

# SMLOUVA O DODÁVCE SOFTWARE

uzavřená dle § 1746 odst. 2 zákona č. 89/2012 Sb., občanského zákoníku, v platném znění,  
kterou níže uvedeného dne, měsíce a roku uzavřely smluvní strany:

## 1. Fakultní nemocnice Hradec Králové

se sídlem: Sokolská 581, 500 05 Hradec Králové – Nový Hradec Králové  
zastoupená: prof. MUDr. Vladimírem Paličkou, CSc., dr. h. c., ředitelem  
IČ: 00179906  
DIČ: CZ 00179906  
bank. spojení: Česká národní banka  
číslo účtu: 24639511/0710  
**jako objednatel** (dále jen „objednatel“)  
na straně jedné

a

## 2. Becton Dickinson Austria GmbH

se sídlem: Handelskai 94-96, 1200 Vídeň, Rakousko  
zastoupená: Mag. Christian Hanke  
IČ: ATU 46732102  
DIČ: .....  
bank. spojení: BNP Paribas Fortis SA/NV Austria Branch  
číslo účtu: IBAN AT30 1810 0101 3421 0100 SWIFT: GEBAAATWW  
zapsána v OR/ŽR: FN 179907  
**jako zhotovitel** (dále jen „zhotovitel“)  
na straně druhé.

## Článek 1 Účel smlouvy

- 1.1 Smluvní strany uzavírají tuto smlouvu za účelem dodání a implementace softwarového řešení pro podporu preskripce, plánování a přípravy parenterální výživy (dále jen PV) pro specifikované činnosti objednatele, přiměřeně integrovaného s ostatními systémy IT objednatele. Softwarové řešení musí být uživatelsky komfortní a automatizované, bezpečné, s kontrolou všech relevantních procesů.
- 1.2 S ohledem na shora uvedené bere zhotovitel na vědomí, že objednatel je největším poskytovatelem zdravotních služeb v Královéhradeckém kraji, přičemž řádný chod jeho systému PV představuje klíčovou složku pro řízení jeho provozu, mající podstatný vliv na poskytování zdravotních služeb objednatele.

## Článek 2 Předmět smlouvy

- 2.1 Předmětem této smlouvy je závazek zhotovitele dodat a implementovat softwarové řešení PV systém objednatele (dále jen „dílo“), vše blíže specifikováno v článku 3, a závazek objednatele za řádně a včas poskytnuté plnění zaplatit smlouvenou odměnu.

- 2.2 Tato smlouva se uzavírá v souladu se zadávací dokumentací objednatele ze dne 2. 10. 2018, a to na základě výsledku veřejné zakázky malého rozsahu s názvem „Software pro parenterální výživu FN HK“ zadané dle interní směrnice č. 2 o zadávání veřejných zakázek v souladu s ustanovením § 31 zákona č.134/2016 Sb., o zadávání veřejných zakázek, v platném znění (dále jen „veřejná zakázka“), pod evidenčním číslem veřejné zakázky: P18V00146397 a nabídkou zhotovitele ze dne 9. 10. 2018, která je společně se zadávací dokumentací veřejné zakázky nedílnou součástí této smlouvy.

### **Článek 3** **Specifikace předmětu smlouvy**

- 3.1 Předmětem smlouvy je dodání a implementace softwarového řešení PV systému objednatele s podporou udržitelnosti minimálně po dobu 4 let, a to v rozsahu a s vlastnostmi vymezenými v zadávací dokumentaci objednatele ze dne 2. 10. 2018, nabídce zhotovitele ze dne 9. 10. 2018 a přílohy č. 1 této smlouvy.
- 3.2 Dílem se rozumí všestranně moderní systém, který bude bez významnějších změn provozuschopný po řadu let, založený na moderních, všeobecně uznávaných a praxí ověřených technologiích a standardech včetně platformy pro vývoj systému, typ a verze využívané databáze, bezpečnost systému apod. Systém musí umožňovat budoucí rozvoj podle požadavků objednatele např. formou akvizicí nově vytvořených SW modulů nebo rozšiřování na další pracoviště.
- 3.3 V rámci implementace softwarového řešení je dále součástí předmětu smlouvy:
- instalace díla na zařízení objednatele,
  - inicializace databáze,
  - přepojení modalit,
  - realizace integračních vazeb dodávaného díla s ostatními systémy v rámci IT infrastruktury objednatele,
  - školení zaměstnanců objednatele rozdělené pro uživatele systému a pro správu systému,
  - instalace testovací prostředí dle požadavků objednatele a v rozsahu stanoveném v zadávací dokumentaci veřejné zakázky,
  - provedení testů,
  - zkušební provoz.
- 3.4 Nedílnou součástí předmětu smlouvy je dále:
- dodávka časově a místně neomezených licencí potřebných pro provozování a užívání dodaného díla objednatelem v rozsahu specifikovaném v nabídce zhotovitele a zadávací dokumentaci veřejné zakázky,
  - uživatelská dokumentace v rozsahu potřebném pro běžný provoz systému a pro běžnou správu systému, včetně popisu databázového modelu a struktury tabulek.

### **Článek 4** **Doba a místo plnění**

- 4.1 Zhotovitel se zavazuje realizovat dílo v následujících termínech:

- Zhotovitel uvede plnění do zkušebního provozu do 1 měsíce od podpisu smlouvy. Předpokládaná délka zkušebního provozu je 1 měsíc.
- Dokončení celého díla provede zhotovitel nejpozději do 2 měsíců od podpisu smlouvy.

Objednatel si vyhrazuje právo z provozních důvodů přiměřeně posunout výše uvedené termíny, přičemž v tomto případě zhotoviteli nevzniká nárok na případné další náklady s tím související.

