PEDOMAN
PENGUJIAN DAN KALIBRASI ALAT KESEHATAN

IMPROVING CALIBRATION SYSTEM OF MEDICAL EQUIPMENT IN THE HOSPITAL
Product 3 second stage activities

DEPARTEMEN KESEHATAN RI
DIREKTORAT JENDERAL PELAYANAN MEDIK
JAKARTA 2001
<table>
<thead>
<tr>
<th>No</th>
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<th>Keselamatan dan Jenis Keluaran</th>
<th>Nilai Ambang Batas</th>
<th>Nilai Penyimpangan yg Dijinkan</th>
<th>Standar</th>
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<tr>
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<td>Inkubator Penawatan</td>
<td>a. Arus boor pada kabel pembunian</td>
<td>≤ 500 µA</td>
<td>± 5 %</td>
<td>IEC 601-1-1 Clas I, Type BF</td>
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<td>b. Arus boor pada selangkup</td>
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<td>c. Patient probe</td>
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<td>d. Alat display tekanan</td>
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<td>f. Konsentrasi N₂O</td>
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<td>-</td>
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<td></td>
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<td>e. Amplitudo alatasi</td>
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Health Devices

Inspection and Preventive Maintenance System™

Major Procedures

Fourth Edition
Revised and Expanded
Health Devices

INSPECTION AND PREVENTIVE MAINTENANCE

Procedure/Checklist 410-0595

Infant Incubators

Used For:
- Incubators Infant Incubators [17-132]
- Incubators Infant Transport [17-1128]

Commonly Used In: Delivery rooms, neonatal ICUs, nurseries, ambulances, and aircraft.
Scope: Does not apply to neonatal incubators or transport incubators, see Procedure/Checklist 17-1312.
Risk Level: ECRl Recommends: High: Hospital Assessment.

<table>
<thead>
<tr>
<th>Type</th>
<th>ECRl-Recommended Interval</th>
<th>Interval Used By Hospital</th>
<th>Time Required</th>
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<tr>
<td>Major</td>
<td>12 months</td>
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<td></td>
</tr>
<tr>
<td>Minor</td>
<td>NA*</td>
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*Minor intervals for transport incubators should be every 3 months.

Overview

Infant and transport incubators provide warmth to help an infant maintain a normal body temperature and are often essential for an infant's survival. Most incubators warm the infant by a forced or natural flow of heated air. One type, no longer in production, supplements air convection with radiant infrared energy from heated bunsen and hood walls.

Infant incubators are designed primarily for in-hospital use at specific locations, operate on AC line power in a temperature-controlled indoor environment, and rest on relatively high moveable stands. Transport incubators provide thermal support during transfer within the hospital or by car, ambulance, or aircraft to another hospital. Transport incubators are both portable and mobile, operate from a variety of power sources, including self-contained batteries; have stands that are relatively low or adjustable in height to fit into vehicles with restricted overhead clearance; and may be required to operate in ambient conditions much colder than those found in a hospital.

Deaths and injuries to neonates have occurred in incubators. Reports include thermostatic failure that caused incubator overheating and infant hyperthermia, malfunction or design defects that produced fires and presented electrical shock hazards, and poor transport incubator performance or power failure due to improperly maintained batteries or unreliable battery-charger-level indicators. Because incubators are bulky and mobile, they are often subject to rough handling, especially transport units, that may degrade performance and physical condition. Periodic inspection may reveal hazardous deficiencies that could harm patients.

Citations from Health Devices

Mercury contamination in incubators and elsewhere. 1981 Dec: 11615-8
Transport incubators [Evaluation]. 1982 May: 11; 179-91
Update: Transport incubators. 1982 Sep: 11: 201
Ak-Shields C-200-1, C-200-2, and T-100 infant incubators [Hazard]. 1987 Jul: 15; 27-2
Ak-Shields Vickers C-100 and C-200 infant incubators [Hazard]. 1987 Jul: 15; 27-2
Ak-Shields C-24, C-100, and C-200 infant incubators [Hazard]. 1987 Nov: 16; 27-2

ECRI 1508 E. River Ave. Atrium, Building 2A. 19042-2891 USA
Telephone: 1-800-423-5000  Fax: 1-800-331-1975  E-mail: info@ecr1.org
Inspection and Preventive Maintenance System

Malfunctioning temperature probes and Air Shields Vicerra C-100 incubators [Hazard]. 1990 Jul 19:245.


