The Vickers SP 120 analyser:
an instrument evaluation

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Introduction
For logistic, if not economic, reasons the larger clinical chemistry departments handle much of their work by automated multi-channel analysis. Their commonest purpose—chemistry departments handle much of their work by automated multi-channel analysis. Their commonest purpose—

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Operation
Each day the process controller calculates the inter-reaction corrections and the phasing times for each channel, from an “Initial Tray” loaded with phasing material. As the run progresses, the software program calculates all the corrections and times taken from this tray are used throughout the day or until another Initial Tray is run.

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the sample number read by the laser beam. These results are the material of the provisional reports, printed individually per patient who is identified only by these three numbers.

With a remote terminal the patients' identification data can be typed in and, on a subsequent command, merged with the analytical data and again printed out, this time as fully identified patient reports.

The quality control program is run at the end of the day's analyses, to give mean, SD, CV and SE of the control sera tested that day. The same calculations can also be carried out for the patient data and this operation may be restricted by using exclusion limits.

A one-day summary of results is also printed, in alphabetical order of patients.

A 30-minute wash-through period ends the working day.

**Clinical laboratory evaluation**

The basic difference between the two systems is a shorter sampling time in the SP 120 complex, less than half that of the SMA 12/60, with consequent changes in the final colorimetric peak and the method required for reading it. These therefore were the aspects examined.

The sampling and wash times for both systems were measured with a stopwatch and compared with the theoretical values taken from the programming. Sample volumes — a direct function of sampling times — were calculated for each system from the weighed contents of 40 cups. The proportional volume of reagents used was calculated for two typical runs of 200 patients' samples.

**Linearity** was measured in a series of samples placed in ascending and descending order of concentrations. Adjoining duplicates of these samples were loaded and analysed once each on 3 days as part of runs standardised in the usual way, and the second of each duplicate pair of results was taken. For most channels the serum was Wellcomcontrol Autoset H, dissolved in less than the prescribed volume, and its aqueous dilutions to 80, 50, 40, 20 and 10 per cent. For the enzyme channels, sera from patients were mixed in known proportions to give a series of values.

Precision measurements, both intra-batch and inter-batch were made by a 20-day comparison of 10 sets of results from each system at high, medium and low levels using sera available from Technicon Co Ltd., for SMA post-maintenance performance checks. Drift was not measured separately but deduced from the precision measurements.

A high-concentration and a low-concentration serum were used to observe carryover. Wellcomcontrol Autoset H was taken for the high serum H and an aqueous 1:1 dilution of Ortho Diagnostic normal control serum as the low serum L. This measurement was taken on four days, on days 1 and 3 of which one sample plate of four low — high sequences (samples loaded as LLLLLHHHHLLLLHHHHLLLLHHHHLLLLHHH) were analysed, while on the 2nd and 4th day the sequences were reversed. There was one such run on both systems each day.

**Results**

The **sampling time** of the SMA 12/60 is programmed as 5 s, its **wash time** as 6 s, and the SP 120 program cuts these times to 25 s for sampling and a 5 s wash. The values found in practice are slightly but measurably different, 53 s and 4 s for the SMA 12/60 cut to 24 s and 3 s by the SP 120. **The sample volumes** aspirated during these times (mean ±SD of 40 measurements each) are correspondingly reduced from 2.05 ±0.012 cm3 to 0.94 ±0.022 cm3, a saving of over half the sample, with a more variable uptake (CV 0.59 for the SMA 12/60, 2.30 for the SP 120) which, given steady state conditions, does not seem to affect the overall precision.

There is also a saving in reagents used with these samples, though this is partly offset by the longer setting-up time required by the SP 120 system (about 40 min, twice that of the SMA 12/60 alone). A typical troublefree run of setting up the combined system and processing a batch of 200 samples with, in addition, their complement of standard and control sera, will require 66.5% of the reagent volume consumed for the same load by the SMA 12/60.

