VIAMED

MANAGEMENT MEETING 6.10.93

MINUTES

1. Meeting called to review forthcoming assessment of BS5750 Pt 2. Present at the meeting:- John Lamb, Jean Lamb, E. Gillespie, Derek Lamb & Steve Hardaker.

POINTS RAISED

Office:-

1. Management review meetings to take place at least once per year.

2. Suppliers register must be checked every 6 months to ensure suppliers are still BS registered or have gained registration.

3. Outstanding orders book to be updated, tidied up.

4. Goods Inwards proceedure to be looked at again and updated if necessary.

5. Viamed Orders binder to be updated weekly (i.e completed orders taken out and placed into corresponding binder).

6. Audits must be carried out every month.

Workshop/QA Area.

1. Stock books to be checked and updated if necessary.

2. No items are to be left at any time on workbenches unless otherwise specified.

3. Calibration Register to be updated.

4. Check anti-static protection (i.e mats, leads etc). Ensure checklist is completed before use.

5. Ensure worksheets are fully completed before returning to office for invoicing.

6. Repair items going into the workshop are to be tagged with the worksheet number clearly stated on it. This tag is not to be removed at anytime.

5/5/94

Viamed Ltd. 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT
Telephone: 0535 634542 / 636757 Fax: 0535 635582
Registration No. 1291765 in England

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MANAGEMENT MEETING 17.09.94

MINUTES

1. Due to the importance and nature of this meeting, all company members present.

POINTS RAISED

BS5750:- Service assessment (KF) due on 4.10.94.
Office and W/Shop assessment due approx 18.10.94.

Procedure changes:

1. Non-Viamed stock. All customers should be informed of items which are not covered by BS5750.

2. Stock checks are now on-going all year.

3. Items requiring special storage must be labelled and comply in full to manufacturers conditions.

4. All goods, however urgent must not go out without first having gone through BS5750 procedure.

5. All goods purchased from other companies must be stored in original packaging. The packaging is to be removed and replaced with Viamed packaging before going out to the customer.

6. Full responsibility regarding the quality of items sold is at the discretion of the Managing Directors providing the item complies with the minimum acceptable quality required.

7. Any queries or complaints regarding BS5750 matters to be addressed to Office Manager.

8. Demonstration equipment:- value = £50,000 at the begining of the year. We are now tracking and logging all equipment (ie. where is has come from and where it is currently). All slips sent into the office by salesmen must have the part No, serial No and Hospital to which it has been sent.

9. Pressure gauges must be logged and tested every six months approximately.

10. All Service/Operator manual updates must be logged.

11. Test Equipment: We now have a safety tester. ESD checks:- check every station every time they are used and log accordingly.

12. Training records were handed out to be updated and returned to Office Manager.

20/9/94

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Viamed Limited, 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT
Tel: 01535 634542 / 636757 Fax: 01535 635582
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MANAGEMENT MEETING 28.10.95

MINUTES - Taken by E. Gillespie (Office Manager)

Staff Members present - John LAmb, E. Gillespie, Derek Lamb, Steve Hardaker.

POINTS RAISED

Procedures Discussed.

1. Non-Viamed stock. All stock items now marked with * apart from Epic Probes - still to be done.

2. Audit for Stock still to be done. Bird, Teledyne and Mennen already stock checked. Checks are now on-going all year.

3. Anti-Static items - kept in bags with anti-static labels on them. Gloves to be used by all members of staff touching contaminated goods. No cleaning procedures have been given for Epic Probes - to be sent in the near future or training given.

4. All goods being despatched have tested stickers and date of the test on them. Certificates of Conformity are issued when necessary and goods are sent in original packaging whenever possible.

5. Demonstration equipment was logged and checked in October 1995 by Steve Hardaker and Derek Lamb. A Stock movement file is also now in operation for equipment being sent out to the salesmen. Updated every two months.

6. Test equipment is checked as required or every 12 months. A calibration update is currently in progress.

7. Audits. Because of the pressure the Company is presently under, audits are to be carried out over a 10 month period (i.e one per month) from January to October.

8. Quality Planning:- Turnover for the Company increasing, complaints are decreasing, therefore, general quality has improved. The only problem presently is with Epic as we have no equipment to test probes before they leave the building. Currently in the process of purchase of test equipment and training for repairs to probes.

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MANAGEMENT MEETING 28.10.95 - AGENDA UPDATE.

Further to BS Audit on 27.3.96. it was noted that several points on Appendix A of VM/COP/13 were not reflected in the meeting. As the points omitted are continually being discussed and updated. it was not thought valuable at the time to log as 'points raised' as concentration was placed on matters of importance. It has now been noted that all points however trivial. must be minuted on the meeting agenda.

1. Contract review.Picking. Packing & Despatch.

Noted on item 4 of meeting.

2. Purchasing Controls - Omitted from Minutes.

This is continually revised and updated on a weekly basis.

3. Supp/Sub-contractor Performance - Omitted from Minutes

The point was raised at the meeting and agreed to be in order. Not noted on minutes.

4. Storage and Stock Control - Noted on item 5 of meeting.

5. Customer Complaints - Noted on item 8 of meeting.

6. Calibration - Noted on item 6 of meeting.

7. Documentation & Records - Omitted from Minutes

The point was raised at the meeting and agreed to be in order. Not noted on minutes.

8. Training - Omitted from Minutes

Training records updated in Oct 95 - not required to be updated until Nov 96. Not discussed in depth as of no relevence. Omitted from minutes.

9. Audits - Noted on item 7 of meeting.

10. Review of Responsibilities

Responsibilites of all relevent Departments noted on Viamed Official Health & Safety Policy which is checked/updated annually for insurance purposes.

11. Resources - Noted on items 3 & 8 of meeting.

12. Quality Planning - Noted on item 8 of meeting.

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MANAGEMENT MEETING 26.11.96

MINUTES - Taken by E. Gillespie (Office Manager)

Staff Members present - John Lamb, E. Gillespie, Derek Lamb, Steve Hardaker.

POINTS RAISED

Procedures Discussed.

1. **Contract Review:**

All despatches have test stickers and dates. Certs Of Conformity issued when necessary on non Viamed stock. Measuring Tape offer still standing on sales of cells and probes. All stock items marked with *

2. **Purchasing Controls**:

Continually assessed. Any outstanding purchase orders are checked on a weekly basis.

3. **Supplier/Sub-Contractor Performance**

Above contacted annually for update on QA performance.

4. **Storage & Stock Control**

Will be removing all Bird Stock early 97. Demo equipment to be checked at the end of December. General stock check updated constantly and audited at random (1 per month).

5. **Customer Complaints:**

Not currently out of hand. All warranty items of stock continually being replaced/repaired free of charge.

6. **Calibration:**

Test equipment is checked as required by audit or every 12 months. All Epic repair calibration equipment test procedures currently being set up.

7. **Documentation & Records:**

Library for all documentation up to date. No problems.

8. **Training:** Records updated as per audit this year.

9. **Audits.**

All audits now complete for 1996 apart from COP/10 (Audits). Viamed now staging audits every month between January to October.

BSI REGISTERED STOCKIST FS 28343 BSI REGISTERED FIRM FS 28344

Viamed Limited, 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT
Tel: +44 (0) 1535 634542/636757 Fax: +44 (0) 1535 635582
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10. **Review Of Responsibilities**

Responsibilities of all relevent Departments norted on Viamed Health & Safety Policy which is updated annually for insurance purposes.

11. **Resources.**

Cleaning proceedured for Epic in progress. Full manual being produced. Epik UK hope to achieve ISO9002/EN46002 by July 1997. Vandagraph - end 1997.

12. **Quality Planning:**

Turnover for the Company increasing. 4 new member of staff recruited in 1996 to cover increase in workload. All employees trained within Viamed.

The Chairman gives his thanks to all members of the Company for all the effort given - no faults atall reported on the last BS audit (Nov 96). We have now achieved EN46001.

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Management Review DATE 1997

Contract Review Picking Packing & Despatch

This was delayed to March due to Steve Hardaker & Liz Gillespie leaving the Company. Diane Macdonald is now new representative, Darren Boldy now in charge of QA. 15 months since last one but small meeting has taken place. Helen has found problems with stock records now being rectified.

Purchasing Controls

New system required for purchasing is due 1998 . Poor deliveries and part deliveries causing problems.

Main companies Mennen & MCI late MCI has improved of

Supplier\Sub contractor Performance

Checked completely every year and updated where required

Storage & Stock Control

Goods in OK Major stock check December 1997 for accounts

Customer complaints

Still at a low level. Possible problems with Epic repairs being addressed - Peter doing reports

Sheffield - Mennen given notice of distribution agreement severance. Sheffield final meeting taken place 8 April 1998.

Calibration

No problems

Documentation & Records

Needs a complete overhall in 1998 John Lamb to remove old agencies to a nonconforming area.

Bird/Mennen

Training

Still ongoing Epic needs constant attention QA Meetings to be held weekly then monthly.

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Viamed Limited, 15 Station Road, Cross Hills,
Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
Email info@viamed.co.uk
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Internal Quality Audits

All completed no major problems. BS Audit also problem free

Review of Responsibilities

Diane Macdonald - Administrator to Audits Complaints File and any outstanding problems

Darren Boldy - Q A Engineer

Resources

Stretched due to Rachel Murgatroyd on maternity and people leaving - S Hardaker, E Gillespie and J Anderson. Now being replaced and trained. Steve Nixon is a trained auditor.

Quality Planning Required:

New Products - DL3000 - Tom Thumb (Stuart now building OK)

New services

Test Equipment - BCI purchased - Micheal now building SpO2 Test Boxes

Space

New areas brought into use and Epic repairs extended.

