MEDICAL DEVICES

Programs and disposables COM.TEC®

Programs	Therapy	Disposables
TPE	Therapeutic plasma exchange	PL1
RBC	Therapeutic red cell exchange or depletion	PL1
Adsorption	Therapeutic plasma treatment e.g. immunoadsorption	P1R
Depletion	Depletion of platelets or white blood cells	C4L

Programs	Leukocyte	Disposables
autoMNC stem cells	Automatic collection of peripheral blood stem cells, mononuclear cell collection or depletion	P1YA
autoMNC lymphocytes	Automated collection of lymphocytes in dual needle mode for consecutive photochemotherapy or DLI*	P1YA
MNC	Peripheral blood stem cell collection, mononuclear cell collection or depletion	P1Y
BMSC	Bone marrow stem cell processing in vitro	P1Y + BMSC
Granulocyte	Granulocyte collection	P1Y
PBSC-Lymphocyte	Peripheral blood stem cell collection, lymphocyte collection or depletion	C4Y
RV-PBSC	Peripheral blood stem cell collection, reduced collection volume	RVY

Programs	Platelet	Disposables
PLT 5d	Platelet collection, 5-day storage (simultaneous plasma harvest possible), platelet depletion	C5L
PLT 5d	Platelet collection, Triple-concentrates, 5-day storage (simultaneous plasma harvest possible)	C5LT
PLT 5d-SN	Single needle platelet collection, 5-day storage (simultaneous plasma harvest possible)	S5L

*DLI (donor lymphocyte infusion)



COM.TEC®

THE MULTI-PROCEDURAL APHERESIS PLATFORM



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COM.TEC® -

the multi-procedural apheresis platform

Highly efficient therapeutic protocols

- Plasma or red cell exchange
- Cell depletion
- Plasma treatment with active and passive columns

Multi-procedural platform

- Cell collection
- Therapy
- · Cell donation

Leukocyte collection

- · Stem cell collection
- Lymphocyte collection (for ECP)*
- Granulocyte collection

COM.TEC® represents state of the art apheresis technology. The versatile applications for therapeutic plasma or red cell exchange, stem cell as well as platelet collections and cell depletions with only one device make the COM.TEC® the multi-procedural platform.

COM.TEC® offers reliable technology of camera controlled interface management for highly efficient procedures.

The easy to operate device is focussed on donor, patient and operator safety.

* Extracorporeal Photopheresis

The highlights:

Donor/patient tailored procedures

Donation as well as therapeutic protocols

Multiple safety systems = focus on donor/patient safety

e.g. hemolysis detector, air detector, centrifuge temperature sensor, ACD drip* monitor, low extracorporeal volume, pressure monitors

- Automatic or manual process management for all procedures
- Yield prediction for stem cell collection
- Automatic procedure printout GMP** compliance

