目录

[1 市场环境 5](#_Toc505600427)

[Market Environment 5](#_Toc505600428)

[1.1 新产品/改进的基本原因 5](#_Toc505600429)

[Rationale for new Product / Product modification 5](#_Toc505600430)

[1.2. 当前市场的状况 5](#_Toc505600431)

[Current Market Situation 5](#_Toc505600432)

[1.3. 竞争对手状况 6](#_Toc505600433)

[Competitive Situation 6](#_Toc505600434)

[1.4. 预期销售国/预期市场介绍 6](#_Toc505600435)

[Planned Sales Countries/Planned Market Introduction 6](#_Toc505600436)

[1.5. 预期销售价格及数量 6](#_Toc505600437)

[Planned Amount & Prices 6](#_Toc505600438)

[2 应用 7](#_Toc505600439)

[Application 7](#_Toc505600440)

[2.1. 医疗指示 7](#_Toc505600441)

[Medical Indication 7](#_Toc505600442)

[Chronic kidney failure 7](#_Toc505600443)

[2.2. 预期用途 7](#_Toc505600444)

[Intended Use 7](#_Toc505600445)

[3 环境 8](#_Toc505600446)

[Environment 8](#_Toc505600447)

[3.1. 使用环境（地理及正常运行） 8](#_Toc505600448)

[Operation Environment (geographic and functional) 8](#_Toc505600449)

[Operation操作 8](#_Toc505600450)

[Storage存储 8](#_Toc505600451)

[Power Supply供电 9](#_Toc505600452)

[Water supply进水 9](#_Toc505600453)

[3.2. 用户 9](#_Toc505600454)

[User 9](#_Toc505600455)

[4 功能 10](#_Toc505600456)

[Machine Functionality 10](#_Toc505600457)

[4.1. Therapy治疗方法 10](#_Toc505600458)

[4.2. 总设计需求 11](#_Toc505600459)

[General Design Requirements 11](#_Toc505600460)

[4.3. 可用性和可操作性 12](#_Toc505600461)

[Usability/Operability 12](#_Toc505600462)

[4.3.1. 准备 13](#_Toc505600463)

[Preparation 13](#_Toc505600464)

[4.3.2. 治疗 18](#_Toc505600465)

[Therapy 18](#_Toc505600466)

[4.3.3. 治疗后 23](#_Toc505600467)

[4.3.4. 工程模式 30](#_Toc505600468)

[Technical Service Mode (TSM) 30](#_Toc505600469)

[4.3.5. 用户维护以及维修 30](#_Toc505600470)

[Service & Maintenance by the user 30](#_Toc505600471)

[4.4. 运行参数 31](#_Toc505600472)

[Performance Parameter 31](#_Toc505600473)

[4.4.1.9. 抗凝 46](#_Toc505600474)

[Anticoagulation 53](#_Toc505600475)

[4.4.3. 数据交互 53](#_Toc505600476)

[Data Interface 53](#_Toc505600477)

[4.4.4. 安全需求 53](#_Toc505600478)

[Safety Requirements 58](#_Toc505600479)

[4.4.5. 帮助以及报警概念 58](#_Toc505600480)

[Help and alarm concept 58](#_Toc505600481)

[4.4.6. 生命周期/ 保修 / 可靠性 58](#_Toc505600482)

[Life cycle / Warranty / Reliability 60](#_Toc505600483)

[4.4.7. 语言管理 60](#_Toc505600484)

[Language Management of the device 60](#_Toc505600485)

[4.4.8. 成本框架 60](#_Toc505600486)

[Cost Structure 61](#_Toc505600487)

[4.4.9. 时间 61](#_Toc505600488)

[4.4.10. Time 61](#_Toc505600489)

[5 相关一次性使用耗材 61](#_Toc505600490)

[Interfaces to Disposables 61](#_Toc505600491)

[5.1. 滤器 61](#_Toc505600492)

[Filter 61](#_Toc505600493)

[5.1.1 Dialyzers 61](#_Toc505600494)

[5.1.2 DF-Filter 62](#_Toc505600495)

[5.2. 血路管 62](#_Toc505600496)

[Blood Lines 62](#_Toc505600497)

[5.3. 浓缩液 63](#_Toc505600498)

[Concentrates 63](#_Toc505600499)

[5.4. 水处理 63](#_Toc505600500)

[Water Supply 63](#_Toc505600501)

[5.5. 消毒液 63](#_Toc505600502)

[Disinfectants 63](#_Toc505600503)

[5.6. 表面清洁？ 63](#_Toc505600504)

[Cleaning Agents 63](#_Toc505600505)

[6 维护需求 64](#_Toc505600506)

[Service Requirements 64](#_Toc505600507)

[7 产品配置, 可选项, 附件 64](#_Toc505600508)

[Product Configuration, Options, Accessories 64](#_Toc505600509)

[8 包装, 运输, 存储 66](#_Toc505600510)

[Packaging, Transport , Storage 66](#_Toc505600511)

[9 产品文档 66](#_Toc505600512)

[Product Documentation 66](#_Toc505600513)

[10 培训 /服务 67](#_Toc505600514)

[Training / Services 67](#_Toc505600515)

[11 销毁 67](#_Toc505600516)

[Disposal 67](#_Toc505600517)

[12 其他需求 67](#_Toc505600518)

[Other Requirements 67](#_Toc505600519)

# 1 市场环境

# Market Environment

## 1.1 新产品/改进的基本原因

## Rationale for new Product / Product modification

1. 市场需要更稳定的新一代的机器;

The market needs a more stable machines;

1. 需要有在线血液透析滤过功能的血液透析机;

The market needs HDF online function;

1. 同时需要有能应对未来可能出现扩展功能的新一代平台;

## 1.2. 当前市场的状况

## Current Market Situation

TBD

## 1.3. 竞争对手状况

## Competitive Situation

TBD

## 1.4. 预期销售国/预期市场介绍

## Planned Sales Countries/Planned Market Introduction

TBD

## 1.5. 预期销售价格及数量

## Planned Amount & Prices

TBD

# 2 应用

# Application

## 2.1. 医疗指示

## Medical Indication

Chronic kidney failure

## 2.2. 预期用途

## Intended Use

The dialysis machine can be used for implementing and monitoring hemodialysis treatments for patients with acute or chronic kidney failure.

The system can be used for hospitals, health and dialysis centres and limited-care centres.

The system must be operated by qualified and trained staff only or by trained patients.

Depending on the model, the following types of therapy can be carried out with the system:

该透析机可用于急性或慢性肾功能衰竭患者血液透析治疗的实施和监测。

该系统可用于医院、保健和透析中心和有限的护理中心。

该系统必须由合格或受过培训的人员或受过培训的病人操作。

可以使用该系统进行以下类型的治疗：

* Hemodialysis (HD), high-flux, midd-flux, low-flux
* 血液透析（HD）、高通量、中等通量、低通量
* Isolated ultrafiltration (ISO UF): Sequential therapy
* 单纯超滤（ISO UF）：序贯疗法
* Online Hemodiafiltration (HDF)
* 在线血液透析滤过（HDF）

# 3 环境

# Environment

## 3.1. 使用环境（地理及正常运行）

## Operation Environment (geographic and functional)

The machine must be able to operate worldwide, also implicating a flawless operation in high altitude countries (e.g. La Paz, Bolivia alt. 3600m NN), high temperature and humid countries. Water quality can be below European or AAMI standard.

本机必须能够在世界范围内，也暗示一个完整的操作在高海拔的国家（如拉巴斯、玻利维亚，海拔3600m NN），高温和潮湿的国家。水的质量可以低于欧洲或AAMI标准。

The machine is exposed to chemicals (disinfectants) and cleaning agents as well as blood. In hospitals, magnetic fields from nearby MRT’s could be possible. The direct, unintended contact with water and/or liquid from sodium bags or other infusions, is likely.

这台机器暴露在化学药品（消毒剂）和清洁剂以及血液中。在医院里，附近铁路运输系统的磁场可能是可能的。直接或意外地接触来自钠袋或其他输液的水和/或液体。

### Operation操作

* Permissible ambient temperature. +10 to + 40°C
* 允许的环境温度：+ 10到40°C
* Permissible humidity: 15 to 70%
* 允许湿度：15至70%
* Permissible atmospheric pressure: 650 to 1.060 mbar
* 允许大气压力：650至1.060毫巴

### Storage存储

* Permissible ambient temperature without fluid: -20 to +60°C
* 允许环境温度无液：20到60°C
* Permissible humidity: 15% to 80%
* 允许湿度：15%至80%
* Permissible atmospheric pressure: 650 to 1.060 mbar
* 允许大气压力：650至1.060毫巴

### Power Supply供电

* 电源Power: AC220×（1±10%）V，50×（1±2%）Hz；
* 最大功率Max.consumption:1800+?

### Water supply进水

* 温度Temperature：5℃～35℃；
* 压力Pressure: 0.5 MPa～0.6MPa
* 进水流量Flow Rate：1000mL or more
* 要求Quality: YY 0572-2005(or ISO13959:2009)

## 3.2. 用户

## User

The main user is a trained and qualified nurse, but also physicians and minor qualified medical staff might operate the machine. In limited-care centres and patients are expected to work with the system.

The working condition in a dialysis centre is likely to yield stress situations so handling errors are to be expected. Moreover, new staff is recruited constantly in dialysis centres, thus untrained persons are frequently confronted with the system. Applicants usually operate several machines at a time (e.g. six machines). An interruption and a later continuing of a function and/or an interruption of a function and continuing by another user is common.

Safety concept, ergonomics and menu guidance must consider these facts.

For installation, maintenance and service, field and support technicians are main users.

主要用户是经过培训合格的护士，但医生和未合格的医务人员也可以操作这台机器。在有限的护理中心，病人将期望与该系统一起工作。

透析中心的工作条件很可能会产生压力，所以处理错误是可以预料的。此外，新的工作人员经常在透析中心被招募，因此未受过训练的人经常面临该系统。申请者通常一次操作几台机器（如六台机器）。中断和继续一个功能和/或另一个用户的继续或中断是常见的。

# 4 功能

# Machine Functionality

### 4.1. Therapy治疗方法

Hemodialysis with low- and high-flux dialysers. Acetate and bicarbonate modes or isolated ultrafiltration (ISO-UF)

低和高通量透析器透析。醋酸和碳酸氢钠的模式或单纯超滤（iso-uf）

#### 4.1.1 Double needle treatment双针治疗:

Twin needle dialysis with low- and high-flux dialysers. Acetate and bicarbonate mode

低和高通量透析器透析双针。醋酸盐和碳酸氢盐模式

#### 4.1.2 Single needle treatment 单针治疗:

Adequate Single needle dialysis system with low- and high-flux dialysers. Acetate and bicarbonate modes.

适当的单针透析系统的低和高通量透析器。醋酸盐和碳酸氢盐模式。

##### 4.1.2.1 Single-needle double pump单针双泵

##### 4.1.2.2 Single Needle Klick-Klack (SN-KK) 单针单泵

with one pump /e.g. in order to continue a double needle therapy after cannula failure

用一个泵，/例如 插管失败后临时使用，方便后续进行双针治疗。

##### 4.1.3 Online Hemodiafiltration / Hemofiltration在线血液透析滤过、血液滤过

**Online Hemodiafiltration (Pre/Post)** **在线血液透析滤过（前/后）**

Dialysis with substitution liquid and high-flux dialysers. Acetate and bicarbonate modes (double needle mode only).

高通量透析器和置换，有透析液流过透析器，醋酸盐和碳酸氢盐模式（双针模式）。

**Online Hemofiltration (Pre/Post)** **在线血液滤过（前/后）**

Dialysis with substitution liquid and high-flux dialysers. No dialysate flow (double needle mode only).