Test apparatus and supplies

- Ground resistance meter
- Leakage current meter or electrical safety analyzer
- Patient-probe simulator capable of simulating a range of temperatures as well as dry and saline droplets
- Calibrated glass or electronic thermometer accurate to within 0.1°C in the clinical range
- Oxygen source and meter
- Hand gun or hair dryer
- For transport incubators with lead-acid batteries: hydrometer to measure specific gravity of the batteries; float markings should cover the range from 1.240 to 1.280 to within 0.001 accuracy available from any scientific apparatus supplier. Note: automotive hydrometers that indicate only GOOD or BAD without numerical specific gravity indications are not suitable.

Special precautions

Examine all mercury-in-glass thermometers and high-temperature thermometers. If broken, replace and clean the unit carefully using appropriate precautions. For mercury spills, see Health Doctor, 1981 Dec, 1:125 and the "IOM Safety" article behind the Guidance Table in this binder. ECRI recommends replacing all mercury-containing components in infant incubators.

CAUTION: Never and transport or use. Destroy all mercury on contact upon use.

Procedure

Before beginning an inspection, carefully read this procedure and the manufacturer's instruction and service manuals; be sure that you understand how to operate the equipment. The significance of each control and indicator and the alarm capabilities. Also determine whether any special inspection or preventive maintenance procedures, or frequencies, are recommended by the manufacturer.

If it is necessary to inspect several incubators that have patient probes, it may be convenient to use a patient-probe simulator to test indicator accuracy and temperature control effectiveness of all probes simultaneously. The procedure is essentially the same as that used in Temperature Monitors Procedure Checklist 425. It may be necessary to use different connectors to accommodate the probes of the incubators being inspected.

If an incubator is being tested in use, ask the clinical personnel if they can perform a temporary substitute or request that they notify you when the incubator is free for inspection.

1. Qualitative tests

1.1 Check/Grounding. Examine the overall exterior condition of the incubator. Check that the control panel is clean, that all labels and markings are legible, and that the adhesive tape or plastic residue is present. Remove any tape. Check all rubber or plastic gaskets in the incubator for signs of deterioration (e.g. cracks).

The hood condition is important for proper control of the incubator environment. Ensure that the hood is free of cracks, warping, or other signs of deterioration. Determine whether any parts are missing or incorrectly assembled. Examine all ports for proper alignment and sealing.

Consult the instruction manual for a general exploded diagram of the incubator. Remove the hood, bed, and other parts and thoroughly inspect the interior for foreign objects, deterioration, or misalignment of internal components that could interfere with performance. Look for contamination of the air supply and blocked air intake or humidity passages caused by improper placement of the humidity tray, or gaskets.

Examine the humidity apparatus for deterioration, contamination, and missing or incorrectly assembled parts.

1.2 Measure/Furniture. Check all screws, nuts, and fasteners are tight. Sometimes a loose screw may not be easy to detect visually. Use a screwdriver and systematically try to tighten every screw on the hood.

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Operate iris-type port closures to ensure proper function. Examine the iris diaphragm and port sleeves for tears. A torn or otherwise damaged iris indicates the integrity of the closed-chamber system. Consult the manual to determine if the iris is disposable, which should not be discarded after each incubator use. You must replace worn disposable iris sleeves, since they will be routinely replaced when the interior is sterilized for the next incubator application. Verify with a qualified personnel that the practice is enforced and that disposable iris sleeves are not removed.