The system shows good **linearity** over the ranges tested for the individual channels. Linearity could be assumed for the SMA 12/60 but was checked in the case of albumin where at first sight the SP 120 results seemed less obviously linear: there was no difference between the two systems. Table 1 gives the slopes and intercepts of the regression lines for each channel together with correlation coefficients R and SD of the points about the fitted line.

**Analytical precision** was calculated on the results of the 20-day trial of high medium and low sera. Those runs with data due to malfunctioning analytical channels and faulty printouts which were immediately obvious were excluded. This left the data of runs showing their analytical precision and still containing any faults that could go undetected in the course of routine operation. Table 2 gives the number of days for each machine and each level of sera on which no exclusions were made. Table 3 gives the results of intra-batch precision as an average within-day precision value over the 20 day period. Table 4 places the inter-batch precision figures in their context by comparing them with the recommended values for the Technicon post-maintenance performance check.

There is no difference in performance of the urate and lactate dehydrogenase (LDH) channels, and in three others, total protein, calcium and low-level cholesterol (there is no difference at medium and high levels) precision is lower but not to a clinically noticeable degree. Two channels, bilirubin and aspartate transaminase (AST) give results that are noticeably worse at low concentration, and this being limited to the normal range, where the clinical context tolerates wide variation will be balanced against the definite fall-off in analytical precision.

Both channels right themselves at the two higher levels. The

| Table 1 | Linearity of SP 120 - SMA 12/60 complex analyser |
|---------|---------------------|
| Analysis | Units | R | Intercept | Slope | SD of Points |
| Total protein | g/l | 1.000 | 0.2 | 1.00 | 1.24 |
| Albumin | g/l | 0.988 | 7.2 | 9.55 | 5.83 |
| Calcium | mmol/l | 0.999 | 1.00 | 1.21 |
| Phosphatase | mmol/l | 0.999 | 0.99 | 1.75 |
| Cholesterol | mmol/l | 0.993 | 0.97 | 4.52 |
| Iron | µmol/l | 0.990 | -7.2 | 1.07 | 5.78 |
| Urate | mmol/l | 0.990 | 0.99 | 1.51 |
| Creatinine | µmol/l | 0.999 | 38.3 | 0.97 | 1.82 |
| Total bilirubin | µmol/l | 1.000 | -2.8 | 1.01 | 2.12 |
| Alkaline phosphatase | IU/l | 1.000 | -4.9 | 1.01 | 9.23 |
| LDH | IU/l | 0.999 | 14.9 | 0.99 | 2.07 |
| AST | IU/l | 0.994 | 3.0 | 1.05 | 4.74 |

| Table 2 | Number of days during the 20 day precision trial for which no exclusions were made as a result of obvious faults |
|---------|---------------------------------------------|
| Analysis | Low Serum | Medium Serum | High Serum |
| Total protein | SP 120 | SMA 12/60 | SP 120 | SMA 12/60 | SP 120 | SMA 12/60 |
| Albumin | 20 | 20 | 20 | 20 | 20 | 20 |
| Calcium | 19 | 19 | 19 | 19 | 19 | 19 |
| Phosphate | 18 | 20 | 19 | 20 | 19 | 20 |
| Cholesterol | 20 | 20 | 20 | 20 | 20 | 20 |
| Iron | 16 | 20 | 16 | 20 | 16 | 20 |
| Urate | 20 | 20 | 20 | 20 | 20 | 20 |
| Creatinine | 20 | 20 | 20 | 20 | 20 | 20 |
| Total bilirubin | 16 | 20 | 16 | 20 | 16 | 20 |
| Alkaline phosphatase | 20 | 20 | 20 | 20 | 20 | 20 |
| LDH | 16 | 20 | 17 | 20 | 16 | 20 |
| AST | 18 | 18 | 20 | 20 | 20 | 20 |
iron estimation appears precise only in mid-scale, and both ends of the range show very marked deterioration. We feel that the baseline value, which the SP 120 takes, may be interfered with by the early rise curve of the iron channel thus accounting for the lower SP 120 values. The SMA 12/60 iron method (using ferrozine) is a demanding one requiring exceptional attention to its upkeep, and it seems that its present form will not stand up to operation with half the sample at twice the rate.