随着高通量透析器的透析液和置换，无透析液流过透析器（仅双针模式）。

## 4.2. 总设计需求

## General Design Requirements

* + Dimension of machine机器尺寸:
    - width : max.550 mm
    - 宽度：max.550毫米
    - height: max. 1500mm
    - 高度：最大1500mm
    - depth: max. 740mm
    - 深度：最大740mm
  + Weight: max. 85 kg standard version
  + 重量：最大？公斤标准版
  + No edges, corners, glyphs regarding the front
  + 无边，角，沟
  + Surfaces must be easy to clean
  + 表面必须易于清洁
  + Surface resistant against disinfection (see 5.7), blood, acid, bicarbonate and corrosion
  + 表面耐消毒（见5.7）、血、酸、碳酸氢钠和腐蚀
  + Smooth passage from main housing to mechanical components
  + 容易抵达机器内部机械部件
  + All components should be arranged on an ergonomical height for user
  + 所有组件必须安装在一个符合人体工程学的高度
  + All necessary handling must be possible in a way the user is not disturbed by other components. it must be enough place between components
  + 用户所有必要的处理必须尽可能不受其他组件干扰的情况下处理。组件之间的位置必须是足够的。
  + Machine must be easy to move
  + 机器必须移动方便
  + Machine must be stable
  + 机器必须是稳定的
  + Machine must be statically stable in declines of 10°.
  + 必须在10°能稳定住
  + Machine should have an individual innovative look, no “Me-too” product
  + 机应该有一个个人创新外观
  + Colours should fulfil medical trends
  + 颜色应符合医疗趋势

## 4.3. 可用性和可操作性

## Usability/Operability

The usability should be benchmark in dialysis and follow the general principles:

可用性应该是透析的基准，遵循一般原则

* Easy and intuitive concept for the user to avoid handling errors
* 方便和直观的概念，为用户避免错误处理
* Focusing on the product intended use
* 专注于产品的预期用途
* Easy, fast and ergonomic set-up of disposables
* 容易，快速和人性化的耗材操作
* Easy and ergonomic access to machine interior for service
* 方便和人性化的进入机器内部进行服务
* Making functions obvious, consistent, clean, self-explanatory (graphic style, dimensions, color, interaction) supported by help and training functionalities
* 功能要明显，一致/不矛盾，干净，(图形样式，尺寸，颜色，交互)通过帮助和培训功能自我解释
* Minimizing interactivity and input need displaying short though focused and meaningful texts - avoiding technical jargon and applying user specific terms
* 最小化交互和输入需要显示短暂而集中的和有意义的文本，避免专业术语和应用用户的具体条款
* A certain amount of recognition of the UI compared to old device
* The concept of icons must be followed
* Icons and most important buttons must be positioned in the most ergonomically way and clearly structured
* 图标和最重要的按钮必须位于最符合人体工程学的位置，并且结构清晰
* Most important functions must be easily reached, less sub menus (max 3 levels of menus)
* 最重要的功能必须很容易到达，减少子菜单层（最大3个层次的菜单）
* Un-used buttons / icons should not be displayed
* 不应显示未使用的按钮/图标

### 4.3.1. 准备

### Preparation

#### Time时间

* Max. preparation time Standard 10 min, Online 13 min (from Program Selection to “ready to connect”). If the time goal can technically not be reached, it must be tried to come as close as possible to these times, as time saving is one of the major topics regarding ergonomics and efficiency
  + 最大准备时间标准10分钟，在线13分钟（从程序选择到“准备连接”）
* Also possible an optional choice: quick and non-automatic (Standard 10 min, online 13 min) or long and fully automatic (Standard 12 min, Online 15 min) (from Program Selection to “ready to connect”)
  + 也可能：快速和非自动（标准10分钟，在线13分钟）或长和全自动（标准12分钟，在线15分钟）（从程序选择“准备连接”）
* Remaining time of preparation is displayed
  + 显示准备的剩余时间

#### Disinfection residuals 消毒残留

* No checking for disinfectant residuals (exclusions with disinfectants with low conductivity might be necessary). No checking for citric acid in any way.
  + 没有检查消毒剂残留（用电导率低排除可能是必要的）。不以任何方式检查柠檬酸。

#### Screens屏幕

* After booting. a “Program Selection” screen should appear to select HD/O-HDF/O-HF or Disinfection
  + 开机后。“选择程序”屏幕会出现选择HD/O-HDF/O-HF或消毒
* Possibility to Program selection from “Preparation”
  + 可能从“准备”状态进行程序选择

#### Main screen

* Possibility to enter patient’s name and ID, date and time via soft key
  + 主屏幕应该可以通过软键输入病人姓名和ID、日期和时间
* Possibility to read Patient Therapy Card
  + 可以阅读病人治疗卡
* Possibility to download and display all stored data
  + 可以下载和显示所有存储的数据
* Access to machine data values (formerly “Wrench” icon) including SW version & working hours
  + 主屏幕可以访问机器数据值包括SW版本和工作时间
* Access to formerly “Folder” functions Data storage, Brightness, Language, Disinfection & Filter data
  + 主屏幕,可以访问功能数据存储，亮度，语言，消毒和过滤器数据。
* “Wiper” function to deactivate touch few seconds
  + ,冻结屏幕功能，停用几秒钟触摸。
* Possibility to initiate “Start Priming” function (necessary in combination with self-insertion of blood pump segment)
  + 可以启动“启动预冲”功能（与血泵段的自动插入相结合）
* Access to functions for: Help, Stand-by, Program selection, Connect patient, Heparin bolus
  + 主屏幕,可以访问功能：帮助、待机、程序选择、连接病人、肝素 bolus
* Main screen “Preparation” should display: Patient’s name, Date and time, Text “Preparation” & Test status, PV & PA display (graphical & numerical), Blood pressure, MAP & PR, BP & Heparin rate
* 主屏幕“准备”应显示：病人的姓名，日期和时间，文本“准备”和自检状态，PV和PA显示（图形和数字），血压，MAP和PR，血泵和肝素速率。

#### Sub menus子菜单:

* Following sub menus to be opened from main screen via icons and/or shortcuts: UF, dialysate, limits, SN, HDF/HF (Online machines), BPM, Kt/V, Priming , Overview, Levels (see Therapy Mode except Rinsing, below)
  + 下面的子菜单可从主屏幕的图标和/或快捷键打开：超滤、透析液、限值、SN、HDF /HF（在线机器）、BPM、Kt/V、预冲、概况、液位调节（见治疗模式除了预冲，下同）

#### Sub menu Priming预冲子菜单

* Should content setting possibility for blood line filling: BP rate & Priming volume
  + 血路管预冲可设置内容：BP速率和冲洗量
* Values值:
* BP rate for filling 30…600 ml/min default 150
  + 预冲血泵速度30…600 ml/min默认150
* Priming volume 0…6000 ml/min default 500
  + 预冲容量：0…6000 ml/min 默认500
* BP rate for rinsing 30...400 ml/min default 200
  + 循管阶段血泵速度30...400 ml/min默认200
* Rinsing time 01...59 min default 59
  + 循管阶段时间01...59 min默认59
* Blood flow for connecting patient 50...600 ml/min default 100
  + 引血血泵速度：50...600 ml/min 默认100
* Display of actual rest blood side rinsing volume
  + 显示实际剩余冲洗量
* Should content setting possibility for rinsing with UF
  + 循管同时可超滤
* Display of actual rest UF rinsing time & volume
  + 显示实际的剩余UF时间和量

#### Messages信息

* Message: „Last disinfection with [method] on [date] 消息, “最后消毒[方法] [日期]
* Message „Connect concentrate“ after start (excluding CCS if a coupling is not necessary) 消息,开机后，连接浓缩液提示，(不包括CCS中央供给浓缩液)

#### Tests

* All blood side and dialysate tests should be performed automatically by the machine
  + 所有的血液和水路侧检测应该由机器自动完成
* Self-test for DF side only 1x/day according to norm
  + 自检滤器（cut filter）正常1次 /天
* Power supply test tones and TLC test tones must be that short，tones as short as possible,for speaker check
  + 电源测试音调和TLC测试音调必须尽可能短，用于扬声器检查。
* BP starts automatically for test BS
  + BP开始自动自检（不超过25%圈，装管能检）
* BP stops automatically after test BS

自检后自动停止

#### Stand-by mode待机模式

* After preparation there should be the possibility to activate a stand-by mode of the dialysate flow. The flow should be reduced much as possible in order to save permeate and concentrate
  + 准备完成后 应该有可能激活透析液的待机模式，尽量可能减少水与浓缩液。
* A warning should indicate the state of reprocessing
  + 应有警告，处于待机状态
* The maximum time of reprocessing should be setable
  + 最大的待机时间应该是可设定的
* Display of the state “Stand by” on monitor
  + 显示状态“待机”在主屏幕上
* Flush of DF side in Stand-by mode every 15 min (setable) to avoid bacteria growth

待机模式每15分钟（可设定）冲滤器Cut-filter一次以避免细菌的生长

#### Mute mode静音模式

* Mute mode in preparation ,mute of sounds (max. 120 sec.)
  + 静音模式（最多120秒- 静音）
* Activation / deactivation via button by nurse
  + 护士通过按钮激活/关闭

Indication that mode is active (e.g. symbol) on screen

主屏有指示其处于激活（如屏幕上的符号）

#### Others其他

* No need for nurse to set levels (fully automatically preparation) minimum Standard lines
  + 不需要护士设置液位（全自动准备）的最低标准线
* Preset BP speed 100 ml/min all mode
  + 默认预置血泵速度 100 ml/min
* During preparation, after connecting concentrates max. one interaction (connecting couplings)
  + 在准备过程中，连接浓缩液最大一次人机交互（减少确认，等待）（连接供回接头后1min后填充）
* After BP start for circulation, start of UFP automatically
  + 循环管路下血泵启动后，自动启动UF泵
* Auto fill in preparation and empty of bic cartridge at reinfusion（disconnection ）
  + 准备，结束治疗时自动运行干粉桶充液和排空
* Function, running time to continue after disinfection mode （72）
  + 功能、运行时间继续消毒模式后，下次消毒时间，计时
* Prime Bloodline (with saline bag) during disinfection is possible for next treatment
  + 预冲（盐水袋）可在消毒过程中运行，为后续治疗准备
* Re-use blood line dialyzer : UF for preparation should be possible
  + 剂
* Ultrafiltration during circulation of Blood line possible
  + 过程中可能启用超滤的
* Use of dry and wet dialyzer
  + 可使用干、湿透析器
* BP Stop after phase（fill up） „Rinsing（end of Priming,minimum 400ML done ） with UFP“ (setable)
  + 填充阶段完成后，停血泵。预充（冲管）管路同时开UF（可设定）
* BP Stop after blood side tests selftest (setable)
  + 血路侧自检后，血泵停止（可设定）
* BP stop after rinsing（Priming） volume is reached (setable)
  + 预充管路量达到后血泵停止（可设定）
* Clear message that after rinsing volume is reached, BP start should be combined with recirculation of saline in order to avoid empty saline bags
  + 明确信息，预充量达到后，以生理盐袋组成循环回路，避免盐水袋被吸空
* Possibility to change brightness of display
  + 可以改变显示器亮度
* Screen saver (black, return with alarm or touch)
  + 屏幕保护（报警或触摸，返回）
* Possibility to change languages
  + 可以改变语言
* Possibility to check disinfection & Filter data
  + 可以检查消毒和过滤器数据

#### Connecting patient连接病人

* Use component requirement Comparison & Confirmation of treatment parameters automatically by the machine
* Preset BP speed 100 ml/min
  + 预置血泵速度100 ml/min
* Stop BP when red detector detects blood
  + 当检测器检测到有血时停止血泵
* Option of automatic bypass deactivation, (optional Technic setting)
  + 禁止自动旁路选项（可选技术设置）

