Badge-Based Air Monitoring Method for Evaluating Volatile Organic Compound Emissions from Newly Manufactured Neonatal Incubators

Tool Reference

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1. Introduction

1.1. Purpose

This document describes the procedures for testing incubators for release of volatile organic compounds (VOCs) to determine whether neonate patients could be exposed to elevated levels of formaldehyde, cyclohexanone, and other VOCs that off gas from a newly manufactured incubator.

Strategic Research Purpose:

> Investigate the time-dependent release of cyclohexanone and seven (7) volatile organic compounds (VOCs) and three (3) semi-volatile organic compounds (SVOCs) using representative incubators and operating at clinically relevant, worst-case temperature and humidity.

1.2. Background

In 2023, the FDA evaluated published literature that reports elevated levels of formaldehyde, cyclohexanone, and other volatile chemicals (such as human-made chemicals used and produced in manufacturing) from neonatal incubators. Potential sources of these airborne chemicals include materials used in the construction of neonatal incubators, as well as natural and human-made sources external to the incubator.

Neonatal incubators are critical to the care for newborns in hospital settings, such as neonatal intensive care units (NICU). The incubators help create an optimal environment for newborns that need support in regulating their body temperature by providing heated and humidified air within an enclosed bed compartment.

After initial review of the current literature evidence, the FDA concluded that the information reported is inadequate to assess the potential exposure and risk to newborns and others (such as health care providers) of airborne chemicals (formaldehyde, cyclohexanone, and other volatile chemicals) that may be released from neonatal incubators. Factors that may contribute to the release of these chemicals into the air from neonatal incubators include increased temperature and humidity. In addition, the concentration of these airborne chemicals may decrease over time. However, further testing and analysis is needed to determine whether these airborne chemicals are released from certain neonatal incubators, the types of chemicals being released, contributing factors to the release of chemicals, the amount and length of time of exposure, and the potential risk of exposure to health.

Exposure to elevated levels of formaldehyde or cyclohexanone may lead to problems such as neurological impairment or respiratory problems (such as asthma, decreased lung function, inflammation, or irritation), which is concerning for neonates who may have immature pulmonary functions and other co-morbidities.

As of January 2025, the FDA was not aware of adverse events related to the use of neonatal incubators and exposure to airborne chemicals and that new neonatal incubators currently supplied in the United States do not demonstrate concerning levels of airborne chemicals.

This protocol will test incubators that are operating at a relevant worst-case clinical use to determine:

- when the maximum concentration of a volatile compound in ambient air inside the incubator occurs,
- assess whether the concentration in ambient air inside the incubator changes over time,
- determine whether the maximum concentration of a volatile in ambient air inside the incubator exceeds the tolerable exposure threshold that applies to the volatile compounds derived in accordance with ISO 10993-17 *Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents* (ISO 10993-17), and

- If necessary, determine the number of days until the concentration in ambient air inside the incubator is below the derived tolerable threshold.

The testing will be performed on final finished incubators, that may include a "burn-in" process to reduce VOC release prior to use. The following airborne VOCs will be quantified:

- acetaldehyde
- benzaldehyde
- butyraldehyde
- crotonaldehyde
- cyclohexanone
- formaldehyde
- glutaraldehyde
- hexaldehyde
- propionaldehyde
- tolualdehyde (a.k.a. toluene)
- valeraldehyde

Note that this protocol provides screening-level data for VOC emissions but does not include toxicological risk assessment or determination of whether detected concentrations exceed health-based exposure limits. Tool users must conduct separate risk assessments according to ISO 10993-17 to determine acceptability of detected VOC levels for their specific device and intended patient population.

1.3. Intended Audience

This document is intended for use by medical device manufacturers conducting pre-market testing, with secondary users encompassing FDA reviewers assessing VOC emission data, hospital biomedical engineers, and research laboratories. Users require basic understanding of air monitoring principles and laboratory procedures, along with knowledge of proper monitoring badge handling, environmental condition maintenance, and analytical laboratory coordination.

2. Objectives of the Test protocol

- Determine the identity of chemicals released from newly manufactured incubators during simulated worst-case clinical use.
- Identify the highest airborne quantity for each chemical released in a 24-hour exposure period.
- Establish if the release declines in a time-dependent manner to a health-based tolerable airborne concentration, i.e., an exposure level without an appreciable harm to health.