Four channels show improvement in precision when operated under SP 120 conditions. These are creatinine and inorganic phosphorus, the clinically critical low level of albumin (at higher concentrations the two systems are equivalent) and alkaline phosphatase, particularly at the lower end of range.

An early impression — or perhaps suspicion — that mid-point precisions might be best, with a general falling-off at the end of ranges, was not confirmed by our results.

This impression does, however, remain in the inter-batch precision (Table 5). Here the variations in bilirubin and, again, iron stand out, together with the high-level alkaline phosphatase results. In the day-to-day measurement of AST the SP 120 system is preferable, though it now appears best in the clinically unimportant low range. For the rest, the two systems perform about equally. The levels of performance are generally acceptable except for high-level creatinine and low-level bilirubin, in both of which an inadequate performance in the

| Analysis                  | Units    | Machine | Low Mean | CV  | Medium Mean | CV  | High Mean | CV  |
|---------------------------|----------|---------|----------|-----|-------------|-----|-----------|-----|
| Total protein             | g/1      | 12/60   | 0.68     | 45.0| 1.51        |     | 1.04      | 62.0| 1.68      |     |
| Total protein             | g/1      | SP120   | 0.81     | 45.0| 1.81        |     | 1.40      | 62.0| 2.26      |     |
| Albumin                   | g/1      | 12/60   | 0.53     | 27.0| 1.96        |     | 0.62      | 35.0| 1.77      |     |
| Albumin                   | g/1      | SP120   | 0.48     | 27.0| 1.77        |     | 0.60      | 35.0| 1.72      |     |
| Calcium                   | mmol/l   | 12/60   | 0.029    | 2.02| 1.45        |     | 0.032     | 2.43| 1.32      |     |
| Calcium                   | mmol/l   | SP120   | 0.043    | 2.05| 2.08        |     | 0.057     | 2.44| 2.33      |     |
| Phosphate                 | mmol/l   | 12/60   | 0.045    | 0.84| 4.76        |     | 0.040     | 1.15| 3.44      |     |
| Phosphate                 | mmol/l   | SP120   | 0.029    | 0.81| 3.64        |     | 0.034     | 1.14| 2.98      |     |
| Cholesterol               | mmol/l   | 12/60   | 0.08     | 2.3 | 3.48        |     | 0.08      | 3.20| 2.59      |     |
| Cholesterol               | mmol/l   | SP120   | 0.11     | 2.2 | 5.15        |     | 0.13      | 3.10| 4.27      |     |
| Iron                      | mmol/l   | 12/60   | 0.43     | 18.8| 2.34        |     | 0.43      | 26.1| 1.66      |     |
| Iron                      | mmol/l   | SP120   | 1.91     | 31.0| 1.45        |     | 2.07      | 21.7| 0.95      |     |
| Urate                     | mmol/l   | 12/60   | 0.004    | 0.21| 2.11        |     | 0.005     | 0.40| 1.28      |     |
| Urate                     | mmol/l   | SP120   | 0.005    | 0.21| 2.12        |     | 0.006     | 0.39| 1.41      |     |
| Creatinine                | mmol/l   | 12/60   | 6.44     | 105.0| 6.14       |     | 1.81      | 340.0| 0.53     |     |
| Creatinine                | mmol/l   | SP120   | 4.91     | 92.0| 5.07        |     | 1.56      | 331.0| 0.47     |     |
| Total bilirubin           | mmol/l   | 12/60   | 0.72     | 14.50| 4.95       |     | 1.73      | 58.38| 2.98     |     |
| Total bilirubin           | mmol/l   | SP120   | 1.70     | 14.75| 11.50      |     | 2.34      | 60.5 | 3.88      |     |
| Alkaline phosphatase      | IU/1     | 12/60   | 2.44     | 14.2| 17.18       |     | 3.85      | 63.9 | 6.02      |     |
| Alkaline phosphatase      | IU/1     | SP120   | 1.59     | 21.3| 7.45        |     | 2.27      | 85.2 | 2.66      |     |
| LDH                       | IU/1     | 12/60   | 2.54     | 120.0| 2.12       |     | 2.12      | 227.0| 1.17      |     |
| LDH                       | IU/1     | SP120   | 3.63     | 112.0| 3.24       |     | 2.58      | 226.0| 1.14      |     |
| AST                       | IU/1     | 12/60   | 1.43     | 23.3| 6.13        |     | 2.63      | 47.2 | 5.57      |     |
| AST                       | IU/1     | SP120   | 2.29     | 19.5| 11.74       |     | 2.15      | 42.4 | 5.05      |     |

