STERILIZATION OF SYRINGES BY INFRA-RED RADIATION

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The introduction of sterile syringe services into hospitals in Britain has focused attention on the inadequacies of the present methods of sterilization. Hitherto the normal practice has been to use either steam sterilizers or hot air ovens. The principal disadvantage of the former is that they are expensive to install, and their present design leaves much to be desired (Bowie, 1955). Furthermore, syringes cannot be sterilized assembled or lubricated, and the syringe containers, whether multiple or single, must be so constructed that steam can freely penetrate to all surfaces of the syringe (Stewart, 1957; Darmady and Hughes, 1955). After sterilization a separate process is necessary to seal the containers before distribution to the user.

Although syringes in their containers can be sterilized presealed in a hot air oven, a hot air oven also has its disadvantages. In a previous communication (Darmady and Brock, 1954), it was shown that many hot air ovens at present manufactured show considerable variation of temperature from one part of the oven to another, and that even distribution of heat can be achieved by a fan. Even then the "load" must be limited and carefully arranged. Another difficulty is that the time taken to reach the sterilizing temperature (usually considered to be 160° C.) is lengthy, and in most instances is about 50 minutes. To ensure sterilization, a further holding time of half an hour to an hour is necessary, the total process taking a minimum of 80 minutes. Such a time may seriously interfere with the smooth flow of work, and may necessitate a number of hot air ovens. For these reasons it was decided to search for a form of sterilization which would fulfil as far as possible all the necessary criteria. These are:

(1) That all articles should be sterilized ready assembled in presealed containers.

(2) That all the articles should reach the sterilization temperature in the shortest possible time.

(3) That all articles should receive the same treatment.

(4) That the sterilization process should be of simple operation and continuous in action.

Construction of the Apparatus

The apparatus consists of a metal moving belt designed to move at 4 in. a minute (Fig. 1). (This speed was selected as the result of time and motion studies by Brigadier Welch, of the Nuffield Provincial Hospitals Trust, as being the optimum time necessary for an orderly to fill and load a tray with syringes.) The syringes were placed in single layers on trays which were constructed of galvanized sheet metal of a pattern normally used for baking in the hospital kitchen and were therefore robust and cheap. They measured 17 by 11 by 1½ in.

As soon as the trays were loaded they were placed on the moving belt, and then passed into an insulated tunnel over which "infra-red" projectors were placed at predetermined positions. For this investigation it was decided to use projectors that were available commercially. The projector consists of three elements surrounded on one side by a convex, highly polished metal reflector. Such projectors have either a 4 KW. or a 2 KW. load, and are fitted with regulators to supply a high, medium, or low output of heat. They were placed at right angles over the moving belt. Four in all were used; the first two ensured that the syringes were brought to the sterilizing temperature, and the remaining two that the temperature was maintained for the requisite period of time. Before the apparatus could be put into routine use, a number of investigations were necessary.

Heating-up Time

The time taken for the syringes and containers to attain the sterilizing temperature was first considered. For this purpose, a 2 KW. projector was placed 4 in. above the bench. The assembled syringes in various containers, into which a thermocouple had been placed, were exposed under the centre of the projector, and readings obtained at half-minute intervals. (The method of preparing a syringe and container for thermocouple readings is described later.)

FIG. 1.—A general view of the infra-red moving belt sterilizer in use. A syringe orderly is placing the trays of syringes in presealed containers on the moving belt before sterilization.

The results are shown in Fig. 2. It is seen that a 2 ml. syringe placed in a pyrex test tube reached 180° C. in approximately three minutes after being placed under the projector, whereas a syringe in a dull black, anodized container of the London Hospital pattern took between three and a half and four minutes, and a syringe in a dull, aluminium Nuffield container approximately four and a half minutes.

A 20 ml. syringe in a pyrex glass container took approximately four minutes, in an anodized, dull black London Hospital or Nuffield container approximately five minutes, and in a highly polished, black container six and a half minutes. These results therefore indicated that the choice and type of surface of the container were of importance.