^{*} ACD: Acid Citrate Dextrose

^{**} GMP: Good Manufacturing Practice

COM.TEC® -

state of the art in apheresis technology

Chambers for 3 groups of procedures



Stem cell collection



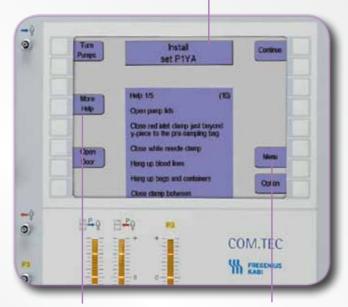
Platelet donation



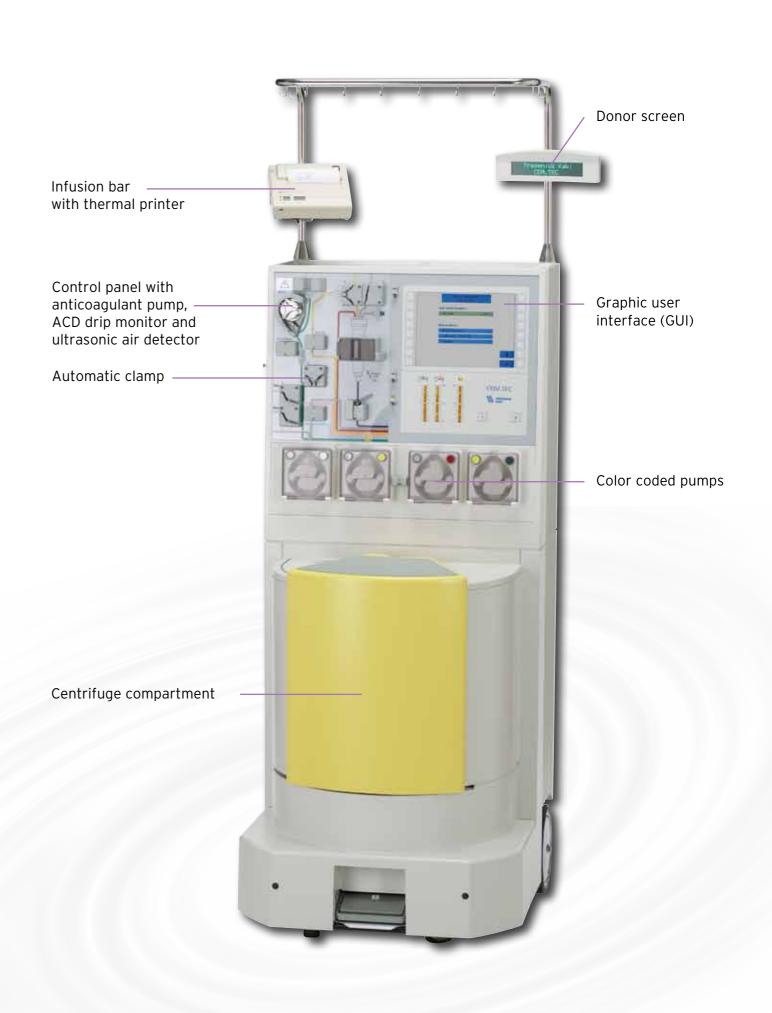
Therapeutic and depletion

Simple user guide on a self-acting guidance

Important procedure steps are explained in the user guide main route



More detailed descriptions as submenus are available on request by <Help> key Menus for entry of initial donor/patient values for detailed calculations of product parameters for all protocols



COM.TEC® — the complete range of procedures



Stem cell collection

- Variable protocol selection due to different donor/patient conditions
- Protocol selection dependent on targets
- Lymphocyte collection for consecutive photo-chemotherapy or donor lymphocyte infusions (DLI)
- CD34+ prediction

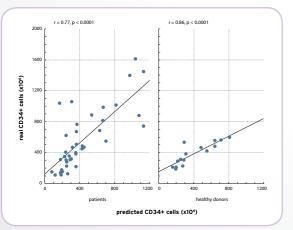


Figure 1: Correlation between predicted and real CD34+ cell counts in leukapheresis collections of patients (r = 0.77, p < 0.0001) and donors (r = 0.86, p < 0.0001). (Del Fante et al., Journal of Clinical Apheresis 2006; 21:227-232)

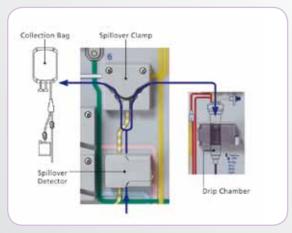
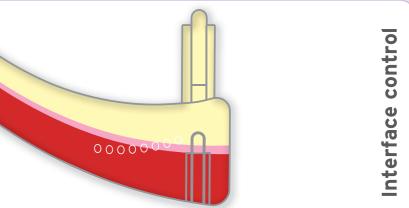


Figure 2: autoMNC procedure for automated collection: The spill-over sensor detects the passing cell fraction and triggers the spillover clamp from "return" to "collection". (internal data)



Parameter	Mean	±	SD
Volume (mL)	355	±	42
Total WBC content (x10¹º)	2.99	±	0.8
Total granulocyte content (x10¹º)	1.98	±	0.7
Total platelet content (x10¹º)	24.4	±	6.4
Total RBC content (x10 ¹²)	2.11	±	4.64
Dose of PMNs/ concentrate/kg (x10°)	0.78	±	0.57
Dose of PMNs/ concentrate/m² (x10°)	21.2	±	11.4





^{*}Sachs UJH., Reiter A, Walter T, Bein G, Woesmann W: Safety and efficacy of therapeutic early onset granulocyte transfusion in pediatric patients with neutropenia and severe infections, Transfusion 2006; 46: 1909-1914