Table 4 Inter-batch precision of the two systems based on mean of daily means. Three sera (Technicon Ltd) at three concentration levels. Their inscribed values IV and values determined by the two systems are given in SI units, together with their variations (as SD). The SD or CV given with each analysis is the maximum acceptable variation for the post maintenance performance checks of the SMA 12/60 agreed by DHSS and Technicon Co Ltd.

| Analysis                  | Units    | IV Low SMA 12/60 | IV Medium SMA 12/60 | IV High SMA 12/60 |
|---------------------------|----------|-----------------|---------------------|------------------|
| Total protein             | g/1      | 45              | 60                  | 85               |
| SD 1.5                    | 0.6      | 27              | 35                  | 43               |
| Albumin                   | g/1      | 35              | 45                  | 82               |
| SD 1.3                    | 0.6      | 27              | 35                  | 43               |
| Calcium                   | mmol/l   | 2.00            | 2.50                | 3.00             |
| SD 0.038                  | 0.02     | 2.02            | 2.43                | 2.85             |
| Phosphate                 | mmol/l   | 0.50            | 1.30                | 2.10             |
| SD 0.33                   | 0.08     | 0.81            | 1.15                | 2.10             |
| Cholesterol               | mmol/l   | 2.6              | 3.9                 | 6.5              |
| SD 0.19                   | 2.3      | 2.2              | 3.1                 | 4.5              |
| Iron                      | mmol/l   | 0.05             | 0.08                | 0.11             |
| SD 0.012                  | 0.10     | 0.12             | 0.10                | 0.12             |
| Creatinine                | mmol/l   | 90              | 340                 | 620              |
| SD 3% at 180              | 5.8      | 97              | 331                 | 579              |
| Total bilirubin           | mmol/l   | 17              | 68                  | 140              |
| SD 1.7                    | 1.5      | 15              | 59                  | 127              |
| Alkaline phosphate        | IU/1     | 25              | 100                 | 200              |
| SD 5.0 at 200             | 21.3     | 14              | 64                  | 156              |
| LDH                       | IU/1     | 120             | 220                 | 400              |
| SD 25%                   | 21.3     | 12              | 227                 | 359              |
| AST                       | IU/1     | 25              | 45                  | 135              |
| SD 2.5 at 100             | 19       | 48              | 43                  | 124              |
SMa 12/60 method is further sharpened under SP 120 conditions. The same sharpening effect is seen in the iron method.

Neither intra-batch nor day-to-day precision data give any indication of a significant drift effect in routine running conditions but they do not disprove its presence. The SP 120 system improves the intra-batch analysis of AST, an SMA system, with a few instances (bad traces on the SMA 12/60) excluded. Carryover is apparently affected only the inter-reaction between viscous solutions, not its precision.

Negative values in the SMA 12/60 system probably have random causes; additional instances amongst the SP 120 results suggest over-correction by the inter-reaction calculation, and there are sixty cases in our SP 120 compared to twenty-three in the SMA 12/60 series. Even in its present form, however, the formula keeps carryover to an acceptable level inside the 5% limit.

### Discussion

Our teething troubles have been limited to the programming (and in particular its response to mechanical events in the SMA 12/60). Low concentrations on two channels (bilirubin and LDH) were on two occasions printed out as zero. On one occasion failure of a colorimeter lamp spilt two channels, but no error message was printed. An air bubble passing through the flow cell at a critical moment during Initial Tray readings may give a wrong phasing time, faulty inter-reaction calculation, or a high blank leading to falsely low results. Such a mistake occurred three times without an error message showing it, once while the bubble passing through the flow cell was observed on the oscilloscope. Conversely, on one occasion error messages were printed, though the oscilloscope had indicated normal function. A highly efficient debubbler or a further refinement in software is needed to exclude this possibility.