- 4.2 V případě konektivity do datové sítě objednatele je nutné bezodkladně po podpisu smlouvy, nejdéle však 4 týdny před plánovanou instalací, informovat IT oddělení objednatele na adrese [helpdesk@fnhk.cz](mailto:helpdesk@fnhk.cz). Oznámení o skutečném datu instalace je nutné provést nejdéle 3 pracovní dny předem.
- 4.3 Pro vzdálený přístup zadavatel požaduje využít stávající infrastrukturu FN HK – založenou na přístupech přes VPN koncentrátory, které jsou vlastněny zadavatelem. Přístup na server(y) bude realizován pomocí služby „Vzdálená plocha“ (RDP - protokol TCP/3389, nebo SSH – protokol TCP/22).
- 4.4 Zhotovitel je povinen průběžně informovat objednatele o realizaci plnění díla na kontrolních dnech a předkládat informace o stavu rozpracovanosti. Termíny kontrolních dnů určí objednatel. Objednatel je oprávněn na základě informací získaných od zhotovitele předkládat připomínky k rozpracovanému řešení a návrhy na jeho úpravy (dále jen „připomínky“). Zhotovitel je povinen vynaložit maximální možné úsilí při zapracování těchto připomínek do díla, případně objednateli řádně v písemné formě odůvodnit, proč nemohou být připomínky akceptovány.
- 4.5 Zhotovitel je povinen připravit plnění do testovacího provozu v kompletní podobě a obsahující testovací data, nejpozději 2 pracovní dny před protokolárním zahájením zkušebního provozu. To proto, aby objednatel byl schopen provést první testování díla z hlediska splnění podmínek dle této smlouvy pro zajištění provozu PV systému v prostředí objednatele a zhotovitel byl následně schopen upravit a zapracovat připomínky. Zkušební provoz bude zahájen po podpisu protokolu o předání díla do zkušebního provozu oprávněnými zástupci smluvních stran.
- 4.6 V případě, že v průběhu zkušebního provozu budou ze strany objednatele identifikovány vady díla anebo nedodělky, je objednatel oprávněn prodloužit délku zkušebního provozu tak, aby dílo bez vad a nedodělků bylo ve zkušebním provozu minimálně po dobu 14 dní.
- 4.7 V rámci zkušebního provozu bude prováděno, za nezbytné součinnosti zhotovitele, testování a ověření funkčnosti díla na zařízení objednatele, a to s ohledem na podmínky a požadavky stanovené objednatelem na základě této smlouvy.
- 4.8 Veškeré vady díla anebo nedodělky zjištěné v průběhu zkušebního provozu je objednatel povinen oznámit zhotoviteli písemně. Zkušební provoz bude ukončen podpisem akceptačního protokolu pověřenými zástupci smluvních stran, a to v případě, že dílo bude v rámci zkušebního provozu bez vad a nedodělků nebo bude vykazovat nepodstatné vady či nedodělky (např. chybové hlášky, které nemají vliv na funkčnost softwaru). Při ukončení zkušebního provozu budou tyto vady či nedodělky písemně specifikovány a bude stanovena lhůta k jejich odstranění.
- 4.9 Místem plnění je Fakultní nemocnice Hradec Králové, se sídlem Sokolská 581, 500 05 Hradec Králové – Nový Hradec Králové.

- 4.10 Závazek zhotovitele bude splněn písemným předáním řádně a včas provedeného díla v odpovídající kvalitě objednateli po úspěšném ukončení zkušebního provozu podpisem akceptačního protokolu a převzetím díla pověřenými zástupci smluvních stran. Součástí předávaného díla je i veškerá předepsaná či nezbytná dokumentace a povinné doklady ke zhotovitelem použitým výrobkům a protokol o proškolení příslušných zaměstnanců objednatele.
- 4.11 Zhotovitel vyzve písemně objednatele k předání a převzetí díla nejméně pět pracovních dní předem.
- 4.12 Vlastnické právo k dílu přechází na objednatele okamžikem protokolárního plnění, tzn. po akceptaci.
- 4.13 Právo užití té části díla, která podléhá ochraně podle zákonů upravujících práva duševního vlastnictví, přechází na objednatele okamžikem předání díla.
- 4.14 Nebezpečí škody způsobené při provádění díla nese zhotovitel, a to až do okamžiku akceptace dané etapy pověřenými zástupci smluvních stran.
- 4.15 Kontaktní osobou, kterou objednatel pověřil k převzetí díla a k jednání jménem objednatele při zajišťování plnění předmětu smlouvy je Mgr. Jiří Kotlář, 495 832 127, [jiří.kotlar@fnhk.cz](mailto:jiří.kotlar@fnhk.cz).
- 4.16 Kontaktní osobou, kterou zhotovitel pověřil k předání díla a k jednání jménem zhotovitele při zajišťování plnění předmětu smlouvy je Renata Petöcz, tel.:+43660 4626593, e-mail: [renata.petocz@bd.com](mailto:renata.petocz@bd.com).

