

	Standard Operating Procedure	SOP Number G-204	Revision 3
	Calibration Verification of Digital and Analog Timers	Effective Date 05/16/19	Page Page 1 of 3
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1.0 Purpose

The purpose of this SOP is to describe the procedure for the single point calibration verification of digital and analog timers.

2.0 Scope

This procedure is for the calibration verification of digital and analog timers. This SOP does not cover the calibration or repair of any time measuring device.

3.0 Responsibility

- 3.1 It is the responsibility of QC Laboratory Personnel to follow this procedure.
- 3.2 It is the responsibility of QC Laboratory Management to ensure the procedure is current and is being followed.

4.0 Definitions

- 4.1 ISO – International Organization for Standardization
- 4.2 IEC – International Electrotechnical Commission
- 4.3 NIST – National Institute of Standards and Technology
- 4.4 ANSI – American National Standards Institute
- 4.5 NCSL – National Conference of Standards Laboratories
- 4.6 QC – Quality Control

5.0 References

- 5.1 G-201-F2, Form, Calibration Certificate
- 5.2 G-201, SOP, Calibration Program

<p style="text-align: center;">Standard Operating Procedure Calibration Verification of Digital and Analog Timers</p>	<p style="text-align: center;">SOP No G-204</p>	<p style="text-align: center;">Rev 3</p>	<p style="text-align: center;">Page 2 of 3</p>
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6.0 Procedure

- 6.1 Refer to SOP G-201 Calibration Program for calibration schedule and instructions on the documentation of the calibration verification.
- 6.2 It is recommended that fixed calibration Timers/stopwatches are replaced at least every five years. Timers/stopwatches that can be calibrated should be calibrated at an external calibration lab at least once every five years.
- 6.3 If a timer/stopwatch fails internal calibration verification and the instrument is able to be calibrated the unit must be calibrated and recertified by an external laboratory before returning to service.
- 6.3.1 Exception: If the timer is a component of a larger piece of equipment and specific calibration instructions are available, the timer may be adjusted by personnel familiar with and qualified to perform the adjustment.
- 6.4 Verification Process:
- 6.4.1 For use as a reference standard select a NIST traceable timer/stopwatch that has been externally calibrated and verified in compliance with ISO/IEC and/or ANSI/NCSL requirements. Internally calibrated timers/stopwatches do not qualify as reference standards.
- 6.4.2 To minimize technician error a minimum of 30 minutes is required to verify the accuracy of a timer/stopwatch.
- 6.4.3 The common tolerance for digital timers/stopwatches is +/-0.1%. The common tolerance for analog timers is +/-1 minute after 60 minutes unless otherwise specified by the manufacturer.
- Note:** Analog timers should not be used for critical time measurements.
- 6.4.3.1 If “count up” mode is available for the devices, the reference stopwatch and the unit to be verified should be activated simultaneously. Both devices will then be stopped simultaneously. The maximum and minimum variation will be calculated from the reference device and the time from the unit to be verified will be compared to the reference range to determine if the unit is within tolerance.
- 6.4.3.2 If “count down” mode is the only mode available for the device, the reference stopwatch and the unit to be verified should be activated simultaneously. The countdown will begin at 31 minutes for digital

units that measure minutes and seconds and 61 minutes for analog units and digital units that measure down to the minute. The unit to be verified will be stopped when the reference time reaches 1 minute. If the unit to be verified has reached 0 minutes before the reference timer reaches 1 minute then the unit fails. Otherwise, the maximum and minimum variation will be calculated from the reference device and the time from the unit to be verified will be compared to the reference range to determine if the unit is within tolerance.

6.4.4 All instrument information, calibration verification and environmental data should be documented on form G-201-F2 Calibration Certificate.

6.4.4.1 For equipment that has a digital readout of the time, the timer of the device can be manually adjusted to bring the readout into the acceptable range when compared to a NIST traceable reference. If the digital display is out of specified limits and cannot be adjusted, an offset can be recorded on the calibration verification documentation and the display labeled with the offset adjustment.

6.4.5 The common verification cycle for time indicators is 1 year.

6.4.6 If a timer is removed from service for any reason including failed verification the device in the Calibration Schedule must be lined out with the notation "removed from service." The device is no longer permitted in GMP work areas.

6.4.7 For devices that pass verification, a calibration sticker will be attached and the unit returned to service.

6.4.8 Some devices that have time read-outs are only for reference and must be noted as so. These devices are not to be used to record temperature and a secondary, traceable temperature reading device must be used for GMP activities.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/25/10	New	-	-
1	04/04/13	Changed the SOP format & number	13-247	B. Johns
2	07/01/15	Biennial review: Changed SOP format. Transitioned SOP from calibration to calibration verification.	15-0578	B. Johns
3	04/08/19	Scheduled review: Added information about time monitors that are for reference purposes	19-0244	J. Maignan