

Dry heat sterilization is an acceptable method of sterilization, provided that the load is exposed to one of the following minimum time/temperature relationships:

Sterilizing temperature band °C	Minimum holding time (minutes)
160 to 170	120
170 to 180	60
180 to 190	30

**These are the holding times only. The total cycle time will be longer because it includes:**

- **the heating time**, - the time required for every item of the load to reach the sterilizing temperature, which can vary considerably and depends on the composition of the load,
- **the holding time**, - the time for which the load must be held at the sterilizing temperature,
- **the cooling time**, - the time taken by the load to cool to a temperature at which the operator can remove items from the sterilizer safely.

To be certain that the sterilizer will produce sterilized devices consistently, it is imperative that:

- the selected temperature is achieved and maintained throughout the load for the duration of the relevant sterilizing time,
- appropriate safeguards operate to prevent normal access to a load during a cycle, or in the event of the cycle failing,

and that the sterilizer is:

- maintained in accordance with the manufacturer's instructions,
- tested periodically to check that safety features (e.g. door locks, overheat cutouts etc) and the automatic controller are functioning properly and the instrument readings are correct,
- not overloaded and it is loaded to ensure the effective circulation of air.

Each sterilizer should have a log book in which comprehensive records of all checks, tests, faults, repairs and modifications are made and retained.

The temperature must reach and remain within the sterilizing temperature band, throughout the sterilizing stage (holding time) and for not less than the required time specified in the table. To ensure this, the user should test the sterilizer at least once each week it is used, to verify that it is producing sterilizing conditions.

The test entails running a test load cycle and recording, or noting, the temperatures and corresponding times throughout the sterilizing stage and comparing them with the Master Temperature Record\*. **If any value is outside the specified limits, the load must not be used** and the sterilizer should be taken out of service, re-tested and repaired if necessary. It should be returned to service only when it is known to be functioning correctly.

All observed values (e.g. from the temperature gauge and stop watch) obtained during the test should be noted and retained in the sterilizer log book. A recorder attached to the sterilizer simplifies the testing procedure.

The test may be performed with a load, provided there is a Master Temperature Record for that load. If the test is satisfactory, the load may be released for normal use.

\* The Master Temperature Record should be the record of time and temperature values obtained by a competent test person, using calibrated test probes, when the sterilizer was known to be working correctly e.g. during works tests, validation etc.