent light.

Test Method:	AS 2062 - 1977
Penetrant:	Fluorescent dye Ardrox 970 P10
Dwell Time:	20 minutes
Cleaning:	Wiping with clean cloth
Developer:	Ardrox 9D6F
Development Time:	30 minutes
Result:	No crack indications observed

4.0 CONCLUSION

Endurance testing In accordance with ISO 7206-3 1988 at a load range of 0.41 to 4.1kN was performed on the femoral prothesis with no fatigue cracking or other damage being observed.

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SENIOR METALLURGIST