1.2 Control/Brakes. If the device moves on casters, check their condition. Remove accumulation of lint and thread from around the casters and be sure that they turn smoothly as appropriate. Check the operation of brakes and wheel locks if the unit is so equipped. Conductivity checks, where appropriate, are usually done more efficiently as part of a check of all equipment and furniture in an area.

1.4 AC Plug/Receptacles. Examine the AC power plug for damage. Attempt to wiggle the blades to determine that they are secure. Shake the plug and listen for rattles that could indicate loose screws. If any damage is suspected upon the plug and inspect it.

1.5 Line Cord. Inspect the cord for signs of damage. If damaged, replace the entire cord or, if the damage is near one end, cut out the defective portion and replace a new power cord or plug with the same polarity as the Home. Check line cards of battery chargers.

1.6 Strain Relief. Examine the strain relief at both ends of the line cord. Be sure that they hold the cord securely.

1.7 Circuit Breaker/Fuses. If the device has a circuit breaker, check that it operates freely. If the device is protected by an external fuse, check its value and type against that marked on the chassis, and ensure that a spare is provided.

1.8 Tubing/Hoses. Check the condition of all tubing and hoses. Be sure that they are not cracked, kinked, or dirty. Inspect all oxygen outlets to make sure that they are clean and free of foreign matter.

1.9 Cables. Inspect the cables (e.g., sensor, electrode, remote control, and their strain relief for general condition. Examine cables carefully to detect breaks in the insulation and to ensure that they are secured securely in the connectors of each end to prevent rotation or other strain.

1.10 Exterior/Connectors. Examine all electrical cables and connectors for general condition. Electrical contact plug or surfaces should be straight, clean, and bright.

1.11 Probes. Examine all patient probes to ensure that they are clean and are not cracked, brittle, or otherwise deteriorated. If the hospital has more than one type of infant incubator, ensure that probes clearly identify the associated unit. Improperly interchanged probes of different types or from different manufacturers may adversely affect temperature control.

1.12 Filters. Inspect the air filter for signs of clogging; if the filter looks dirty, replace it and note this on Line 4 of the inspection form. Check the air filter assembly to ensure that air flow is unimpeded. Clogged or improperly installed filters can raise the oxygen concentration above safe levels. Change filters regularly according to the manufacturer's recommendations, and record the date you install a new filter.

Attach an oxygen source with a flowmeter to each oxygen port and use your hand to feel that gas is flowing into the chamber. Vary the oxygen flow and check that manufacturer-specified maximum and minimum flow rates can be achieved.

1.13 Controls/Switches. Before moving any controls or alarm limits, check their positions. If any of them appear inoperative (e.g., a temperature control turned to the end of its range, consider the possibility of inappropriate control use or backup device failure. Record the settings of these controls that should be returned to their original positions following the inspection.

Examine all controls and switches for physical condition. Secure mounting, and connection. Where a control should operate against flex-limit stops, check for proper alignment as well as positive stopping. Check membrane switches for membrane damage (e.g., from fingernail or pen. During the course of the inspection be
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1.14 Heater. Disassemble the heating element to expose the heating element. Examine the element for severe discoloration or foreign deposits. Heating elements normally change color with use, but dark, distinct surface spotting may indicate that material has come into contact with the element, possibly after drilling through the air duct. Foreign matter touching the hot surface could cause a fire or the generation of noxious fumes. If you find such discoloration examine the control unit component for signs of overheating, e.g., dulling, blistering. If these terminals connect the heating element to the control circuitry, check that they are tight.

Operate the heater to verify that heater controls function properly, e.g., that a variable temperature control knob, in fact, cycle the heater off and on as the set point is varied.

1.15 Motor/Fan. Inspect the fan blades for deterioration or damage, such as rusting, plastic warping, or lost blades. Ensure that the fan is securely attached to its drive shaft and that the coupling is present and intact. Check that clearance between the fan and the housing is adequate by looking for signs of rubbing. In some cases, an improperly inserted control module and heater assembly in the incubator base has been disassembled and the blower is preventing air circulation and causing overheating.

