

	Standard Operating Procedure		SOP Number <b>D-821</b>	Revision <b>4</b>
	<b>DicksonOne Data Loggers</b>		Effective Date <i>04/02/21</i>	Page <b>Page 1 of 4</b>
Written by/ Date <i>SS 02/17/21</i>		Reviewed by/ Date <i>Laura Mulade 02-22-21</i>		Approved by/ Date <i>[Signature] 02-22-21</i>
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## 1.0 Purpose

This procedure is applicable for the operation of DicksonOne Data Loggers and use of the DicksonOne Cloud Web Application.

## 2.0 Scope

This procedure provides specific instructions for the DicksonOne Cloud Web Application that is used in conjunction with both the Display Data Loggers (DWE) and Touchscreen Data Loggers (TWE/ TWP). This procedure will define the scope of the DicksonOne cloud application along with data logger management.

## 3.0 Responsibility

- 3.1 QC laboratory personnel are responsible for the application and compliance of this procedure.
- 3.2 QC Laboratory Management are responsible for the execution of and compliance to this procedure.
- 3.3 QC Laboratory Management is responsible for keeping the SOP current with latest Ion Labs practices.

## 4.0 Definitions

- 4.1 **QC** - Quality Control
- 4.2 **Data Logger** – Device used in conjunction with a sensor or sensors to capture temperature and/ or relative humidity data in real time

## 5.0 References

- 5.1 G-206 Verification of Digital Temperature and Humidity Recording Devices
- 5.2 F-505 Environmental Monitoring Program
- 5.3 DicksonOne Cloud: <https://www.dicksonone.com>

## 6.0 Procedure

- 6.1 DicksonOne WIFI devices and associated Cloud Web Application allow real time monitoring of the temperature and relative humidity in any location as required. This allows for real time notification in the event of any temperature and/ or humidity excursion.
- 6.2 Device Placement
  - 6.2.1 Data loggers are placed throughout all Ion Labs facilities where GMP environmental monitoring is required. See SOP F-505 Environmental Monitoring Program for the locations and designator of each logger.
- 6.3 Logging into DicksonOne Cloud Web Application
  - 6.3.1 DicksonOne is an internet cloud-based environmental monitoring system featuring an easy-to-use interface for monitoring critical variables from a computer, tablet or smart phone.
  - 6.3.2 DicksonOne Cloud Web Application is password protected so that only authorized users may use the system.
  - 6.3.3 Each user authorized by the system administrator is granted access to the web application.
- 6.4 Configuration of Data Loggers/ Sensors (Devices)
  - 6.4.1 Both display and touchscreen loggers are able to be registered on the DicksonOne Cloud Web Application.
  - 6.4.2 Prior to data logger/ sensor registration, company WIFI details must be installed and configured on each data logger.
  - 6.4.3 Devices record both temperature and % relative humidity with the exception of those locations in which RH is not significant, i.e. refrigerators, freezers, incubators.
  - 6.4.4 Data points are recorded in 15 minute intervals unless otherwise justified.
- 6.5 Data Retrieval
  - 6.5.1 Login to the DicksonOne Cloud Web Application for access to all data.

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- 6.5.2 Data for each device can be downloaded at any time and graphed for evaluation.
- 6.5.3 The recorded data can be sorted by location, Dickson unit, channel, temperature, relative humidity, and date.
- 6.6 Data Storage
  - 6.6.1 Data is stored in the DicksonOne Cloud indefinitely.
- 6.7 Excursion Alarms and Warnings
  - 6.7.1 Alarms can be created for each data logger that will alert designated personnel for any pre-defined excursions.
    - 6.7.1.1 For example, devices installed to monitor temperature and RH will have alarms set so that personnel are notified after ~ 2 readings (30 minutes) when the temperature and/ or humidity are outside of the pre-defined ranges.
    - 6.7.1.2 Notification can be via email or text message as set-up in the web application.
    - 6.7.1.3 Alarms will also be set so that notification to designated personnel occurs if the device goes offline and/ or data is not being collected.
    - 6.7.1.4 Any alarms or warnings should be acknowledged in the web application and an appropriate comment written to explain the cause.
    - 6.7.1.5 Any excursions lasting longer than 24 hours will be addressed by laboratory management to assess any impact from the excursion.
- 6.8 Reporting Data
  - 6.8.1 Data for each device may be downloaded, graphed, and printed as needed.
  - 6.8.2 Historical data for each data logger is stored indefinitely in the DicksonOne cloud.
  - 6.8.3 When a device is no longer needed or removed from service, the data recorded may be archived through the DicksonOne web application.
- 6.9 Event Logs/ Audit Trail
  - 6.9.1 The Events Log automatically records information about how an organization is using the DicksonOne system.

6.9.2 The Events Log creates an audit trail that can be referenced at any time.

6.9.3 The user name, time, date, device (when applicable), and a brief notation are added to the log when any of the following events occur:

6.9.3.1 Users log in or out of the DicksonOne Web Portal

6.9.3.2 Device or location information is added or changed

6.9.3.3 Alarms are added or changed

6.9.3.4 Users are added or their permissions changed

6.9.3.5 Data is exported

6.9.3.6 Annotations are made or changed in the graph area.

## 7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	New	-	-
1	02/26/13	Reformatted SOP.	13-124	B. Johns
2	01/20/15	Reformatted SOP. Added TK150 data loggers. Updated software information. Added use of USB cable for TK150. Added reference information for G-206 and F-505. Increased detail of filing procedures. Added model specifications. Biennial Review.	15-0079	B. Johns
3	08/01/17	Updated SOP to reflect requirements of new equipment, TP125 and SP125 data loggers.	17-0764	N. Zhang
4	02/17/21	Updated SOP to reflect new data logger procedures and portal access. Updated recording interval to match Environmental Monitoring Program protocol. Adjusted SOP Title. Grammatical issues corrected.	CC-21-0060	J. Sassman