



DIALYZER ASSEMBLY SYSTEM

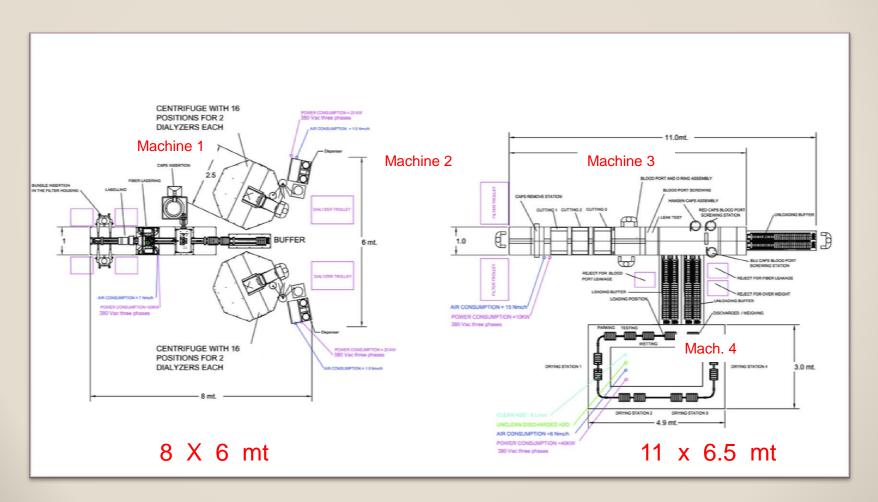
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Dialyzer assembly system Lay out example







Dialyzer assembly system

Tecnoideal has developed a complete assembly system for the production of PS/PES hemodialyzer.

Machinery and tools allow a production of 400 dialyzers/hour, based on a continuous process concept.

Customized assembly machines are designed for an automated and reliable production process, with a minimal need of manpower.

Quality control "in process", assures complete traceability of each dialyser produced.





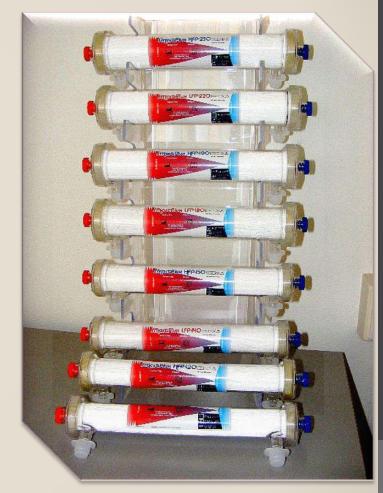


Dialyzers configuration:

The line processes filters of different sizes (diameters) but of standard length and same connector position.

- □Standardization of the filter ports position, allow processing filters with different surfaces
- □ Qick operations of set up on each machine gives flexibility to the filter production line

2.3 mq



1.1 mq



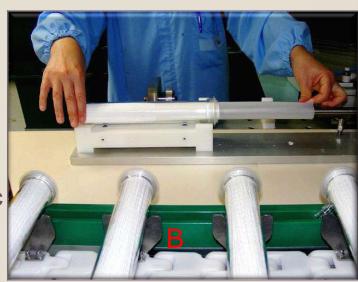
Preparation for PUR potting of fiber bundles

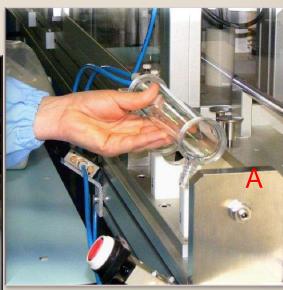
Bundle insertion

The preliminar operation the for the potting of the filter heads

Process can be:

- Manual
- > Semi-automatic
- Automatic





Assembly of a potting cap ring by mechanical locking. Operation performed with the pneumatic press

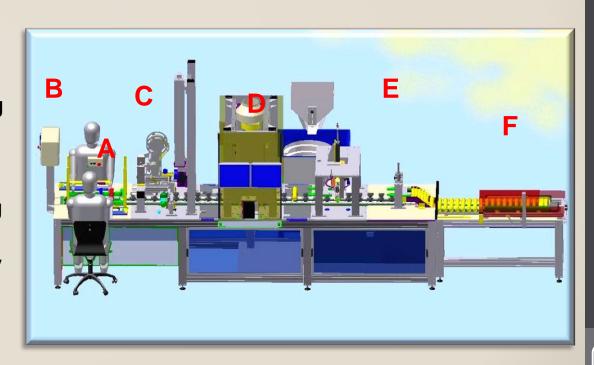
In manual or semi-atomatic 100 % inspection of the bundles is possible Plastic sheet removal can be done manually or automatically



Machine 1

Typical assembly operation for PUR potting of hollow fiber filters

- A- assembly of a potting cap ring
- B- Inspection and bundle insertion
- C- Label or data printing
- D- Laser fiber sealing.
- **E- Potting cap assembly**
- F- Unloading on conveyor buffering for next potting operations.



