



CONAIR MEDLINE®
EQUIPMENT CLEANROOM
READY



Why MedLine?

MedLine equipment fulfills two important needs for medical device manufacturers:

1. Easy implementation by the user into their highly regulated environment.
*Conair does most of the **certification homework** for medical processors!*
2. All MedLine equipment is **designed to meet compliancy specifications** for medical processing.



Why MedLine?

Examples:

Powder coated white paint, cleanroom complaint material components.

Fully calibrated and traceable operating parameter testing.

Sanitation considerations and exhaust minimization or elimination.



Steps for applying MedLine equipment

1. Identify the equipment use location:

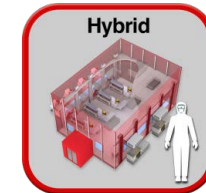
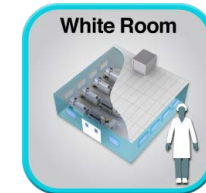
This helps Conair clarify specifications.

a. NON-CLEAN ROOM USE:

- For easy implementation into an existing manufacturing line for medical compliance.
- For inclusion in a future clean room.
- Otherwise, standard Conair equipment will suffice.

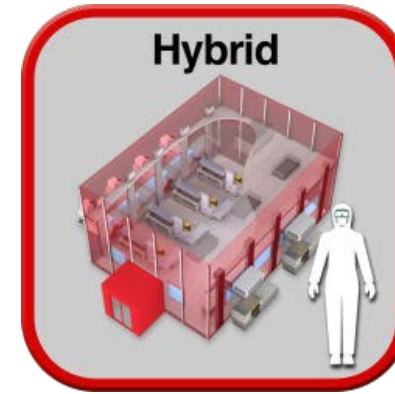
b. CLEAN ROOM USE: Four clean room types:

- **White room**
- **ISO 8 clean room**
- **ISO 7 clean room**
- **Hybrid clean room**



Steps for applying MedLine equipment

1. Identify the equipment use location



Different cleanliness levels drive different installation requirements.



Steps for applying MedLine equipment

2. Clarify MedLine compliancy:

MedLine equipment provides compliance-ready specifications for easy implementation by medical manufacturers:

- ISO International Standards Organization
- FDA Food and Drug Administration
- ICH International Conference on Harmonization Compliance
- CFR Code of Federal Regulations



Conair provides a list of medical manufacturing compliancy codes with each MedLine equipment and system quote.



Steps for applying MedLine equipment

2. Clarify MedLine compliancy:

Some details:

Factory calibration

- Sensing devices critical to equipment operation are calibrated with certified measuring instruments to verify that the equipment provides optimum performance.

Calibration certificate

- A document, accompanied by a dated equipment sticker, verifies that calibration has been performed on required components to meet requirements that will assure the equipment functions at optimum performance.

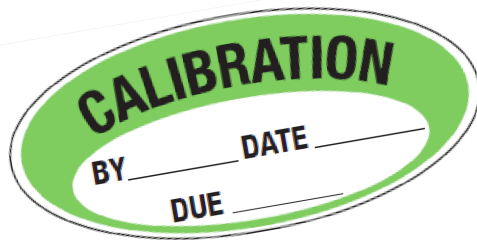
Calibration label

- A dated and initialed label, (accompanied by a signed and dated calibration certificate) that is affixed to the equipment that verifies that calibration has been performed on a specific month and year and provides the next calibration date interval requirement.



Steps for applying MedLine equipment

2. Clarify MedLine compliancy:



Certificate of Calibration

Product: _____ Model Number: _____
Serial Number: _____ Date: _____

Specified Requirements: The MedLine Adiabatic cooler has been tested to the latest revision of Conair test procedures. The test verifies the RTD is functioning within acceptable parameters. Full operation of the unit for its intended use and function has been inspected and verified.