### 4.3.2. 治疗

### Therapy

#### Main Treatment Screen should display主治疗屏幕应显示:

* Status bar indicating the status
  + 状态栏指示状态
* date & Time
  + 日期及时间
* If patient card will be used, also mention patient name should be mention
  + 如果使用病人卡，显示病人的名字
* Art. & venous pressures (graphical & numerical)
  + 动，静脉压（图形和数值）
* TMP, dialysate pressure (optional set button) (graphical & numerical) (Default TMP; (setable engineer screen available or not)
  + TMP或透析液压力（可选，设置按钮）（图形和数值）（默认TMP）；（工程可设置）
* UF rate & volume (act. value)
  + 超滤率和已超滤量
* remaining time for HD/HDF/HF
  + HD/HDF/HF剩余的时间
* blood flow display ml/min
  + 血流速度显示ml/min
* Sub rate (HDF/HF treatment only)
  + 置换液速度(HDF/HF only)
* Conductivity or mmMol by touch can change during use (setable engineer screen available or not)
  + 电导率或mmmol（工程可设置）
* Indication that Profile is used
  + 曲线治疗时有指示正在使用曲线治疗
* Also there must be a possibility to enable the following functions: Bypass, UF Minimum or stop (setable in Eng. Screen), Disconnect patient, Screen wiping (second main screen), Online Bolus (second main screen), Exchange Cartridge (second main screen)
  + 也必须有可能使以下功能：旁路，最低UF或停止UF（工程可设置），断开的病人，冻结屏幕（第二主屏），在线补液（第二主屏），更换干粉桶（第二主屏幕）
* It is possible to make changes in Menu during treatment. If nobody touch the screen it will jump back to treatment screen after setable time.
  + 治疗期间可以设置参数。如果没有人触摸，固定时间后（可设置），屏幕会跳回到主屏幕
* For Factory technicans it should be possible to skip self test
  + 工厂工程技术人员应该可以跳过自检

#### Timer window计时器窗口

* The following setting should be possible: absolute time, time interval, on/off one shot & cyclical, sound, To-do
* Display of running time (countdown)
* Touching To-Do button, a soft key should open and a list of stored To-Do’s
* Entered texts should be stored and listed for further use and choice for future treatments
* After time expires sound and/or information text should appear
* Sound and/or text to be confirmed for disappearing
* Timer active in Preparation, Treatment and Disinfection mode
* Countdown continuing after switch from disinfection to preparation
* Countdown independent from all phases (preparation /therapy /disinfection)
* Values:
* 00:00…23:59h absolute time
* Intervals 0:01…10:00 h

#### Overview window(second Main screen) 总览（第二主屏幕）

* Overview window should display the following parameters (actual & set):

DF flow, conductivity, concentration (mmol) & temperature, UF, Pressures, Heparin, cumulated Online bolus, SN and O-HDF/HF parameters, ~~Sequential~~ ISO time （）and UF, Kt/V calculation, BPM (option), oxygen saturation (Option)

窗口应显示以下参数（实际与设定的）：

透析液流速，总电导，设定钠(mmol)，温度，压力，肝素，累计补液量，单针和在线HDF/HF参数，~~序贯~~ISO时间和UF，Kt/V，BPM (血压计),血氧

#### Silent screen (screen safer) 无声屏幕（屏幕保护）

* Silent screen should display minimum the following parameters

Remaining time, UF rate, BP speed, art and venous pressure

**无**声的画面应显示最小参数如下：

剩余时间，超滤速率，血泵速度，动和静脉压

#### Profiles曲线治疗

##### availibility of UF, Bicarbonate, sodium, Heparin, dialysate flow and temperature profiles

##### 可用超滤、碳酸氢盐、钠、肝素，透析液流量和温度曲线

##### profiles have to be combined with each other

##### 曲线可以相互结合

##### At least one fix combination of UF + sodium profile

##### 至少一个固定结合，超滤+钠曲线

#### History trends历史记录（趋势图）

##### The following parameters should be visible graphically as trends for nurses in treatment (default): PA, PV, TMP, UF and DF flow, Bic & final conductivity, BP speed)

##### 下面的参数应该是护士可见，历史曲线趋势图（默认）：PA、PV、TMP、超滤和透析液流速，B和最终的电导率，血泵速度）

##### Also incidents and errors should be visible. Errors in clear text not only code numbers

##### 同时事件和错误应该是可见的。错误不仅仅是代码编号还有文字。

##### Trend viewer easily accessible from main window

##### 趋势图容易从主窗口进入

##### Graphic be displayed above a time axis (Therapy time)

##### 图形在时间轴上显示（治疗时间）

##### A cursor line to see value at a certain time

##### 光标线用于看特定时间的数值

##### Trend history accessible for user with 20 last trends and current one

##### 用户可以访问20个最后趋势和当前趋势的历史记录

##### History Trends from Preparation, Therapy & Disinfection must be available,must be there

##### 在准备、治疗和消毒时趋势必须是可用的，

#### Kt/V calculation Kt/V计算

##### Kt/V calculation should be available

##### Kt/V计算应可用

##### Calculation should content a graphic showing the current value and the target Kt/V line

##### 计算应该包含图形显示当前值和目标Kt/V线

##### The actual value and the target value displayed numerically

##### 实际值和目标值用数字显示

#### Others其他

##### Access to machine data including SW version & working hours

##### 可访问包括软件版本和机器工作时间数据

##### Possibility to change dimming of display (HW or SW)

##### 可改变显示亮度（硬件或软件）

##### Screen saver: complete dark for night dialysis, except display of time

##### 屏幕保护程序：完全黑暗的夜间透析用，除了显示时间

#### End of therapy (EOT) 治疗结束

##### EOT to be indicated by sound and message automatically after treatment time is reached (message to continue UF if not reach)

##### 治疗结束，治疗时间到达，声音提示和消息提示（如果没有达到UF目标，是否继续UF）

##### BP run until confirmed

##### 血泵一直运行直到确认结束

##### When “Disconnect” button is touched in treatment, the second confirmation to cancel is displayed

##### 当治疗期间“回血”按钮被按，需二次确认

##### EOT window with possibility to enable the following functions: emptying dialyser & cartridge, back to therapy, overview（important parameter of last treatment ）, disinfection

##### 治疗结束窗口，可能使以下功能：排空透析器和干粉桶，回到治疗，总概述，消毒

##### After return blue coupler, Empty of Dializer and Bic Cartridge start automatic

##### 供液接头（蓝）接回机器后，排空透析器和干粉桶自动启动

##### *After return red coupler*, device change to disinfection screen.

##### 回液接头（红）接回机器后，设备进入消毒屏幕

##### Overview should show the blood volume, the Kt/V, heparin, UF, substitution and infusion volume, Profiles, Use of options

##### 总概述应该显示血容量、Kt/V、肝素、UF、置换液、输液量、曲线、使用选项last treatment

##### Possibility to continue therapy (only until blue coupler is not on device / empty function not active)

##### 可能继续治疗（供液接头（蓝）不在设备/排空未启动前）

##### Data storage in EOT: Possibility to write and erase Patient Therapy Card**,** possibility to download and display all store data

##### 数据存储：可能写和擦除的病人治疗卡，可能下载和显示所有存储数据

##### Start disinfection only when no blood is detected.

##### 只有在没有检测血液时才能开始消毒

##### Possibility to continue re-infusion（blood return） after confirmation than can start (volume control),2.27 note

##### 可能在确认后继续再灌注（容量控制）

##### Return blood until air detect or volume reach

##### 回血直到检测到空气或回血量达到

##### Preselected treatment parameters should be storable on chipcards or via a network system

##### 预选治疗参数，可储存在卡上或通过网络系统储存

##### EOT Sound selection from a treatment menu ~~according to 60601-1-8, 60601-2-16~~

##### 根据~~60601-1-8，60601-2-16~~ ，EOT的声音选择

##### If air is detected an instruction how to solve the problem should be displayed

##### 如果检测到空气，应指示如何处理2.27 note

### 4.3.3. 治疗后

#### Post-Processing (After Treatment)

#### Hardware硬件

##### Detection if disinfection canister is full or empty by detect air. The inflow volume is guaranty by precise UF Pump stroke.

##### 通过检测空气（除气腔）检测消毒罐是空的还是满，流入量通过精确超滤泵保证。

##### The conductivity of the disinfectants should be monitored (adjustable min and max limits by a technician) (chlorine = sodium hypochloride, citric acide, per acetric acid )

##### 消毒剂的电导率应监测（技术员可调最小和最大限度）（氯，次氯酸钠，柠檬酸，过氧乙酸）

##### An accidental patient treatment with Chlorine or any other chemical disinfectant must be excluded. End of post Rinse ,check conductivity (temperature before selftest ) and This could also be achieved by changing the conductivity of Chlorine in order to prevent an accidental misuse. The same for temperature. (setable limit for both)

##### 意外使用氯或其他化学消毒剂治疗病人必须排除。这也可以通过改变氯的电导率来实现，以防止意外误用。温度同样。（工程可设定限制值）

##### ~~To safe energy and permeate all disinfection modes should be realized in a way that after filling with disinfectants the machine will be switched in a short circuit. Short circuit means a loop between the water inlet and the drain line internally in the machine.~~

Loop for disinfection

##### 为了保证安全的能量和渗透，所有的消毒方式都应该以消毒剂的形式实现，机器会短路。短路是指机器内部的进水管和排水管之间的一个回路。

##### After disinfection, machine must be free of chemical residuals (IEC 60601-2-16 request)

##### 消毒后，机器必须无化学残留（IEC 60601-2-16要求）

##### After disinfection, there must be no need for staff to check for residuals (exclusions with disinfectants with low conductivity might be necessary)

##### 消毒后，必须不需要工作人员检查残留（用电导率低方法排除是必要的）

##### There should be no dead spaces in the hydraulic circuit

##### 水路回路中应没有死角

##### Sodium hypochloride can sucked also from front suction tube (setable available or not)

##### 次氯酸钠可以从前面吸入管吸入（工程可选择）

##### Connection of main disinfection canisters in the back of the machine

##### 在机器的背面连接主要消毒罐

##### Changing canisters must be easy for nurse without liquid spilling on floor

##### 护士更换消毒罐必须容易且无液体洒在地板上

##### Extractable rack to place at least one 10 L canisters in the back of the machine if not integrated in machine

##### 可拔出的支架放置至少可放置一个10 L罐在机器后面，如果没有集成在机器

##### Disinfection valve is monitored to avoid flow in wrong direction or mechanical construction avoid wrong direction.

##### 监测消毒阀或机械结构，避免流向错误。

#### Software软件

##### During the installation of the machine the customer should decide what kind of disinfection modes he wants。Only these modes should be indicated on the screen.

##### 在安装机器时，顾客应决定他需要什么样的消毒方式，只有这些模式应显示在屏幕上。

##### After leaving EOT, the disinfection screen should open and the preset method (citric acid) should be selected. A change to other is possible by user. Start of process need to be done manual.

##### 离开结束治疗后，消毒屏幕应打开，预置方法（柠檬酸）应选择。用户可以更改其他预置消毒方式。开始需要手动完成。

##### During initial pre rinsing phase, user should have the possibility to select different method. IT should be possible to stop a running program any time and next pre-rinse make sure that no chemical reaction happen in next disinfection.

##### 在前冲洗阶段，用户应有选择不同消毒方法的可能性。任何时候都可以停止运行的程序，并在下次消毒前确保下次消毒不会发生化学反应（无残留或残留不影响消毒）。

##### All steps (pre-rinsing, heating, circulating, post rinsing) should be performed automatically by the program

##### 所有步骤（前冲洗、加热、循环、后冲洗）应由程序自动执行。

##### If alarm occure during disinfection the process the system stop. The user can continue or stop.certain time no touch ,post Rinse ,shut off ;not count ; beginning ,30 min alarm shut off ,not start

* 如果报警发生消毒过程的系统停止时。用户可以继续或停止。

##### If alarm is not confirmed for e.g. 30 Min. system bypass related area and finish disinfection. Machine can be not used for next treatment.

##### 如未确认报警，例如30分钟。系统可旁路相关区域和完成消毒。但机器不能用于下一步治疗。

##### The status of the disinfection in time, mode and date should be indicated and stored even after switch off.

##### 消毒的时间、方式和日期应注明和储存（硬储存）。

##### In case of powerfail, machine will not allow to go to treatment. There should be a message after recover to perform a new disinfection. (with mandatory forced rinse)

##### 万一消毒掉电，机器将不允许治疗。恢复后应该有一条信息来进行新的消毒。（同时强制性冲洗）

##### There should be a information on the screen at what date and what kind of disinfection had been performed (disinfection history minimum 10).