Choice of Containers

Although a glass test tube used as a container allows syringes and needles to be seen, there are certain disadvantages in the use of glass. First, glass is liable to break, and constitutes a severe hazard to the operator; second, the cost of replacement of glass test tubes is high. (At one time in our Service this amounted to £26 a month.) Furthermore, it is clear that the apparatus must ensure that the largest article, i.e., a 20 ml. syringe, receives adequate heat treatment. This of course inevitably leads to overheating of the small articles, such as 2 ml. syringes. To overcome

this, it was decided that 2 ml. syringes should be packed in dull, aluminium containers, and 20 ml. syringes should be packed in aluminium containers painted dull black, thus ensuring that the 2 ml. and 20 ml. syringes reached similar temperatures in the same period of time. This obviates the need to alter the heat output for different sizes of syringe.

Position of Projectors

It was, however, also clear that two infra-red heaters were necessary to ensure heat for the first six minutes of the syringes' passage through the tunnel. For convenience the two projectors, each 12 in. wide, were placed 2 in. apart giving some overlap of heat, and providing six and a half minutes' exposure to heat.

Maintenance of Sterilizing Temperature

Soon after the initial experiments had been concluded, it was noted that, when syringes in metal containers were withdrawn from the effects of radiation the temperature in the syringe continued to rise. The reason for this was not clear, but it was thought to be due to the heat exchange between the cooling outer metal case and the syringes. However, to prevent overheating it was found by experiments that with suitable insulation of the tunnel the temperature did not start to fall until the syringes had travelled 45 in. (11½ minutes). This fall in temperature could

FIG. 2.—Temperature recordings of 2 ml. and 20 ml. Chance interchangeable syringes placed in varying types of containers exposed to an infra-red projector show different rates of heat taken up. It is noticeable that heat is taken up much more quickly in glass, while syringes in bright shiny aluminium containers were greatly delayed. Painting the aluminium containers with a dull matt black paint greatly improves their ability to take up heat. The heat taken up by 2 ml. syringes in dull Nuffield pattern containers is comparable with the performance of 20 ml. syringes in matt black containers of either the London Hospital pattern or the Nuffield type. Glass=Pyrex glass test tube. L.H.P.=London Hospital pattern container of spun aluminium. Nuffield=Nuffield pattern container of extruded aluminium. The prefix "dull" implies that the container has been boiled in soda to produce a matt finish. The prefix "black" implies that the container has been painted with matt black heat-resisting paint. The prefix "shiny black" implies that the container has been treated with glossy black heat-resisting stove enamel paint.

be counteracted if a third 12-in. projector was placed at a slightly higher level (7 in.) above the moving belt. At 72½ in. (18 minutes) from the entrance to the tunnel there was a fall in temperature and a fourth projector was found necessary. As this was sited near the exit a rather higher heat output was required. With these syringe containers a tunnel 89 in. (22¼ minutes) in length was found to be necessary.

Temperature Variation

When "infra-red" is used as a heat source variations in temperature sometimes occur. These may be due to alterations either in mains voltage or in the elements themselves.

In this machine it was not possible to stabilize the mains voltage, although it is understood that the heat output varies with the square of the voltage. Although the variation of heat may appear formidable, this can easily be overcome either by fitting a mains voltage stabilizer, or by controlling each element thermostatically.

The use of a tray with a single layer of containers and syringes placed on a moving belt of constant speed ensures that each article receives the same heat treatment. Figs. 3 and 4 show the temperature recordings of various types of 2 ml. and 20 ml. syringes placed in the same type of containers and placed on the same tray during its passage through the tunnel. It is noticeable that, in spite of a variation in type,

FIG. 3.—Various kinds of 2 ml. syringes were exposed in the same type of containers side by side on a metal tray to the moving belt infra-red sterilizer. It is seen that all syringes received a minimum temperature of 180° C. for at least 16 minutes, and that after heat stabilization the variations of temperature did not exceed 15° C.

all the 2 ml. syringes reached a temperature of 180° C. within 90 seconds of each other, that the maximum heat variation was less than 14° C., that all the syringes exceeded the minimum sterilizing temperature permissible, and that all were subjected to the same heat source for the same period of time (± 2 minutes). With the exception of the "vim" syringe, which has a highly polished metal nozzle, all those of 20 ml. size packed in the same type of container reached 180° C. within 90 seconds of each other. The variation of temperature was less than 10° C. and was maintained above the minimum sterilizing temperature, though this was lower than that reached by the 2 ml. syringes

during the same period of time (± 90 seconds).^{*} These results compared more than favourably with those obtained in hot air ovens even when fitted with a fan. It is noticeable that, although the 20 ml. syringes did not reach the sterilizing temperature as quickly as the 2 ml. syringes, their fall in temperature at the exit of the tunnel was rather longer.

