INSTRUMENT

CHECK SYSTEMS

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Preface

The material in this monograph has been compiled over the last ten years from our experience in trying to check instruments, locate trouble, and eliminate it. It is interesting that at the beginning of this period, questions put to several company representatives were turned away with the comment that the instruments were better than any available means the user had for checking them; therefore, checking was not really necessary. Now the pendulum has swung—a full 180°. Some governmental regulations require that every function of each instrument be checked daily before using the instrument. There are, however, no directions yet available for checking every instrument. The check procedures now being worked out by users and manufacturers together will hopefully produce this information soon. Only with experience can checking procedures be evaluated and those eventually chosen that can reasonably be done at specific time intervals to safeguard the validity of the answers produced on the instruments.

General information about how a class of instruments works is not specific enough to check the function of individual instruments. We have therefore discussed specific instruments as examples of their class. The instruments chosen should not be considered as the best suited, or the least suited, for their purposes. They are the instruments with which we have had enough experience to work out the necessary checking procedures. While test directions are not exactly referable to other instruments, the points discussed for the examples can serve as leads to determine the precise information needed for other instruments.

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Instrument Check Systems

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General Principles for Instrument Check Systems

The overall objective of check systems for our instruments in the clinical laboratory is to restrict the variation of the instrument's function to such an extent that the general level of precision chosen for the laboratory tests can be maintained. Without digressing to a discussion of the philosophy of quality control, it is necessary to state the following concepts as the limiting factors for establishing the general level of precision chosen for tests in any one laboratory:

1. The normal range for the test must have been established for the particular procedure using the particular instrument in the particular laboratory.
2. The allowable error for the test must have been calculated. Tonks' formula is the most commonly used generalization:[9]

$$\text{Allowable limit of error in } \% = \frac{(\text{¼ of normal range})}{(\text{Mean of normal range})} \times 100.$$

Originally Tonks recommended that the allowable limit of error be ± 10%. Recently he modified this overall limit and suggested that ± 20% may be the best attainable limit for enzyme methods such as amylase, LDH, acid, and alkaline phosphatase.[10] Usually the allowable limit of error in percent is equated to ± 2 coefficient of variation (CV).

$$\text{Coefficient of variation} = \frac{1 \text{ Standard deviation}}{\text{Mean value}} \times 100.$$

Where standard of deviation (SD) is calculated by the replicate equation:

$$1 \text{ SD} = \pm \sqrt{\frac{\Sigma (\bar{x} - x)^2}{n}} .$$

3. The actual day-to-day error, or ± 2 SD control values, must have been plotted and monitored. Not all tests will fit into Tonks' allowable error, but we must strive to limit the error to this value whenever possible and practical.
4. The value chosen for the control must, if possible, be that which most quickly detects problems within each test procedure for the particular constituent being determined.

When the general level of precision for laboratory tests is held within the limits thus described, the amount of error allowed for instruments must be held to a minimum. This is not easy to do, and if the instrument is not constantly monitored, the instrument alone can cause more error than is allowed for the whole procedure. On the other hand, out-of-control values are sometimes wrongly blamed on an instrument.

Failure to recognize two rather elementary contributions to laboratory performance of instruments can nullify the effectiveness of the most carefully constructed check systems for specific instruments. These include proper respect for the electrical circuits, especially grounding, and careful attention to basic equipment.

Stacy has estimated that 90 percent of the difficulties involved in instrumentation result from overloaded power lines or 60 cycle interference.[7] Many of these problems have been minimized by the manufacturers of our current instruments by such means as:

1. Including stable transformers within the instrument itself.
2. Shielding sensitive parts of the circuits, especially input leads.

3. Building containers for low-level impedance stages of the circuit.
4. Providing adequate grounding between the components of the instrument.