##### 在屏幕上应该有一个信息，在什么日期，进行了什么消毒（消毒历史记录最低10次）。

##### Possibility to enable the following functions (before start disinfection): Timer for CF filter(display,change ), Disinfection history, Configuration (one button opening sub menu for switch off weekly Timer, switch off time weekly Timer, weekly Timer configuration), BPM

##### 可启用下列功能（在开始消毒前）：CF过滤器的时限，消毒历史，配置（一个按钮打开子菜单，关闭，关闭时间，每周定时器配置），BPM

##### Possibility to enable the following methods: rinsing, hot citric. chemical, Pure water, hot, Inline heat rinse IHR (central chemical, central rinsing , hot central) with setable flow

##### 有可能使下列方法：冲洗，热柠檬。化学、纯水热、中央热冲洗IHR（中央化学、中央冲洗，中央热）与可设定流量。

##### Possibility to start blood pump to fill AV line during disinfection with saline bag

##### 在消毒时可用盐水袋预充AV管路。

##### Monitoring and counting of rinsing volume of blood side and considering volume in preparation (just display of Speed and volume at same position like during treatment)

##### Performance of Blood side test during disinfection

##### 监测和计数血液侧预充量，并考虑准备过程中的容积（仅在处理过程中在相同位置显示速度和量）

##### Access to information of last treatment / Tren

##### 可查看最后治疗的信息/历史趋势图

##### “Wiper” function to deactivate touch for few seconds

##### “冻结”功能使触摸停止几秒钟。

##### After disinfection, there should be an automatic change to Program selection. If bloodline is installed to venous clamp box, machine start with test for next treatment. If no blood line machine switch off after setable time if nobody touch the screen.

##### 消毒后：1如果血路管路安装静脉夹盒，自动跳到自检，下次治疗（软件加压力头看有无管）。2，如果没有人触摸屏幕后，固定时间后，自动关机。

##### 500 disinfections should be stored in the machine (standard & online)

##### 500消毒记录应存放在机器（标准及在线机器）

##### Minimum 10 Stored disinfections should be available for nurse via “disinfection history” icon

##### 最低10次存储消毒记录，护士可通过“消毒历史”图标查看

##### In disinfection history record, date, end time, method and indication if OK or not ok

##### 消毒历史记录包括，日期，结束时间，方法和指示如（OK或not OK）

##### Timer functionality should be fully available also after changing to program selection/preparation (time run should continue)

##### 定时器功能在更换程序选择/准备之后也应该完全可用（时间应该继续运行）

##### BPM functionality should be fully available

##### BPM（血压计）功能应该完全可用

##### Availability of reading trend data during disinfection

##### 消毒期间可阅读历史趋势图/数据

##### Maximum idle times to be set in TSM (default 72h standard). Message “out-of-operation time exceeded” to be activated / deactivated in system Configuration by Technician

##### 最大闲置时间可被设定在工程模式TSM（默认72h标准）。由操作人员在系统配置中激活/停用的“非操作时间超出”的消息

##### Possibility to set intervals for chemical disinfection in TSM. Message “chemical disinfection necessary” according to interval

##### 可能在TSM设定化学消毒的时间间隔。按间隔要求提示“需要化学消毒”

##### Concentration of connected canister；Concentration of mixed solution；formula can choose

##### 混合溶液的浓度

##### 连接消毒液浓度可设

##### Time for pre rinse, circulation and post rinse for each chemical individual.

##### 每种化学消毒的前冲洗、循环和后冲洗时间各自独立。

##### Minimum set value should be equal to disinfection validation report

##### 最低设定值应与消毒确认报告相同

##### Possibility to activate mandatory disinfections (in TSM). (eg. After have more then 72h or after change of CF filter)

##### 可激活强制消毒（TSM）。（例如，超过72h或CF滤波滤器更换后）

##### water supply errors will stop counting pre and post rinse time and flow. Continue if water is back.

##### 供水错误将停止计算前后冲洗时间和流量。如果水回来，继续。

##### It is possible to make changes in Menu during disinfection. If nobody touch the screen it will jump back to disinfection screen after set able time.

##### 消毒过程中可以使用菜单。如果没有人触摸屏幕，一定时间后它会跳转回消毒屏幕。

##### For technician there should be a way to skip mandatory disinfection

##### 对于技术人员，应该有办法跳过强制消毒。

#### Main Disinfection Screen should display消毒主屏应显示:

##### Status bar indicating the status

##### 状态栏，指示状态

##### Date & remain Time or finish time Setable by technician， Percentage until finish

##### 日期&剩余时间或完成时间（工程可设定显示哪种），百分比直至完成

##### Real Temperature and conductivity is displayed by touching bargraph (returing after 10 sec.)

##### 实际温度和电导率，可通过触摸光柱显示（10秒后恢复。）

##### Display of disinfection method and agent

##### 消毒方法和消毒剂的显示

##### Graphics showing disinfection phase and remaining time, e.g. pie chart

##### 显示消毒阶段和剩余时间的图形，如饼图

##### Blood pump speed and volume

##### 血泵速度和累积量

##### BPM menu possible to open with values (systolic, diastolic and pulse rate)

##### BPM菜单可以打开值（收缩，舒张和脉搏率）

##### **Thermal disinfection validated process热消毒的过程（验证）**

##### 85 °C at t201 after dialyser couplings for certain time (Time and temperature should be setable)

##### 85°C经过C T201（透析器接头后）一定时间（时间和温度可设定）

##### **Chemical disinfection (per-acetric Acid) validated process化学消毒（过氧乙酸）过程（验证）**

##### Different validated chemicals, set in TSM, can be selected by the user. The disinfectant volume, time, temperature conductivity and rinsing time must be set in TSM by a technician. Citric acid shall **not** be part of the chemical disinfectant selection. After solution intake there should be a circulation and an automatic rinsing phase.

##### 不同验证的化学消毒液，在TSM可设，可由用户选择。消毒剂的量、时间、温度，电导和冲洗时间必须可由技术员在TSM中设定。柠檬酸不应成为化学消毒剂选择的一部分。消毒液进机器后应有循环和自动冲洗阶段。

##### Complete time total max. 40 min (wish)

##### 完成时间总计40分钟（希望）

##### **Chemical disinfection (chlorine) not validated process / for treatment of drain(hospital tube )化学消毒（氯）过程/排水处理（不验证）post rise time shout validat(no remain )**

##### Different validated chemicals, set in TSM, can be selected by the user. The disinfectant volume, time, temperature conductivity and rinsing time must be set in TSM by a technician. Citric acid shall **not** be part of the chemical disinfectant selection. After solution intake there should be a circulation and an automatic rinsing phase.

##### 不同验证的化学消毒液，在TSM可设，可由用户选择。消毒剂的量、时间、温度，电导和冲洗时间必须可由技术员在TSM中设定。柠檬酸不应成为化学消毒剂选择的一部分。消毒液进机器后应有循环和自动冲洗阶段。

##### Complete time total max. 40 min (wish)

##### 完成时间总计40分钟（希望）

##### **Chemical disinfection Citric acid Thermal with decalcification validated process柠檬酸热消毒及脱钙过程（验证）**

##### 83°C and citric acid, extra icon

##### 83°C和柠檬酸，额外的离子

##### Complete time to reach Temperature at T201 (max. 20 min)

##### 在T201达到温度所需时间，最多20分钟

##### Complete time of all process (Pre/circulate and Post) 45 min. (wish)

##### 完成所有进程的时间（前冲/循环和后冲）45分钟（希望）

##### **Chemical citric acid hot Short cleaning ~~disinfection~~ ~~thermal~~ not validated process短柠檬酸热（不验证）**

##### 85 °C after the dialyser couplings (just reach)

##### 透析器接头后85°C（只需到达）

##### must not be named “Disinfection”

##### 不能叫“消毒”

##### Complete time max. 10 min (wish)

##### 完成时间最大10分钟（希望）

##### Name should be “Short thermal citric hot”

##### 名称应为“短热柠檬酸”

**END 06.09.2017**

In general if time is not reached for hold temperature it should extend automatic maximum for 10. Min.

一般来说，如果预定时间没有达到保持温度，它应该最大能延长10分钟。

If the time goals can technically not be reached, it must be tried to come as close as possible to these times, as time saving is one of the major topics regarding ergonomics and efficiency

如果在技术上不能达到时间目标，就必须尽量靠近这些时间，因为节约时间是人类工效学和效率的主要议题之一。

#### Central cleaning (IHR) 中央清洁（IHR）

##### A central cleaning from the ring mains should be possible including water inlet and outlet tube and parts of the machine

##### 中央清洗应该是可能的，包括进水管和出水管以及机器的部件。

##### **Central thermal disinfection中央热消毒**

##### Hot permeat should rinse at 83°C through water inlet tube and machine

##### 应冲洗83°C热渗透水通过进水管和机器

##### **Central chemical disinfection中央化学消毒**

##### Permeat mixed with chemical disinfectant should rinse through water inlet tube and part of the machine

##### 渗透水混合与化学消毒剂应通过进水管和机器的一部分

##### (OM shout contain hint with rinsing before next treatment by user responsibility)

##### （OM应含有提示，在下一次治疗之前由用户负责冲洗）

##### **Central rinsing中央冲洗**

##### Cold permeat should rinse from ring mains through water inlet tube and machine

##### 冷渗透应冲洗/通过进水管和机器

##### **For that purpose Flow and time should be setable. There is no separation between the different styles.**

##### **为此流量和时间应可设定。不同方式之间没有区别。**

#### Auto switch off 自动开关机

##### After the disinfection or rinse mode the machine should be switched off automatically if desired, set by nurse. If nobody touch the screen machine switch off after setable time.

##### 消毒或冲洗模式后，如有需要，应自动关闭机器，由护士设置。如果没有触摸机器，一定时间后自动关闭机器。

#### Auto switch off and on自动关闭和开启

##### Automatic switch off and on at a preset time & date if desired, set by nurse

##### 如果需要，在预设的时间和日期自动关闭和打开功能，由护士设置

#### Weekly disinfection configuration每周消毒配置

##### It should be possible for the user to configure a weekly disinfection program that runs automatically. Each day should include two operations.

##### 用户应该可以配置每周自动消毒程序。每天应包括两次程序。

##### Weekly program should be programmable for whole week.

##### 每周配置应可编程整周。

### 4.3.4. 工程模式

### Technical Service Mode (TSM)

#### The TSM mode should be divided into levels TSM模式应该是分层次的:

##### System configuration level for qualified nurses

##### Level for technicians, company staff and production staff (including system configuration)

##### Access should be by password. Different one for all groups. Higher Password should include rights to lower password

##### Password level from low to high level are non, nurse, technician (technic), company ingeneer and production staff

#### Calibration

##### Automatic check for plausibility of calibration data

##### Easily accessible and clearly marked calibration points with defined connection for reference meters

##### Analogue and digital values displayed in one screen plus currently calculated sensor value

##### Indication of test failure

##### Display of flow diagram and blood circuit diagram with active function

##### Possibility to address single components like valves and pump

##### Automatic tests to check condition of pump

##### Debugging: Preparation tests can be performed in TSM step by step by technician

##### Trend history record for temperature, pressure, conductivity (all 30 secounds)

### 4.3.5. 用户维护以及维修

### Service & Maintenance by the user

##### The user should be allowed to use the following cleaning agents for the outer surface of the machine without damaging the machine.

##### The fan filter should be easy to clean

##### The CUT filter should be easy to exchange

##### The disinfectant canister can be changed easy

### 4.4. 运行参数

### Performance Parameter

#### 4.4.1. 部件以及必需功能的参数

#### Components & Required Functional Parameters

##### 4.4.1.1. 供水以及水路部分

##### Water Supply & Hydraulics

##### The inlet water must be suitable for dialysis. following European and AAMI standards

##### outlet tubes must stand central thermal disinfection temperature

##### The inner walls of outlet tubes must be as GOOD against biofilm as possible

##### Inlet tube is not part of shipment. OM mention only spec. like pressure, temperature, inner diameter and that it don`t contain toxic components

##### The inner diameter of inlet / outflow tube connector max 9 mm

##### The inlet / dialysate outlet connector should be positioned at the back of the machine,

##### An integrated water inlet particle filter retaining particles > 300 µm,

##### For shipment a cover is needed on all connectors to avoid insects enter device

##### In case of water absence a sequential therapy is performed and clearly indicated to continue treatment, After water supply is recovered, the therapy mode before is continued. During sequential UF same UF rate is used like before. It is setable if time remain or add.

