The new Cell Separator

COM.TEC
COM.TEC General Design

- Infusion bar with thermal printer
- Graphic user interface (GUI)
- Control panel with anticoagulant pump, ACD drip monitor and ultrasonic air detector
- Automatic valves
- Color coded blood pumps
- Centrifuge compartment
- Big wheels
COM.TEC General Design

- Centrifugal separation
- Continuous flow device
- New Single Needle capability
- Seal-less closed disposable sets (umbilical tubing)
- Components collected outside centrifuge
- Coupling of the parameters with the whole blood flow for a continuous high product quality
- Short dwell time inside the centrifuge
- Low extracorporeal volume
- Donation as well as therapeutic protocols
COM.TEC Interface Control

- Completely automated procedures using CCD camera (PLT procedures) or IR beam interface detection (8 - holes, C4, PL1 chamber)

- Detection in the separation chamber determines IF position at every rotation

- Plasma pump is constantly optimizing the plasma flow

- Constant component quality and purity throughout the procedure
COM.TEC Safety Systems

1. Fail-safe electronic circuit for top priority safety systems
2. Automated safety check prior to procedure mandatory
3. Anticoagulation safety by drip monitor plus monitoring of pump operation
4. Hemolysis/hematocrit monitoring of plasma line plus centrifuge cabinet temperature monitor
5. Inlet and outlet pressure monitor plus pressure monitor for externally connected device (e.g. Prosorba® Column)
COM.TEC  Safety Systems

6. Replacement fluid detector for exchange treatments

7. Return line air detector

8. Return line clamp with optical detector for blood detection

9. Leakage detector inside the centrifuge (automatically tested)

10. Supervision of extracorporeal volume by additional PC board
Important procedure steps are part of the user guide’s main route.

More detailed descriptions are available on request (by <Help> key) as sub-menus.

Menus for entry of initial values for detailed calculation for donor/patient or product parameters for all protocols.
COM.TEC Protocols

- PLT 5d (Platelet collection in dual needle)
- PLT 5d-SN (Platelet collection in single needle)
- PBSC-Lym* (Peripheral stem cell collection, lymphocytes)
- RV-PBSC* (Peripheral stem cell collection, reduced volume)
- MNC* (Peripheral stem cells, mononuclear cells)
- Granulo* (Granulocyte collection)
- Deplet* (Cell depletion)
- TPE* (Therapeutic plasma exchange)
- RBC* (Therapeutic Red blood cell exchange or depletion)
- Adsorb (Plasma treatment)
- BMSC (Bone marrow stem cell processing in vitro)

* = optional emergency single needle capability
COM.TEC Sets

- Donor lines including needle
- Storage bags
- ACD-line
- Drip chamber
- Pump segments
- Separation chamber
• C5L dual needle set for platelet collection 5 day storage
• S5L single needle set for platelet collection 5 day storage
• C4Y dual needle set for stem cell collection
• RVY dual needle set for stem cell collection with reduced product volume
• P1Y dual needle set for mononuclear cells and stem cell collection
• PL1 dual needle set for therapeutic plasma exchange and RBX
• P1R dual needle set for plasma treatment
COM.TEC Separation Features

- Parameter coupling to whole blood flow for optimized product quality
- Cell collection outside the centrifuge and
- Short dwell time inside the centrifuge
- Low extracorporeal volume (180 ml)
COM.TEC Objectives

- Platelet collection of 3,3 x 10^11 in 40 - 60 minutes
- White blood cells contamination < 5 x 10^5
- Single Needle separation within 1 hour
- Software for data management
- Fully automatic stem cell procedure
- Reduction of noise during separation
- Increasing operator comfort
COM.TEC Realisation

- New separation chamber C5
  - increased efficiency in platelet collection (60%)
  - improved reliability in WBC contamination (< 5* 10E5 /PC)
- New large colour display and enlarged donor display
- New fast SN - program (single dose platelets in ~60 min)
- Apheresismaster, wireless data communication
- Noise reduction about 4 dBA
COM.TEC Platelet Collection

- Excellent platelet yields due to whole blood standardization by plasma recirculation
- Very competitive collection times adding to short handling cycles
- Optional extra plasma collection
- Excellent and consistent low leukocyte contaminations
- PC Menu - algorithm for tailoring of product
- Increased efficiency in single needle mode by 100% whole blood recirculation
- Donor Menu - algorithm for tailoring of anticoagulation and procedure
COM.TEC New separation chamber C5

whole-blood

plasma

interface

RBC barrier

2200 rpm

RBC

platelets
COM.TEC  Function of plasma recirculation

- whole blood pump
- recirculation pump
- cell pump
- plasma pump
- storage bags
- C5 chamber

Fresenius Transfusions GmbH
Fresenius HemoCare
• Apheresis of Mononuclear Cells (MNC’s) containing the CD34⁺ fraction

Status:

• Highest efficiency of CD34⁺ cells (70 - 90 %)

• Low content of contaminating cells like
  - Platelets
  - Red blood cells
  - Granulocytes
### Average Cell Concentrations in a Leukopheresis Product

<table>
<thead>
<tr>
<th>Cell Type</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>20-150000 /10^3/µl</td>
</tr>
<tr>
<td>RBC</td>
<td>0,5-1,2 /10^6/µl</td>
</tr>
<tr>
<td>Hb</td>
<td>0,8-2 g/dl</td>
</tr>
<tr>
<td>Hct</td>
<td>4-8 %</td>
</tr>
<tr>
<td>Plt</td>
<td>~20% loss</td>
</tr>
<tr>
<td>CD34+</td>
<td>depends on the pre value of CD34+ cells (linear correlation in a certain range)</td>
</tr>
<tr>
<td>MNC</td>
<td>80-95%</td>
</tr>
<tr>
<td>Neutr. Gran.</td>
<td>~10%</td>
</tr>
</tbody>
</table>
COM.TEC
New features for COM.TEC Stem Cell Apheresis