However, as Stacy points out: "None of these shielding measures can be effective unless the ground to which one attaches the shielding and the ground side of the circuit actually make good electrical contact with the ground of the power lines supplying the building." The radiators and water pipes frequently used as grounds in the laboratory are unsatisfactory for current sophisticated instruments. Many newer laboratories have "three prong" outlets and use only "three wire" plugs from instruments. However, to be an effective ground, the outlet must be connected to an earth electrode of low resistance. The entire system of the institution should be periodically reviewed and checked for the *actual* earth resistance of the system.[5] Factors that may change the grounding system include the following:

1. A plastic pipe or conduit coupling can completely nullify the low-resistance path to earth.
2. If the water table is gradually lowering, what was formerly an effective ground may result in simply an electrode in dry earth of high resistance.
3. Resistance of the soil increases with decreasing temperature so that during below-freezing periods the grounding system is much less effective.
4. Expansion of facilities, especially computer and communication systems, quickly overloads the grounding system.

Inadequate grounding is more dangerous than no grounding because it promotes a sense of false security.

As long as the grounding system is basically sound, a grounding plug may be used in one outlet of a double receptacle and a sensitive instrument in the other to reduce small interferences. Figure 1-1 illustrates the plug we find useful for the Coulter Counters and pH meters. The common side of the line is connected by a ½ amp fuse to the ground. One certainly cannot use such a plug until an electrician has actually verified that the wiring is standard and that the feedback on the

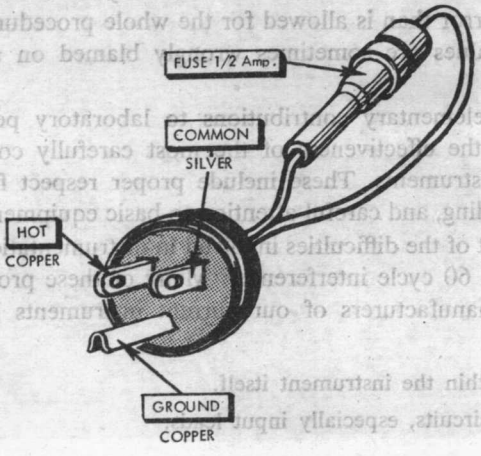

Figure 1-1. *Grounding plug for reducing line interference.*

common line is minimal. The user must also be careful to avoid ground loops when plugging several pieces of equipment together; only one ground is allowed for such combinations.

All laboratory personnel should be instructed concerning electrical hazards commonly present in the laboratory. The slightest shock felt while using equipment should be reported immediately, and the equipment should not be used again until it has been repaired. Low current of only 20 milliamperes through the body can cause fibrillation, and 100 milliamperes is almost certain to be fatal.[8] A résumé of safety precautions can be aptly quoted as a list of "Don'ts," author unknown.

DON'TS

1. Don't by-pass fuses with jumpers, coins, etc.
2. Don't increase capacity of fuse before ascertaining circuit conditions.
3. Don't replace a fuse more than once unless you know why it has blown and have remedied the fault.
4. Don't work on equipment when hands or clothing are wet.
5. Don't risk contact between live circuits and rings, wristwatches, bracelets, zippers, etc.
6. Don't ever take shock intentionally. Testing outlets with the two-finger method is a way of demonstrating stupidity.
7. Don't use solvents containing alcohol for cleaning electrical equipment. Alcohol damages most types of insulation varnishes.
8. Don't use spring clips for grounding portable equipment.
9. Don't use water, soda and acid, foam, loaded stream or anti-freeze types of fire extinguishers on electrical fires. They may cause fatal shock. Use dry chemical, carbon dioxide, or vaporizing liquid.

The function of such basic equipment as water baths, centrifuges, and timers must be monitored consistently. Medicare regulations require that records show this information.[3,4] However, each institution must establish practical time sequences and details for complying with the statement: "all equipment is in good working order, routinely checked and precise in terms of calibration."