## Článek 5

### Cena díla a licenční poplatky

- 5.1 Cena díla byla sjednána dohodou smluvních stran a činí 1.964.750,- Kč bez DPH. Bližší specifikace ceny díla je uvedena v příloze č. 3 této smlouvy.
- 5.2 Cena díla se sjednává jako konečná a maximálně přípustná. V této ceně jsou zahrnuty veškeré náklady zhotovitele spjaté s realizací díla, exportem dat ze současného systému do nového, a to včetně licenčních poplatků a nákladů spjatých s pracemi souvisejícími s realizací díla, které zhotovitel měl nebo mohl předpokládat. K ceně díla bude připočtena DPH podle aktuálně platné sazby.
- 5.3 Úhrada ceny díla bude provedena akceptací. Zhotovitel doručí faktury po akceptaci.
- 5.4 Kromě náležitostí uvedených v zákoně č. 235/2004 Sb., o dani z přidané hodnoty, ve znění pozdějších předpisů, je zhotovitel na faktuře – daňovém dokladu - povinen uvést tyto údaje:
- a) označení dokladu jako faktury,
  - b) číslo smlouvy dle číslování objednatele,
  - c) den vystavení, den odeslání a den (lhůta) splatnosti faktury,
  - d) konečný příjemce a místo plnění,
  - e) IČO a DIČ smluvních stran,
  - f) označení peněžního ústavu a čísla účtu, na který má být placeno,
  - g) počet příloh a kontaktní údaje osoby, která daňový doklad vystavila,
  - h) název a evidenční číslo veřejné zakázky,
  - i) prohlášení zhotovitele, že ke dni vystavení faktury není veden v registru nespoléhavých plátců daně z přidané hodnoty.

- 5.5 Na faktuře – daňovém dokladu je zhotovitel povinen uvést položky rozdělené na typ investičních nákladů a provozních nákladů. Zvlášť požadujeme položku samostatně vyčleněnou pro licence.
- 5.6 Pokud faktura předložená zhotovitelem neobsahuje všechny zákonem a smlouvou stanovené náležitosti, je objednatel oprávněn ji do data splatnosti vrátit s tím, že zhotovitel je poté povinen vystavit novou fakturu s novým termínem splatnosti. V takovém případě není objednatel v prodlení s úhradou faktury. Nová lhůta splatnosti, co do počtu dnů nikoli kratší než lhůta původní, započne běžet dnem řádného doručení opravené či nově vystavené faktury objednateli.
- 5.7 Splátnost faktur je 30 dní ode dne jejich prokazatelného doručení objednateli. Platební povinnost objednatele se považuje za splněnou dnem, kdy je příslušná částka odepsána z bankovního účtu objednatele.
- 5.8 Veškeré platby mezi smluvními stranami se uskutečňují prostřednictvím bankovního spojení uvedeného v záhlaví této smlouvy. Zhotovitel prohlašuje, že uvedené číslo jeho bankovního účtu splňuje požadavky dle § 109 zákona č. 235/2004 Sb., o dani z přidané hodnoty, v platném znění, a jedná se o zveřejněné číslo účtu registrovaného plátce daně z přidané hodnoty.
- 5.9 Zhotovitel prohlašuje, že ke dni uzavření této smlouvy není veden v registru nespolehlivých plátců daně z přidané hodnoty a ani mu nejsou známy žádné skutečnosti, na základě kterých by s ním správce daně mohl zahájit řízení o prohlášení za nespolehlivého plátce daně dle § 106a zákona č. 235/2004 Sb., o dani z přidané hodnoty, v platném znění.
- 5.10 Objednatel, jako příjemce zdanitelného plnění, je oprávněn, v případě, že zhotovitel je v okamžiku uskutečnění zdanitelného plnění veden v registru nespolehlivých plátců daně z přidané hodnoty, uhradit částku odpovídající výši daně z přidané hodnoty na účet správce daně za zhotovitele. Uhrazení částky odpovídající výši daně z přidané hodnoty na účet správce daně za zhotovitele bude považováno v tomto rozsahu za splnění závazku objednatele uhradit sjednanou cenu zhotoviteli.
- 5.11 Objednatel neposkytuje zálohové platby.

## **Článek 6**

### **Práva a povinnosti smluvních stran**

- 6.1 Zhotovitel je povinen provést dílo podle této smlouvy, tj. veškeré dodávky a implementaci kompletně a ve vysoké kvalitě, v rozsahu dle této smlouvy, zadávací dokumentace veřejné zakázky a nabídky zhotovitele. Stejná ustanovení platí i pro činnosti, výrobky, zařízení a dodávky všech dodavatelů zhotovitele. Zhotovitel má právo vykonat veškeré práce způsobem, který považuje za nejvýhodnější k řádnému provedení díla při respektování účelu této smlouvy, dohodnutého časového postupu, smluvních termínů a dalších práv a povinností dle této smlouvy. Postup prací musí odpovídat v tomto rámci zájmům objednatele.
- 6.2 Zhotovitel je povinen při provádění předmětu plnění dodržovat veškeré platné normy, zákony, prováděcí vyhlášky a metodiky týkající se jeho činnosti pro objednatele. Pokud porušením těchto předpisů vznikne škoda, nese veškeré vzniklé náklady zhotovitel.
- 6.3 Zhotovitel se zavazuje při poskytování plnění v prostorách objednatele či jeho smluvních partnerů dodržovat veškeré interní předpisy a pravidla objednatele či jeho

smluvního partnera, jež mu budou ze strany objednatele písemně oznámeny. Zhotovitel nesmí zasahovat do obsahu dat zpracovávaných v rámci plnění, jakýchkoliv dat objednatele či jeho smluvních partnerů ani provést zásah, který by ovlivnil či mohl ovlivnit funkcionalitu hardware objednatele či jiného software provozovaného na hardware objednatele, včetně pracovních stanic, pokud nebude s objednatelem dohodnuto jinak.