Per the review and testing conducted by Conair and based upon the successfully completed fore mentioned test procedures, Conair confirms that this product conforms to the above specified requirements of Conair's quality and functionality standards. This calibration/certification should be performed annually from the date of this certificate. Please see owner's manual for calibration procedures

Authorized signature _____

For any further compliance information please contact Customer relations at: 814-437-6861 or service@conairgroup.com



FM11.01b/XXXX



Steps for applying MedLine equipment

2. Clarify MedLine compliancy:

ISO conformance documentation

- International Standards Organization conformance documentation. Control documents that are traceable and auditable with qualification signatures, dates and reviewed-by signatures in accordance with ISO 13485, CFR, cGMP (current Good Manufacturing Practices).

IQ checklist

- Installation Qualification checklist. A controlled document checklist that details installation requirements, verifies that each step is properly performed and that the equipment may be operated as intended.

PM checklist

- Preventative Maintenance checklist. A controlled document checklist that details the necessary equipment maintenance intervals for maintaining adequate calibration and audit compliancy.



Steps for applying MedLine equipment

2. Clarify MedLine compliancy:

Installation Qualification (IQ) checklist

TPCML001-0115

MEDLINE[®]
CONAIR

Positive Displacement Pump Installation Checklist

Before beginning

⚠ The User Guide that came with your equipment provides detailed safety information and procedures for installation, operation, troubleshooting, and maintenance of your equipment. Refer to the User Guide for more detailed information. Always follow all required safety procedures.

➡ Conair recommends that you make a copy of this original checklist, to be used for your records, prior to making any marks on the document.

After following the instructions contained in the Installation section of the Conair User Guide that came with the equipment, verify installation by the following Checklist:

- Set or mount the Vacuum Pump.
- Connect Power - Voltage _____ (fill in required voltage).
- Check Motor Rotation.
- Install the Vacuum Lines.
- Connect the Dust Collector Vacuum Outlet to the Pump Inlet.
- Connect the pump control to the material conveying system control pump output.

Serial Number: _____ Model: _____

Performed by: _____ Date: _____

Reviewed by: _____ Date: _____

Phone: 724.584.5500 | Instant Access 24/7 — Parts and Service: 800.458.1960 | Parts and Service: 814.437.8861
info@conairgroup.com | www.conairgroup.com

TPCML001-0115

MEDLINE[®]
CONAIR

Positive Displacement Pump Preventative Maintenance Checklist

Before beginning

⚠ The User Guide that came with your equipment provides detailed safety information and procedures for installation, operation, troubleshooting, and maintenance of your equipment. Refer to the User Guide for more detailed information. Always follow all required safety procedures.

➡ Conair recommends that you make a copy of this original checklist, to be used for your records, prior to making any marks on the document.

Refer to the User Guide for more detailed maintenance procedures.
Check the box by each procedure as it is completed. Sign and date the form for your records.

Monthly

- Clean or Change Pump inlet filter.

Every six (6) months

- Check Vacuum Relief Valve — See User guide for adjustment procedure.

Every twelve (12) months

- Check V belts — refer to the User Guide for adjustment — refer to the User Guide.
- Grease Pump bearings — Refer to the User Guide.
AS REQUIRED — OIL CHANGES as per the SAE or Synthetic.
Schedule in the User Guide (select the check box that applies to your pump).
- Change Oil for SAE Oil 1500 Hours.
- Change Oil - Synthetic 6,000 hours.

Serial Number: _____ Model: _____

Performed by: _____ Date: _____

Reviewed by: _____ Date: _____

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Preventative Maintenance (PM) checklist