A general classification of these items includes:

1. Temperature controlled spaces—Check temperature measuring devices against a National Bureau of Standards (NBS) certified thermometer. Some refrigerators and incubators must be equipped with a recording temperature device.
2. Autoclaves—Kilit Ampules* are convenient to check for adequate sterilization.
3. Balances—Evaluation includes condition of knife edge and pans. When one stamps on the floor, does the free-swinging pan vibrate? Are NBS weights used

*Available from BioQuest, Division of Becton, Dickinson & Co., Cockeysville, Md.

to check calibration? It is simpler to subscribe to a service contract from a reputable company than to attempt to check or service sensitive balances.

4. Centrifuges—Check various speeds with a photo-tachometer. Check the time and speed required to produce a constant volume for packed blood cells.
5. Timers—Check with reliable stopwatch.
6. Power supply, batteries and light sources—Check their output.
7. Volumetric measuring apparatus—Check calibration and delivery against certified equipment. From our experience it is impossible to check all items; spot checking appears the only practical approach.
8. Shakers and rotators—Check frequency of shakers and rotators for a given time period.

Ideally, the original evaluation of the instrument should also include a specific set of check procedures that can be recorded for later comparisons. In reality, laboratories presently fall short of the ideal situation for two reasons: (1) incomplete original evaluations are the usual circumstance for instruments that have been in use for some time, and (2) specific sets of check procedures for instruments have not been well identified. A suggested protocol for the original evaluation of automated instruments recently published could well be used also for other instruments.[2, 6] A generalized outline of this protocol is printed as the *Appendix,* page 307. Specific check procedures are also being developed slowly by individual users and manufacturers of instruments. There is, therefore, hope of approaching the ideal goal. Meanwhile, technologists can work with what information we do have to monitor instruments more effectively.

By judicious selection of the level of the control value to pinpoint the most vulnerable point on the calibration curve due to either the instrument or the procedure, the medical technologist can eliminate unnecessary control samples and also choose the most likely level at which a control value will detect a change in the instrument. For example, any colored solution read on a Coleman Junior spectrophotometer may be represented by Curve A of Figure 1-2. This example is the calibration of the Babson method for alkaline phosphatase.[1] Curve A is almost a straight line, and this is the response to be expected for a new photocell. Curves B and C, although they are the calibration curves for other Coleman Junior spectrophotometers, demonstrate the changes in slope for this calibration curve when the photocell ages. From A to B to C occurs with any colored solution when calibration curves are compared over a long period of time. If the chosen control value is at the high end of the calibration curve, this changing calibration curve will be readily detected. In Figure 1-2, a control value of 120 units would be ideal. When this principle is applied to the hemoglobin calibration curve, a value of 16 grams is the most efficient control range. With this range, the calibration change can be detected long before most of the patients' values are affected.

Still considering hemoglobin, two examples come to mind for out-of-control values that cannot be blamed on the spectrophotometer. The first instance involves shifts in the maximum absorbance wavelength for oxyhemoglobin when water used in the reagent (sodium carbonate) contained either ammonia-like contaminant