- 6.4 Zhotovitel a objednatel se zavazují vzájemně se neprodleně informovat o skutečnostech, které znemožňují, resp. podstatně omezují, plnění jejich povinností z této smlouvy, a to do 7 pracovních dnů ode dne vzniku takové skutečnosti. V opačném případě odpovídá ta smluvní strana, která svou informační povinnost řádně nesplnila, druhé smluvní straně za škodu, vzniklou v příčinné souvislosti s porušením informační povinnosti dle tohoto odstavce.
- 6.5 Zhotovitel se dále zavazuje uchovávat všechny doklady, dokumenty a data po dobu a způsobem stanoveným platnými právními předpisy ČR, např. zákonem č. 563/1991 o účetnictví, v platném znění, a zákonem č. 499/2004 Sb., o archivnictví a spisové službě a o změně některých zákonů, v platném znění.
- 6.6 Zhotovitel prohlašuje, že je srozuměn s tím, že je podle ustanovení § 2 písm. e) zákona č. 320/2001 Sb., o finanční kontrole ve veřejné správě a o změně některých zákonů, v platném znění, osobou povinnou spolupůsobit při výkonu finanční kontroly prováděné v souvislosti s úhradou zboží nebo služeb z veřejných výdajů.
- 6.7 Smluvní strany jsou povinny dodržovat právními předpisy stanovené povinnosti k ochraně práv průmyslového a jiného duševního vlastnictví, jakož i chránit práva spadající do autorského práva, ochrany obchodního, hospodářského a státního tajemství.
- 6.8 Zhotovitel je povinen zajistit, aby objednatel nabyl příslušná oprávnění z práv duševního vlastnictví, která se týkají předmětu této smlouvy a jsou nezbytná pro řádné plnění této smlouvy.
- 6.9 V rámci poskytování součinnosti nesmí docházet k nadměrnému zatěžování objednatele aktivitami, které dodavatel jakožto odborník na dodání díla by měl být schopen vyřešit vlastními silami. Objednatel poskytne zhotoviteli nezbytnou součinnost spočívající zejména v přípravě informací, dokumentů a dat, které jsou ze strany objednatele nezbytné poskytnout pro řádné dokončení díla nebo důvodně a včas zhotovitelem požadovány. Objednatel poskytne zhotoviteli součinnost do 5 pracovních dní ode dne písemného vyzvání k poskytnutí součinnosti, nedohodnou-li se smluvní strany jinak.

## **Článek 7**

### **Odpovědnost za vady**

- 7.1 Záruční doba počíná běžet od řádného protokolárního předání plnění prostého vad a nedodělků a činí 24 měsíců.
- 7.2 Zhotovitel se zavazuje, že plnění bude mít vlastnosti stanovené zadávací dokumentací veřejné zakázky, obsahem nabídky zhotovitele, touto smlouvou a technickými normami vztahujícími se na dílo, a to po dobu poskytnuté záruky bez ohledu na skutečnost, zda se jedná o vadu skrytou nebo zjevnou, která mohla být ze strany objednatele identifikována před datem protokolárního předání.
- 7.3 Zhotovitel se zavazuje v rámci realizace obou etap odstranit veškeré vady a nedostatky, a to ve lhůtách níže uvedených. Zhotovitel je povinen nastoupit na odstranění vady

označené jako porucha do dvou hodin od jejich nahlášení a tuto závadu odstranit do 12 hodin od nahlášení, nedohodnou-li se smluvní strany jinak. Zhotovitel je povinen nastoupit na odstranění vady označené jako závada do čtyř hodin od jejího nahlášení objednatelům a tuto vadu odstranit do 24 hodin od jejího nahlášení, nedohodnou-li se smluvní strany jinak.

7.4 Zhotovitel poskytuje objednateli záruku za to, že:

- poskytnuté plnění bude od okamžiku jeho dodání do konce záruční lhůty bez vad a bude fungovat v souladu se specifikacemi uvedenými ve smlouvě (včetně specifikací rozhraní a spolupráce s moduly a systémy od jiných softwarových výrobců),
- zrealizované plnění správným, nezkráceným a úplným způsobem zpracovává veškerá data,
- plnění ve své dodané nebo dodavatelem implementované podobě nebude obsahovat viry nebo jiné dysfunkce, které by zabránily objednateli užívat předmět plnění nebo které by způsobily, že předmět plnění přestane fungovat nebo jeho fungování bude omezeno nebo jinak negativně ovlivněno,
- zrealizované plnění bude řádně fungovat v prostředí objednatele, zejména že bude fungovat na jeho IT infrastruktuře, bude zajišťovat přebírání a předávání dat z/do stávajících informačních systémů objednatele,
- jakékoli plnění dodavatele dle smlouvy ani užívání předmětu plnění ze strany objednatele dle této smlouvy neporušuje a ani nebude mít za následek porušení jakéhokoliv práva duševního vlastnictví třetích osob. V případě, že zhotovitel poruší tento závazek, je zhotovitel odpovědný za veškeré důsledky z toho plynoucí, zejména je povinen neprodleně zajistit objednateli právo užívat plnění, jež nebude narušovat práva duševního vlastnictví třetích osob a nahradit objednateli veškerou škodu, která tím byla objednateli způsobena. Zhotovitel prohlašuje, že je oprávněn poskytnout objednateli licenci na poskytnuté plnění.
- instalaci a implementaci plnění bude ze strany zhotovitele poskytována s odbornou péčí v souladu s touto smlouvou a prostřednictvím pracovníků zhotovitele disponujících dostatečným vzděláním a zkušenostmi s poskytováním daného plnění,
- funkcionalita plnění bude po celou dobu ode dne přijetí předmětu plnění do okamžiku ukončení poskytování Podpory plnění v souladu s touto Smlouvou a v souladu s v té době platnými právními předpisy České republiky, metodikami a dalšími normami, které se vztahují k dané problematice a činnosti objednatele.

7.5 Objednatel má vůči zhotoviteli tato práva z odpovědnosti za vady:

- a) právo na bezplatné odstranění reklamovaných vad,
- b) právo na poskytnutí přiměřené slevy z ceny odpovídající rozsahu reklamovaných vad či nedodělků,
- c) právo na odstoupení od smlouvy, kdy vady či nedodělků jsou takového charakteru, že podstatně ztěžují či dokonce brání v užívání díla. Za vady podstatně ztěžující či dokonce bránící v užívání díla se považují i vady, které jsou opakovaného charakteru.