QA moved to basement with more room

New labelling system installed

Stock records computerised with hard copy

Training

Epic meeting : ongoing

Quality Planning

Needs expansion. D Macdonald liasing with H Lamb. H Lamb is an outside auditor being trained by John Lamb

Achievement of Quality Policy.

Epic returns - D Boldy to discuss with P Lamb

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VIAMED

Present

John Lamb, Derek Lamb, Diane Macdonald, Darren Boldy

Minutes:

Diane Macdonald

16/4/98

Viamed Limited, 15 Station Road, Cross Hills,
Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
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Management Review DATE 29.01.99

Contract Review Picking Packing & Despatch

New method tried for Export and if successful will be extended to all areas.
MW will pick and assemble orders instead of office staff

Purchasing Controls

New system about to be installed for purchasing . Poor deliveries and part deliveries have still caused problems. Main companies Mennen & MCI. Mennen is no longer and agency. MCI is improving

Supplier\Sub contractor Performance

Checked completely every year and updated where required

Storage & Stock Control

Goods in OK. Annual full stock check at Dec 31st. 1998. externally audited by accountants.

Customer complaints

Still at a low level

Calibration

No problems

Documentation & Records

Overhauled completely in 1998 to remove old agencies to a non conforming area.

Mennen and Bird removed

Training

Still ongoing

Internal Quality Audits

All completed no major problems. BS Audit also problem free

Review of Responsibilities

D.Boldy confirmed as QA supervisor

f:\Audit \Manrev98

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Resources

1999 New accounts package to incorporate Order processing, Goods return, dual company stock sharing. Possibly batch and serial numbers.

Quality Planning Required:

New Products

Vaporisers from A & E Services A & E are ISO9001

Betatherm thermometer probes to be assembled in Viamed.

New services

production of SPO2 probes and cables

Test Equipment

Spectral analysis of probes essential. Equipment to be purchased in Jan 1999

Space

New production area brought into use - Stuart Vann responsible for this area

Tom Thumb new responsibility for Stuart Vann

Equipment

Production techniques to be reassessed particularly with respect to handling LED's (visit to PDI January)

Quality Planning

Procedures under constant review and continually upgraded when required

Achievement of Quality Policy.

1998 saw improvements in the overall standard of QA

Present

John S Lamb

Derek Lamb

Diane Macdonald

Darren Boldy

Minutes:

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Management Review 1999

DATE 07.01.2000

Contract Review Picking Packing & Despatch
New method tried for Export and if successful will be extended to all areas.
MW will pick and assemble orders instead of office staff
Works need refining to be estimated late 2000.

Purchasing Controls

New system is now installed for purchasing . Poor deliveries and part deliveries have still caused problems in 1999. Better monitoring in place now. MCI is improving

Supplier\Sub contractor Performance

Checked completely every year and updated where required Suppliers now on database.

Storage & Stock Control

Goods in OK expept boxes for repairs need cleaning and more care on checking repairs in. Annual full stock check at Dec 31st. 1998. externally audited by accountants.

Customer complaints

Still at a low level

Calibration

No problems-production checked for ISO9001 no updating required.

Documentation & Records

CE & Design files overhauled & on CD

Training

Still ongoing

Internal Quality Audits

All completed no major problems. BS Audit also problem free in 1999

Review of Responsibilities

Meeting now planned for major review

Resources

New accounts package was installed July 1999 to incorporate Order processing, Goods return, dual company stock sharing. (batch and serial numbers still a problem).

Quality Planning Required:

New Products

None

New services

N I B P

Test Equipment

Equipment to be purchased in Jan 2000 for spectral analysis

Space

Under review

Equipment

Production techniques reassessed particularly with respect to handling LED's. About to install drying cupboards.

Quality Planning

Procedures under constant review and continually upgraded when required Now weekly production/QA meetings.

Achievement of Quality Policy,

1999 saw improvements in the overall standard of QA

Present

John S Lamb

Derek Lamb

Diane Macdonald

Darren Boldy

Steve Nixon

Minutes:

07/1/00

f:\Audit \Manrev98

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Management Review 2000

Contract Review Picking Packing & Despatch

Picking & packing is now controlled by stock room and not the invoice typists.
Procedure is to be changed as a picking list is now generated by Opera instead of using the original orders. The Invoice typist generates the picking list by typing in the order.

Purchasing Controls

New system is now installed in Opera . Poor deliveries and part deliveries have still caused problems in 2000. mainly from Clinipol, Technomed/MSB, and PDI. More comprehensive monitoring is now in place

Supplier\Sub contractor performance

Checked completely every year and updated where required Suppliers now on database and Opera is being continually expanded

Storage & Stock Control

Annual full stock check at during December 2000. Externally audited by accountants.

Change of staff . DB now in overall control. Stock more tightly controlled and monitored by Opera on a daily basis.

Picking Packing & Despatch; & Repair are all under review and need updating to reflect the parts being controlled by Opera. 2001 should see the procedures finalised and fine tuned. At present they are being modified and stock re-organised so that the procedures stay with ISO requirements but utilise Opera to the full

Customer complaints

Still at a low level during 2000

Calibration

No problems-production checked for ISO9001 no updating required.

Documentation & Records

CE & Design files have been overhauled & are on CD. Paperport is being introduced.

This will remove the need for more than one manual for each piece of equipment as all procedures and manuals will be available on a read only computer system.

Management Review 2001

Training

Still ongoing. 2000 saw this increased to involve all company staff in basic customer relations and company image

Internal Quality Audits

All completed no major problems. BS audit also problem free in 2000, except for a recommendation to increase the scope of the design specification brief.

Review of Responsibilities

MW has left the company. DB has assumed overall responsibility for the execution of company . QA policies in all areas from goods in to goods out including manufacture and repair

Resources

Opera starting to show value as more information is fed in and more procedures are brought on line (batch and serial numbers still a problem). More staff have been employed and more will be required in 2001. Space is the major problem and is being continually addressed.

Test equipment is being upgraded and added to.

New test equipment is under design

New tools have been employed

New processes (drying racks etc.) have been designed and employed

New processes to further improve consistency of the quality of the products manufactured are being evaluated with a view to installation in 2001

Quality Planning Required:

New Products

None requiring new QA procedures

New services

None

Test Equipment

Equipment to be purchased in Jan 2001 see resources

Space

Under review

Equipment

Management Review 2001

Production techniques continually being reassessed particularly with respect to handling LED's. and detectors

Quality Planning

Procedures under constant review and continually upgraded when required

Weekly production/QA meetings have proved very successful.

Achievement of Quality Policy.

2000 saw small general improvements in the overall standard of QA

Present

John S Lamb

Darren Boldy

Steve Nixon

Stuart Van

Minutes:

JSL

Management Review 2001

Needs updating after meeting

Contract Review Picking Packing & Despatch

New Electronic "Opera" system in use and is speeding up throughput and reducing mistakes.

Purchasing Controls

Poor deliveries and part deliveries have still caused problems in 2001. Mainly Technomed

Supplier\Sub contractor Performance

Checked completely every two years and updated where required on an ongoing basis. Suppliers now on database.

Storage & Stock Control

Goods in OK: Annual full stock check at Dec 31st. 2001 externally audited by accountants.

Repairs in to be moved in 2002

Customer complaints

Still at a low level and completed in reasonable time frames: Electronic copies on paperport

To be logged better via Goldmine in 2002. Will need new procedure written in 2002. Existing paper complaints to be scanned into paperport. Paper system used in parallel

Calibration

No problems for ISO9001 no updating required.

Documentation & Records

CE & Design files overhauled & on CD.

New drawings for Sp)2 extension cables & production started. Repairs to be re-drawn next.

All ISO procedures and QA manuals except master have been withdrawn and distributed company wide on an intranet. Issue 3 2001.

Updating and correction of errors now in operation and working

Existing procedures under review and new versions being upgraded to take Golmine and Opera into account: includes Goods IN, Picking Packing and despatch.

SpO2 procedures have been added into the main ISO file as have Vandagraph (in progress of updating)

and company admin. procedures

Backups are too big for floppy disks so are now on CDROM.and hard disks. OPERA, Goldmine are backed up daily. Paperport at regular intervals.

In 2002 procedures will become more precise.

Training

Still ongoing

First Aid courses for all staff held in 2001 and will be extended to new staff in 2002

Basic customer relations 2001

HSE for all staff in 2001 to be extended in 2002

Goldmine training required

Paperport training at company meetings

Internal Quality Audits

All completed no major problems. BS Audit produced low level problems for the first time mainly due to more stringent application of MDD and MDA interpretations

All corrective actions and preventative actions have been addressed.

Weekly/monthly meetings reducing even further the minor errors in the system

New electronic systems need to bed in for a while see if further discrepancies arise.
Most day to deviations are corrected as soon as they are found.

Intranet

This will be the method of distributing information of all types throughout the company

ISO9001/EN46001

HSE Information

Technical Manuals

Production procedures

Repair procedures

Office administration procedures

Review of Responsibilities

Jason Harmer Office Administration

Michael Green Overall responsibility for Production, Repair and final QA

Stuart Vann Goods Inward including QA, Stock control, Picking, Packing, Despatch

Resources

New accounts package running well and old problems starting to disappear fast

Order processing, Goods return, dual company stock sharing up and running.

New Viamed stock numbers started.

Quality Planning Required:

New Products

Possibly:-

Oxyarm

New SpO2 Testers

Foetal simulator

New services

Video cables

ECG cables

Eco Clips

Test Equipment

Cable low ohmn tester

Equipment to test LED'd Voltage & current

Lighting being changed for colour correction on visual inspection

Space

New warehouses in Ireland & Eastburn now operational but controlled from Viamed office

New additional staff required

New extension 2002

New facilities for Incoming QA 2002

Equipment

New construction Jigs designed and implemented

Hand tools and consumables standardised

New test box required for SpO2

Quality Planning

Procedures under constant review and continually upgraded when required by users

Now weekly production/QA/Stock meetings.