3. Equipment

3.1. Equipment Table

P/N	Item	Qty	Notes
1	Incubator Under Test	1	Will be cleaned prior to testing per IFU
2	Aldehyde Monitoring Badges[1]	35	5 badges per day x 7 days for each incubator
3	Cyclohexanone Monitoring Badges[1]	35	5 badges per day x 7 days for each incubator
4	Temperature and Humidity Meter	1	Used for Outside Temperature and Humidity Readings
5	Incubator Cleaner	1	Used for cleaning the incubator per IFU

3.2. Equipment Description

3.2.1. Incubator Under Test

The incubator under test should be a final finished device and setup with all included components (such as a bed mattress) as if it was purchased new and has never been run. Before testing begins, all accessible internal surfaces should be cleaned in accordance with a cleaner recommended in the incubator's IFS and clean in accordance with the cleaner's IFU.

3.2.2. Aldehyde Monitoring Badges[1]

This Aldehyde/Formaldehyde Badge Monitor collects a sample of airborne aldehydes of interest (i.e., Aldehyde Panel). The Aldehyde Panel includes formaldehyde, glutaraldehyde, acetaldehyde, benzaldehyde, butyraldehyde, crotonaldehyde, hexaldehyde, propionaldehyde, and valeraldehyde. Each badge is identifiable by a serial number and is logged based on its position and placement in the Laboratory Request Form (LRF). These badges will be returned to the analytical laboratory within the recommended time after sampling from the badge manufacturer for analysis. This analysis complies with the validated methods: OSHA 1007, NIOSH 2016, OSHA 64, and EPA TO-11. NOTE: Some

3.2.3. Cyclohexanone Monitoring Badges[1]

This monitor uses one badge to collect a sample of the last required compound: cyclohexanone. Each badge is identifiable by a serial number and is logged based on its position and placement in the LRF. These badges will be returned to analytical laboratory within the recommended time after sampling from the badge manufacturer for analysis. This analysis complies with the validated methods: AT L-OV, NIOSH 1500, NIOSH 1550, and NIOSH 1604.

[1] **NOTE:** Some monitoring badges might be not to detect the same amount of chemicals as the ones used for protocol validation. It is important when selecting badges that they can detect all the required chemicals listed above in Background Section (Section 3.2) and are analyzed using a validated method. There should be a minimum of 35 badges for each badge type used. Typically, only two types of badges are needed.

3.2.4. Incubator Cleaner

This cleaner should be a cleaning agent that is recommended for cleaning the surfaces of the incubator under test and outlined as a recommended cleaner in the incubators IFU. Using the cleaner should be performed using the cleaner's IFU.

3.3. Testing Facility

The testing location should have no windows and be climate controlled throughout the day.

4. Test Protocols

The following sections describe the procedures used over a 7-day testing duration to sample air for released VOCs inside and external to an incubator during operations that represent a clinically relevant, worst-case condition. Prior to testing, testers are encouraged to discuss specific procedures and conditions through a Q-Submission.

4.1. Test Conditions

All tests will adhere to the following conditions.

- Before testing begins, all accessible internal surfaces will be wiped with incubator manufactures recommended cleaner in accordance with the cleaner's instructions for use.
- All incubator portholes will be closed during testing, except for approximately 5 min for the daily placement and removal of badges.
- Test incubators will be held at a temperature of 37°C and humidity set to 70% representing the clinically relevant, worst-case condition. For humidity, the water reservoir levels shall be monitored at least twice every 24 hours and refilled with distilled and deionized as necessary.

4.2. Test Procedures

The following will describe the procedure to set up the incubators, daily badge placement, and disposition of badges to the commercial analytical lab to collect the data. The main protocol section (4.2.1) is the starting point for each incubator test. Sections 4.2.2, 4.2.3 are performed at the beginning of the test. Sections 4.2.4, 4.2.5, and 4.2.6 are performed on each day (24-hour data collection) through the final data collection day (Day 7). Sections 4.2.7, 4.2.8 are performed at the end of the data collection.

4.2.1. Main Protocol

1. Conduct the Incubator Disinfection protocol outlined below (4.2.2).
2. Position incubator for testing, verify their new condition, and confirm all external badging placement points.
3. Follow Startup Procedure Below (4.2.3) 24 hours after performing the corresponding disinfection protocol.
4. Perform Badge Placement protocol below (4.2.4).
5. After 24 hours, perform Badge Removal protocol below (4.2.5).
6. Repeat Step 4, Perform Lab Request Protocol below (4.2.6), and Repeat Step 5 consecutively above for a total of seven (7) consecutive days.
7. At the end 7 days, perform Badge Shipment to Analytical Lab (4.2.7)
8. Perform Receipt of Analytical Lab Reports protocol (4.2.8)

4.2.2. Incubator Disinfection

1. Without any disassembly, clean any internal exposed surface of the incubator inside the hood and wait for it to clear according to the cleaner's IFU.
2. Follow the cleaning instruction for the reusable mattress cover, if provided.