##### 0,5 – 6 bar

##### Inlet temperature

##### 10 – 32°C

##### Water monitoring

##### Low water alarm from integrated monitoring device

##### Heat exchanger

##### to be integrated for economical/ecological reasons

##### available as Option depend on country/area

##### should be setable in Option setting for self test and disinfection

##### Possibility to mechanically remove/bypass the heat exchanger by a technician e.g. in case of warm water inlet temperature

**Status 08.09.2017**

##### Hydraulics

##### There should be no parts of the hydraulic which are not part of the disinfection circle (no dead spaces). Water inlet, central acid supply and disinfection inlet should be small as possible.

##### Tubes and components should be easy to identify in order to reduce service times. This could be achieved e.g. by labelling tubes and components according to their function

##### Optimized arrangement of measuring points

##### Separation water from electronic parts

##### Components should be easy to remove without removing other components first

##### Components should be possible to remove without removing screw

#### 4.4.1.2. 血路部分

#### Blood Side

##### Blood pump

##### 2-roller peristaltic pump with handle/crank, low hemolysis,. The motor should be switched off if the door will be opened.

##### Rollers have arrows to show clockwise direction for manual blood returning

##### Default for 8/12 mm pump tubes or other tube with 2 mm wall

##### One pump for twin needle treatment, SN-KK

##### Delivery rate

##### 20 – 620 ml/min (ID 8 mm)

##### 10 - 460 ml/min (ID 6 mm)

##### steps free for data input

##### with +/- button set able steps e.g. 5 ml/min.

##### Tolerance

##### ± 10% (-200 to +400 mmHg) or max. +/-10 ml/min depending on bigger one

##### ± 25% (-300 to -201 mmHg) or max. +/-10 ml/min depending on bigger one

##### Pressure

##### Intake pressure: up to -500 mbar

##### Pumping pressure: 0 – 1.500 mbar

##### Pump housing

##### should be adapted to front in a way corners and edges are avoided for easy cleaning

##### Position

##### Pump & housing should be positioned on the machine in a way that enables a lateral blood in and outflow

##### Others

##### Changing AV lines and dializer during therapies must be able without new tests

##### Short cut of AV line (paused treatment mode)

##### Setable reminder for bypass, hep pump stop, BP stop, BP cover open, UF off, Paused mode Max 15 Min.)

##### Reminder start, no blood detction or disconnect not pushed

##### Handle/Crank for manual blood return

##### Automatic Battery operation of BP during treatment. Alarm with message that device is under battery operation. BP speed change to Battery blood pump speed setting if it is higher.

##### Pressure sensors

##### For arterial and venous pressure a connection check should be integrated

##### Arterial pressure (PA)

There should be a possibility to measure the arterial pressure.

##### Protection system: Test prior to start of therapy or in disinfection mode at zero point +/- 10 mmHg

##### Measurement range: -500 to +400 mmHg

##### Tolerance: ± 10 mmHg on the actual value

##### Limits: adjustable within operating range, adjustable width for static limits window. Set of window with “alarm reset”. After BP speed change the window is reset and set again after set able time.

##### Dialyser inlet pressure (DIP)

###### If SN treatment is not used the SN Pressure transducer can be used to monitor DIP

##### Dialyser inlet pressure between blood pump and dialyser, measurement 0 – 700 mmHg

##### Protection system: Test prior to start of therapy or in disinfection mode

##### Test: BP start / VClamp close, stop BP when 200 mmHg reach at vp. Compare VP with DIP within 10 mmHg.

##### Measurement range: 0 – +700 mmHg

##### Tolerance: ± 10 mmHg on the actual value

##### Limits: adjustable within the range.

12.09.

##### Venous pressure (PV)

There should be a possibility to measure the venous return pressure

##### Protection system: Test prior to start of therapy or in disinfection mode

##### Test proposal: BP start 100 ml/min, Ven. Clamp close and create +200 mmGH for 5 Sec when BP stop

##### Pressure drop 10 mmHg (setable). Pressure must be reached in 60 sec

##### Limits are monitored by the function and control systems.

##### Measurement range: -200…700 mmHg

##### Tolerance: ± 10 mmHg on the actual value

##### Warnings when sudden venous pressure drop occur

##### Limits: adjustable within operating range, adjustable width for static limits window. Set of window with “alarm reset”. After BP speed change the window is reset and set again after set able time.

##### Single needle pump pressure (SN-P)

##### A pressure measurement used to regulate the SN blood pump and V- clamp and if option installed A-Clamp is there also.

##### Used for switch pressure (setable)

##### For SNSP limits for Up/down

##### Limit window

##### The following values should be displayed numerical: PA, PV, DIP, TMP, DP, SN-P (SN only in SN window)

##### The following settings should be possible: max DIP, Delta DIP/VP (pressure lost), max TMP, min TMP, Delta TMP, max PV, Delta PV,

##### Venous delta window should adapt automatically to rising pressure values during therapies 2 mmHg every two minutes or quicker

##### Venous delta limits adjustable for nurses in System configuration level

##### All values in absolute numbers

##### Set values:

##### Delta PA 10…100 mmHg default 70

##### DIP max 100…700 mmHg default 700

##### Delta DIP 100…700 mmHg default 150

##### max/min TMP 300 – 700 mmHg /-100…10 mmHg default 500/0

##### Delta TMP 10…100 mmHg default 50

##### max PV 100…400 mmHg default 250

##### Delta PV 10..100 mmHg default 70 in system configuration level only

##### TMP

##### TMP should be calculated and displayed PV and DP (TMP=VP-DP +53 mmHg)

##### TMP Zero Calibration after 10 Minutes / UF off (offset definition)

##### Different Pre Offset for TMP Zero

##### DIP value (if SN available) should be included in TMP algorithm

##### Min & max TMP limit monitoring, alarm if reached

##### adjustable range of the min TMP see above

##### adjustable range of the max. TMP see above

##### TMP delta in absolute values, adjustable for nurse

##### Tolerance +/- 15 mmHg

##### TMP Range – 100 /+ 600 mmHg

##### warning if TMP delta limit is reached

##### Delta values adjustable by nurse see above

##### possibility to turn TMP monitoring off

##### during SN treatment no TMP display and on same position SN Pressure

13.09

##### Air detector

Ultrasonic air detector, can be realised with a sensor directly detecting on the bloodline.

##### Solution/ Sensitivity

##### Air bubbles at > 20µl, micro foam with cumulated volume

##### should be detected. 0,3 µl

##### Bypass of air detector

##### A bypass of the air detector should not be possible for nurses.

##### Protection system

##### Automatic cyclical checks during operation phase

##### Red detector

Functions:

##### If blood is detected while connecting the patient the blood pump will be stopped

##### (setable/adjustable)

##### If no more blood is detected in disconnect mode, the blood pump will be stopped

##### Detection of blood in disinfection mode, trigger of alarm (machine misuse)

##### Position in air detector / venous clamp.

##### Arterial clamp (Option)

An arterial clamp, for use in single needle mode is option in 2-pump machines.

The valve open in case of power loss.

##### Venous clamp

A venous clamp, for use in single needle mode or for blocking of the blood flow in case of alarms. The valve closed in case of power loss.

##### Level adjustment system

An level adjustment system should be integrated

##### possibility to adjust venous level in preparation and disinfection from screen

##### possibility to adjust venous level in treatment (blood) from screen

##### The reaction time of the system must be short

##### Window with “arrow” buttons (up/down) to adjust on touch

##### Possibility to adjust level in case of air detector alarm in venous drip chamber including text instruction

##### The system must set level in a way that treatment can be started (tests must be passed). Nurse has the possibility to re-adjust the levels via arrows

#### 4.4.1.3. 透析液方案

#### Dialysis Solution

##### Temperature

##### Tolerance: ± 0,5°C at the dialyzer

##### Range: 33-40°C

##### Lower range protective system: 33°C

Protection system

##### Temperature sensor, excessive temperature 41°C

Profile

##### Selection of linear or exponential profile

##### Conductivity

Selectable by a qualified technician, the indication in mS/cm and mmol/l should be possible. For the indication of mmol/l, the user can select between 8 types of concentrates.

User can select a concentrate name.

Selection of source can be made by nurse.

##### Tolerance

##### ± 0,3 mS/cm on the final conductivity

##### Range

##### Conductivity bicarbonate 2 –3,8 mS/cm (Bic without sodium and bic cartridge) default 3,0 mS

##### Conductivity bicarbonate 4 –6,7 mS/cm (Bic with sodium) default 5,3 mS

##### End conductivity 12.5 – 15,5 mS/cm, default 14,0 mS/cm

Protection system

##### Monitoring through dual conductivity sensors +/-5%

##### Temperature-compensated measurement 25°C (Factor 2.05%/°)

##### Dialysate flow

##### Range

##### 300 – 800 ml/min adjustable step free / +/- in steps of 10 ml/min (setable step)

##### Flow tolerance

##### ± 10 % of the selected value

##### Flow pressure range

##### +400 to – 450 mmHg

##### Pressure tolerance

##### ± 10 mmHg of the selected value

##### Pressure limits

##### Upper limit +300 mmHg < return flow pressure

##### Lower limit – 300 mmHg

##### Indication of the dialysate pressure

##### During self test limits are open to maximum.

##### The dialysate pressure will be indicated in the total overview as trans membrane pressure (TMP).

##### Dialysate window

##### The following values should be displayed: bic & total conductivity in mS, concentration bic and final in mmol, DF flow, temperature, profiles yes/no, concentrat type, mode (bic/acetate), display of ratio

##### The following settings should be possible: bic & end cond in mS, concentration bic and final in mmol, DF flow, temperature, profiles, concentration type, mode (bic/acetate),

##### Set values:

##### Temperature 33-40°C

##### Dialysate flow 300…800 ml/min (standard), 300…800 (HDF) default 500

##### Bicarbonate conductivity2,0–3,8 mS/cm default 3,0 (bic with sodium and cartridges)

##### Final conductivity 12,5…15,5mS/cm default 14,2

##### Bic concentration 20… 38 mmol/l default 30

##### Final concentration 125…160 mmol/l default 140

##### Concentrate types: set by technicians

##### Bicarbonate /acetate dialysis (Acetate is off and changeable by technician)

##### Heater

##### The dialysate must be heated

**14.09.**

##### Degassing system

##### Mechanical through regulated vacuum. Even at considerable pressure drops, a loss of effectiveness of the dialyser as a result of additional air bubbles in the dialysate should be prevented

##### -0,8 bar (-600 mmHg) should be reach on north earth

##### Rinsing bridge

For connecting dialysate couplings during disinfection and preparation.

##### Couplings must be easy to dismount from bridge

##### A sample port integrated in inlet tube. Available as accessory, not standard

##### A flow meter integrated in inlet tube. Available as accessory, not standard

##### Filter in the outlet line should be inside the main housing, not external

##### No filter should be installed in front of inlet coupler

##### Blue couple is inlet, Red is drain (standard, setting for inlet and drain coupler colour because of Fresenius)

##### Rinsing bridge: Dead space free couplings (wish)

##### Blood leak detector

##### Red sensitive in order to detect blood.

##### Should be positioned inside the machine.

##### Easy maintain and calibration

##### PD

Sensor to measure dialysate outlet pressure

##### Accuracy +/- 10 mmHg

##### Bicarbonate holder

##### Possibility to connect bicarbonate holder to the machine with standard BIC Cart

##### In all sizes even 1200g

##### Auto detection of position with auto filling

##### Integrated in disinfection witch checking of flow

##### Concentrate Supply

##### Concentrate from canisters, central container containers (option) and Hook for acid Bag (option)

##### Canisters

##### It should be possible to draw acetate, acid and bicarbonate, citrate and Bicarbonate concentrates directly from canisters with suction rods

##### All sorts of common canisters (6L, 10L) and reach bottom of any canister

##### Canisters easy to position or deposition in front of machine without problem (enough space)

15.09.