Project meetings on a monthly basis

Achievement of Quality Policy.

2001 saw general improvements in the overall standard of QA

Advisory notices and recalls

None

Vigilance system

Complaints: Repair levels no sudden increases out of line with increase in sales.

Most batch problems are located before despatch

Surveillance cards still being sent out but very few are returned

Best indication is the level of sales and repeat business and the number of distributors wanting the products.

MDA Queries

Nascor :

Request for the Documentation and query on classification MDA have not come back

Bradford R I

Report on no enclosure of instructions with a repair. The MDA accepted our reply

Present

John S Lamb

Derek Lamb

Steve Nixon

Stuart Vann

Michael Green

Jason Harmer

Minutes:

J S Lamb

21/01/02

Management Review 2002

QA overview discussed (see Quality Assurance document)

Contract Review Picking Packing & Despatch

"Opera" system in use :

More users to be added

More features to be opened up in 2003

Multi-warehouse; B.O.M.; Vendor assessment: Return to Vendor

Has it speeded up throughput : Yes

Reduced mistakes.: Yes

Outstanding. Long delivery notes causes crashes. Add extra blank line

Purchasing Controls

Companies

Poor deliveries

Part deliveries

Supplier\Sub contractor Performance

Rate **A. B. C. D. E.** To be started by Helen lamb and reviewed at monthly meetings

Supplier	Quality of Product	Delivery Times	Accuracy
Teledyne			
Dolphin			
Technomed			
Appleyards			
PDI			
Osco			
RS			
Farnell			
Electromed			

Storage & Stock Control

Annual full stock check at Dec 31st. 2001 externally audited by accountants.

Was stock accurate?: Yes

Errors in ECG cables due to Technomed: to be corrected 2003

Customer complaints

Still at a low level and completed in reasonable time frames:

To be logged better via Goldmine. Will need new procedure written in.

Existing paper complaints have been scanned into paperport. Paper system used in parallel

Calibration

No problems for ISO9001 no updating required.

Documentation & Records

CE & Design files need updating in 2003 continuous process: added to by changes in MDD

New drawings for:-

SpO2 Probes production}

Extension cables production } needs final verification

Repairs.}

ISO 9000 2000 procedures Target June 2003

QA manuals : To be upgraded for new and existing non SpO2 products into new format (SW)

Existing procedures under review and new versions being upgraded to take Golmine and Opera into account: includes Goods IN, Picking Packing and despatch.

Backups are too big for floppy disks so are now on CDROM.and hard disks. (10-15GB)

OPERA, Goldmine are backed up daily.

Drive Z,T,&W daily.

Paperport at regular intervals.(monthly)

Training

Still ongoing: to be checked more frequently (HL)

First Aid courses any more required: Yes

HSE basic course requirements : New personel

Goldmine training required

Paperport training at company meetings

New Procedures written for : Paperport: Archiving: Checklist

Internal Quality Audits

All completed; no major problems. BS Audit produced problems mainly due to more stringent application of MDD and MDA interpretations in MDD Essential requirements and New Risk assessment.

2003 All exisiting CE files to be upgraded

All corrective actions and preventative actions have been addressed.

Weekly/monthly meetings reducing even further the minor errors in the system

Intranet

Does it need upgrading

ISO9001/EN46001

HSE Information

Technical Manuals

Production procedures

Repair procedures

Office administration procedures

Review of Responsibilities

Jason HarmerOffice Administration

Michael Green Overall responsibility for SpO2 Production, Repair and final outgoing QA

Stuart Vann Goods Inward including incoming QA, Stock control, Picking, Packing, Despatch 2003?

Kevin Rush QA procedures

Robert Tedder Recus cabinets/Tom Thumb construction & service (S.Vann)

James Brown Resus cabinets/Tom Thumb construction & service (S.Vann)

Mark Southgate Goods in

Simon Watmough Technical services

Helen Lamb Internal Audits

Resources

Stock. Teledyne spares: Rare but Teledyne parts do cause problems. To be listed and new stock levels instituted (DL SW.)

Engineering: Requires Test boxes (End January)

Kontron Datex sockets still required see Attached

QA: Extra space for QA Administration: extra person for routine production

Export

Sales

Quality Planning Required:

New Products

Possibly:-

New SpO2 Testers

Foetal simulator (EMC report required)

New services

Video cables

ECG cables

Eco Clips

Foetal transducer repairs

Expansion/ upgrade to SpO2 repairs

Test Equipment

Cable low ohmn tester

Equipment to test LED'd Voltage & current

Lighting changed for colour correction on visual inspection

Space

New extension 2002 almost complete with new office layout

Should increase control over stock and QA

New facilities for Incoming QA

Equipment

New construction Jigs

What progress

Hand tools and consumables standardised

New test box required for SpO2

Quality Planning

Procedures under constant review and continually upgraded when required by users

Weekly production/QA/Stock meetings.

Are they minuted correctly

Project meetings on a monthly basis

Achievement of Quality Policy.

2002 saw general improvements in the overall standard of QA

13485 & CDMAS

Advisory notices and recalls

None

Vigilance system

Complaints: Repair levels no sudden increases out of line with increase in sales.

Most batch problems are located before despatch

Surveillance cards still being sent out but very few are returned: Being abused : to be re-evaluated 2003

Best indication is the level of sales and repeat business and the number of distributors wanting the products.

Cotlids redesigned

Nufer heaters upgraded

MDA Queries

Nascor :

Nufer

Headboxes

Software Audits

Checklist

Present

John S Lamb

Derek Lamb

Steve Nixon

Stuart Vann

Michael Green

Jason Harmer

KevinRush

Siimon Watmough

Minutes:

John S Lamb

Friday, 10 January 2003

Quality Assurance

There is an expression "Quality is free"

This is true if it stops errors and mistakes reaching the customers as returns and failures outside the company are much more expensive than correction inside.
All external problems involve one or more of the following.
Travel
Postage
Repair time
Replacement parts
Finance costs of invoices and repayments passing through the account
Administration time sorting out paperwork and payments
Administration time in sorting out procedures.

Good QA can be paid for out of these expenses saved. Hence "Quality is free"

However if the job was carried out correctly in the first instance QA would be minimal 100% and would cost the company as an extra stage in production/repair.

Every product has a cost penalty.

Goods IN – Storage- Goods QA – Goods out running costs are about 11% in Viamed

This assumes no QA maintenance and no substantial rejects.
We can have a perfect QA system but it costs
Meeting times
Procedures
Time for QA
Time for perfection.
Most systems can be 95% correct and maintained at this level at a low cost
The other 5% can absorb massive resources of time and energy.

We need to ensure.
Our system produces good quality trouble free products.
It is maintained in line with legislative requirements
It is maintained in line with our requirements
It does not place us at an competitive disadvantage.

We can over-engineer, over-manufacture, and over-QA until our products cannot be sold in the market.
We need to get the balance right.

1. Procedures correct
2. Procedures adhered too
3. Product manufactured/repaired in-line with procedures
4. All meetings productive and recorded (13485) economical with time. (Diaries)
5. Actual QA before administration of QA

2003 offers an opportunity for growth in sales/production/and repair if we can reduce and maintain cost levels.

Paperport

Introduction

Paperport is an electronic filing and storage system.
Imagine a Filing cabinet with drawers and individual files.
Some files can be opened by anyone in the company others are restricted.
In Paperport the files open to all start with a letter (A)

Electronically there can be more levels of filing than in a paper system
e.g.
Take ISO.
All our ISO files are found (D) ISO Information Level 1
There can be many or few major groups of files in Level 1
In the ISO system we will usually have 6 or 7
(D) BSI information
This contains basic information on BSI
(D) ISO Quality Manual
This contains the latest and most current Viamed company Quality manual
(D) ISO EN Documentation
This contains the actual BS : EN ; & ISO standards
(D) ISO 9000 Current (year)
This contains all the current company procedures
Manufacture
Repairs
Administration
QA procedures
Office procedures
Vandagraph procedures
(D) Management reviews
This contains the Management review minutes

(D) ISO 9000 2000 ISO 13485
This file will change its name as standards change. It the update file when the procedures are amended but are are yet included in the current procedures

All the groups (A) >> follow a similar format

New information & Upgrades

Files in an electronic system can easily be modified and erroneous information inserted without traceability.
For this reason all the open Files are read only.
Upgrades and new information can only be added by a director.

New information

New Information should be scanned into ppupdate

Upgrades

To upgrade a file first duplicate it in Paperport
Add a postnote with the modification or highlight the errors and add text.
Print the modified page to Paperport either black & white or colour.
CHECK The graphic is set to 200 dpi or 300 dpi

COMPANY OPERATING PROCEDURES

Checklist

Created:	26 May 1998	VM3/COP/20.09	Issue 3	
Revised:	09 January 2003		**Page1**	**of 2**

Week commencing Date:

Daily	Procedure	Responsibility	Mon	Tues	Wed	Thu	Frid
Cheques Entered	A.P. Cheques						
Payments UK	A.P.OPFIN2						
Payments Export	A.P. EXPAY						
Stock Book entered	COP/07						
Daily Print out of Invoices							
Repairs IN entered	COP/09						
Repairs OUT entered	COP/09						
Bank Statements							
Email	COP/03						
Telephone Orders completed	COP/03						
Faxes addressed & actioned							
Goods in Entered	COP/05						
P.O Placed	COP/04						
Filing							
Sickness							
Holidays							
Outstanding Orders							

	Procedure	Responsibility
Outstanding UK Customer Orders	COP/03	
Outstanding EX Customer Orders	COP/03	
Outstanding Quotations UK		
Outstanding Quotations Export		
Outstanding Follow ups		
Outstanding UK Repairs	COP/09	
Outstanding Export Repairs	COP/09	
Loan/SAM/WAR File print out		
Outstanding P.O's print out		
Computer Backup		

Monthly	**Proceedure**	**Responsibiliy**	
ISO Audit	COP/13		
Customer Complaints	COP/10		
Outstanding Repairs	COP/09		
Demo File			
Sales Statistics UK			
Sales Statistics Export			
UK monthly Sales			
UK monthly Credits			
Export monthly Sales			
Export Monthly Credits			
Export List of outstanding Debtors			
Export List of Credit notes			
Aged Debtors list UK			
Aged Debtors list Export			
Export Statements on Plain Paper			
Commissions			
Loan File			
Reminders	A.P.Remind		
Emergency Lighting			
PAT			
Oxygen pipe line			
Fire Alarm			
Water Sump Pump / Boiler - Bostrite			
Check List			

VIAMED

SOCKETS for TEST BOXES

KONTRON

DATEX

HP

SIEMENS

CRITICARE

NIHON KOHDEN

MARQUETTE

ODAM BRUHER.