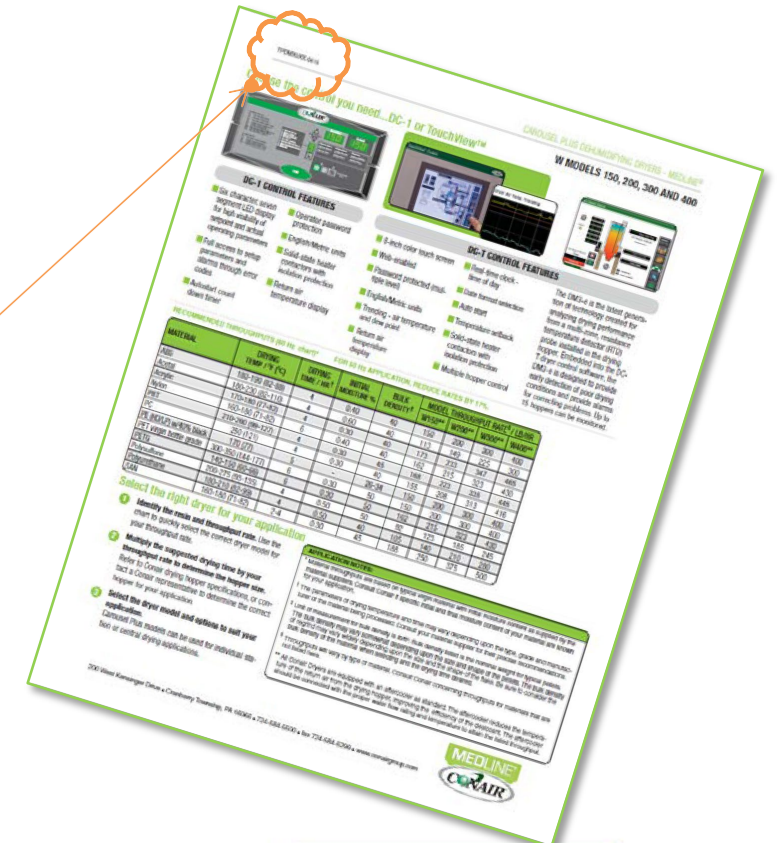
Steps for applying MedLine equipment

2. Clarify MedLine compliancy:

Revision control

- Highly controlled, equipment-related documents with revision-specific document numbers assigned. When changed, the document's revision number changes so that all revisions and updates are documented and traceable.

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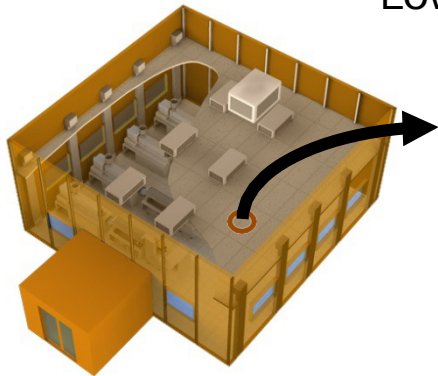


Steps for applying MedLine equipment

2. Clarify MedLine compliancy:

Exhaust minimization or elimination

- A procedure to effectively deal with exhaust discharge that is primary to the operation of some equipment.
 - Water-cooled chillers can be applied in place of air-cooled models.
 - Vacuum valves used for resin conveying can be remote mounted outside of the clean room to discharge vacuum air.
 - Additional hardware may be provided for routing moist, hot and/or particulate exhaust air from the cleanroom as required.
 - Low thru-put equipment minimizes exhaust to acceptable ISO room levels.



Discharge air routed out of the cleanroom



MicroWheel dryer



Steps for applying MedLine equipment

3. Select equipment:

Start with the MedLine brochure to understand how MedLine equipment fits your medical manufacturing requirements.



Steps for applying MedLine equipment

3. Select equipment:

MedLine brochure can be ordered from the Conair website



A screenshot of the Conair website's 'CLEAN ROOM READY' section. The page features a blue and green color scheme. At the top, there is a navigation bar with the Conair logo, a search bar, and a phone number (+1.724.584.5500). Below the navigation bar, there is a large banner with the text 'CLEAN ROOM READY' in large, bold, black letters. To the right of the banner, there is a green call-to-action button that says 'Click here to order our MedLine brochure.' Below the banner, there is a smaller image of a clean room and a brochure. The brochure has the text 'CLEAN ROOM READY' and 'MEDLINE CONAIR'. Below the brochure, there is a small text box that says 'Conair MedLine® auxiliary equipment is pre-evaluated, pre-configured, pre-calibrated, fully-documented and ready for installation in your clean room.'