## Článek 8 Mlčenlivost

- 8.1 Zhotovitel se zavazuje zachovávat přísnou mlčenlivost a bez předchozího písemného souhlasu objednatele nezveřejnit či jiným způsobem nezpřístupnit, ať už záměrně či nevědomě, třetím osobám informace týkající se plnění předmětu této smlouvy, a to i po skončení či zániku platnosti této smlouvy.
- 8.2 Zhotovitel není oprávněn jakkoliv nakládat s daty obdrženy od objednatele, přenášet je, zálohovat či kopírovat jakoukoliv jejich část bez vědomí objednatele.
- 8.3 Zhotovitel se zavazuje udržovat v tajnosti předané podklady, technickou dokumentaci i další informace, které se dozvěděl v souvislosti s touto smlouvou a prováděním díla. Zhotovitel je povinen k ochraně tohoto obchodního tajemství zavázat i osoby, které použije k provedení díla.

### **Článek 9 Smluvní sankce**

- 9.1 V případě, že se z důvodů na straně zhotovitele dostane zhotovitel do prodlení se splněním lhůt stanovených v čl. 4.1, 4.2 a 4.5 této smlouvy, zaplatí zhotovitel objednateli smluvní pokutu ve výši 2.000,- Kč za každý i započatý den prodlení.
- 9.2 Jestliže se zhotovitel dostane do prodlení s nástupem na řešení požadavku s prioritou poruchy dle čl. 7 odst. 7.3 této smlouvy, je objednatel oprávněn uplatnit smluvní pokutu 1.000,- Kč za každou započatou hodinu prodlení.
- 9.3 Jestliže se zhotovitel dostane do prodlení s nástupem na řešení požadavku s prioritou závady dle čl. 7 odst. 7.3 této smlouvy, je objednatel oprávněn uplatnit smluvní pokutu 1.000,- Kč za každou započatou hodinu prodlení.
- 9.4 Jestliže se zhotovitel dostane do prodlení s odstraněním požadavku s prioritou poruchy dle čl. 7 bodu 7.3 této smlouvy, je objednatel oprávněn uplatnit smluvní pokutu 1.000,- Kč za každou hodinu nefunkčního systému.
- 9.5 Jestliže se zhotovitel dostane do prodlení s odstraněním požadavku s prioritou závady dle čl. 7 bodu 7.3 této smlouvy, je objednatel oprávněn uplatnit smluvní pokutu 10.000,- Kč za každý den prodlení.
- 9.6 Jestliže zhotovitel poruší svůj závazek uvedený v čl. 8 této smlouvy, je objednatel oprávněn uplatnit vůči zhotoviteli smluvní pokutu ve výši 100.000,- Kč za každé takovéto porušení zvláště, a to i opakovaně.
- 9.7 V případě, že objednatel bude v prodlení se zaplacením předložené faktury zhotovitele, zaplatí zhotoviteli smluvní úrok z prodlení ve výši 0,025 % z dlužné částky za každý den prodlení.
- 9.8 Zaplacením smluvní pokuty není dotčeno právo objednatele na náhradu škody vzniklé porušením smluvní povinnosti, které se smluvní pokuta týká.

### **Článek 10 Závěrečná ujednání**

- 10.1 Tato smlouva nabývá platnosti dnem jejího podpisu oprávněnými zástupci obou smluvních stran a účinnosti dnem jejího uveřejnění v registru smluv.
- 10.2 Tato smlouva a všechny právní vztahy s ní související se řídí českým právním řádem, zejména zákonem č. 89/2012 Sb., občanským zákoníkem, v platném znění.

- 10.3 Objednatel je oprávněn od smlouvy odstoupit zejména v případě, že:
- zhotovitel neuvede dílo, obsahující testovací data, do testovacího provozu v kompletní podobě, a to alespoň 1 týden před plánovaným zahájením zkušebního provozu dle harmonogramu,
  - Provádí-li zhotovitel dílo v rozporu se zadáním, popř. předmětem této smlouvy nebo v kvalitě nesplňující obecné technické požadavky, a to i přes písemné upozornění objednatele, anebo kdy vadý či nedodělky jsou takového charakteru, že podstatně ztěžují či dokonce brání v užívání díla ke stanovenému účelu.
- 10.4 Zhotovitel není oprávněn postoupit pohledávku plynoucí z této smlouvy třetí osobě bez písemného souhlasu objednatele.
- 10.5 Odstoupení od smlouvy musí být provedeno písemně, jinak je neplatné. Smluvní strany dohodly, že odstoupení od smlouvy je účinné uplynutím tří dnů ode dne jeho doručení zhotoviteli.
- 10.6 Jestliže bude platnost smlouvy ukončena dohodou, či odstoupením zhotovitele před dokončením díla, smluvní strany protokolárně provedou inventarizaci plnění veškerých činností provedených k datu, kdy byla ukončena platnost smlouvy, a na tomto základě provedou vyrovnání vzájemných závazků z toho pro ně vyplývajících.
- 10.7 Veškeré změny smlouvy lze provést pouze formou písemných vzestupně číslovaných dodatků podepsaných oprávněnými zástupci obou smluvních stran.
- 10.8 Předmět smlouvy poskytnutý na základě této smlouvy, resp. práva a povinnosti z této smlouvy vyplývající, přechází při zániku objednatele na jeho právního nástupce.
- 10.9 Všechny spory, které vyplynou z této smlouvy nebo v souvislosti s ní, se strany především pokusí řešit vzájemnou dohodou. Nedojde-li ke smíru, budou všechny spory, vzniklé z této smlouvy nebo v souvislosti s ní, řešeny u věcně a místně příslušného soudu v České republice.
- 10.10 Tato smlouva je vyhotovena ve dvou stejnopisech s platností originálů, z nichž každá ze smluvních stran obdrží jedno vyhotovení.
- 10.11 Smluvní strany prohlašují, že je jim znám obsah smlouvy a že tuto smlouvu uzavřely na základě svobodné a vážné vůle. Na důkaz této skutečnosti připojují své podpisy.