Viamed Limited · 15 Station Road · Cross Hills
Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634542/636757 Fax: +44 (0)1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

BS EN ISO9001 BS EN 46001
Company registered in England, No. 12917565

VIAMED

10/1/03

OXIMETERS REQ'D FOR TESTING

SIEMENS

HP

ODAM BRUHER

MARQUETTE

NIHON KOHDEN

FOR PRODUCTION / QA

KONTRON

NONAMETRIX

DATASCOPE

DATEX

SENSORMEDICS

MASIMO

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Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634542/636757 Fax: +44 (0)1535 635582
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MANAGEMENT REVIEW 2003

SUB-AGENDA

The following points need to be addressed within this review due to the forthcoming assessment visit by B.S.I.:-

1. Any changes made from the previous Technical visit (9th October 2002) need to be incorporated into the Paperport tree, as currently only old copies are available for viewing.
2. The customer complaints register, and any outstanding complaints need to be brought up to date.
3. A full review of the audit programme needs to be undertaken and all audits need to be completed.
4. All previous corrective actions need to be completed.
5. The Post Market surveillance procedure needs to be initiated, and shown to be producing recordable results.
6. If possible, any manufacturing of Microstim, Tom Thumb and Thermocot testing be in-progress. Also that the appropriate manufacturing procedures and subsequent test results are available.
7. A review of the attached Year-end statistics needs to be addressed.

The statistics show various areas of reject categories.

PRODUCTION:

The statistics are produced from the last two months of 2002 due to these being the only recordable figures. They show that from 476 probes manufactured, 160 were found faulty at the test stage. This represents a 33.6% failure rate. These are broken down into three main areas; Human, Design and Component.

HUMAN:

The two major points within this category can be attributed to:

a) One batch of 25 probes not having the pad mounts glued into the shell. This was immediately remedied and is no longer a cause for concern as it is now common practice during all production and repairs.

b) The second problem was in The assembly of the springs into the clips, this has been categorised as a human error as all the springs tested in stock were found to be correct and uniform in tension readings, therefore assuming that the method of assembly needs to be looked at for any possible improvement.

DESIGN:

One major point within this category can be attributed to the failure statistic, this is the on-going problem with the Ohmeda probes which are still currently being assessed by the Design department.

COMPONENT:

Within this category, the main factor for failure was with Sensor and L.E.D. faults found at the testing stage. However, as with the repair department, all components are now being tested prior to any assembly work being carried out. This should now reduce this figure to a more acceptable level.

REPAIRS:

The statistics are produced from the full records for 2002. They show that from 4707 probes repaired, 329 were found faulty at the test stage. This represents a 7% failure rate. These are broken down into various sub-categories and only show two specific human errors:

Faulty strain relief (not glued), QTY 19
Cracked shells QTY 12

However, with the remainder of the faults there are a significant number of component failures.

Faulty Sensor QTY 78
Faulty L.E.D. QTY 34
Components wired wrong way round QTY 32
Incorrect monitor readings QTY 59

The remainder of the faults found were over a wide range of categories, but could, in the main, be attributed to human error.

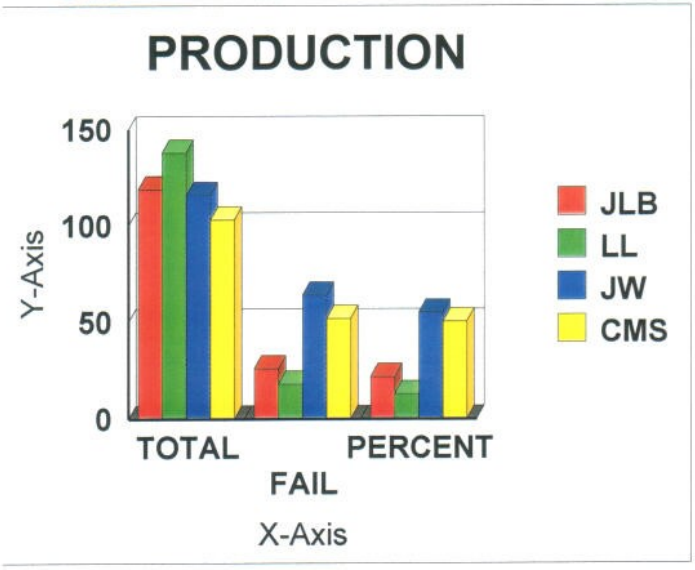
When looked at in the full context of the monthly graphs, it can be seen that there are certain peak times for failures.

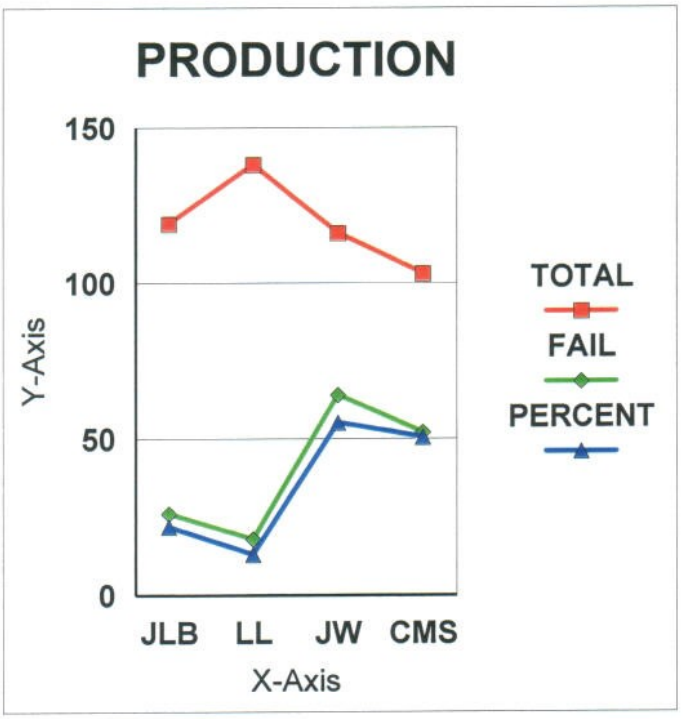
January, February and March:- two new operatives had recently moved into repairs as such they failure rate was high, however it does show a reducing rate over the three month period.

July and August was when another new operative was moved into repairs, this failure rate reduced when the operative was moved back into production.

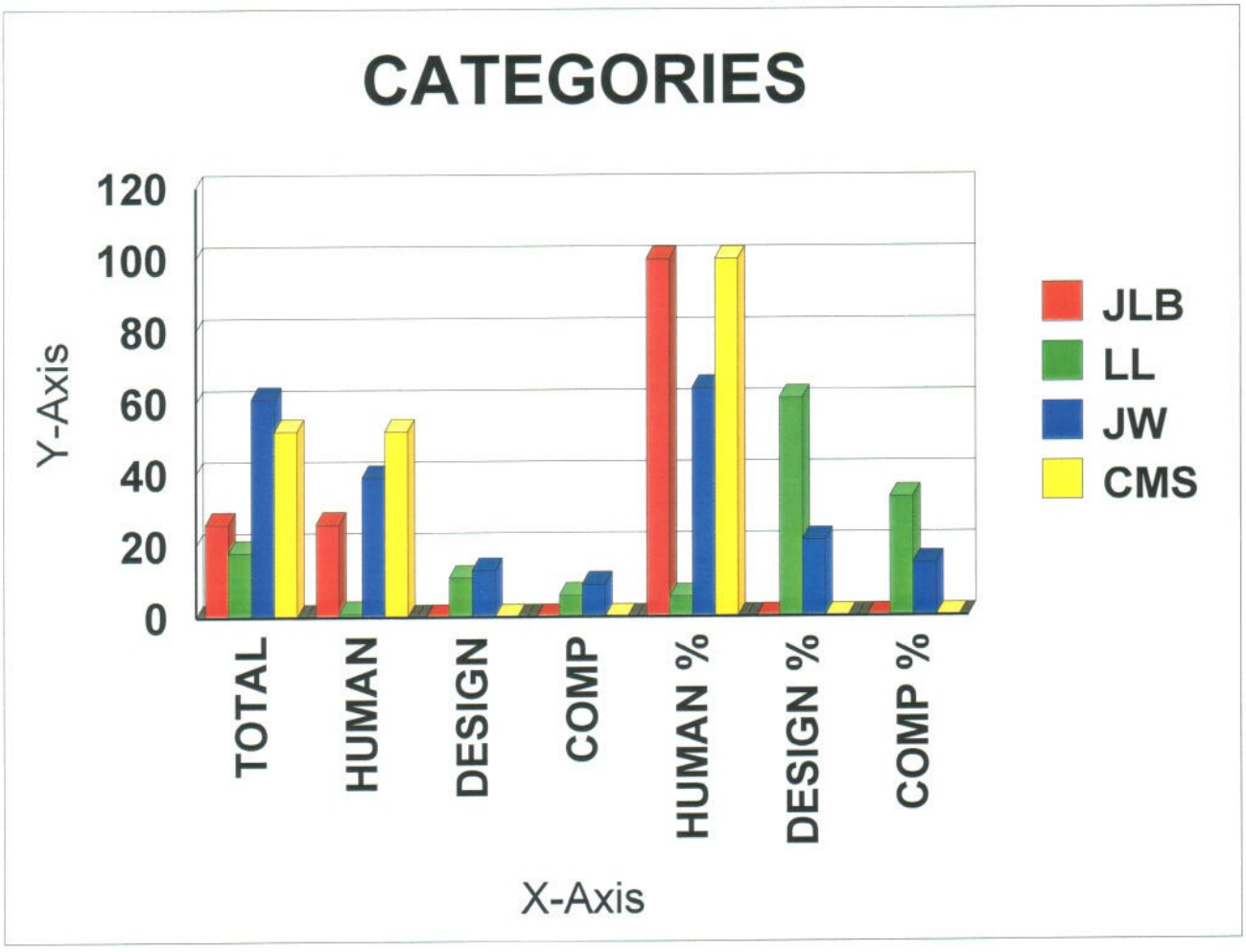
November and December show another increase in failure rate due to two more operatives being moved into repairs. The failure rate should once again drop as the New Year progresses.