Machine dimensions in cm are: L 450 : D 120 ; H 205

Filter labelling



- •The filter labelling can be done automatically; the following options are also available:
- Label printing of the data by using laser technology
- Temporary traceability laser-engraved on cartridges
- Automatic label application on filter housing





- Variable data (batch and expiration date) are programmed by a PC connected to the laser printer.
- The system gives the maximum flexibility and the complete traceability of each dialyzer during the process.





Laser beam fiber sealing

The head of the bundle is treated with a CO₂ laser beam to melt and close the fibers ends

- Laser fiber sealing is performed by customized programs based on the bundle diameter and fiber material
- The laser guarantees a reliable process of fiber end melting to assure proper sealing
- Fumes produced in the process are collected by an exhaust system to prevent health hazards and bundle contamination



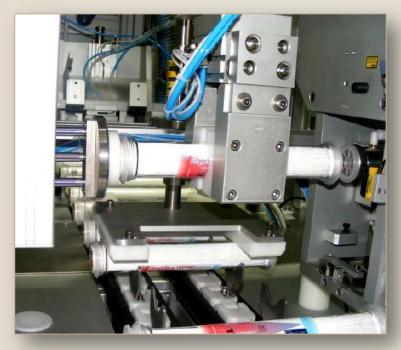
Laser beam chamber connected to fumes removal system





Potting cap assembly

Plastic caps can be automatically positioned on filter heads



Capping of the potting ring is made by positioning two plastic caps on the filter heads



The caps are sorted by feeder bowl and mechanically locked on the plastic ring previously assembled on the filter housing





Potting area



A buffer before the potting operation allows the balancing of the machines to prevent unnecessary stocking and trasportation of the filters from one station to the next.

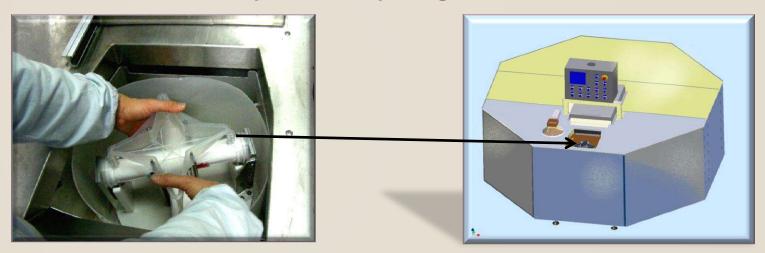
Machine



Filter potting with PUR by centrifugation

Machine configurations:

- Round centrifuges with two filters for each position, on a rotating carousel
- The carousel have 16 position for potting.



- * Customized programs can be stored and recalled for a quick set-up of the machine
- One operator can manage the loading and unloading operations.
- * PUR is injected automatically while the two filters are rotating.
- Delivery time of the system is about 36 s; 200 dialyzers/h each centrifuge. Total 400 dialyzers.





Mixer for potting with PUR

System features:

- □ PUR mixer designed for continuous, reliable work and easy mantainance.
- Degassing of PUR components is done continuously. The machine can work three shifts.
- Machine refilling with the two component is automatic and based on weighing on board of the component storage
- Easy and reliable set-up of the components proportion and qty to dispense





PUR mixing and dispensing

System features:

- □ The mixing head uses a static highefficiency mixer.
- □ This avoid to use solvent for cleaning the mixing device.
- ☐ The mixing operation results cheap and clean.
- Customized programs can be stored and recalled for a quick set-up of the machine







Potting by centrifugation

The operator loads two filters and a re-usable reservoire in the centrifuge cell

The manual loading position has a safety door that remains locked during centrifugation

In the next position the mixing head injects the PUR directly in the potting reservoire during rotation.

