Laminar Flow Clean Benches
Clean Air Device

PART 1 – GENERAL

1.1 REFERENCES

The publications listed below form a part of this section to the extent referenced.
The publications are referred to within the text by the basic designation only.
EU GMP
ISO 14644

1.2 DESIGN AND PERFORMANCE CRITERIA

A. Provide a clean and sterile work area as per ISO 14644 Class 5 and EU GMP Grade A Guidelines.
Clean Bench shall operate in an efficient and sustainable manner.
B. Electrical consumption of new units shall be no greater than: 270 watts for nominal width 0.9m / 3ft and 1.2m / 4ft units; 550 watts for nominal width 1.5m / 5ft and 1.8m / 6ft units

1.3 SUBMITTALS

Product Data - Clean Benches
Clean Bench – Operating Manuals
Clean Bench – Demonstration
Factory Test Report - provided with units

1.4 QUALITY ASSURANCE

A. Each Clean Bench must be constructed and installed in accordance with ISO 14644
B. All Clean Benches must carry a side mounted, easily accessible manufacturer's plate giving type, date of manufacture, serial number and CE mark.
C. All Clean Benches, after installation, to be certified as passing the appropriate airflow tests and also to include measured airflows at the time of the test
D. A factory test for each Clean Bench validating proper performance including:
1. HEPA Filter leak test
2. Horizontal air velocity and uniformity (Unidirectional/Laminar)
3. Particulate monitoring test
4. Alarm test/Function

1.5 QUALIFICATIONS

A. Manufacturer
1. Company with minimum fifteen years documented experience in the construction of Clean Benches
2. Clean Bench should be of European manufacture and have spare parts readily available.

1.6 WARRANTY

A Manufacturer's warranty against defects in material or workmanship covering parts & labour must be available for a period of 24 months. Standard exceptions for filters and lamps shall apply.

PART 2 – PRODUCTS

2.1 MANUFACTURERS

A. Thermo Scientific

2.2 CLEAN BENCHES

A. Exterior dimensions
1. Nominal 0.9m / 3ft width (HWD) – 1170mm x 1000mm x 810mm or 46.1" x 39.4" x 31.9"
2. Nominal 1.2m / 4ft width (HWD) - 1170mm x 1300mm x 810mm or 46.1" x 51.2" x 31.9"
3. Nominal 1.5m / 5ft width (HWD) – 1170mm x 1600mm x 810mm or 46.1" x 63.0" x 31.9"
4. Nominal 1.8m / 6ft width (HWD) - 1170mm x 1900mm x 810mm or 46.1" x 74.8" x 31.9"
5. Nominal 1.8m / 6ft width & 95cm / 3ft height (HWD) - 1475mm x 1900mm x 1010mm or 58.1" x 74.8" x 39.8"

B. Additional Height Range with Stand
1. Adjustable Height Stand - Work surface heights from 760 to 960 mm adjustable in 50mm increments.
2. Castors with Stand - Work surface height of 860mm

C. Interior dimensions
a. Nominal 0.9m / 3ft width (HWD) - 645mm x 920mm x 585mm or 25.4" x 36.2" x 23.0"
b. Nominal 1.2m / 4ft width (HWD) - 645mm x 1220mm x 585mm or 25.4" x 48.0" x 23.0"
c. Nominal 1.5m / 5ft width (HWD) - 645mm x 1520mm x 585mm or 25.4" x 59.8" x 23.0"
d. Nominal 1.8m / 6ft width (HWD) - 645mm x 1820mm x 585mm or 25.4" x 71.6" x 23.0"
c. Nominal 1.8m / 6ft width & 95cm / 3ft height (HWD) - 950mm x 1820mm x 785mm or 37.4" x 71.6" x 30.9"

2.3 CONSTRUCTION

A. Side Windows should be manufactured from tempered safety glass with access port for tubing
B. Unit shall have rigid plenums. (Non- rigid, fabric type plenums are not acceptable.)
C. H14 HEPA Filter, scan-tested, zero-probe HEPA filter, 99.995% efficient on most penetrating particle size (H14 per EN 1822), serviceable and removable from front of unit.
D. Type G3, Easy Change Prefilter for the intake air
E. Mounted fluorescent lighting fixture.
F. 3 x 230V Receptacles as standard (Power sockets) or 2 x 120V GFI sockets

2.4 PERFORMANCE REQUIREMENTS

A. Clean Bench must have "brushless" DC motors to ensure lower energy consumption and low heat emission.

B. The motor must automatically adjust the airflow speed as the filter starts to load.

C. Power consumption: Not to exceed 270 watts for nominal 0.9m / 3ft width, 1.2m / 4ft width. 550 watts for nominal width 1.5m / 5ft and 1.8m 6ft.

D. Clean Bench must provide 2 levels of airflow velocity settings.
Regular : 0.45m/s +/- 20% or 89fpm +/- 20%
Reduced flow : 0.23m/s +/- 20% or 45fpm +/- 20%

E. Must have alarm set points as per ISO 14644 and GMP Annex 1 of ±20%

F. Visual indicator on the display panel for the following features:
1. Safety status of the cabinet - The cabinet must display performance criteria to ensure the user that they are working under safe conditions.
2. Hours of operation
3. Time of day
4. Unidirectional air velocity (m/s)
5. Operating time of optional UV lights
6. Timer for delayed start

G. The cabinet must provide an indicator for its performance to ensure that the user knows when it is time to exchange the HEPA filter or schedule routine service.

H. No HEPA filter leakage ≥ 0.01% of upstream concentration.

I. Alarm monitoring must be done via a pressure sensor.

J. All Airflow measurements within 20% of average.

2.5 ERGONOMIC OPERATION REQUIREMENTS

A. Side windows to increase all round vision, and to allow more light into the work zone.

B. Work area illumination: No less than 1000 Lux at the work surface

C. Noise levels must be <55 dB(A) at level 1 velocity setting. Noise levels must be <60dB(A) at level 2 velocity setting.

2.6 ACCESSORIES

A. Multiple work surface options including Melamine and Stainless Steel.

B. Option of a Transparent hinged windscreen

C. U.V Disinfection option

D. U.V resistant night cover option

E. Service valve taps

F. Adjustable footrest

G. Clean and safe cable and tube routing provision in the side of the Clean bench

H. IV bag holder

I. Ergolign saddle stool