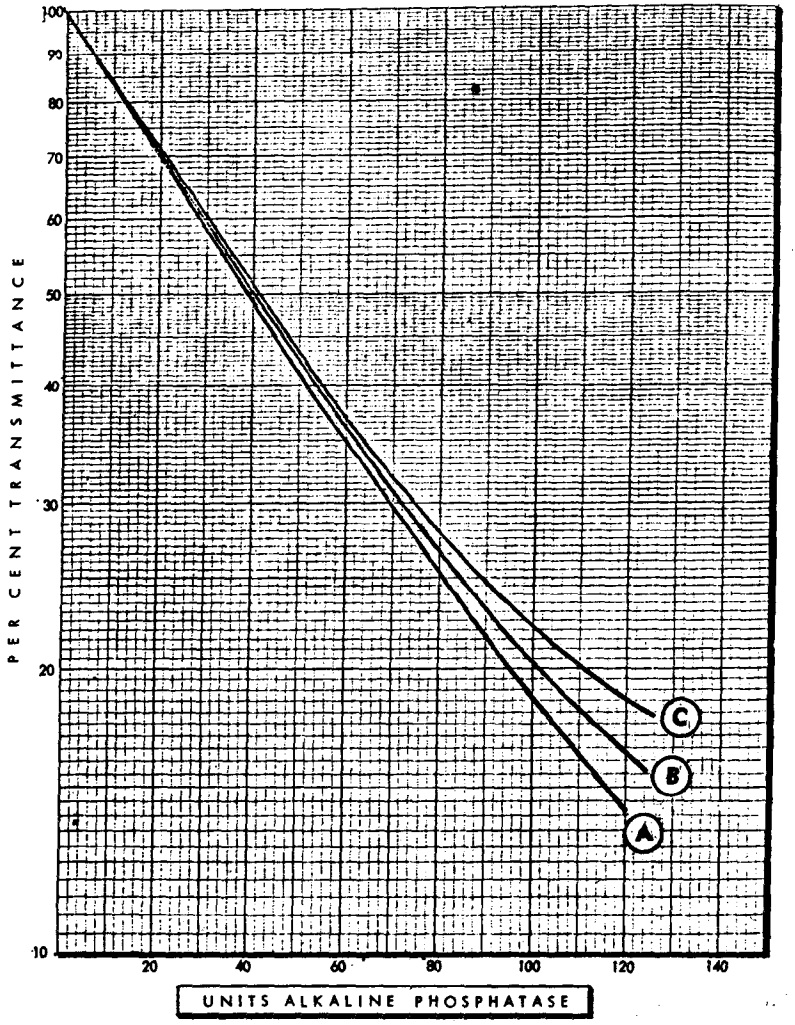

Figure 1-2. *Calibration curves for Babson alkaline phosphatase method using Coleman Junior spectrophotometers.*

or copper. The narrower the slit width, the more readily this shift will show up. Therefore, varying results will be obtained with routine colorimeters using 550 mμ filter, and/or the Coleman Jr. and Beckman DU spectrophotometers at 540 mμ. The second instance involves the cyanmethemoglobin method when the diluent requires approximately 20 minutes to produce a solution with correct spectral characteristics. In this test the usual reading time of 2 to 5 minutes gave answers as much as one gram higher than the correct value.

One must, therefore, consider as many factors as possible in choosing the checking procedures for laboratory tests. To be considered are the peculiarities of

the instrument, the tests for which it is used, the reagents, and the people using the instrument. If the operator of the instrument can be persuaded to keep an accurate record of problems (symptoms, causes, and cures), this information can form the backbone of the check system for that instrument. There must be enough checkpoints to detect trouble with an instrument, but the system must remain practical. If a checkpoint doesn't really provide information after a reasonable trial period, it should be dropped. Laboratories have no time to play games; efforts put into all procedures must be well spent. Also there must be willingness to change even the best thought-out checking procedures. Instruments are continually being changed, and new instruments are being introduced. The process of building check systems must likewise change to keep the checking process valid.

Check systems for instruments mean different things to the three types of people involved with instruments: the manufacturer, the electronics technician, and the laboratorian. Their approaches will vary in relation to their own degree of expertise in electronics.

The manufacturer must ascertain that each component of his instrument meets his specifications. *Component* here relates to small single parts or to subunit modules. Often the equipment used to check the instrument is much more costly than the instrument itself. Therefore, the checking procedure used by the maker often cannot be directly followed either by the service department technician or the user. In the past, it has sometimes been hard to get from manufacturers specific information about how to check instruments. Even yet, schematics are sometimes withheld from the purchaser under the stated reason of protecting the privileged information of the manufacturer. More often the manufacturer has been reluctant to have repairs attempted by people less qualified than factory-trained representatives. As more instrumentation is used in medical laboratories, there is a growing need to include on the institution's staff electronics personnel who can service the instruments. Manufacturers are being requested to provide sufficient information about the instruments to allow as much repair work as possible in the field in order to decrease "downtime" of the instruments. The ideal working arrangement includes the cooperative efforts of the manufacturer, the electronics technician, and the operator; more and more such joint efforts are evolving.