RODUCTIO	TOTAL	FAIL	PERCENT
JLB	119	26	21.85
LL	138	18	13.04
JW	116	64	55.17
CMS	103	52	50.49



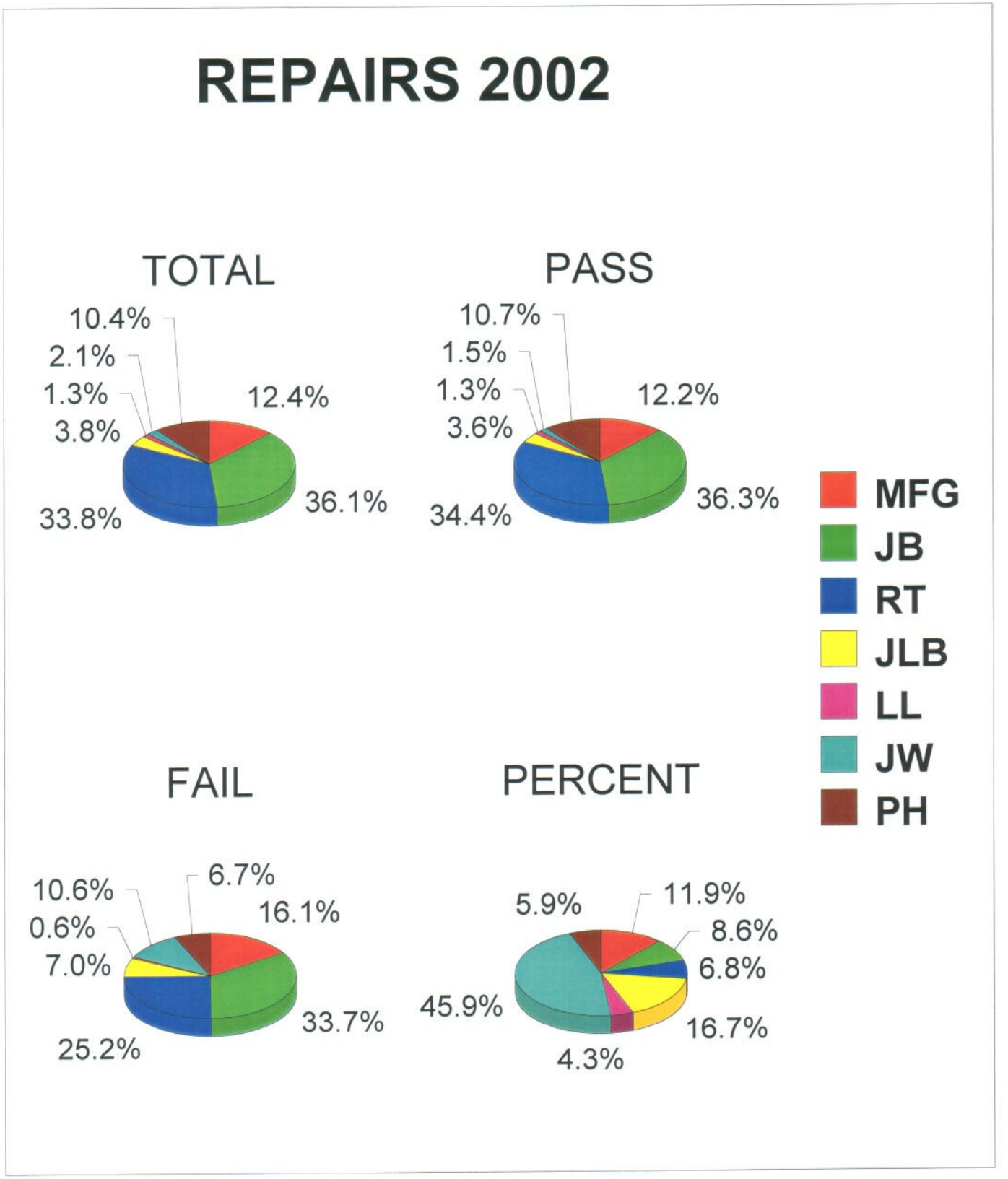


ATEGORIE	TOTAL	HUMAN	DESIGN	COMP	HUMAN %	DESIGN %	COMP %
JLB	26	26	0	0	100.00	0.00	0.00
LL	18	1	11	6	5.56	61.11	33.33
JW	61	39	13	9	63.93	21.31	14.75
CMS	52	52	0	0	100.00	0.00	0.00

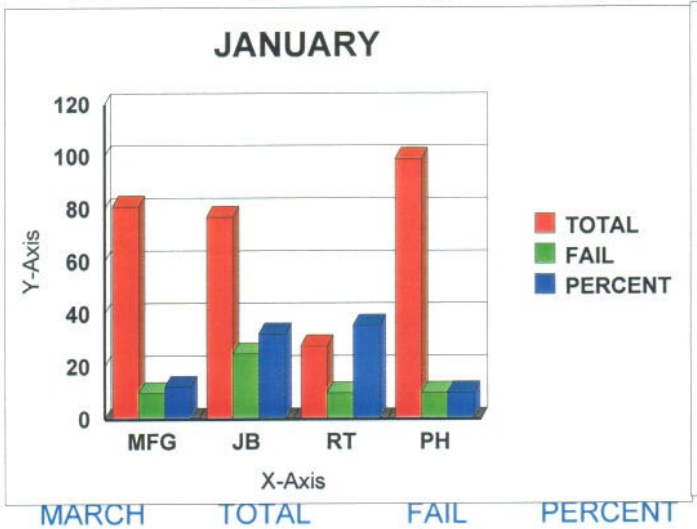


EPAIRS 200	TOTAL	PASS	FAIL	PERCENT
MFG	586	533	53	9.04
JB	1699	1588	111	6.53
RT	1591	1508	83	5.22
JLB	181	158	23	12.71
LL	61	59	2	3.28
JW	100	65	35	35.00
PH	489	467	22	4.50
TOTAL	4707	4378	329	6.99

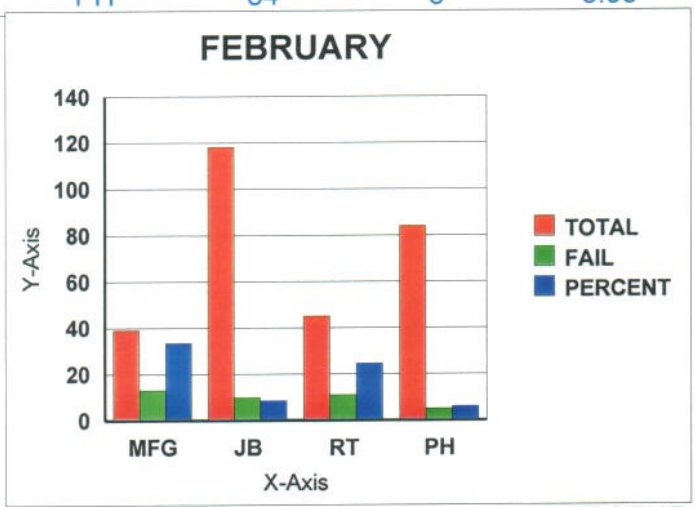
REPAIRS 2002



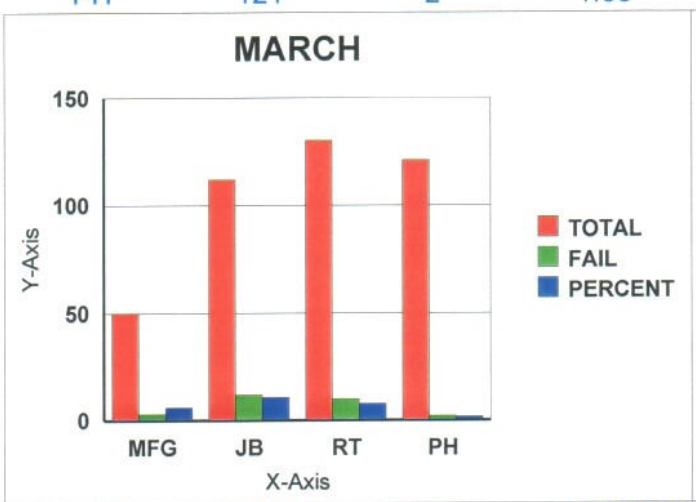
JANUARY	TOTAL	FAIL	PERCENT
MFG	81	10	12.35
JB	77	25	32.47
RT	28	10	35.71
PH	99	10	10.10