Check the service manual to determine if the fan motor requires lubrication. Oil as recommended and note on Line 1.2 of the inspection form. Check the sound level inside the incubator; noisy operation may indicate that the fan motor or housing assembly needs service.

In some incubators, the fan is visible at the back of the control module if the module is removed. If possible, expose the fan and operate it and watch for wobbling or excessive vibration. If possible, spin the fan with your finger, tilt the power-off, and make sure that it turns smoothly.

1.16 Fluid Level. Check all fluid levels, including those in lead-acid batteries.

1.17 Battery/Charger. Examine the physical condition of batteries and battery connectors if readily accessible. Check operation of interlocked power-off alarms if so equipped. Each battery should have an identification number and an accurate log of operating time, recharge, service, and inspections to permit early detection of deteriorating performance. Operate the unit on battery power for several minutes to check that the battery is charged and can hold a charge. Check remaining battery capacity by activating the battery test function. Check the condition of the battery charger, and to the extent possible, confirm that it does, in fact, charge the battery. When it is necessary to replace a battery, label it with the date.

A lead-acid battery, in the same case as the charging circuit can cause problems unless the battery is kept clean. Wash off acid and other materials that may collect on top of the battery. Insure the electrolyte or a yellow-white powder on the battery, check for containing deposits or components of the charging circuit may cause rapid deterioration. Wire components clean, or replace the charging circuit if it appears corroded. Check for obstructions in the vent caps and associated venting system. If necessary, clear the venting system with a stiff brush or blow the tubes through a straw inserted into the vent hole.

1.18 Indicators/Displays. During the course of the inspection, confirm the operation of all indicators, indicators, meters, gauges, and visual displays on the unit and chargers. If so equipped, verify that all segments of a digital display function.

1.19 User Calibration/Self Test. Verify operation of these features, where applicable.

1.20 Alarms. Operate the device in such a way as to activate each audible and visual alarm. Check that any associated interlocks function.

Check the action of the disconnected probe alarm. If the unit is so equipped. Also, if it has alarms for open- or short-circuited patient temperature probes, test these with open and short-circuited probe plugs. If the device has an alarm-silence feature, check the method of reset, i.e., manual or automatic, against the manufacturer's specifications.

1.21 Audible Signals. Operate the device to activate any audible signals. Confirm appropriate volume, as well as operation of volume controls.

1.22 Labeling. Check that labels clearly and concisely identify the functions of all controls, switches, and connectors. Because incubators may administer supplemental oxygen, they
Infant Incubator

should carry a WARNING—FIRE HAZARD placard, since textiles, oils, and other combustibles ignite easily and burn intensely in oxygen-enriched air. Exposing an infant to high oxygen concentrations may cause retrolental fibroplasia and possible blindness. Thus, incubator labeling should also include the following WARNING: EXPOSING INFANTS TO ELEVATED OXYGEN CONCENTRATIONS MAY CAUSE BLINDNESS.

1.2.3 Accessories

Hood thermometer. Check the hood thermometer for cracked glass and separation of the liquid column. If the liquid column has separated, it might be possible to consolidate it by removing the thermometer and carefully dipping it in hot water. If the thermometer has an expanded space at the top, the liquid will pool in the small reservoir chamber. When the gap in the column disappears into the pool, cool the thermometer and recheck it for column separation. Repeat the process if necessary. If the thermometer does not have reserve space at the top, the heated liquid will expand until it completely fills the thermometer, after which pressure will build up. The pressure may eliminate the column separation, but it may also break the thermometer. Even with a reserve space, overheating the thermometer may break it. In either case, do not let the thermometer go too fast or too high a temperature while attempting to consolidate the column. Replace the thermometer if it is cracked.

Mattress. If the mattress position is adjustable, check the ease of motion and security of the locking mechanism. Examine the mattress for tears, indentations. If the unit is to be used in the presence of flammable anesthetics, check that a conductive mattress cover is being used.