4.2.3. Startup Procedure

1. Ensure that incubator portholes are in the closed position.
2. Ensure that water reservoir level is full. Levels should be monitored and checked at least twice every 24 hr.
3. Turn on the incubator per the instructions for use.
4. Set following temperature and humidity conditions according to the instructions for use.
    a. Temperature: 37˚C
    b. Humidity: 70%

4.2.4. Badge Placement[2]

1. For each day of VOC data collection, the following badges are required:
    a. five (5) Aldehyde Monitoring Badges (ALDH badges)
    b. five (5) Cyclohexanone Monitoring Badges (for cyclohexanone, CYC badges, if needed).
    c. If more badge types are needed place them 50 mm away from the last column of badges.
2. Unwrap three (3) aldehyde ALDH badges, record their unique S/Ns in the corresponding data Sheet tables (Blank template provided in Section 5.) and on the return mailing pouch. Initial the data sheet to indicate the S/N has been recorded. Follow the badge manufacturer's IFU.
3. Open the caps on the aldehyde badges and place them on the mattress **inside** the incubator through the portholes according to Figure 1 below.

[2] **NOTE:** If only one type of badge is used, then only the first row 150 mm from the wall should be used. If more than two badge types are required, then add another row of badges, each badge type should be separated by 50 mm in all directions.