It should be added that in some preliminary investigations the temperature dropped at the edge of the belt, and for this reason temperature measurements

^{*}It was clear that for the "vim" syringe the projectors would have to be placed at lower levels to ensure a slightly higher output of heat.

FIG. 4.—Various 20 ml. syringes were placed in the same type of containers on a standard tray, and submitted to the moving belt sterilizer. It is noticed that with exception of the "vim" syringe, which has a highly polished nozzle, all the syringes received a temperature of 180° C. or more for a period of 15 minutes and that the variation of temperature did not exceed 10° C. after heat stabilization.

were taken in the central portion of the belt, as only this part was used for sterilization. (This is being overcome in the design of the new machines by ensuring that the projectors exceed the width of the belt, and the sides are adequately lagged.)

Thermocouple and Bacteriological Tests

In order to test the sterilizing ability of the machine bacteriological tests were carried out in conjunction with thermocouple readings. The procedure was to replace the plunger by a test tube containing about

0.1 g. of dried spore-bearing earth supplied by Dr. B. Lacey, of the Westminster Hospital. The syringe and dummy plunger were placed in a container and sealed in a manner similar to routine practice. The thermocouples were of the type recommended in B.S.I. No. 2648:1955 for the testing of drying ovens, and were connected by long leads to a multiple point recorder of the direct reading pattern (5° C. interval). The metal ball of the thermocouple was passed into the plunger so that it was in direct contact with the internal surface. The plungers were specially drilled or

FIG. 5.—One hundred and twenty-eight temperature recordings of syringes in presealed containers have been compared with bacteriological tests on the moving belt infra-red sterilizer. Although on each occasion the period of exposure to heat was 22½ minutes, in many of the investigations the projectors were deliberately altered to give too high or too low a temperature. The results have been divided into three groups. The black area indicates the results of 10 temperature recordings in syringes in which the temperature did not exceed 160° C., nine of which were not sterile. The upper limit of the black area indicates the temperature recordings in which the syringe was sterile. The hatched area shows the results of 41 investigations, 35 where the recordings were between 160° C. and 180° C., of which 21 were sterile, and six others where the temperature exceeded 180° C. for periods up to seven minutes were not sterile. Eighty-one recordings in the third area which exceeded 180° C. indicated by a clear zone were found to be sterile. The lower limit of the clear area shows the temperature recordings of a syringe which was submitted to 180° C. or more and proved not to be sterile. It had received the highest and longest temperature yet found, and which was not sterile. The upper limit indicates the highest and longest level of temperature tested.

had their ends removed. The syringe was then placed in its container and sealed.

The assembled syringes and containers, either attached to a thermocouple or with a test tube of dried earth, were placed side by side on a metal tray loaded with its full complement of syringes. Usually two or three readings were obtained from the same tray. The loaded tray was placed on the moving belt, and, as soon as it had entered the tunnel, readings were taken at minute intervals timed by a stop-watch.

The comparison of the length of time the syringe was held at given temperatures was compared with the bacteriological results. It is of course true that the temperature reached by the syringe containing a thermocouple may not be identical with that containing the dried earth. The thermocouple, however, was placed inside the plunger to provide an extra margin of safety, since it is clear that the temperature of the cavity within the barrel was certainly higher than that recorded in the plunger.

After the syringes were processed, the tube containing the spores was removed. Its contents were divided in about equal proportions between a tube of digest broth and another of Robertson's cooked meat medium. These were incubated for 48 hours at 37° C., and subcultured on to blood agar. The subculture from the broth tube was incubated aerobically and from the Robertson's tube anaerobically for 24 hours at 37° C. No growth on either was taken to mean that the spores had been killed.

Subculture on to solid media appears to be important, as growth was sometimes obtained from what visually appeared to be a clear sterile fluid. The lag period for spores which have been heated nearly to death point is longer than for those not so treated. No attempt was made to identify the organisms concerned.

Bacteriological Results

Although independent temperature readings and bacteriological tests have been done on

very many occasions, comparisons between the two were made 128 times. For some of these investigations the projectors were deliberately altered to give either too high or too low temperatures. The total duration of exposure to heat was always $22\frac{1}{2}$ minutes. The results obtained can be divided into three groups: (1) When the temperature at no time exceeded 160°C .; (2) when the temperature exceeded 160°C . but not 180°C .; and (3) when the temperature reached 180°C . or more for varying periods.