Přílohy:

- 1) podrobná specifikace předmětu díla
- 2) specifikace ceny díla

**Za zhotovitele:**

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# **BD Cato™ TPN**

## Medication Workflow Solutions

### User Manual

Version 2.38

2017

Becton Dickinson Austria GmbH

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Becton Dickinson Austria GmbH  
Medication Workflow Solutions  
part of Becton Dickinson, Medical Surgical Systems  
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## Change History

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## Table of Contents

<b>1. INTRODUCTION</b> .....	<b>1</b>
<b>1.1 Intended Use</b> .....	<b>1</b>
<b>1.2 Using the Manual</b> .....	<b>2</b>
<b>1.3 Basic Operating Instructions</b> .....	<b>2</b>
1.3.1 Shortcuts and Toolbar .....	2
1.3.2 Different Font Colors and Modes .....	4
1.3.3 Barcodes .....	5
<b>1.4 Start Program and License Administration</b> .....	<b>5</b>
1.4.1 First Start .....	5
1.4.2 Switching Users .....	5
<b>1.5 Changing Own Password</b> .....	<b>5</b>
<b>2. MASTER DATA</b> .....	<b>7</b>
<b>2.1 Introduction: the Master Data Sheet "Companies"</b> .....	<b>7</b>
2.1.1 Searching For a Company .....	7
2.1.2 "Display Data" Mode .....	8
2.1.3 Editing Data .....	8
2.1.4 Printing Master Data .....	8
2.1.5 Event Log .....	9
2.1.6 Entering a New Company .....	9
2.1.7 Saving or Rejecting the Data of a Company .....	9
2.1.8 Deleting a Company .....	9
2.1.9 Additional Remarks Regarding the "Companies" File .....	10
<b>2.2 Centers and Units (Advanced Introduction)</b> .....	<b>10</b>
2.2.1 Creating Centers and Units .....	11
2.2.2 Unit Management .....	11
<b>2.3 Basic Data</b> .....	<b>12</b>
2.3.1 (Possible) Medical Results .....	12
2.3.2 (Possible) Dosage Forms .....	18
2.3.3 (Possible) Container Materials .....	19
2.3.4 (Possible) Empty Container Types .....	19
2.3.5 (Possible) Routes of Administration .....	20
2.3.6 (Possible) Medical Result Groups .....	20
2.3.7 (Possible) Active Ingredient Groups .....	20
2.3.8 (Possible) IV Lines .....	20
<b>2.4 Product Master Data</b> .....	<b>21</b>
2.4.1 Active Ingredients .....	21
2.4.2 Products .....	21
2.4.3 Dosage Forms of a Product .....	23
2.4.4 Strengths of a Product .....	25
<b>2.5 Empty Containers</b> .....	<b>27</b>

<b>3. REPORTS</b> .....	<b>29</b>
<b>3.1 Master Data Lists</b> .....	<b>29</b>
<b>3.2 Preparation List</b> .....	<b>29</b>
<b>3.3 Requirements List</b> .....	<b>30</b>
<b>3.4 Lot Tracking</b> .....	<b>30</b>
<b>3.5 Cost Center Accounting</b> .....	<b>30</b>
3.5.1 Establishing Product Consumption .....	31
3.5.2 Carrying Out Cost Center Accounting .....	32
<b>3.6 Patient List</b> .....	<b>34</b>
<b>4. ADMINISTRATION</b> .....	<b>35</b>
<b>4.1 Users and Permissions</b> .....	<b>35</b>
4.1.1 Special Password .....	35
4.1.2 User Groups .....	35
4.1.3 Creating and Maintaining Users .....	36
4.1.4 Event Log for Users .....	38
<b>4.2 Settings</b> .....	<b>39</b>
4.2.1 Basic Settings .....	39
4.2.2 Preparation / Dispense .....	40
4.2.3 Printers .....	42
4.2.4 IT Settings .....	42
4.2.5 BD Cato™ TPN Basic Settings .....	45
4.2.6 BD .....	46
<b>4.3 Dosing Rules</b> .....	<b>49</b>
<b>4.4 Preparation Site Administration</b> .....	<b>49</b>
<b>4.5 Manage Statuses/Flags</b> .....	<b>49</b>
<b>4.6 Determine Layout of Labels</b> .....	<b>50</b>
<b>4.7 Compounder Configuration</b> .....	<b>50</b>
4.7.1 ExactaMix 2400® (TPN Compounder from Baxter) .....	50
4.7.2 Neocare medOC® .....	51
4.7.3 medOC VMC .....	52
4.7.4 IMF .....	53
<b>4.8 Hardware Configuration</b> .....	<b>54</b>
<b>4.9 Internal Billing Prices</b> .....	<b>54</b>
<b>5. TEMPLATES</b> .....	<b>57</b>
<b>5.1 24h Medication Templates</b> .....	<b>57</b>