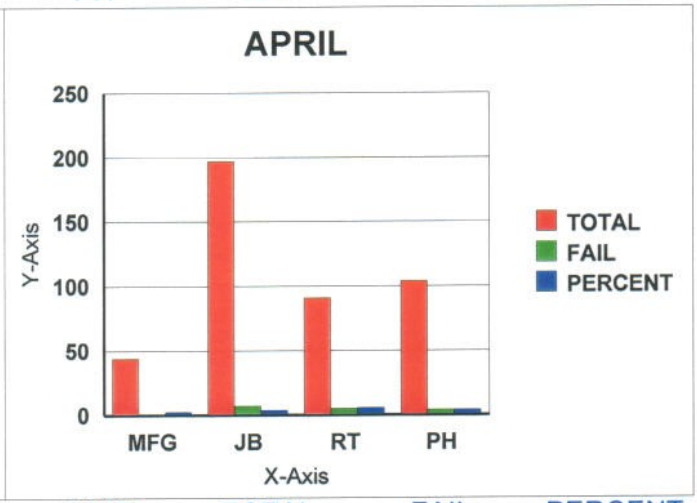
FEBRUARY	TOTAL	FAIL	PERCENT
MFG	39	13	33.33
JB	118	10	8.47
RT	45	11	24.44
PH	84	5	5.95



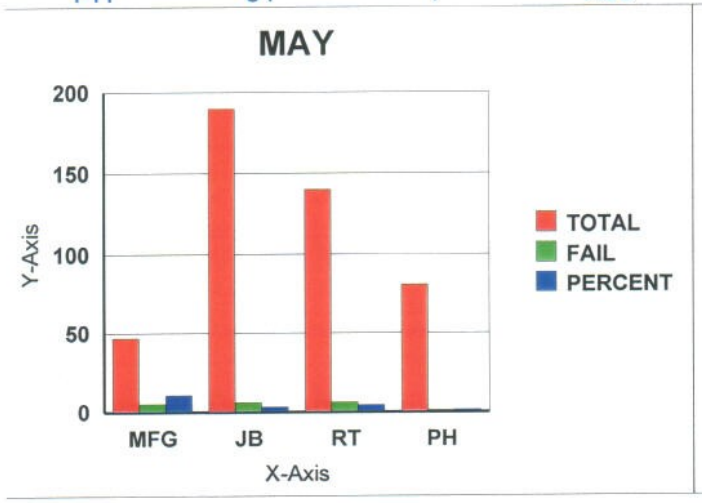
MARCH	TOTAL	FAIL	PERCENT
MFG	50	3	6.00
JB	112	12	10.71
RT	130	10	7.69
PH	121	2	1.65



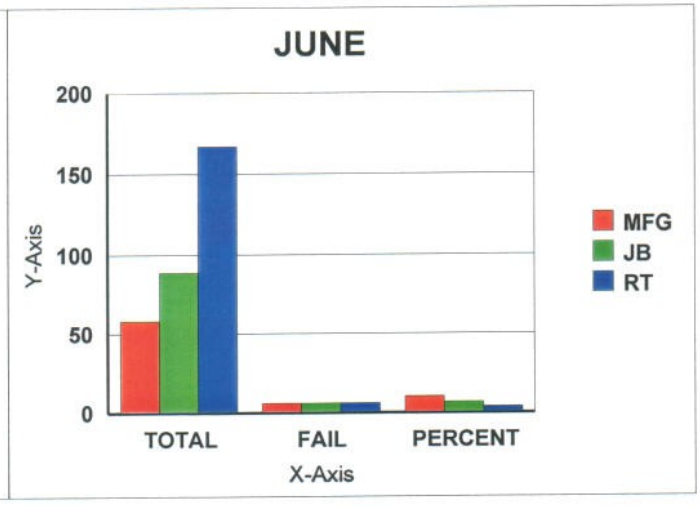
APRIL	TOTAL	FAIL	PERCENT
MFG	44	1	2.27
JB	197	7	3.55
RT	91	5	5.49
PH	104	4	3.85



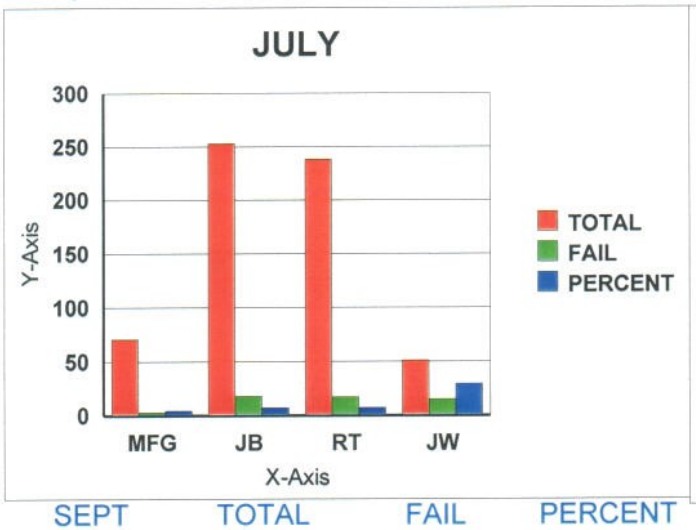
MAY	TOTAL	FAIL	PERCENT
MFG	47	5	10.64
JB	190	6	3.16
RT	140	6	4.29
PH	81	1	1.23



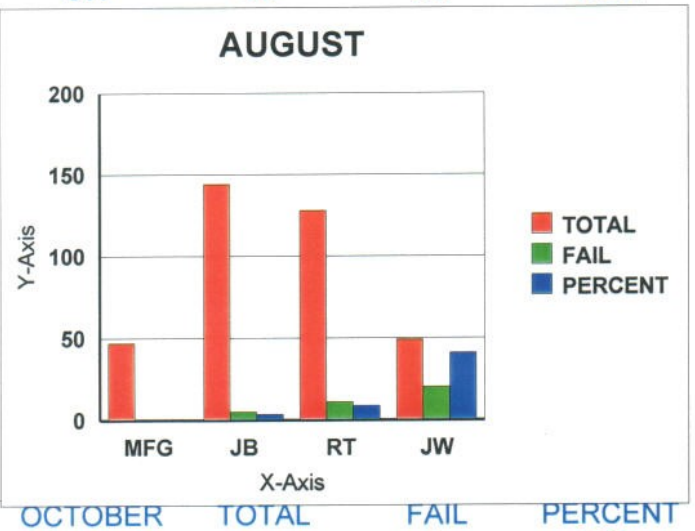
JUNE	TOTAL	FAIL	PERCENT
MFG	58	6	10.34
JB	89	6	6.74
RT	167	6	3.59



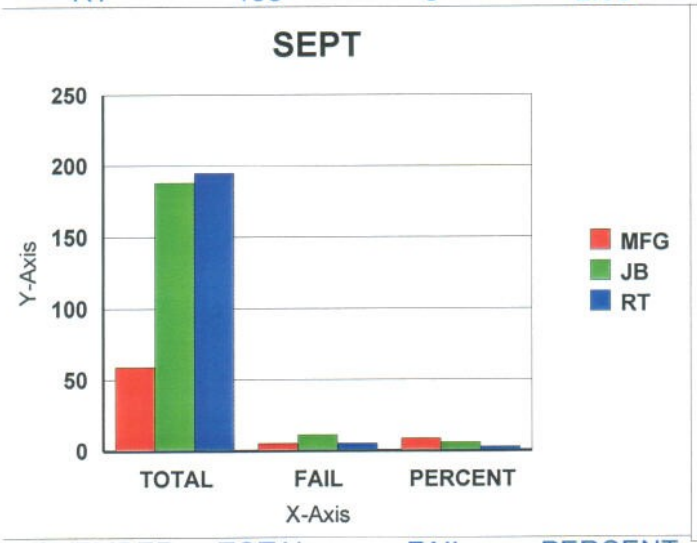
JULY	TOTAL	FAIL	PERCENT
MFG	71	3	4.23
JB	253	18	7.11
RT	238	17	7.14
JW	51	15	29.41



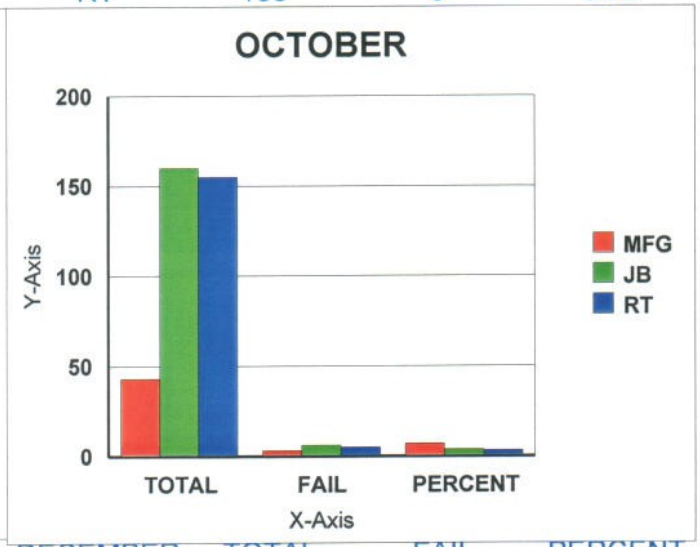
AUGUST	TOTAL	FAIL	PERCENT
MFG	47	0	0.00
JB	144	5	3.47
RT	128	11	8.59
JW	49	20	40.82