##### Concentrate rods

##### There must be quivers for concentration rods closed by lids, integrated in the disinfection cycle.

##### It must be possible to draw out the rods with one hand only.

##### Lids close automatically when rods are extracted

##### When return the rods, by one hand the lids need to be open before

##### The tubes of the rods should not overhang from machine

##### Red and blue colour for lids should be used

##### Filter should be inside of device

#### 4.4.1.4. 超滤

#### Ultrafiltration

The max. UF-rate can be limited by programming the value in the machine or on a Patient Therapy Card. During UF-profiling the UF-rate per segment should be indicated.

##### UF-range: 0-4000 ml/h (option: up to 8000ml/h}

##### The range can be set for HD/O-HDF, ISO UF/ profiles (by technician password)

##### \*UF-tolerance: max. ± 30 ml / hour or 1%, depending which is bigger

##### UF-profiles: Some preset profiles, also free programmable

##### UF window

##### The following set values should be displayed: UF volumen, time, UF rate, UF min rate, UF max rate, Button to change to UF profile, sequential time & volume screen

##### If UF goal is reached, treatment time continue until end with UF minimum. If treatment time is first reached also uf rate continue until end.

##### By using profiles the minimum step time is 5 Min. If the user try to activate a profile close to end of treatment, there will be a message that it is impossible.

##### The following setting should be possible: UF volume, time, UF rate, UF min rate, UF max rate, UF profile, sequential time & volume

##### Values:

##### Maximum treatment time is 12h

##### UF volume 0…48000 ml default 0 ml

##### UF time 0:01…12:00 min default 4:00

##### UF profile

##### UF min/max 0…4000 ml/h default 1000

##### ISO UF: max rate 0…4000 ml/h default 1000

##### A change of treatment mode (HD to OHDF is possible, but profile need to be stop before.)

##### Isolated UF (ISO-UF)

##### Display Text “ISO UF” on status bar

##### Running time must be clearly visible

##### After end of ISO UF, previous treatment (e.g.HD) should start (restart when interrupted) after acoustic and optical sound without confirmation

##### Setting of ISO UF parameter time and volume and rate in sub menu “UF”, independent of profiles

##### It should be setable if ISO UF time is included normal treatment time or not. The ISO UF volume should be part of Treatment volume

##### Warning message after 1h sequential

#### 4.4.1.5. 机械部件

#### Mechanical Parts

##### Housing

##### Surface must be smooth and easy to clean

##### Surface material must be resistant to common disinfections (chlorine)

##### Touch (display) should be also resistance, but alcohol excluded

##### No sharp corners and edges, glyphs and slots which are difficult to clean (on front)

##### Hygienic “clean” looking colour

##### Inflammability according to UL 94 Vx

##### Entering of liquids / particles according to IPX 1

18.09.

##### Front

##### The following components should be part of the front side: BP, air detector, Heparin pump, tube holders, Online ports (Online machines only), drain port, suction rods

##### All attached components must not of a 90° angle to the front but rather a rounded passage

##### Suction rod quivers below front

##### Front door must open without interfering with suction rods

##### The setting of the AV lines must be self-explaining meaning that the user understands easily where to position blood chambers and blood lines to minimize errors. This should be in display not print on housing.

##### In order to get access to the machine, it must be possible to open front

##### The front side access should be opened completely (at least 90°) and remain in position while opened

##### It should be easy to be opened

##### Back side

##### Main power switch on back side

##### Connection of power cord and wall connections: inlet water, outlet to drain, CCS tubes (option)

##### For cables and tubes there should be a hook or clamp on the rear side of the machine.

##### Possibility to place a disinfection canister on the back side of the machine or at least one on an extractable rack

##### Position of CF filter with cover should be on back side

##### Handle should be on back side

##### Connector for external communication is from Back side

##### Foot

##### The size of the foot should not exceed a width of 510mm and a depth of 650mm

##### There should be a place to position two 10 L concentrate canisters on the foot front side

##### Take care of leakage detection (e.g. deepening) inside machine

##### Opening for rinse out liquids e.g. from canisters

##### No vermin must enter machine 5 mm (e.g. mouse)

##### Distance between ground and machine foot according to norm to prevent injury of staff (IEC60601 / either so small no staff can put foot under the rim or large enough)

##### Brake(s)

##### Brake should be easily accessible

##### Hit from above to tighten brake

##### Wheels

##### Wheels must guarantee an easy movement of machine

##### Wheel must have a modern smart design

##### Wheels must partly be covered

##### By using break the rotation and wheel should be stopped

##### Handle(s)

##### There should be (a) handle(s) in order to move the machine

##### Storage options

###### There should be various storage options integrated in the machine

##### A flat storage possibility for e.g. medical devices

##### A storage possibility for BPM Cuff

##### A storage possibility for disposables / A4 papers on top or right side

##### Infusion pole

##### A metal infusion pole should be integrated in the housing frame size, (not outstanding)

##### Height of pole should be adjustable

##### Pole extractable from 1,61m to 2m from ground

##### On top of pole should be three or four hooks for infusions

##### Pole or top of pole to be dismounted for transport

##### Infusion stand is part of left handle

19.09.

##### Dialyser holder

##### Holder for a dialyser attached to machine on right hand side on ergonomically good position 110 cm high

##### Position can be changed from front to side (rotation possible)

##### holder must hold all sorts of common capillary dialysers diameter 28…66 mm

##### No damage when machine is moved and holder is outstanding

##### Easy to clean

##### No sharp corners

##### Minimum 2 Tube holder

##### Rubber at the inner side of holder

##### One hand use

#### 4.4.1.6. 电子部件

#### Electronical parts

##### Nominal voltage 230V AC +/- 10%, 50 Hz +/- 2%, (optional 110 V AC +/- 10% 60HZ)

##### Electrical ground: via cable (not delivered at shipment, available as accessory)

##### Cables: Possibility to connect all kinds of power cords to the machine according to country specifications (4 options: SCHUKO, CEE, UK, US Plug)

##### Power cord for Standard machines: China Plug

##### Power switch: Unintended power switch off must be avoided

##### Possibility to power machine with key on monitor.

##### Disconnect Power cable – machine switch to battery power

##### Switch off from rear side – machine switch off complete

##### Switch off by soft key from front during treatment – machine remember last condition incl.

##### Power supply: Test tone for user to check if speaker works (max. 3 sec) ISO 60601-1-8

##### Interior: Separation of electric parts from hydraulic that no leak can damage components

##### USB port for service technicians easily accessible

##### Sound design for warning, alarm, info has to follow ISO 60601-1-8

#### 4.4.1.7. 抗凝泵

#### Anticoagulation pump (Heparine Pump)

#### 4.4.1.8. 显示器

#### Monitor

#### 4.4.1.9. 可选部件

##### It must be a flat screen monitor, technology LCD or equivalent technique

##### LED backlight

##### The cross dimension must be at least 15’’ (diagonal)

##### Long time available > 10 year

##### Touch screen

##### The UI must be performed via Touch screen, pressure sensitive

##### Monitor housing

##### The monitor should have fix position (no rotation)

##### Monitor must be tight and withstand user operation when pressed

##### The angle of the monitor must be specified in a way, that tall standing people as well as small sitting people both acknowledge the display.

##### No liquid/particles must enter into monitor housing according to IPX 1 / IP 21

##### No edge between monitor housing and touch / must be easy to clean

##### Card Reader RFID must be easily accessible for user

##### Hard keys

##### The following hard keys should be available: from left to right: on/off, Reset alarm, Alarm mute button

##### Possibility to power machine with hard key

##### Hard keys must be positioned in the most ergonomically way, integrated in monitor /monitor housing or optically integrated in touch

##### Status indicator

##### A status indicator should indicate the status green, yellow (orange) and red (check with standard)

##### Integrated in monitor or nearby

##### If positioned on top of monitor, visible from all side

20.09.

#### Options

### 4.4.1.9. 抗凝

##### 4.4.1.9.1 ABPM

Non invasive blood pressure measurement.

##### Blood pressure cuff position in the left side of housing

##### The length of the cuff tube should be normal size for upper arm size L (but available as accessories in S, M, XL)

##### Cuff: innovative , comfortable, smooth, nice design

##### Suitable for all arm and leg

##### Hardware

##### Measured values SYS, DIA, PR, MAP

##### Values;

##### Systole 45 – 280 mmHg

##### Diastole 15 – 220 mmHg

##### Mean. art. Press. 25 – 240 mmHg

##### Pulse 30 – 240 beats/min

##### Tolerance of sensor: blood pressure: 5 mmHg, pulse: ± 2% or 2 beats/min

##### A reset of the module should be possible without switching off/on the Dialysis machine

##### Cuff pressure 0 – 300 mmHg pressure for the cuff

##### Possibility to perform MTC by technician according EN 1060-3

##### Software

##### Easy access to start ABPM measuerement

##### On or off condition should be possible via icon.

##### Display of current blood pressure value in all modes if ABPM is active

##### Single-measurement can be activated by an icon.

##### Inflating pressure setable (factory default 180 mmHg)

##### Next individual cuff pump pressure 30 mmHg above last systolic value

##### Setting & activation possibility of frequency of measurement (1...120 min)

##### Limits adjustable by nurse: (also for Patient card). Alarm function can be activate or deactivate by technician.

##### SYS lower 65…220 default 80, upper 80…245 default 200

##### DIA, lower 40…130 default 40, upper 40…220 default 130

##### PR. lower 40…100 default 50, upper 100…200 default 140

##### Display of numerical set limits

##### A cyclical measurement must be possible, also in disinfection

##### A graphic of all the values of the therapy displayed with SYS, DIA, MAP, PR

##### 4.4.1.9.2 DF-filter

##### A holder to attach the DF filter

##### A bypass of the connectors must be possible.

##### Device will be also available without CF filter

##### The operation hours of the DF filters should be recorded and indicated, a warning should be displayed 10 h before filter expires before disinfection start.

##### Location: Placed at the back side of the machine and integrated into leak detection

##### Disinfection: The flow path of the DF-filter lines must be disinfectable.

##### Chemical disinfections must not harm filter (min 30 x Chlorine must be possible)

##### There must be a setting which filter is used (self test, disinfection)

##### A frequent trans-membrane rinsing to transport air out of filter (setable time: default 60 Min.)

##### A rinsing program to empty filter during change: initiated by icon, all necessary steps to be performed automatically (emptying, filling, disinfection citric thermal, reset of operation hours), with instructions

##### Colour of couplings should be equal to Online filters

##### Accessibility easy without special tools

##### Self test for DF filter (Housing and Membrane) Both filter / test time reduction

##### Counter for: Operation time (with flow), disinfections, treatment and chlorine

##### Lifetime min 150 treatment/disinfection

21.09.

From 26.09.:

##### 4.4.1.9.3 Battery power supply

##### Battery is a customer place (field) Option.

##### The battery should run minimum 20 min. within the first 4 years. No dialysate circuit support, but Blood and heparin pump running, monitoring functions (pressures, clamp, air detector) active. Clear indication that machine is running on battery.

##### Display for voltage, charging and estimated capacity

##### Indication if battery is low (10,8V)

##### Standard PB battery 12V DC 7Ah

##### Battery should be not in warm area (separation from Hydraulic and electronic) with stable temperature.

##### 4.4.1.9.4 Bicarbonate cartridge holder

##### Possibility to mix warm water with bicarbonate powder in a cartridge, placed in a holder and connected with tubes to the hydraulic system.