• Automatic collection of autologous plasma

• Blood flow decrease to 10 ml/min minimum especially for pediatric patients

• Prediction of apheresis time

• Automation of the procedure by prediction of the volumes for Cycle, Spillover and Buffy Coat

• Prediction of the CD34+ concentration in SC Concentrate calculated by patients pre value.
COM.TEC - Apheresismaster

- bi-directional transmission between COM.TEC and server-PC
- connection to the center data base by ISA Net
- printing of protocols on any printer
Comparison AS.TEC 204 versus COM.TEC
## COM.TEC

Changes compared to AS.TEC 204

<table>
<thead>
<tr>
<th></th>
<th>AS.TEC 204</th>
<th>COM.TEC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Quality</strong></td>
<td>(-) Platelet collection efficiency partially dependant on donor hematocrit</td>
<td>(+) Standardization of hematocrit for blood to be processed by means of plasma recirculation</td>
</tr>
<tr>
<td></td>
<td>(-) Platelet collection efficiency with C4 chamber limited to 45%-50%</td>
<td>(+) Platelet collection efficiency with C5 chamber improved to 55%-65%</td>
</tr>
<tr>
<td></td>
<td>(-) PAIP option for leukocyte reduction shows a lack of performance in some centers</td>
<td>(+) Additional gain in collection efficiency in single needle mode due to 100% recirculation</td>
</tr>
<tr>
<td></td>
<td>(-) Spill over / scatter detector in collect line not active</td>
<td>(+) Significantly improved leukocyte reduction yields products &lt;1x 10E6 WBC with great reliability</td>
</tr>
<tr>
<td><strong>User Comfort</strong></td>
<td>(-) Single needle protocols require utilization of additional bag press device</td>
<td>(+) Single needle mode for platelet collection with fully automated, pump controlled return cycle</td>
</tr>
<tr>
<td></td>
<td>(-) EL monochrome display Identification of message character difficult Difficult to read from the distance Key operation around display cumbersome</td>
<td>(+) Larger LCD color display Message character identified by screen colors Easier identification of messages from the distance Comfortable key operation with keys arranged to the sides of the display only</td>
</tr>
<tr>
<td></td>
<td>(-) Sound easily identifyable and aggressive</td>
<td>(+) Noise reduced, sound modified and smoothened</td>
</tr>
<tr>
<td><strong>Versatility</strong></td>
<td>(-) Protocol range does not include Red Blood Cell exchange / depletion</td>
<td>(+) Complete protocols range including convenient Red Blood Cell exchange / depletion protocol</td>
</tr>
<tr>
<td></td>
<td>(-) Therapeutic procedures in dual needle mode only</td>
<td>(+) All in-vivo protocols include emergency single needle option</td>
</tr>
</tbody>
</table>
Comparison AS 104 versus COM.TEC

AS 104

COM.TEC
COM.TEC
Changes compared to AS 104

• Completely new disposable with new chamber C5
• New interface detection with CCD-camera
• Installation of a fifth pump for plasma recirculation
• „Best Flow“ for high blood flows (70 ml/min standard)
• Increased efficiency 60% (45% AS 104)
• Procedure time reduced between 20-30 min
• Reliable very low WBC contamination below WHO regulations
COM.TEC

Changes compared to AS 104

- Reduced reinfusion time
- Larger platelet collection bag (1000 ml), better storage conditions for double dose platelets
- Stem cell program with menu prediction of procedure parameters
- Prediction of CD34⁺-yield
- Optional plasma collection for stem cell programs
## COM.TEC Competitor situation

analysis of 4.000 separations from 1998 to 1999

<table>
<thead>
<tr>
<th></th>
<th>DN for 3,0x10E11Plt</th>
<th>SN for 3,0x10E11 Plt</th>
<th>contamination</th>
<th>PLT in plasma</th>
<th>efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>COM.TEC</td>
<td>43 min</td>
<td>63 min</td>
<td>2x10E5</td>
<td>60,000</td>
<td>58,00%</td>
</tr>
<tr>
<td>AS.TEC204</td>
<td>70 min</td>
<td>120 min</td>
<td>1x10E6</td>
<td>52,000</td>
<td>45%</td>
</tr>
<tr>
<td>AMICUS</td>
<td>42 min</td>
<td>62 min</td>
<td>3x10E5</td>
<td>6,000</td>
<td>68,60%</td>
</tr>
<tr>
<td>SPECTRA</td>
<td>51 min</td>
<td>120 min</td>
<td>1x10E5</td>
<td>15,000</td>
<td>54,00%</td>
</tr>
<tr>
<td>MCS 3P</td>
<td>SN only</td>
<td>72 min</td>
<td>filtered 0,5x10E5</td>
<td>11,000</td>
<td>63%</td>
</tr>
<tr>
<td>TRIMA</td>
<td>SN only</td>
<td>48 min</td>
<td>1,5x10E5</td>
<td>14,000</td>
<td>54%</td>
</tr>
</tbody>
</table>

Source: Transfusion; Journal of Clinical Apheresis; Blood; Infusionstherapie und Transfusionsmedizin

blood flow with Amicus only 55 ml/ min; COM.TEC, and Spectra with min.70 ml/min