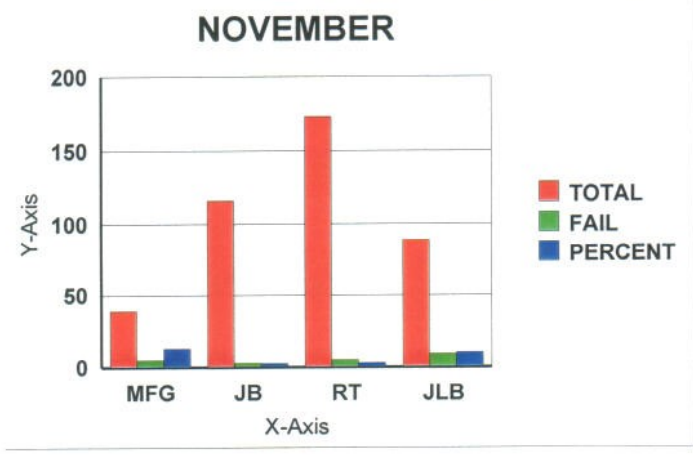
SEPT	TOTAL	FAIL	PERCENT
MFG	59	5	8.47
JB	188	11	5.85
RT	195	5	2.56



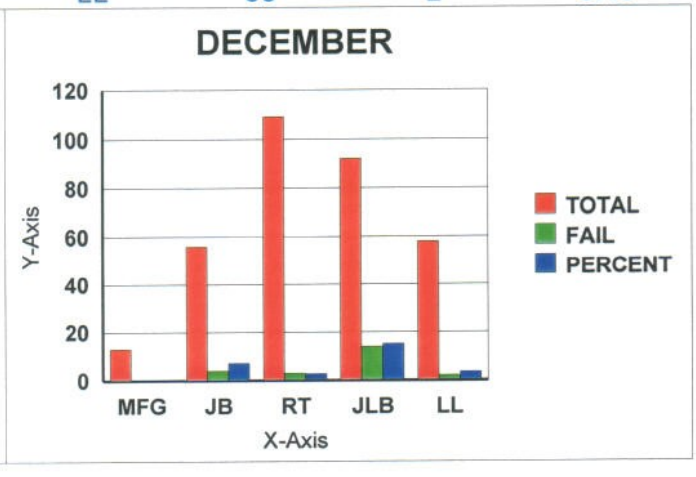
OCTOBER	TOTAL	FAIL	PERCENT
MFG	43	3	6.98
JB	160	6	3.75
RT	155	5	3.23



NOVEMBER	TOTAL	FAIL	PERCENT
MFG	39	5	12.82
JB	116	3	2.59
RT	173	5	2.89
JLB	89	9	10.11



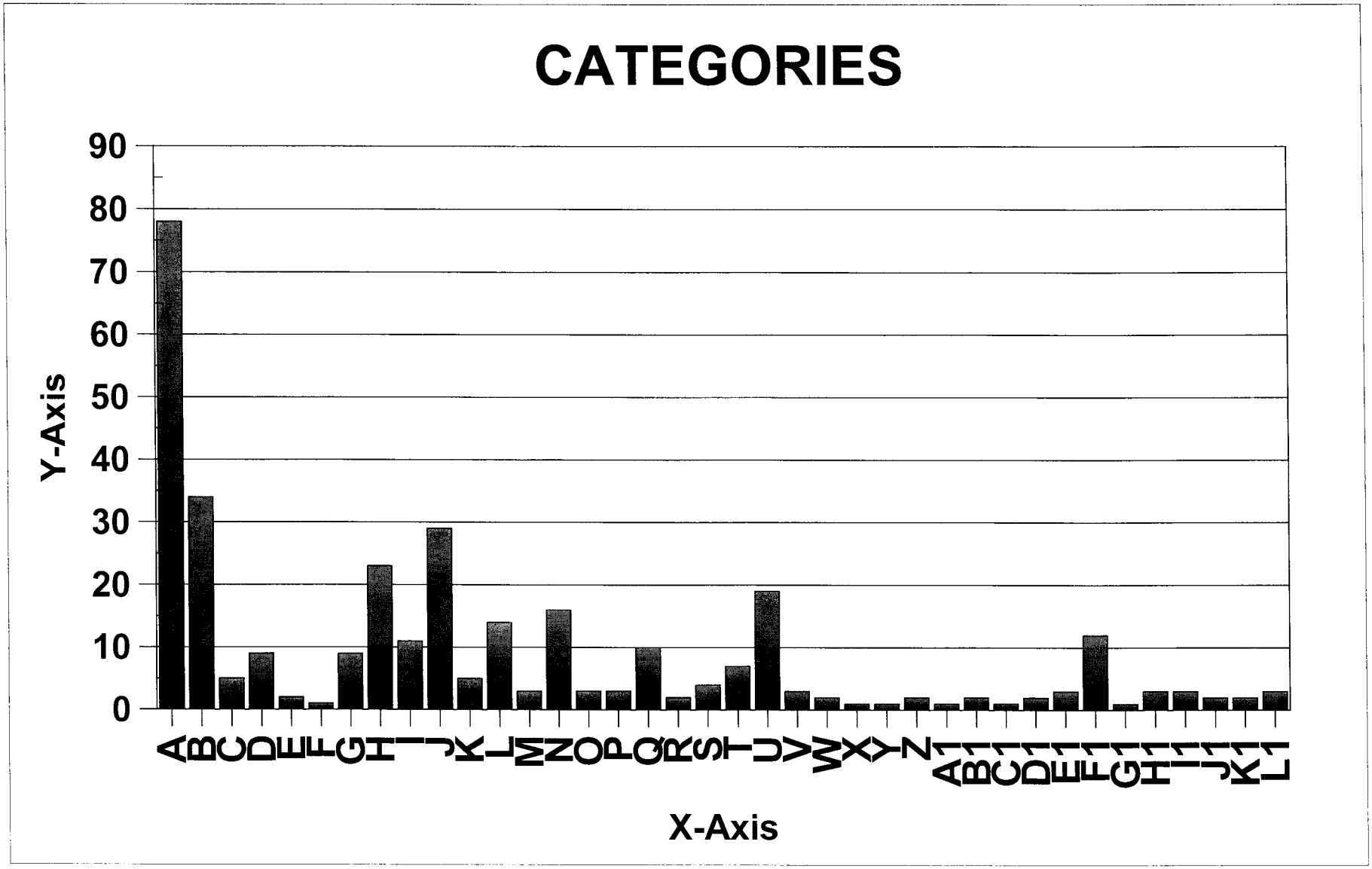
DECEMBER	TOTAL	FAIL	PERCENT
MFG	13	0	0.00
JB	56	4	7.14
RT	109	3	2.75
JLB	92	14	15.22
LL	58	2	3.45



Faulty L.E.D.	No finger reading	Faulty Shield
Faulty red light	Low finger reading	Faulty resistor
Faulty infrared	No DL reading	Damaged connector
L.E.D. wrong way round	Low DL reading	Damaged pins
Faulty sensor	High DL reading	Monitor switch-off
Sensor wrong way round	Intermittent readings	Incompatible probe
		Faulty Cable
		Faulty strain relief
Faulty L.E.D. window	Wrong pads	Faulty labelling
Faulty sensor window	Wrong buttons	No shell sticker
L.E.D. pad marked	Wrong pad mounts	Incorrect dumbbells
Sensor pad marked	Shell not dremelled	Incomplete paperwork
Lumpy pads	Cracked shell	
Pad bloom	Dirty shells	
Pad split	Dirty pads	
Glue / silicone on pads	Dirty cable	
Excessive glue		

STATISTICAL BREAKDOWN OF FAULTS (REPAIRS 2002)

Faulty Sensor	78	A
Faulty L.E.D.	34	B
Faulty Red Light	5	C
Faulty Infra-red	9	D
Faulty Shield	2	E
Faulty Resistor	1	F
Sensor wired wrong	9	G
L.E.D. wired wrong	23	H
No Finger reading	11	I
No DL reading	29	J
Low Finger reading	5	K
Low DL reading	14	L
High DL reading	3	M
Intermittent readings	16	N
Monitor switch-off	3	O
Incompatible Probe	3	P
Damaged Connector	10	Q
Damaged pins	2	R
Faulty L.E.D. window	4	S
Faulty Sensor window	7	T
Faulty strain relief	19	U
Faulty cable	3	V
Wrong pads	2	W
Wrong buttons / pad mounts	1	X
Dirty pads	1	Y
L.E.D. pad marked	2	Z
Sensor pad marked	1	A1
Lumpy pads	2	B1
Pad bloom	1	C1
Pad split	2	D1
Glue / silicone on pads	3	E1
Cracked shell	12	F1
Shell not dremelled	1	G1
Excessive glue	3	H1
Faulty labelling	3	I1
No shell sticker	2	J1
Faulty dumbbells	2	K1
Incomplete paperwork	3	L1


CATEGORIES
90
80
70
60
50
40
30
20
10
0
Y-Axis
X-Axis

Paperport

Introduction

Paperport is an electronic filing and storage system.
Imagine a Filing cabinet with drawers and individual files.
Some files can be opened by anyone in the company others are restricted.
In Paperport the files open to all start with a letter (A)

Electronically there can be more levels of filing than in a paper system
e.g.
Take ISO.
All our ISO files are found (D) ISO Information Level 1
There can be many or few major groups of files in Level 1
In the ISO system we will usually have 6 or 7
(D) BSI information
This contains basic information on BSI
(D) ISO Quality Manual
This contains the latest and most current Viamed company Quality manual
(D) ISO EN Documentation
This contains the actual BS : EN ; & ISO standards
(D) ISO 9000 Current (year)
This contains all the current company procedures
Manufacture
Repairs
Administration
QA procedures
Office procedures
Vandagraph procedures
(D) Management reviews
This contains the Management review minutes

(D) ISO 9000 2000 ISO 13485
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New Information should be scanned into ppupdate
Upgrades
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Add a postnote with the modification or highlight the errors and add text.
Print the modified page to Paperport either black & white or colour.
CHECK The graphic is set to 200 dpi or 300 dpi

Management Review 2002

QA overview discussed (see Quality Assurance document)

Contract Review Picking Packing & Despatch

"Opera" system in use :

More users to be added

More features to be opened up in 2003

Multi-warehouse; B.O.M.; Vendor assessment: Return to Vendor

Has it speeded up throughput : Yes

Reduced mistakes.: Yes

Outstanding. Long delivery notes causes crashes. Add extra blank line

Purchasing Controls

Companies

Poor deliveries

Part deliveries

Supplier\Sub contractor Performance

Rate **A. B. C. D. E.** To be started by Helen lamb and reviewed at monthly meetings

Supplier	Quality of Product	Delivery Times	Accuracy
Teledyne			
Dolphin			
Technomed			
Appleyards			
PDI			
Osco			
RS			
Farnell			
Electromed			

Storage & Stock Control

Annual full stock check at Dec 31st. 2001 externally audited by accountants.