The approach of the electronics technician is usually to get as much information as possible about malfunction from the operator of the instrument and then to attack the schematic. To him the output of the instrument is the final indication of malfunction. He will either work backward from the output or frontward from the input to isolate the defective electronic component. Stacy has broken down the lines of attack into five categories:[7]

1. Too little output per unit of input signal.
2. Zero level drift.
3. Varying gain or random instability.
4. Nonlinear output.
5. Oscillation.

He further develops each category into the systematic isolation of the cause of the problem. The user with enough time and electronic know-how may want to refer to Stacy's approach. Most electronic technicians have their own step-by-step isolation procedure. The most difficult problem to isolate is the one that appears intermittently. If the electronics technician does not happen to be able to catch this problem and isolate it (often by substitution of parts), he will usually react in one of two ways:

1. If he is located in the institution using the instrument, he will watch the instrument and wait for the malfunction to show up—hopefully with more definite and permanent symptoms. Once the problem has progressed this far, the defective part can be replaced. Meanwhile the observation of symptoms serves to provide experience for future similar episodes.
2. If the electronics technician is located in a service department some distance from the institution, his tendency is to replace any suspicious parts. Often the exact cause is never isolated.

The user's approach must be guided by what symptoms he can observe in the normal or correct operation of the instrument and the differences he sees when malfunction exists. By a deliberate process of learning what to look for in each instrument and observing the likely vulnerable portions of its function, the persistent operator can build his own check system. Once he has convinced the manufacturer and the electronics technician that he does share the responsibility of a properly functioning instrument, a joint effort can produce both check systems and maintenance programs.

At the South Bend Medical Foundation, Inc., our first efforts toward building a check system were centered around spectrophotometers. The final "system" includes ten functional characteristics: zero and 100%T, reproducibility, noise and/or drift, resolution, linearity, detector response, source of energy, stray energy, signal control (slit width, amplifier, or gain), and energy selector (wavelength calibration). Once these characteristics were determined to be essentially those necessary to check spectrophotometers, we began looking at other instruments.

The same parameters can be generalized, and similar functions can be identified in other instruments. All instruments have functions which must be checked for zero and maximum response, reproducibility, noise and/or drift, and linearity. Detector response represents the final signal that is translated into a measurable reaction; the count registered on the Coulter Counter, or the titration time of the Cotlove can be envisioned as a similar function for these instruments. Stray energy can be used to designate background counts for the Coulter, overshoot for the end point in the Cotlove, or even emission from contaminating substance used with a flame photometer or fluorometer.

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2

Spectrophotometers

The three most commonly used types of photometers have different levels of performance and degrees of instrumental sophistication. These photometers may be characterized as:

1. Simple instruments using filters and relatively insensitive components and limited to a few tests.
2. Wide bandpass spectrophotometers of intermediate complexity capable of reading most color-reaction tests.
3. More complex (narrow bandpass) spectrophotometers that permit assigning absorbance (OD) change to extinction values or kinetic studies.

The latter type has sufficient capacity for resolution to identify absorption peaks and to scan.

The performance of each instrument must be monitored, but the manner of monitoring increases in complexity in relation to the sophistication of the instrument. Most of the studies of performance have used data obtained with instruments in the third category. Wernimont used matrix algebra operations to examine the behavior of complete absorbance curves obtained with both simple instruments and group three types of instruments.[62] These conclusions were drawn from this study:

1. The instruments used in many laboratories are not well controlled.
2. Performance will not be improved merely by conducting more comparison studies.