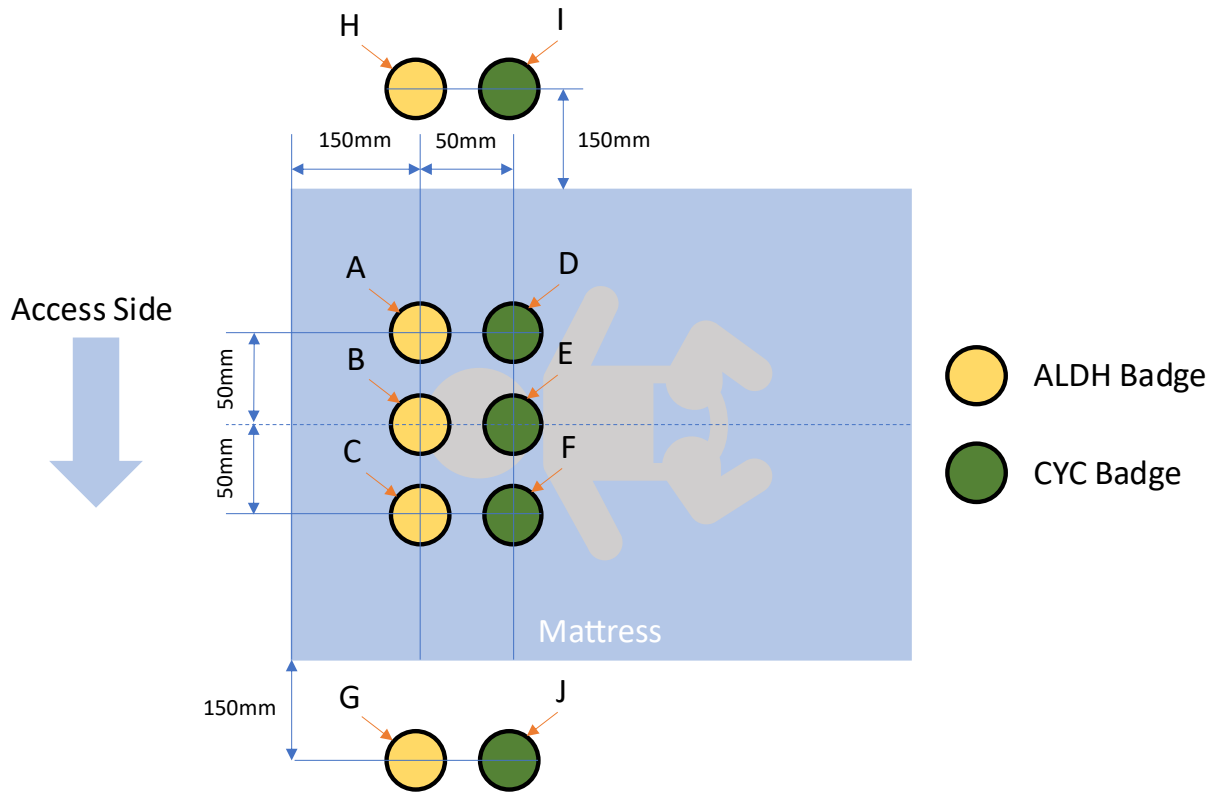

Figure 1: Diagram of Individually Labeled Badge Placements Inside and Outside the Incubator with a reference to the front of the incubator Baby is used for illustrative purposes. Badge placements refer to only two types of badges used for sampling[2].

4. Record the time the badges were placed in the Data Sheet (printable copy provided below) along with temperature, and humidity inside the Incubator, and signed off by the operator's Initials.
5. Repeat Steps 2 through 4 for the cyclohexanone CYC badges (placed **inside** incubator).
6. Unwrap two (2) aldehyde badges (ALDH Badges), record their unique S/Ns in the corresponding Data Sheet tables below and on the return pouch, Initial the Data Table to indicate the S/N has been recorded.
7. Open the caps on the aldehyde badges and place them **outside** the incubator, one on each long side of the incubator, 150 mm from portholes at the same height (See Figure 1).
8. Record the time the badges were placed in the Data Sheet below along with temperature, and humidity outside the Incubator, and signed off by the operator's Initials.
9. Repeat Steps 6 through 8 for the cyclohexanone CYC badges (placed **outside** the incubator).

4.2.5. Badge Removal

1. Remove the three aldehyde badges (ALDH Badges) from **inside** the incubator through the portholes and close the badge caps. Follow badge manufacturer's IFU.
2. Return each badge to its corresponding labeled pouch and seal per manufacturer instructions, make sure to include the clip with the badge.
3. Record the time the badges were removed on the Data Sheet below along with temperature, and humidity inside the Incubator, and signed off by the operator's Initials.

4. Repeat Steps 1 through 3 for removing the cyclohexanone badges (CYC Badges) from inside the incubator.
5. Take the two aldehyde badges (ALDH Badges) from **outside** the incubator and close the badge caps.
6. Return each badge to its corresponding labeled pouch and seal per the badge manufacturer's instructions, make sure to include the clip with the badge.
7. Record the time the badges were removed in the Data Sheet below along with temperature, and humidity inside the Incubator, and signed off by the operator's Initials.
8. Repeat Steps 5 through 7 for the cyclohexanone badges (CYC Badges) **outside** the incubator.
9. Places all the sealed pouches into a designated box

4.2.6. Lab Request Form and Data Sheet Prep[3]

1. Fill out a Lab Request Form provided by analytical laboratory for the badges removed in the designated box. See below for field filling instructions.
    a. **Notes/Comments:** Should list the incubator brand and day number in experiment.
    b. **Name:** Fill in the following format: <Incubator Brand>-D<Day#>-<Badge Position>.
    c. **Serial:** Serial number of the badge.
    d. **Date:** Use the start date of when the badge was placed.
    e. **Start Time:** Fill in the start time from the start date.
    f. **Stop Time:** Fill in the date AND stop time.
    g. **Chemicals Requested:** Check either the box underneath "*Aldehyde Panel*" or "*Cyclohexanone*" depending on the badge type.
    h. **Relinquished By:** Name of person filling out the form and the date of filling.
2. Scan and make a copy of the filled-out lab request form and place the copy in the physical lab notebook and scanned copy in the digital lab notebook.
3. Place the original filled form in the designated box along with the badges and seal the box.
4. Place sealed box in a room temperature location to be shipped out at the end of the procedure.
5. Scan the filled-out data sheet. Place the original in the physical lab notebook and scanned copy in the digital lab notebook.
6. Transfer the data from the data sheet to Excel version of the data sheet on the digital lab notebook.

4.2.7. Badge Shipment to Analytical Lab

1. Ship all the prepared boxes of badges following IFU instructions once the experiment ends. Use an express trackable package to the address provided in the Badge IFU.

4.2.8. Receipt of Analytical Lab Reports

1. Copy analytical lab reports in lab notebook with a duplicate in digital lab notebook.
2. Fill in data from VOC data returned from the analytical lab to the Excel version of the data sheet on the digital lab notebook.
3. Analyze and summarize the data, report findings and interpretation of data, and a determination of whether the levels presented in experiment are acceptable per the derived toxicological risk assessment.