Was stock accurate?: Yes

Errors in ECG cables due to Technomed: to be corrected 2003

Customer complaints

Still at a low level and completed in reasonable time frames:

To be logged better via Goldmine. Will need new procedure written in.

Existing paper complaints have been scanned into paperport. Paper system used in parallel

Calibration

No problems for ISO9001 no updating required.

Documentation & Records

CE & Design files need updating in 2003 continuous process: added to by changes in MDD

New drawings for:-

SpO2 Probes production}

Extension cables production } needs final verification

Repairs.}

ISO 9000 2000 procedures Target June 2003

QA manuals : To be upgraded for new and existing non SpO2 products into new format (SW)

Existing procedures under review and new versions being upgraded to take Golmine and Opera into account: includes Goods IN, Picking Packing and despatch.

Backups are too big for floppy disks so are now on CDROM.and hard disks. (10-15GB)

OPERA, Goldmine are backed up daily.

Drive Z,T,&W daily.

Paperport at regular intervals.(monthly)

Training

Still ongoing: to be checked more frequently (HL)

First Aid courses any more required: Yes

HSE basic course requirements : New personel

Goldmine training required

Paperport training at company meetings

New Procedures written for : Paperport: Archiving: Checklist

Internal Quality Audits

All completed; no major problems. BS Audit produced problems mainly due to more stringent application of MDD and MDA interpretations in MDD Essential requirements and New Risk assessment.

2003 All exisiting CE files to be upgraded

All corrective actions and preventative actions have been addressed.

Weekly/monthly meetings reducing even further the minor errors in the system

Intranet

Does it need upgrading

ISO9001/EN46001

HSE Information

Technical Manuals

Production procedures

Repair procedures

Office administration procedures

Review of Responsibilities

Jason HarmerOffice Administration

Michael Green Overall responsibility for SpO2 Production, Repair and final outgoing QA

Stuart Vann Goods Inward including incoming QA, Stock control, Picking, Packing, Despatch 2003?

Kevin Rush QA procedures

Robert Tedder Recus cabinets/Tom Thumb construction & service (S.Vann)

James Brown Resus cabinets/Tom Thumb construction & service (S.Vann)

Mark Southgate Goods in

Simon Watmough Technical services

Helen Lamb Internal Audits

Resources

Stock. Teledyne spares: Rare but Teledyne parts do cause problems. To be listed and new stock levels instituted (DL SW.)

Engineering: Requires Test boxes (End January)

Kontron Datex sockets still required

QA: Extra space for QA Administration: extra person for routine production

Export

Sales

Quality Planning Required:

New Products

Possibly:-

New SpO2 Testers
Foetal simulator (EMC report required)
New services
Video cables
ECG cables
Eco Clips
Foetal transducer repairs
Expansion/ upgrade to SpO2 repairs
Test Equipment
Cable low ohmn tester
Equipment to test LED'd Voltage & current
Lighting changed for colour correction on visual inspection
Space
New extension 2002 almost complete with new office layout
Should increase control over stock and QA
New facilities for Incoming QA
Equipment
New construction Jigs
What progress
Hand tools and consumables standardised
New test box required for SpO2
Quality Planning
Procedures under constant review and continually upgraded when required by users
Weekly production/QA/Stock meetings.
Are they minuted correctly
Project meetings on a monthly basis
Achievement of Quality Policy.
2002 saw general improvements in the overall standard of QA
13485 & CDMAS
Advisory notices and recalls
None
Vigilance system
Complaints: Repair levels no sudden increases out of line with increase in sales.
Most batch problems are located before despatch

Surveillance cards still being sent out but very few are returned: Being abused : to be re-evaluated 2003

Best indication is the level of sales and repeat business and the number of distributors wanting the products.

Cotlids redesigned

Nufer heaters upgraded

MDA Queries

Nascor :

Nufer

Headboxes

Software Audits

Checklist

Present

John S Lamb

Derek Lamb

Steve Nixon

Stuart Vann

Michael Green

Jason Harmer

KevinRush

Siimon Watmough

Minutes:

John S Lamb

Friday, 17 January 2003

Management Review 2004

Contract Review, Picking, Packing & Despatch

Opera & Goldmine Data entry system now in operation, and ongoing
More features are being added to Goldmine, to assist in this area (DL)

New statistics show that throughput is now increasing
Problems are addressed in the weekly meetings, and solutions sought
This area will be monitored for effectiveness (KR)

Purchasing Controls

Efficiency of one person ordering was questioned – an appointed designate will now be added to allow for ease of order processing (RT)

Changing of the purchase order to request confirmation is to be looked at (DL)

Quarantine of purchased product is to be formalised (including Opera / Goldmine)
JSL to be informed by 01/10/04 of feasibility of returning product to supplier more efficiently (RT), and the use of the Approach database (DL)

Supplier Performance

Electromed was removed as a supplier
Technomed was downgraded to "E"

A review of the old grading system is to be undertaken (KR & RT)
Responsibility for supplier monitoring is now (RT)

Storage & Stock Control

The accuracy of Opera and Physical stock is improving and should be completed together with the move to the new warehouse (DL & RT)
The new warehouse will allocate a bay for antistatic precautions and controls

The non-conforming area is to be assessed with a view to disposing of any non-needed items (JSL & PA)

Waste efficiency will become more of a requirement within the next few months – to begin next year, all concerned will address this, on an ongoing basis

Customer Complaints

11 complaints received since January 2003
9 closed out in a timely manner
2 still open – Kettering (Datascope) & Addenbrook (Heater)

Availability for logging lower complaints is now functioning in Goldmine – personnel to be made aware of the coding (KR) – filtering is available for statistical purposes

Product Performance

A review of the last 6 months statistics show a 50% improvement on the figures from 2003 – in the main the failure rates are from the "A" category, which are a result of component faults. This will be monitored over the next 6 months (KR & MFG)

Calibration

Not all calibration has been done, but is now currently being completed (PA)
A review of the validity and periodicity of calibration items is to be undertaken to ascertain whether certain items actually need 12monthly checks (KR & PA)

Documentation & Records

The CE Files may need to be brought more up-to-date, this will be decided within the next week (JSL & KR)
All the Technical drawings for production have now been completed, including Tom Thumb drawings; new drawings will be completed as required (KR)

The target for the new procedures was completed on time and resulted in the new BS approvals (ISO 13485/2003 & 9001/2000 and CMDCAS)
All the current process procedures area being reviewed for compliance and validity, the new Opera and Goldmine procedures are more, user-friendly (KR).
New procedures for the production and repair products need to be reviewed and streamlined (KR & MFG)

Backup processes are now more tightly controlled with the use of mirror PC's and offsite server applications – Secondary data integrity and retrieval is controlled (DL)

Training

Competency levels have now been addressed and are in place for new personnel
Further Goldmine training may be needed for new staff (DL)

Internal Audits

Up to date (apart from design), but the format is being changed, as they are no longer fully viable due to a process driven system in place (KR)

Intranet

No problems in this area – additions to Goldmine are on an ongoing basis (DL)

Paperport is being reorganised for better user access (JSL & DL)

Review of Responsibilities

RT has now taken over Stock control / Picking & Packing / Despatch

KR now has full responsibility for Internal Audits

PR has now replaced SW on Technical Services

CS Goods Inwards

ES Tom Thumb construction

Resources Required

Production –	Staff required – 3 technicians? – 1 QA? - If disabled persons are considered, then access needs to be addressed (MFG)
Warehouse -	Re-design of space / layout for efficiency (RT) Computers required (2) (DL)
Mechanical -	Tom Thumb operations to be moved to a cleaner environment (DL) Engineering equipment to be moved round to the old Tom Thumb area and the Gas bottles caged in

Quality Planning and Policy

QA of cells etc. to be moved to the new warehouse (RT)
Test boxes still required for QA – ongoing project (PA - 2005)
Development QC to be increased (PA)
All hand tools in personnel tool boxes to be standardised (KR)
Weekly meetings now have the minutes entered electronically in Goldmine

2003 / 04 saw general improvement in the overall standard of Quality – especially with the attainment of 9001/2000 - 13485/2003 & CMDCAS. The policy for 2004 / 05 therefore, remains the same for now.

Advisory Notices and Recalls

1 Advisory notice received
Recall of the "2100 Pulse Oximeter" is still ongoing, but so far not all the of the customers have yet returned them – all information is in Goldmine Links

Vigilance System & Feedback

Vigilance is still functioning as normal

Complaints – The major complaint has been with the R23 & R15 sensors – but constant dialogue with Teledyne has resulted in the sensors now being of a better quality – this will be verified over the next few batches, with 100% testing (RT)

Feedback on all customer satisfaction / requirements / complaints / is now registered in Goldmine and can be filtered and / or reported for analysis. This also is the same for Mail-shots and customer targeting, and for reviewing any possible decline customers / orders

Changes to CE Marked Product

The Apgar Timer is being changed – ongoing project (PA)

The Microstim is being re-engineered – currently being worked on (PA)

Any Other Business

A Health & Safety Management Review meeting is to be scheduled (KR)

Persons Present

John S. Lamb

Derek Lamb

Kevin Rush

Peter Anderson

Michael Green

Robert Tedder