5.1.1 Creating New 24h Medication Template .....	57
5.1.2 Editing 24h Medication Template .....	58
5.1.3 Deleting 24h Medication Template .....	58
<b>5.2 Standard Bag Templates .....</b>	<b>58</b>
5.2.1 Displaying and Editing Standard Bags .....	58
5.2.2 Creating New Standard Bag .....	59
5.2.3 Deleting Standard Bags .....	60
<b>5.3 Therapy Day Template .....</b>	<b>60</b>
5.3.1 Creating New Therapy Day Template .....	60
5.3.2 Displaying and Editing Therapy Day Templates .....	64
5.3.3 Deleting a Template .....	64
<b>6. PATIENTS .....</b>	<b>65</b>
<b>6.1 Maintaining Patient Data .....</b>	<b>65</b>
6.1.1 Unit Assignment .....	66
6.1.2 Cost Unit Assignment .....	66
6.1.3 Case Assignment .....	66
6.1.4 Address .....	66
6.1.5 Comments .....	67
<b>6.2 Medical Results .....</b>	<b>67</b>
6.2.1 Current and Expired Medical Results .....	68
6.2.2 Entering and Editing Medical Results .....	68
6.2.3 Medical Result Graph .....	68
6.2.4 Canceling a Medical Result .....	69
6.2.5 Preliminary Medical Result Data .....	69
<b>6.3 Merging Patient Data .....</b>	<b>69</b>
<b>6.4 Report Patient List .....</b>	<b>70</b>
<b>7. THERAPY DAYS .....</b>	<b>71</b>
<b>7.1 Overview .....</b>	<b>71</b>
<b>7.2 Prescribing a Therapy Day .....</b>	<b>72</b>
7.2.1 Planning the Therapy Day .....	73
<b>7.3 Editing a Therapy Day .....</b>	<b>79</b>
<b>7.4 Setting Statuses via the Context Menu .....</b>	<b>79</b>
<b>7.5 Deleting and Canceling Therapy Days .....</b>	<b>79</b>
<b>7.6 Reorders .....</b>	<b>80</b>
<b>7.7 Printing Therapy Days .....</b>	<b>80</b>
7.7.1 Creating Templates for Printout .....	80

<b>8. SET UP PREPARATION</b> .....	<b>83</b>
<b>8.1 Individual Parenteral Solutions</b> .....	<b>83</b>
8.1.1 Creating a Parts List .....	84
8.1.2 Buttons .....	85
<b>8.2 Setting Up Standard Preparation</b> .....	<b>86</b>
<b>8.3 Setting Up Preparation for a Compounder</b> .....	<b>87</b>
8.3.1 ExactaMix 2400® (EM2400, Baxa Compounder) .....	87
8.3.2 Other Compounder Systems .....	88
8.3.3 Confirming Preparation .....	88
<b>9. PERFORMING PREPARATION</b> .....	<b>89</b>
<b>9.1 Manual Preparation without Gravimetric Check</b> .....	<b>89</b>
<b>9.2 Preparation with Gravimetric Check</b> .....	<b>90</b>
<b>9.3 Neocare Compounders (Serial Interface)</b> .....	<b>91</b>
9.3.1 Equipment .....	91
9.3.2 Filling Process .....	92
9.3.3 Manual Injection .....	92
9.3.4 Gravimetric Check .....	93
9.3.5 Printing Labels .....	94
9.3.6 Conclusion .....	94
<b>9.4 Treatment of Remainers From Preparation</b> .....	<b>94</b>
<b>10. DISPENSE</b> .....	<b>97</b>
<b>11. LOT MANAGEMENT</b> .....	<b>99</b>
<b>11.1 Lot Management of Products</b> .....	<b>99</b>
11.1.1 Creating a New Lot .....	99
11.1.2 Determining a Vial's Average Weight .....	99
11.1.3 Lot Status .....	100
11.1.4 Editing an Existing Lot .....	100
<b>11.2 Lot Management of Empty Containers</b> .....	<b>101</b>
<b>11.3 Lot Management of Standard Bags</b> .....	<b>101</b>
<b>11.4 Event Log for Lot Management</b> .....	<b>101</b>
<b>12. REMAINDER MANAGEMENT</b> .....	<b>103</b>
<b>12.1 Printing a Remainder List</b> .....	<b>105</b>
<b>13. LABELS</b> .....	<b>107</b>

<b>13.1 Entry Form</b> .....	<b>107</b>
13.1.1 Showing and Hiding Label Information .....	107
13.1.2 Assigning a Label Layout .....	108
<b>INDEX</b> .....	<b>109</b>



## 1. INTRODUCTION

### 1.1 Intended Use

#### Functions

##### **(1) Planning and prescription of TPNs, mixed bags, and associated 24h medications.**

The software functions in the area of planning and prescription of TPNs, mixed bags, and associated 24h medications are exclusively for professional use by physicians, care personnel, and clinical pharmacists in hospitals and neonatologic centers.

Doctors can plan and continually edit individualized daily medications for patients with the aid of BD Cato™ TPN. These daily medications are usually created on the basis of therapy templates and pharmaceutical master data which must be entered into the database by physicians or pharmacists before initial use. In addition, it is also possible to enter ad hoc medications that are not based on the therapy templates.

Therapy templates (and the daily medications based on these templates) specify which infusion components shall be administered on a particular day and define for each infusion and component the volume or the active ingredient amount, respectively, the form of administration, and the administration route. Therapy templates and daily medications can contain parenteral and enteral administrations, standard bags, and 24h medications.

The dosages are usually not defined as absolute doses, but instead with reference to a measured or calculated parameter (defined by a qualified user), generally the body height.

Limit values for maximum osmolarity and maximum glucose concentration can be defined by qualified users based on the catheter and are monitored during the entire daily therapy. In addition, a total volume per day can be defined. Limit values for the ratios of certain ingredients to other ingredients can be defined with the aid of dosage rules in the master data.

##### **(2) Preparation of TPNs, mixed bags, and associated 24h medications.**

The software functions in the area of preparation are intended exclusively for professional use by clinical pharmacists and PTAs in hospitals, public pharmacies, or compounding sites.