The instrument can print a wider range of results, at least twice that of the SMA 12/60 chart on some channels. The four optical density ranges expand the scale to an extent where the need to reanalyse above-scale samples almost disappears. Apart from a longer setting-up time and some deterioration in results (though improvement in others) the complex generally scores from a long set-up time and some deterioration in results (though improvement in others) the complex generally scores from a long set-up time and some deterioration in results.

The daily manual phasing procedure is also taken over entirely by the SP 120 program.

The complex is well adapted to operate routine SMA methods, but where they operate close to critical variables, these are magnified under SP 120 conditions. In particular, the Liebermann–Burchard-based cholesterol method requires added care, and the ferrozine iron method should not be installed. With these limitations, the SP 120 complex is a successful adaptation of the widely used SMA series of analysers.

The evaluation was carried out between January and June 1977. The manufacturers were informed of the teething troubles listed in this discussion and took these into account in subsequent modifications.

### ACKNOWLEDGEMENTS

The authors thank the Department of Health and Social Security for providing the system to be tested, Mr W. I. R. Martin, AWRE, Aldermaston, for the statistical calculations and the staff of Vickers Limited Medical Engineering for their co-operation.

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**Table 5** Ratios of between-day SD values: SD SP120/SD SMA 12/60

| Analysis          | Low concentration SD Ratio | Medium concentration SD Ratio | High concentration SD Ratio |
|-------------------|---------------------------|-------------------------------|----------------------------|
| Total protein     | 1.33                      | 1.50                          | 1.07                       |
| Albumin           | 0.50                      | 1.00                          | 0.89                       |
| Calcium           | 1.00                      | 1.18                          | 1.67                       |
| Phosphate         | 1.00                      | 1.00                          | 1.67                       |
| Cholesterol       | 2.00                      | 1.25                          | 1.09                       |
| Iron              | 4.60                      | 3.17                          | 3.00                       |
| Urate             | 1.60                      | 1.40                          | 1.14                       |
| Creatinine        | 1.07                      | 1.00                          | 1.22                       |
| Total bilirubin   | 2.14                      | 1.66                          | 2.07                       |
| Alkaline phosphatase | 1.44                  | 1.22                          | 2.03                       |
| LDH               | 1.31                      | 0.92                          | 1.29                       |
| AST               | 0.33                      | 0.52                          | 1.09                       |

SD ratios in the range 0.70 to 1.40 show no real difference between the machine for between-day precision. Ratios less than 0.50 give strong indication that the SP 120 has less day-to-day variation, and ratios above 2.00 indicate that the SP 120 has greater day-to-day variation than the 12/60.

**Table 6** Carryover. Mean 1% values of high-low and low-high sequences and the number of negative 1% results in each group

| Analysis | SAMA 12/60 | SP120 |
|----------|------------|-------|
| Total protein | 3.14/1     | 3.72/1 |
| Albumin   | 2.89/1     | 2.04/0 |
| Calcium   | 1.38/1     | 2.65/0 |
| Phosphate | 1.70/1     | 1.45/5 |
| Cholesterol | 4.47/0    | 6.33/0 |
| Iron      | 2.64/0     | 3.00/0 |
| Urate     | 1.08/0     | 1.78/1 |
| Creatinine | 1.31/1    | 1.72/0 |
| Total bilirubin | 1.67/0 | 1.03/7 |
| Alkaline phosphatase | 3.29/0 | 1.62/1 |
| LDH       | 1.46/0     | 1.95/2 |
| AST       | 2.90/0     | 3.84/3 |

| Analysis | SAMA 12/60 | SP120 |
|----------|------------|-------|
| High-low | 1.00/1     | 1.00/1 |
| Low-high | 2.00/1     | 2.00/1 |

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