In the first group 10 observations were made; in nine of these the syringes were not sterilized. It was clear, therefore, that it was essential for the temperature to exceed 160°C . In the second group, equivocal results were obtained, for in a series of 35 observations sterility was recorded in only 21. There did not appear to be any direct relation between the length of time and the temperature reached on the one hand, and the bacteriological results on the other. This may have been due to slight variations in the amount of dried earth used as the test organisms; for this reason we concluded that the temperature should exceed 180°C .

TABLE I
HEAT EXPOSURE FOR $22\frac{1}{2}$ MINUTES AT A TEMPERATURE
OF 180°C . OR MORE

Minutes of Exposure at 180°C . or More	Sterile	No. of Tests
1	3	4
2	3	3
3	6	3
4	3	3
5	5	5
6	1	3
7	4	5
8	3	3
9	6	6
10	3	3
11	8	8
12	3	3
13	8	8
14	3	3
15	2	5
16	2	2
17	4	4
18	6	6
19	3	3

In the third group the total duration of exposure to heat was $22\frac{1}{2}$ minutes, during which the temperature recorded always rose to 180°C . or higher, and occasionally 210°C . The results are shown in Table I. In all 87 results were obtained. They showed that when the temperature exceeded 180°C . for more than seven minutes sterility resulted. Only six positive cultures were obtained, one at a one-minute exposure, two at a three-minute, two at a six-minute, and one at a seven-minute exposure.

Discussion

At the beginning of this communication we laid down four criteria for successful sterilization practice. We believe that the four criteria have been very largely fulfilled.

Presealing of containers ensures that sterilization of the syringes can be maintained over long periods of time, and radiant heat provided by this method is sufficient to ensure sterility, even when one of the most resistant forms of spores is used. Furthermore, the reduced "heating-up" time has shown that in practice no damage to the syringe has resulted. The use of dull black aluminium containers has ensured that the larger syringes have received the same exposure to heat as the small syringes. It should be emphasized that the machine used was a prototype constructed from apparatus readily available commercially, and not specifically designed for this purpose. Even so, the variation of heat from one syringe to another was considerably less than that in the normal hot air oven at present in use. Furthermore, the machine ensures that all the syringes receive the minimum heat necessary for sterilization, and, as it is in continuous action, it cannot be overloaded.

Properly designed machines fitted with voltage stabilizers and thermostatically controlled elements would not appear to present difficulties, and indeed manufacturers have already placed such machines on the market. The principal difficulty seems to be that so far no authoritative body has yet laid down a standard organism for test purposes, and therefore the actual temperature and the length of time necessary is still a subject of debate. Since the spores in the dried earth were very heat resistant, it seems probable from the figures obtained that a temperature of 180°C . or more for 11 minutes is adequate to ensure destruction of all the known organisms pathogenic to man. (It is hoped that the results will be the subject of a further communication.)

The fact that syringes and containers are put in single layers on trays which are placed on the moving belt ensures that the sterilizing procedure is simple. Once the loaded tray passes into the tunnel, the operator cannot tamper or prevent the sterilizing process from being carried out in full.

This apparatus has now been in routine use for the past 24 months; no major mechanical faults have developed, and the elements have not required renewal. It is possible that a device to show whether any element is defective might be an added precaution.

In practice the reduction of time necessary for sterilization has reduced the electricity consump-

tion, and thus has saved money. The apparatus could no doubt be used for the sterilization of many other articles, particularly glassware, but might require modifications to its final design; the position of the projectors, for example, might require resetting.

It is probable that the ultimate cost of such a machine would be no greater than that of the necessary hot air ovens. The simplicity of its operation would allow less skilled operators to work it, and still ensure sterility, which is not always obtained in a hot air oven.

Summary

A moving belt infra-red sterilizer for syringes has proved simple to operate; it reduces the "heating-up" time, and allows the syringes to be presealed in their containers before sterilization.

In practice a sterilizing temperature of more than 180° C. for 11 minutes ensures sterility, and a minimum sterilization temperature can be obtained in all the syringes submitted to the machine as measured by multipoint thermocouples.

To ensure that large and small syringes are heated to the same extent, the large syringes are put into matt black containers which heat up more rapidly, and the small syringes into dull

aluminium containers which heat up more slowly.

A rigid technique for bacteriological control by both aerobic and anaerobic culture is laid down. The importance of subculture on to solid media from apparently clear, sterile fluid is stressed.

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