##### A holder attached to the machine to hold the standard bicarbonate cartridge

##### The system must be connected with the machine’s water system

##### Part of disinfection cycle with flow check (e.g. by temperature sensor)

##### Holder should not be outstanding from the side of machine when holder is closed

##### Material must be resistant to bicarbonate, machine disinfectants and surface disinfectants

##### Holder must be easy to open and close

##### Must stand pressure (+0,5 bar) when cartridge is placed and upper lid closed

##### Compatibility to all standard cartridges, and currently available products: Gambro BicCart 650, 720, 1150g, B.Braun, NiproCart, Serumwerke Diacart 720g, Nikkiso Nikkart 750g, Baxter Altracart II 750g cartridges. Further cartridges not mentioned must fulfil same specifications (dimension) as products mentioned above and must be validated.

##### Enable emptying of bic cartridge in preparation and treatment via UI

##### Automatic empty process during disconnection mode when red couple is returned

##### No dripping when open (e.g. empty line)

##### 4.4.1.9.5 Central concentrate supply (CCS)

##### Connection to machine for one concentrate and bicarbonate or for two concentrates from a central supply. Delivering acid and bicarbonate. Both as customer place (field) option

##### The connection of a central concentrate delivery system should be possible on the rear side of the machine.

##### When machine is equipped with CCS, there should be no need for manual connecting/disconnecting of couplings for disinfection. There should be a valve test for leak check.

##### Pressure concentrate supply: 0.to 0,7 bar

##### Possibility to clean CCS tubes to prevent crystallization in service program

##### Tube connector should be maximum 5 mm and produce by plastic.

##### Inlet valve should be on low position to avoid air and crystallization

##### 4.4.1.9.6 Heparin pump

##### The heparin pump is an factory option of the machine for outside of china.

##### It should be partly integrated in the machine front.

##### It should be in an upright position.

##### The delivery rate should be indicated in lE/h (for bolus and continuous modes) and ml/h selectable by a nurse in System configuration. Factory default is ml/h.

##### The heparin pump must be able to monitor 10, 20, 30 ml syringes from all important competitor’s products (Terumo, Fresenius, B.Braun, Dispomed, Monoject, Omnifix and B and D). Type in by diameter by free text. Min. 5 types. With pre setup.

##### Heparin delivered on the pressure side of the blood pump. In that case, the heparin pump has to withstand + 1 bar. Risk analysis has to be considered.

##### Range: 0,1–10 ml/h in steps of 0,1 ml/h

##### Operation: it should be possible to switch off during treatment (Standstill possible)

##### This should be set able by Option

##### Tolerance: ± 10 % of the selected value

##### Indication of operation: The actual operation has to be displayed.

##### Recognition if clamp is still closed during treatment and alarm

##### If manual heparin line clamp is opened after alarm, no heparin bolus must enter blood line because of pressure.

##### In case heparin pump is behind blood pump: no blood must enter heparin line by long tube

##### Alarm handling without taken syringe from heparin pump

##### Heparin bolus if red detector detects blood (TSM). (Selectable auto or manual bolus)

##### Heparin window

##### Possible settings: rate IE or ml/h, volume of bolus, stop time, profile (tbd), Treatment without, syringe type, total volume incl. bolus (also during preparation in different display).

##### Set values:

##### rate 00:00…10:00 ml/min default 0,0

##### stop time before treatment end 0:00…12:00 h default 0:20

##### volume of bolus 0..10 ml default 0,0

##### Syringe type Fresenius 20 ml

26.09. -----------------

##### 4.4.1.9.7 HDF/HF Online Standard (Second pump)

##### “6068” version with two pumps for HDF /HF and HD therapies

##### 5058 can be modified to 6068 in field

##### It should be possible to perform hemodiafiltration (HDF) and hemofiltration (HF) with online substituate. (filtered ultra pure dialysis fluid) in Pre and Post dilution.

##### The fluid should be delivered with a second pump into the A/V system.

##### No combination with Single Needle Double Pump therapy

##### The online fluid should be available for Online priming, also if a HD treatment is selected.

##### The online fluid should be available at the end of therapy for re-infusion (Online-reinfusion) also for HD therapy.

##### The online fluid should be available for Online bolus.

##### Ranges HDF/HF: Substitution rate: 20-400 ml/min ±10%.

##### If dialysate flow is reduce because of high Sub, there is a confirm message.

##### Total amount of substitution volume: 288 L

##### HDF: Dialysate processing: 300-800 ml/min ±10% (1000 ml/Min Option)

##### There must be a function (Flow application) to set Balance chamber flow or real dializer flow.

##### Machine must notice if the substitution line is closed or occluded during HDF/HF treatment.

##### It must be possible to activate or deactivate Online treatment any time

##### If CF filter test fail, there must be possibility to perform standard HD treatment after confirmation.

##### Possibility to select pre- or post dilution HDF

##### Bolus: Infusion bolus from 50 to 250 ml

##### Online fluid must be filtered by two dialysate filters (DF filters). The filters are attached at the back of the machine. They are integrated in machine

##### The working time of the filters has to be monitored and indicated. Default: 750h, 150 treatment or 90 days.

##### Online fluid not to be allowed after expired filters (can be activate or deactivate)

##### Online ports (Online machine only)

##### There must be an inlet and outlet port at the front of the machine to connect A/V system to the water system

##### Lids must be easy to open/close

##### Ports must be part of disinfection cycle

##### Avoiding of wrong flow direction into the outflow port by a monitoring system

##### For online re-infusion in HD therapy, it must be hygienically safe to connect patient’s arterial bloodline to outlet port. E.g. adapter in AV system

##### Ports should not drip of water while opening or closing

##### HDF/HF window

##### Access to sub menu “HDF/HF” via parameter icon on main screen

##### There should an auto-sub function calculating the ratio (%) between substitution and BP rate and suggesting that ratio to the nurse. Nurse can accept or change (Online machines only). Default 20%. Pre 100% and post 40% dilution has different max limit.

##### Sub menu should include (Online machines only)

##### auto sub function button

##### option HDF/HF and Pre and post dilution

##### set button “Substitution flow”

##### set button “Substitution volume”

##### set button “DF flow”

##### set button “Bolus volume”

##### activation start button bolus

##### display ratio BP/sub rate, blood flow, total infusion bolus volume

##### 4.4.1.9.8 Single Needle

##### SN SP (SN KK)

##### It must be easy to use

##### Standard bloodline of HD can be used

##### As Option arterial clamp is available

##### Display of Effective blood flow

##### Change by switch pressure (upper and lower)

##### Stroke volume should be calculate

##### SN time alarm

##### Double Pump

##### Easy to use

##### Principle with 2 blood pump in front of dializer

##### A chamber of 90 ml is between both pumps

##### There needs to be a PSN pressure port

##### There needs to be holder for SN chamber

##### There should be an internal SN expansion chamber of 90 ml

##### As Option arterial clamp is available to minimize recirculation

##### Display of Effective blood flow

##### Change by switch pressure (upper and lower)

##### Stroke volume should be calculate

##### SN time alarm

##### System must be able to treat patients with poor blood offer or bad positioned catheters without constant alarms

##### Blood pump speed must adapt to vessel’s conditions by max. art. Pressure.

##### User has the possibility to set phase / stroke volume (10 – 60 ml)

##### There must be a special SN blood line

##### SN auto function relation arterial BP and SN pump via % setting or volume (absolute value)

### Anticoagulation

### 4.4.3. 数据交互

Antikoagulation with heparin is possible with the Heparin pump (see option chapter)

### Data Interface

### 4.4.4. 安全需求

##### Network

##### A connection to a network system is necessary in order to administer patient data in a data management system. Th**e** network protocol should be TCP/IP via standard Ethernet.

##### HL 7 will be used

##### Uni direction network

##### Protocol is available on request

**26.10.**

##### Patient Therapy Card (available from second version)

##### There should be the possibility of data storage on a IC card (NFC 4K)

##### Display of all related data on machine screen incl. BPM values

##### Plausibility check for treatment data from chip card

##### Nurse must confirm correctness of displayed data

##### After inserting Patient Therapy Card, data should be read out automatically

##### Without data management SW:

##### Data transfer from Patient Therapy Card via Card Reader

##### Patient card store patient information during treatment

##### Possibility to read, write and erase data from Patient Therapy Card from machine

##### After erase default of machine setting is copy to “fresh” ID card

##### Storage of data on Patient Therapy Card automatically or confirmed by user. The following patient parameters should be stored on cards:

##### Patient Card Information (like Christian informed):

21.11.2017

|  |  |  |
| --- | --- | --- |
| Item | Unit |  |
| Patient I.D (should be exist only once, e.g. 8 digit fix and 5 flex |  | Input once / not changeable |
| Birthday | DD/MM/JJJJ |
| Gender (all grey mandatory to create the card, not changeable) | Male / female |
| First Name | - |
| Last Name | - |
| Creation date of card | DD/MM/JJJJ |
| Dry weight of patient | kg |  |
| Weight at treatment start (scale value) | kg |  |
| UF volume (goal) | L |  |
| UF rate | L/h |  |
| High of patient | cm |  |
| Target Kt/V |  |  |
| treatment time | Min |  |
| Treatment mode | HD/HDF/HF |  |
| Sub rate mode | pre/post |  |
| SUB Goal (HDF/HF volume) | L |  |
| Sub rate | mL/min. |  |
| Sub ratio | 0, % |  |
| ISO UF volume | mL |  |
| ISO UF time | Min |  |
| UF-Profile | selection |  |
| Na- Profile | selection |  |
| Heparin rate | mL/min. |  |
| Heparin bolus value | ml |  |
| Heparin Initial bolus No/Yes | On / off |  |
| Heparin stop time | min. |  |
| Heparin auto Start |  |  |
| Concentrate name |  |  |
| prescribed Na | mMol/L |  |
| prescribed BIc | mMol/L |  |
| Temperature | °C |  |
| Dialysate flow | ml/min. |  |
| Ratio with blood flow / factor | 0 = off /0,1-2 |  |
| Processed blood volume |  |  |
| UF max / ISO UF | L |  |
| SN average blood flow |  |  |
| SN stroke volume / (switch time and pressure) | ml |  |
| BPM interval | Min. |  |
| BPM pressure limit | mmHg |  |
|  |  |  |

Table for record o patient card (1 minute record the values):

Conductivity

Temperature

Venous pressure

Arterial pressure

TMP

KT/V

If Patient management SW is used/ installed:

##### only patient ID is read out from chipcard via Reader, and former SW functions are changed to Patient management SW

##### no other data than ID stored on card

##### Patient management SW (technology for connecting through TCP/IP Ethernet network)

Hardware functionality:

##### Uni-directional connection to Patient management Monitor

##### Use of network capability through TCP/IP standard Ethernet network. Built in card reader should be used for patient identification.

##### Card Reader / network interface comes with a software driver which is optimised for uni-directional communication.

##### All available parameters should be transferable through the network. Therapy data, machine data (trend data) as well as preparation and disinfection data. Especially preparation and disinfection data should be sent out independently of the insertion of the chip card.

##### HL7 should be used

##### Data transfer every 30 secondas standard an in case of alarm direct

Information for Network:

|  |  |
| --- | --- |
| Transfered Parameter | Unit |
| Arterial pressure |  |
| Average arterial pressure |  |
| Venous pressure |  |
| Average venous pressure |  |
| Actual Dialysate flow |  |
| Average Dialysate flow |  |
| Actual Dialysate temperature |  |
| Average Dialysate temperature |  |
| Dialysate pressure |  |
| Average dialysate pressure |  |
| Last Disinfection | Date / time / type |
| Actual Online HDF/HF rate |  |
| Average Online HDF/HF rate |  |
| HDF/HF bolus volume cumulated |  |
| HDF / HF Post Time |  |
| HDF / HF Pre Time |  |
| HD/HDF/HF type (treatment type) |  |
| HDF/HF volume |  |
| HD Time |  |
| Treatment time total |  |
| Actual Heparin rate |  |
| Average Heparin rate |  |
| Heparin volume |  |
| ISO UF volume accumulated |  |
| SN Click-Clack time |  |
| Processed blood volume |  |
| Total ISO UF time |  |
| Reinfusion volume |  |
| Average SN Stroke Volume |  |
| Total Heparin bolus |  |
| Actual TMP |  |
| Average TMP |  |
| Actual blood flow |  |
| Average total blood flow |  |
| Effective actual blood flow |  |
| UF time |  |
| Average ISO UF rate |  |
| Effective dialysis time |  |
| Actual UF rate |  |
| Average UF rate |  |
|  |  |
| Remaining UF time |  |
| Actual (current) UF volume |  |
| Final conductivity |  |
| Bic conductivity |  |
| Current Kt/V |  |
| Current Na |  |
| Dialysis device identification |  |
| Patient ChipCard status |  |
| Type of data identification |  |
| Software version |  |
| Dialysis device name |  |
| Dialysis device serial number |  |
| Dialysis device manufacturer |  |
| Treatment end |  |
| Treatment start |  |
| Current Warning State |  |
| Alarm code |  |
| Main phase |  |
| Blood pressure MAP |  |
| Blood pressure Pulse |  |
| Blood pressure diastolic |  |
| Blood pressure systolic |  |

### Safety Requirements

### 4.4.5. 帮助以及报警概念

##### Machine must consider the results of risk analysis

##### Warnings or alarms must be triggered in order to prevent patient from injury in case the machine deviates from its specification due to an error or damage.