□ The reservoire distributes the PUR to the four filter heads, dividing the quantity injected in four equal parts.

 PUR quantity, temperature and centrifugal speed are pre-set parameters







Dialyzers curing buffer

- □ Buffering is by a trolley wich holds ab 500 dialyzers awaiting the curing time
- □ The dialyzers ready at the pick up point are the first loaded, thus more cured; "fi-fo" system
- □ The trolleys are loaded at the centrifuge station then moved next to the cutting machine for the manual loading of the cutting machine





Machine 3

Cutting and final assembly.

The machine performs the following operations:

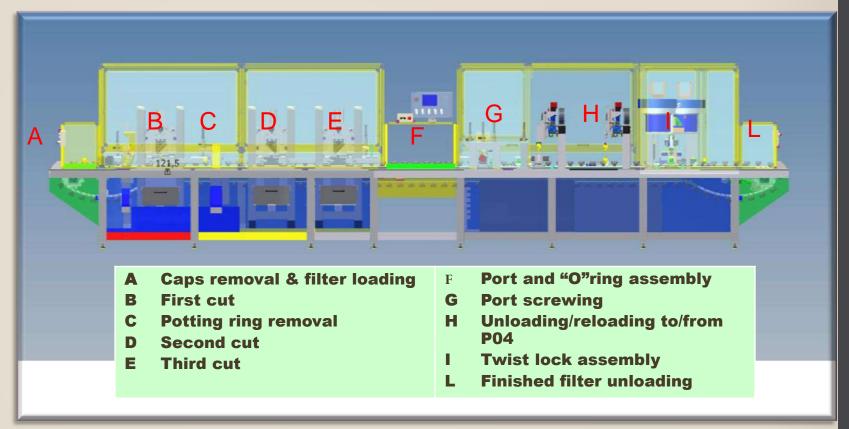
- □ Removal of the potting cap
- □ First cut or rough cut.
- Potting ring removal
- □ Second cut
- □ Final cut
- □ Inspection of filter heads by video camera.
- Manual positioning of the "O"ring and blood port
- Automatic tightening of the blood ports by torquecontrolled screwing.
- □ Leak testing of the "O"ring sealing







Machine 3 - Stations



Features

- Easy handling
- Quick and safe operation
- □ Dimensions cm: L 600 ; P 100 ; H 200



Machine loading

- After buffering and curing the dialyzers are ready for the final process
- □ The dialyzers are positioned in the loading area by one operator.
- □ The loading position, has a buffer of four dialyzers ready to be processed.



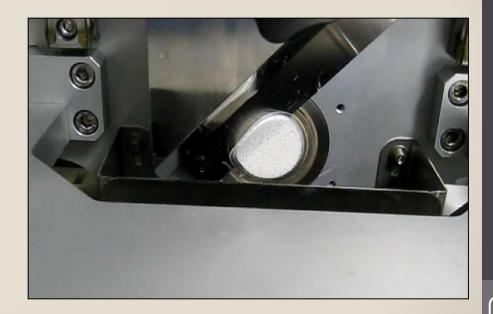




Cutting of the filter heads

The last cut leaves a smooth head surface cutting operation is performed by diamond-sharpened blades

- Depending on curing time and hardness of the PUR material the machine can warm the filter head if needed
- The blade is diamond paste sharpened
- ☐ The thicness of all cuts can be adjusted with high precision by micrometric adjustements





Filter port assembly

- Depending on the configuration of the product, different processes can be managed: semiautomatic or automatic (if the parts are designed for this purpose)
- One common technology uses screwed dialyzer ports and "O" ring seal
- □ The photo refer to the preassembly of ports with "O" rings, ready for the port tightening by automatic screwing at pre-set torque
- ☐ This operation includes an inprocess 100% visual control

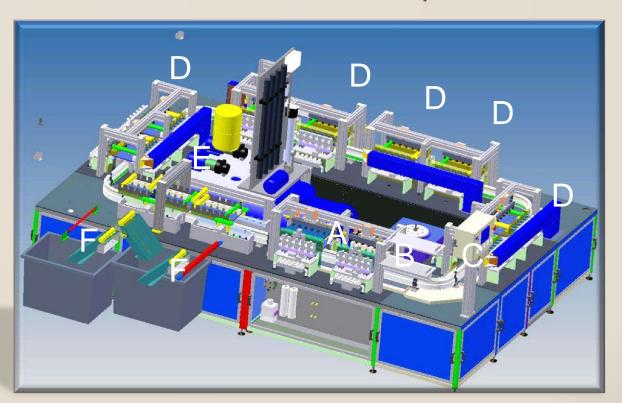


Machine 4



Operations performed are completely automatically:

- A Filter wetting with ultrafiltrated water
- C Leak test with clean air
- E Weight check before unloading on the P03 machine
- **B** Filter drainage and ultrafiltration
- D Water removal by hot air blow in both filter compartments
- F Discharge of the reject in a separate collection bins





Dialyzers testing station

- Automatic loading of 6 filters on shuttles moving on a rail ring
- Multiple working station but individual testing of the filters for leakage
- ☐ Testing parameters can be preset on the testing equipmet; many programs can be stored and recalled for different filter model set-up
- ☐ The filters need to be wet for the leak testing
- On line water treatment with reverse osmosis and ultrafiltration
- Automatic leak test of 6 dialyzers at a time
- The rejects are traced and discharged at the end of the drying cycle
- □ Air to the tester is filtrated to prevent contamination

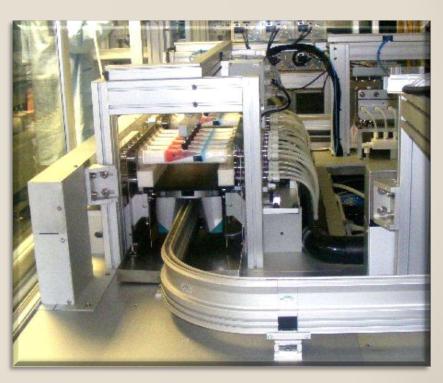


Filter drying



- Shuttles take the 6 filters from one station to another
- Blown air filtrated with absolute filter

- □ Low energy consumption.
- □ The air is both warmed and compressed at the same time by turboblowers
- □ Dehumidifier dries the air recirculated into the system.



Automatic loading of 6 filters on shuttles moving on a rail ring



Loading /Unloading of dialyzers on machine 4

- The dialyzers are individually weighed during the unloading operation.
- □ Dialyzers out of the preset weight range are discharged in a separate bin
- □ Dialyzers rejected in leak test are unloaded in a another reject bin







Final Assembly

Hansen port and blood port assembly with cap protection cap

- □ Vibratory bowl sort out the Hansen cap
- □ The Hansen connectors are automatically capped with plastic cap



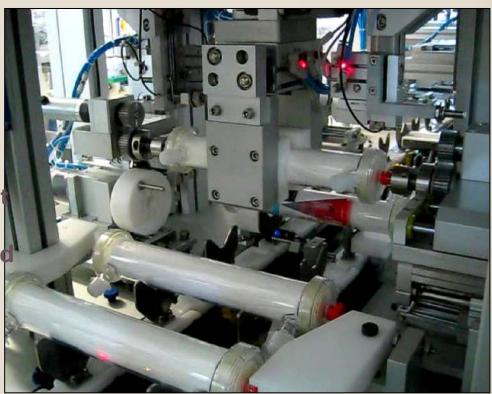




Blood port cap assembly

 A twist-lock cover is automatically assembled to the blood ports

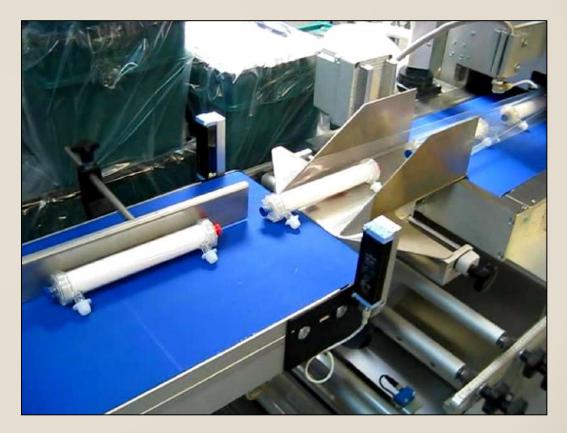
- If the caps are color coded the machine check the correct label position by color sensor for the correct assembly.
- Controlled torque is applied in the screwing of the cap





Dialyzers packaging

Dialyzers are unloaded on a a conveyor belt that feeds the packaging machine



- □ No man power needed in the individual packaging of the products
- □ Packaging operation is simple and reliabile