www.conairgroup.com



Steps for applying MedLine equipment

3. Select equipment:



MedLine resin conveying



Steps for applying MedLine equipment

3. Select equipment:



MedLine dehumidifying dryers



Steps for applying MedLine equipment

3. Select equipment:



MedLine dehumidifying drying systems



Steps for applying MedLine equipment

3. Select equipment:



MedLine blenders

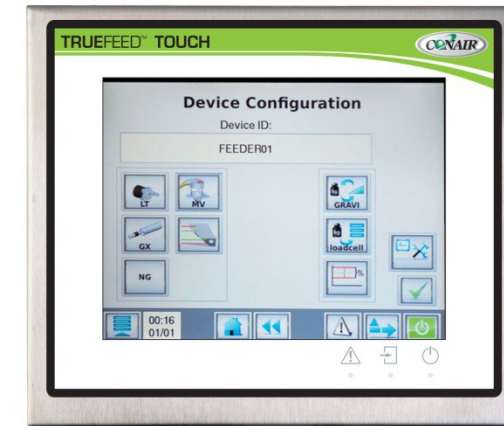


Steps for applying MedLine equipment

3. Select equipment:



MedLine throat metering feeders



Steps for applying MedLine equipment

3. Select equipment:

MedLine liquid
temperature controls



Steps for applying MedLine equipment

3. Select equipment:



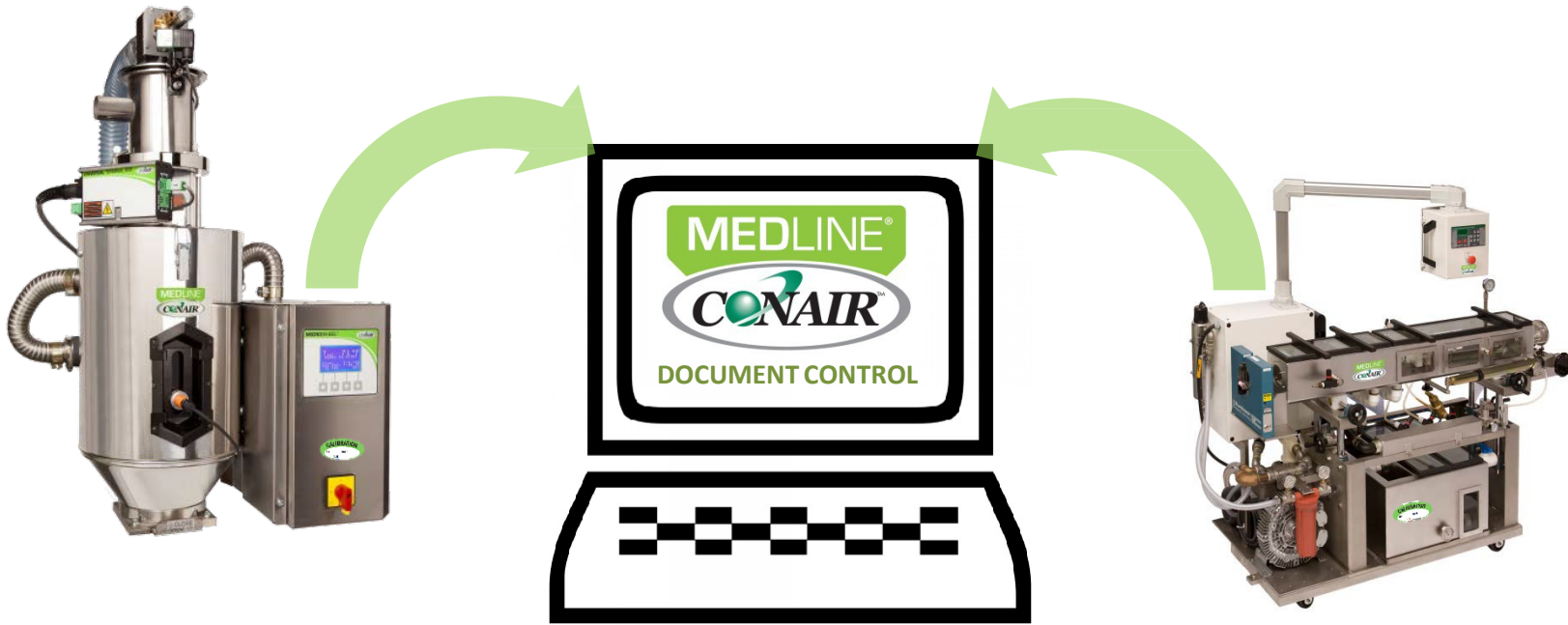
MedLine pipe, tubing extrusion



Steps for applying MedLine equipment

4. Shipment/delivery:

All revision-controlled records on each piece of equipment are permanently stored for easy recall in Conair's centralized MedLine repository.

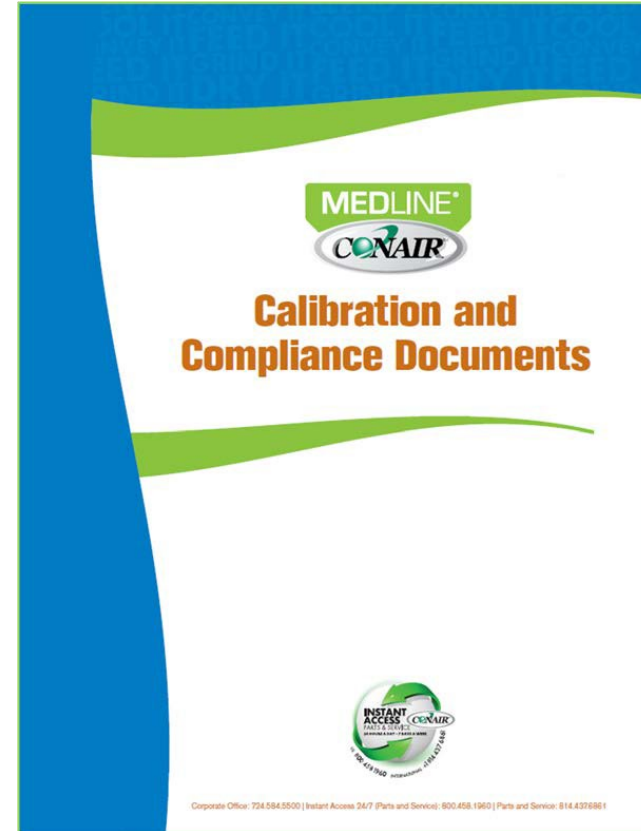
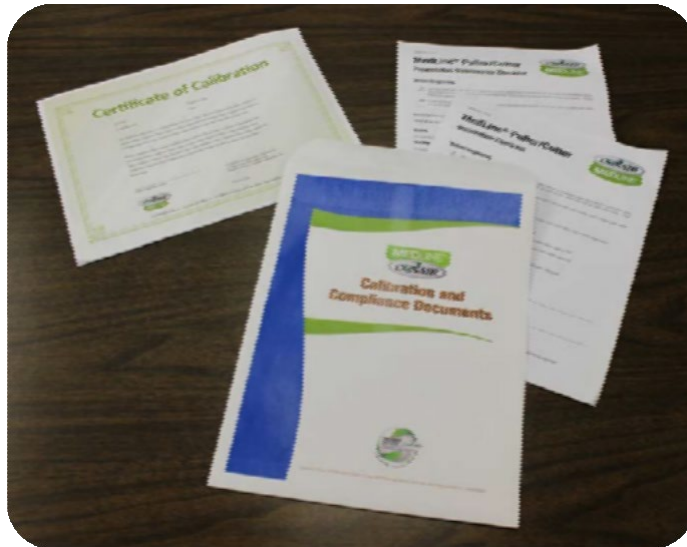


Steps for applying MedLine equipment

4. Shipment/delivery:

A compliance documentation package is shipped with each piece of equipment:

- Calibration certificate
- IQ check list
- PM check list

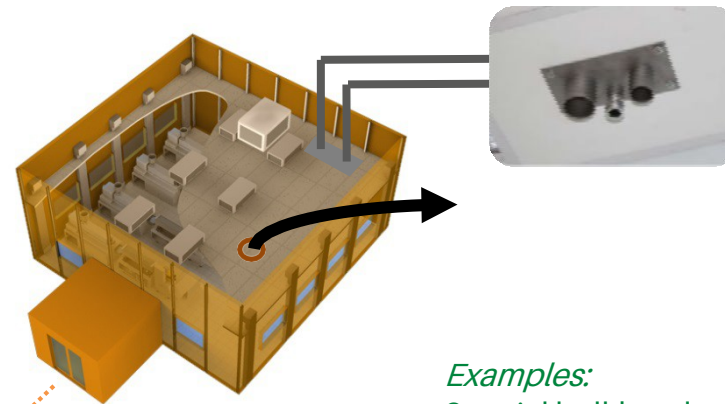


Steps for applying MedLine equipment

4. Shipment/delivery:

If required, Conair Project Services group can provide installation management and/or assistance:

- An experienced Project Manager, assigned to your project, provides:
 - Single point of contact
 - System specification
 - Flow schematic
 - Timeline management
 - Scope-of-work documentation
 - Installation drawings
 - Project records
- Expert installation
- Additional design engineering if required
- Seamless integration with processing machines
- Seamless integration with clean room/infrastructure



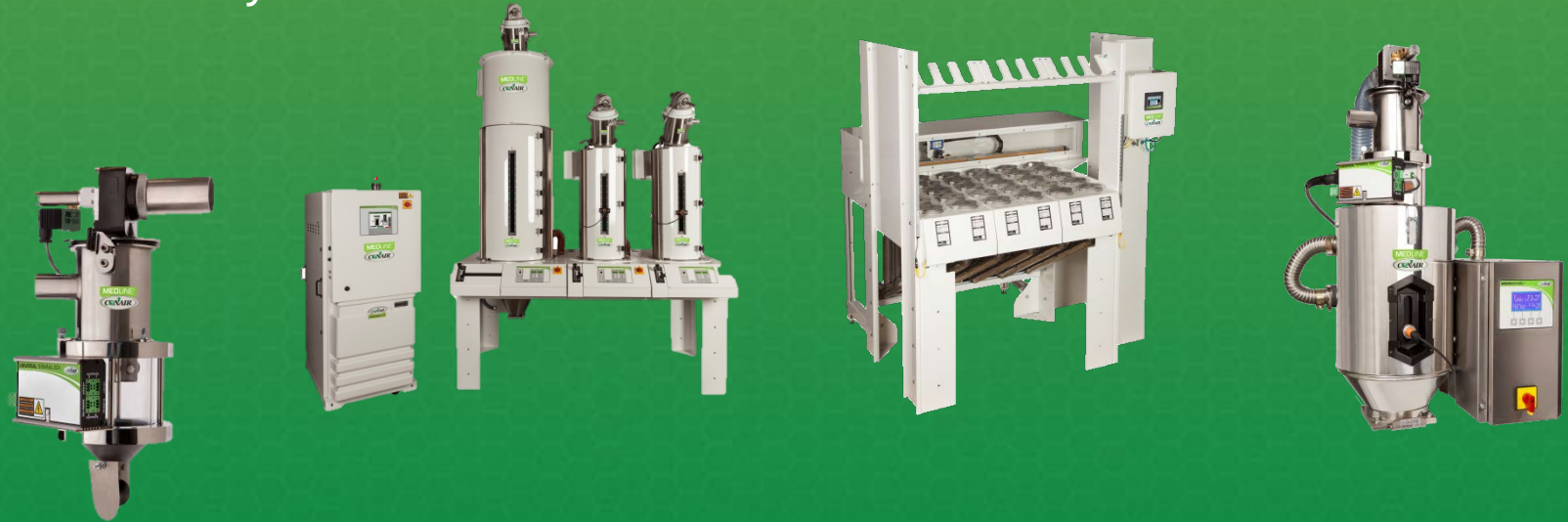
Examples:
Special bulkheads,
vents and cable
penetrations for clean
rooms





CLEANROOM READY CONAIR MEDLINE® EQUIPMENT

Thank you!



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