2. Quantitative tests

2.1 Grounding Resistance. Using an ohmmeter, electrical safety analyzer, or multimeter with good resolution of fractional ohms, measure and record the resistance between the grounding pin of the power cord and exposed unpainted and not oxidized metal on the chassis. We recommend a maximum of 0.5 Ω. If the system is modular, verify grounding of the mainframe and each module.

If the device has an accessory outlet, check its grounding to the main power cord.

2.2 Leakage Current. Measure the leakage current to ground from the incubator chassis and, if the unit has a battery charger, from the charger chassis in all operating modes, including off and during battery operation. Measure while all accessories are. Measuring leakage current with all accessories normally powered from the same line cord connected and turned on and off. This includes other equipment that is plugged into the primary device's accessory receptacles, as well as equipment plugged into a multiple-outlet strip or "water strip" so that all are grounded through a single line or extension cord.

Temperature Control. Check the action of the primary and secondary thermostats with the incubator totally assembled. Although this is a dynamic test, it is essential since proper thermostatic operation depends on the presence of normal airflow patterns. Test the thermostat according to the manufacturer's instructions, and record on the form the temperature at which the safety or backup thermostat turns off the heater. If the manufacturer does not provide instructions, use the following methods, which test both manual and automatic temperature controls.

In the manual mode, the primary thermostat cycles the heater on and off or provides proportional heating or maintains a constant incubator temperature. The operator can adjust the thermostat by changing a setting. In the automatic mode, a patient probe senses the infant's skin temperature, and electronic circuitry controls the heater to keep the skin temperature constant at a clinically desirable level.

To test manual controls, position the calibrated glass or electronic thermometer 10 cm above the center of the mattress, close the hood, set the temperature control to mid-range, allow the incubator to warm up to thermal equilibrium, and record the hood thermometer reading and the true mid-bed air temperature in Item 2. Then, alternately raise and lower the temperature setting. If the primary thermostat
Inspection and Preventive Maintenance System

To check automatic controls, first test the accuracy of the patient-probe temperature indicator. Place the probe and a calibrated thermometer into a cup of water preheated to approximately 37°C. Stir to reduce temperature gradients. Allow the temperature readings to stabilize, and record the patient-probe temperature indication and the true bath temperature in Item 2.4. If the two readings do not agree within 0.5°C, the probe may be defective. Substitute a probe known to be accurate, and repeat the test. If the two readings still disagree, the measuring circuit or sensor is defective and requires recalibration or repair.

Confirm the operation of the temperature control circuit by alternately dipping the probe into cold and hot water, well below and above the set-point temperature respectively. The heater should activate when the probe is cold and turn off when the probe is hot.

2.4 Skin-Temperature Alarms. If the incubator is equipped with high and low skin-temperature alarms, verify that these alarms function. Adjust the skin temperature set point to 37°C. Place the sensor in the incubator and allow the temperature to stabilize. Remove the sensor from the incubator, and verify that the low skin-temperature alarm activates.

To verify the high skin-temperature alarm, place the sensor in a water bath at 39°C and gradually increase the water bath temperature. Note the point at which the high alarm responds.

2.5 Safety Thermometer. To test the operation of the safety thermostat and the high-temperature alarms, disable the primary thermostat or disconnect from the control circuit. Then, repeatedly dip the thermometer in hot water, with the heater on, to verify that the heater remains on continuously. In some cases, this can be achieved by raising the temperature control to its maximum setting. It is possible to speed up the air-temperature rise by suppling the incubator heater output with a hot-air gun or hair dryer. Record the hood thermometer indication and the true mid-bath air temperature at which the safety thermostat and high-temperature alarms respond. Be careful not to heat the hood air too rapidly with the hot-air blower, or the mid-bath air temperature at the alarm point will be abnormally high.

It is because the safety thermostat is often at some distance from the mid-bath area, downstream in the airflow, so that its temperature is high behind the mid-bath air temperature. Also, avoid blowing hot air directly at the thermometers. If a blower is used, allow intermittent bursts of heat and pause for thermal stabilization. Reconnect the primary thermostat that had been disabled in the above procedure and consult the operator's manual to determine the necessary procedure.