[3] These instructions might differ depending on the analytical laboratory. Make sure you follow your specific analytical laboratory's instruction for submitting monitoring badges for analysis.

5. Test Data Sheets

Printable blank test data sheets designed to be printed and used during the experiment are attached below. This sheet assumes two different badge types for analysis, aldehyde (ALDH) and cyclohexanone (CYC) monitoring badges. A digital 508-complaint version of the test data sheet that is filled with example data is stored in the as an Excel sheet as an attachment to this document. The example data and cover sheet can be removed prior to use.

(This Part is Intentionally Left Blank)

Incubator Test Data Sheet

Incubator Brand & Serial # _____

U.S. FOOD & DRUG ADMINISTRATION

Hour/Day (Start - End)	Type	Location	Badge SN	Marked Bag Initials	Date & Time Placed	Placed Temp.	Placed RH	Placed Initials	Date & Time Rmvd	Rmvd Temp	Rmvd RH	Rmvd Initials
0/0	ALDH	In - A										
		In - B										
		In - C										
		Out - G										
		Out - H										
(0-1)	CYC	In - D										
		In - E										
		In - F										
		Out - I										
		Out - J										

Hour/Day (Start - End)	Type	Location	Badge SN	Marked Bag Initials	Date & Time Placed	Placed Temp.	Placed RH	Placed Initials	Date & Time Rmvd	Rmvd Temp	Rmvd RH	Rmvd Initials
24/1	ALDH	In - A										
		In - B										
		In - C										
		Out - G										
		Out - H										
(1-2)	CYC	In - D										
		In - E										
		In - F										
		Out - I										
		Out - J										

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Incubator Test Data Sheet

Incubator Brand & Serial # _____

U.S. FOOD & DRUG ADMINISTRATION

Hour/Day (Start - End)	Type	Location	Badge SN	Marked Bag Initials	Date & Time Placed	Placed Temp.	Placed RH	Placed Initials	Date & Time Rmvd	Rmvd Temp	Rmvd RH	Rmvd Initials
48/2	ALDH	In - A										
		In - B										
		In - C										
		Out - G										
		Out - H										
(2-3)	CYC	In - D										
		In - E										
		In - F										
		Out - I										
		Out - J										

Hour/Day (Start - End)	Type	Location	Badge SN	Marked Bag Initials	Date & Time Placed	Placed Temp.	Placed RH	Placed Initials	Date & Time Rmvd	Rmvd Temp	Rmvd RH	Rmvd Initials
72/3	ALDH	In - A										
		In - B										
		In - C										
		Out - G										
		Out - H										
(3-4)	CYC	In - D										
		In - E										
		In - F										
		Out - I										
		Out - J										

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Incubator Test Data Sheet

Incubator Brand & Serial # _____

U.S. FOOD & DRUG ADMINISTRATION

Hour/Day (Start - End)	Type	Location	Badge SN	Marked Bag Initials	Date & Time Placed	Placed Temp.	Placed RH	Placed Initials	Date & Time Rmvd	Rmvd Temp	Rmvd RH	Rmvd Initials
96/4	ALDH	In - A										
		In - B										
		In - C										
		Out - G										
		Out - H										
(4-5)	CYC	In - D										
		In - E										
		In - F										
		Out - I										
		Out - J										

Hour/Day (Start - End)	Type	Location	Badge SN	Marked Bag Initials	Date & Time Placed	Placed Temp.	Placed RH	Placed Initials	Date & Time Rmvd	Rmvd Temp	Rmvd RH	Rmvd Initials
120/5	ALDH	In - A										
		In - B										
		In - C										
		Out - G										
		Out - H										
(5-6)	CYC	In - D										
		In - E										
		In - F										
		Out - I										
		Out - J										

Incubator Test Data Sheet

Incubator Brand & Serial # _____

U.S. FOOD & DRUG ADMINISTRATION

Hour/Day (Start - End)	Type	Location	Badge SN	Marked Bag Initials	Date & Time Placed	Placed Temp.	Placed RH	Placed Initials	Date & Time Rmvd	Rmvd Temp	Rmvd RH	Rmvd Initials
144/6	ALDH	In - A										
		In - B										
		In - C										
		Out - G										
		Out - H										
(6-7)	CYC	In - D										
		In - E										
		In - F										
		Out - I										
		Out - J										

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