##### In case dialysate composition or temperature is wrong, machine must switch in Bypass and a warning or alarm must be triggered.

##### Leakages in the water system must not lead to UF deviations more than the allowed UF accuracy. In case the UF accuracy is exceeded, a warning or an alarm must be triggered

##### Hardware

##### Two channel controlled system

##### Important functions must be confirmed by nurse

##### No need for nurse to compare Safety or control system values for plausibility

### Help and alarm concept

### 4.4.6. 生命周期/ 保修 / 可靠性

##### 4.4.6.1 Alarm concept

###### There should be 4 states of operation: normal, information, warning, alarm

##### Warnings and alarms (according ISO 60601-2-8)

##### There must be warnings and alarms

##### A warning appears when a minor error is detected by the machine which does not require immediate interaction of nurse

##### An alarm appears when a major error is detected by the machine which requires immediate interaction of the user

##### Warnings must be indicated acoustically and optically different from alarms

##### Alarms must be clearly indicated acoustically and optically

##### If a warning occurs, a text should appear marked in yellow/orange. Text clearly understandable giving clear handling instruction for nurse after push “Info”-button. List of potential causes.

##### If an alarm occurs, a text should appear marked in red. Text clearly understandable giving clear handling instruction for nurse after push “Info”-button. List of potential causes.

##### If more then one alarm occur, all alarm are at same time visible

##### It should be alarm code and the most important one is in top position. Alarm reset is done for all at same time.

##### Mute function if same alarm occur after alarm reset

##### Mute time is setable

##### Touching “info” button, further information about cause of error and required action should be indicate

##### If more then one alarm occur, by next page button you can see the alarms with lower importance

##### Warnings and alarms reduced to a minimum

22.11.

##### Status indicator (light)

##### There must be a status indication indicating the status of the machine:

##### -Red: high alarm priority

##### -Yellow: middle to low alarm priority

##### -Green: flawless operation

##### Indicator should be integrated in the monitor housing or close by

##### 4.4.6.2 Sound concept

##### New sound concept with polyphone sounds, modern & convenient

##### One specific alarm and warning sound (according 60601-1-8)

##### Reduction of unnecessary alarms

##### Possibility to regulate loudness of sound by nurse considering standard requirement

##### Reduction of noise emission during preparation, treatment and disinfection: Benchmark Nikkiso DBB-05 (48dB)

##### Reduction of functional sounds like flap, holder ect.

### Life cycle / Warranty / Reliability

### 4.4.7. 语言管理

25.000 operation hours minimum or 8 years

Garanty periode should be 18 Month from delivery. End customer 12 Month.

Safety inspection and maintenance cycle minimum all 12 Month

### Language Management of the device

### 4.4.8. 成本框架

##### Treatment: in EU countries, the respective language must be implemented in the machine. Outside EU, the following countries must have their native languages: China (Mandarin), Russia, Arabian. Rest of the world English or former colony languages.

##### English and Chineese is mandatory installed and not changeable

##### The TSM mode for technicians should be in English and chineese

##### Configuration mode (TSM level 1) for nurses should be in native language like in treatment.

##### During therapy, maximum 2 languages can be selectable by the user. Switch to another language simply by pressing an icon. When language is changed, the system configuration language must change as well automatically.

##### Machines should be delivered in English. Language upgrade in customer’s countries by technicians. The language files will be sent to the countries by email.

##### Machine and documentation should be same language.

### Cost Structure

### 4.4.9. 时间

##### Target production costs for standard, basic version without options: 4.000€ full serial production

##### Reduction of spare part costs

##### Most spare parts separate available (not only as unit)

### 4.4.10. Time

see chapters 4.3.1 Preparation and 4.3.3 Disinfection

# 5 相关一次性使用耗材

# Interfaces to Disposables

## 5.1. 滤器

## Filter

### 5.1.1 Dialyzers

The use of dialysers without the limitation of UF-factors must be possible by using a volumetric balancing chamber system

##### In accordance to DIN 58352 part 3

##### All types of dialysers low, middle and high flux

##### No restrictions in case of UF-factor. A treatment with a filter with UF factor of 82 must be possible

##### Dialysers with housing diameter from 28…66 mm

### 5.1.2 DF-Filter

The following DF filters must be validated for the machine: Medica UF filter 2.1 m² (3 connector).

In china B. Braun Diacap Ultra (4 connector), because Medica filter has no China validation

The endotoxine cut off test must be available from both filter.

There must be a setting which filter is used. Parameter for test should be also different.

**27.11.**

## 5.2. 血路管

## Blood Lines

##### All bloodlines fulfilling the specifications should be suitable and applicable to the machine. Also bloodlines without Dializer inlet pressure transducers can be used.

##### The volume of the HD lines must not exceed 130 ml (standard arterial & venous line together)

##### Lines must be biocompatible

##### Sterilisation should be not ETO, better x-ray (R) or steam

##### Lines must be DEHP free (bisphenol A)

##### Latex free

##### Lines should have as little blood air contact as possible

##### All chambers should be as small as possible

##### SN line must have SN pressure transducer

##### Pump segments must be resistant to rotations of blood pump 12 h 300ml/min

##### Competitor lines (fresenius 4008, AK200K) can be used without guaranty of flow rate and accuracy ect.

##### Single Needle must be max. 10% higher price

##### Package should contain all needed info according standards

##### Arterial and venous line in separate package

##### HD, SN and Online line

##### Easy to open package

##### Tubes good banding

05.12.

## 5.3. 浓缩液

## Concentrates

##### All common sorts of acetate brands.

##### All sorts of concentrates with standard composition. Also suitable for acetate-free concentrates containing salt acid.

##### Bicarbonate cartridges: Nipro, B. Braun, Gambro and all cartridges fitting to cartridge holder. 620g -1200g

##### Concentrate bags (with hook, in the beginning no spike)

##### A and B Concentrate from canister or central as option

## 5.4. 水处理

## Water Supply

Fulfilling European and AAMI standards.

## 5.5. 消毒液

## Disinfectants

To disinfect the water circuit, the following agents/Process must be validated:

Citric acid 10-50% with diluted concentration of 1%

peracetic acid like Dialox

Hot Water without chemical

sodium hypochlorite can be used as not validated procedure.

The use of Clean Card A & C should be also possible as not validated procedure

## 5.6. 表面清洁？

## Cleaning Agents

For the outer surface, the following agents must be validated:

##### At least one common agent also suitable for touch screen used in China must be validated (still to be defined)

##### At least one common agent used in Europe must be validated (still to be defined)

##### Define incrediance

# 6 维护需求

# Service Requirements

##### 1 years guarantee for end Customer (18 Month from shipment for distributor)

##### Components should have a life cycle of 8 years (approx 25000 operation hours) . Wear and tear parts are excluded

##### SW versions and language must be update from USB stick to machine

##### Copy of settings and parameter by USB

##### An interactive service platform in internet where SW versions, Field Service Information etc. can be downloaded by technicians. Access only for Joyheal staff and external staff being officially trained. ID code required.

##### Service maintenance Kits: Must be available and need to be defined

##### No special tools for service (not customized)

##### All components inside the machine should be easily accessible

##### Service manual, spare part manual, error search documentation, flow diagram in English must be available

##### Training concept to authorize Joyheal, distributor and hospital technician

# 7 产品配置, 可选项, 附件

# Product Configuration, Options, Accessories

With the introduction of the new dialysis machine the customer should get the possibility to order the machine according his individual needs (Modular concept). Therefore it is necessary to develop a new structure of the article codes.

In basic 3 machine type configurations will be available:

1. Single Pump Machine 4048
2. Double Pump Machine 5058
3. Standard Online HDF Machine (two pumps) 6068

The basic configurations (I. / II. / III.) are prepared for operation with concentrate canister. All additional options and accessories can and have to be assembled individually by the customer.

The following options have to be available (also defined in chapter 4.4.1.9), as option also upgradeable in the field:

|  |  |
| --- | --- |
| OPTIONS | Reference chapters |
| * BPM | * 4.4.1.9.1 |
| * DF-Filter | * 4.4.1.9.2 |
| * Battery | * 4.4.1.9.3 |
| * Bic-Cartridge | * 4.4.1.9.4 |
| * Central Concentrate Supply | * 4.4.1.9.5 |
| * Heparin pump | * 4.4.1.9.6 |
| * Plug Schuko |  |
| * Plug China |  |
| * Plug UK |  |
| * DNI (Data Network Interface) |  |

The following accessories have to be offered at least:

|  |
| --- |
| * Blood Pressure Cuff S |
| * Blood Pressure Cuff M |
| * Blood Pressure Cuff L * Blood Pressure Cuff XL |
| * Crank for blood pump |
| * Patient Therapy Card |
| * Several storage shelfs |
| * Dialyzer holder |
| * Sample port |
| * Ground cable |

# 8 包装, 运输, 存储

# Packaging, Transport , Storage

One packaging for worldwide delivery. A lying transport position should be possible-

Packaging material must guarantee protection for machine, no damage.

# 9 产品文档

# Product Documentation

Along with the machine goes a Operating Manual, short instruction, medicine product book and an installation protocol. In order to create and update these manuals, there should be an easy way to download screenshots for the Technical Documentation Managers without connecting a keyboard to the machine. (Chineese orEnglish)

# 10 培训 /服务

# Training / Services

##### Service staff and application specialists will be trained in training courses in China or Germany

##### Training of medical staff (nurses) is performed in the centres by application specialists

##### Joyheal offer a 7 day / 24 h hotline

##### Sparepart will be shipped out within 24h after order. Express delivery is possible on customer cost.

##### CER document is available for Sparepart and consumables to claim guaranty issues.

# 11 销毁

# Disposal

##### The materials used on the machine should be recyclable if possible

##### According to required local regulations

# 12 其他需求

# Other Requirements

##### Therapy

##### Set blood flow & effective blood flow (Joyheal Bloodline only)

##### Emergency function

##### There should be an extended emergency function: When function is activated, the following should happen (default):

##### UF off

##### Arterial bolus (online)

##### Blood pump reduction

##### ABPM measurement if available

##### Content of emergency function configurable and to be activated in TSM

##### This feature may look different or may be neglected completely, as it is patented by FMC.

##### Electronical Parts

* Filters of fans easy accessible for cleaning / exchange. Access from outside without opening machine so that nurses can clean the filters too. A counter for cleaning air filter should be integrated.

##### DF-filter

##### Holder integrated in machine housing

##### Antikoagulation

Citrate anticoagulation is possible with external devices connected to the machine via hardware interfaces

##### Barcode Reader

##### Disposables read out by Barcodes

##### Training Mode

##### A third mode beside Treatment and Technician Mode

##### In the Training or exhibition mode, the machine should be explained (functionality, flowcharts, set-up, options, menu guidance etc…) as well as medical background

##### Operation manual is integrated in Training Mode, linked to explanantions

##### Mode supported by animations movies…

##### Help function supported by animation, graphics, video sequences

Note:

Drain port as option also for 4048 and 5058?

Setting for wet dialyzer

UF during priming of dializer