2.6 Air-Temperature Alarms. If the incubator is equipped with high and low air-temperature alarms, verify that all alarms are functional. Adjust the air-temperature set point to 36°C and allow the air temperature to stabilize. Verify that the low air-temperature alarm, if equipped, activates when the incubator hood is opened.

To verify the high air-temperature alarm, set the air-temperature set point to 37°C and slowly increase the air temperature with an external heat source, e.g., hair dryer or heat gun. Note when the high alarm responds.

2.7 Hood Air Temperature. The mid-bath air temperature and hood thermometer readings taken in Item 2.4 should agree within 1°C.

2.8 Patient Probe. The patient-probe temperature indication and true water bath temperature, also recorded during performance of Item 2.5, should agree within 0.5°C.

2.9 Portafuel Power Supply. Transport incubators only. The portable power supply usually consists of a rechargeable battery, a rechargeable circuit, and associated wiring and connectors. It is essential to keep all parts in good condition to ensure the safe, effective operation of the transport incubator.

Battery types vary, and each requires a different inspection and preventive maintenance procedure. Types commonly used are lead-acid with a liquid or sealed gel, electrolyte, nickel-cadmium, and alkaline batteries. Sealed batteries require lesser maintenance than types to which fluid must occasionally be added to compensate for evaporation.

Measure the specific gravity of lead-acid batteries with a hydrometer, but not while the battery is charging. If the battery is charging at
Infant Incubators

Inspection time: Disconnect the charger and wait at least 15 min before testing the battery. Before taking a reading, quickly fill and empty the hydrometer several times to thoroughly mix the electrolyte, taking care to avoid splashing or spilling. The specific gravity of a fully charged battery should be 1.285. If necessary, check the electrolyte level and measure the specific gravity of the lead-acid batteries at least twice as frequently as every two weeks, depending on use and age of battery.

If the liquid level is low, add distilled or demineralized water to bring the level to the split ring in each cell. Do not overfill. Excess water may boil over and damage the battery case and nearby charging circuits. If the battery has been on a constant trickle charge and the specific gravity is too low and battery voltage is lower than 12.8 V, then the battery is defective or the charger circuit is faulty. The charging circuit may need readjustment.

If the incubator uses nickel-cadmium or gel-electrolyte lead-acid batteries, turn the heater on after the batteries are fully charged, and measure the voltage under load initially and after 15 min of operation. Record the two values. If the voltage decreases more than 10% during this period, replace the battery.

3. Preventive maintenance
   3.1 Clean the exterior and interior
   3.2 lubricate the fan assembly if required
   3.3 Calibrate if needed
   3.4 Replace filter and battery if needed

4. Acceptance tests
   Conduct major inspection tests for this procedure and the appropriate tests in the General Devices Procedure Checklist 008.

Before returning to use
   Set all controls to their normal positions.
KEMENTERIAN KESEHATAN R.I.
DIREKTORAT JENDERAL BINA UPAYA KESAHATAN
BALAI PENGAMANAN FASILITAS KESAHATAN MEDAN

SERTIFIKAT KALIBRASI

INKUBATOR PERAWATAN

TU.01.01/III/6579/2013

Pemilik: RSUD Deliserdang
Alamat: Jl. MH Thamrin
Merk: GFA
Model: YP - 930A
Nomor Seri: 6050930
Tanggal Kalibrasi: 22 Februari 2013
Tanggal Kalibrasi Ulang: 22 Februari 2014

Sertifikat ini diterbitkan berdasarkan hasil pengukuran menurut standard yang telah ditetapkan dengan menggunakan peralatan/penyanding yang telah disetel
Sertifikat ini disertai 1 (Satu) lembar laporan

Medan, 10 Desember 2013
Ptt. Kepala Balai Pengamanan Fasilitas
Kesehatan (BPfK) Medan

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