BD Cato™ TPN supports clinical pharmacists and PTAs both during individualized preparation of TPNs, mixed bags, and associated 24h medications as well as during batch preparation of standard mixed bags. When physicians and pharmacists work together with the software, the medications are entered by the physicians and checked and released by the pharmacists. Should BD Cato™ TPN only be used in a pharmacy or a preparation site, the medications can directly be entered by the pharmacist based on a written prescription by a physician.

Preparation occurs either volumetrically (guided by written preparation instructions) or with the aid of a compounder that is controlled by the software. Optionally, the final product can also be subjected to gravimetric verification.

##### **(3) Other Functions**

BD Cato™ TPN offers functions for providing non-medical individual and cumulative data concerning material consumption, cost statistics, billing data and the like. Concerning these functions BD Cato™ TPN is intended for use by suitably trained professional staff in hospitals, public pharmacies or preparation sites.

#### General Information

There is no limitation on certain patient groups with respect to age, gender, weight, nationality, ethnicity, or patient state, provided that the therapy regimens and calculation bases entered by qualified personnel correspond to the respective individual patient parameters.

The above mentioned users must have education corresponding to their position, must have appropriate knowledge of the language in which the software has been delivered, and must have been provably trained in the use of the software (at least for those parts in which access has been granted by means of user access administration). There is no restriction with respect to age, weight or gender of the users.


Product lifetime: BD Cato™ TPN may only be used as long as the system environment of the system operator meets the system requirements as defined by BD.

## 1.2 Using the Manual

This user manual contains guides and explanations about the individual functions of BD Cato™ TPN as well as numerous examples of the screens - known as *screenshots* - that will help you understand the modules more quickly.

Additionally, throughout the whole manual, attention has been devoted to using imagery consistently in describing recurring tasks or situations.

If, for example, individual buttons or icons are described, these are represented as follows:

 This button stands for the *Save changes* function. The user can now click this button, select the corresponding menu item from the menu **File** or use the *Ctrl+S* shortcut.

### Other symbols used:



A text box with this symbol contains practical information and hints for using the software.



A text box with this symbol contains warnings which are important to minimize the risk of harming a patient.



Next to this symbol you find brief instructions guiding you through previously given explanations using step-by-step directions.

There are likewise places where the text is highlighted, identifying particular sections of text:

- *italic*: Italic script is used to highlight particular words and phrases in the text, for example functionalities, buttons or icons (for example the *Save* icon).
- **bold**: Paths, forms and menus are shown in bold, for example menu **Therapy > Therapy plans > window Therapy Plan Data**.

## 1.3 Basic Operating Instructions

### 1.3.1 Shortcuts and Toolbar

As an application for Windows, BD Cato™ TPN generally follows the common user interface of Windows programs.

On the upper part of the screen you will see a menu bar you can use to call up the various program modules of BD Cato™ TPN. Only those menu items are displayed for which you have permissions (see *Users and Permissions* on page 35).

The symbols used are probably familiar to you from Microsoft Office® programs, including the *shortcuts* usually employed there, which have largely been adopted for BD Cato™ TPN:

- *Ctrl+S*: Save
- *Ctrl+N*: Create new record(s) in the current context
- *Ctrl+O*: Open files
- *Ctrl+F*: Search data
- *Ctrl+P*: Print

Windows users should be familiar with BD Cato™ TPN's toolbar as well:



The symbols shown and the ability to use them depend on the context.

In addition to the common icons for *New*, *Search*, *Open*, *Save*, *Cancel*, etc., there are also some special icons in BD Cato™ TPN:

- ↔ ↔ With the left/right arrow buttons shown on the left, you can quickly and easily switch between program items you are currently using and the one you used just before that without losing data in the meantime. The form you leave will remain unchanged while you switch back to your previous task.
- ↑ ↓ Therefore, you do not need to worry that the data that have not yet been saved will disappear while you are working on another entry form. Within a screen form, you can use the up/down arrow buttons as shown on the left or press the *Page Up* or *Page Down* keys of your keyboard (*PgUp* or *PgDn*) to call up the next or previous record. Please note that this function is only available in the *Display Data* mode (see *Different Font Colors and Modes* on page 4).

### Selection Lists

A special feature are the selection lists developed especially for BD Cato™ TPN. Selection lists enable quick searches to be made, including among large amounts of data (for example patient data).

Entering the first letter of the search criterion (for example patient's last name) and then pressing Enter (↵key) or clicking the arrow button in the upper right corner of the input field limits the selection to the relevant data records. Provided that only one record is available, this record is retrieved; otherwise a short-list appears where you can select the desired record.

Use the mouse or the "Tab" key (⇆ key) to navigate from one input field to the next. Pressing the "Tab" key while holding "Shift" (⇧ key) returns to the previous input field.

- ☰ For a quick, context-related navigation, BD Cato™ TPN offers an additional button with some short lists, displaying the relevant form without having to search for the right menu item.

For example, if you want to enter the manufacturer linked to an infusion, then the former has to be entered into a company file. If this is not yet the case, click the ☰ button in

the entry field for the manufacturer and the corresponding form is displayed.

After entering and saving the manufacturer's data, you can return to the form "Infusion solutions" using the left/right arrow buttons.

### Date Fields



This icon appears next to date fields. When you click this icon, a calendar opens in which you can select a certain date which is then inserted into the field by BD Cato™ TPN.



In each date field in BD Cato™ TPN, you can enter today's date by pressing the shortcut *Ctrl+Alt+T* and tomorrow's date by pressing *Ctrl+Alt+M*. It is also possible, by pressing the combination of *Ctrl+Alt+ 0 (... 1, 2,...9)*, to enter the date of a day ahead (for example *Ctrl+Alt+5* is the date in 5 days).

### Tabs

In some forms, (especially master data with a great deal of information), the data are divided into several sub-forms. In these cases, "tabs" are shown. To switch to a particular tab, simply click it.

#### 1.3.2 Different Font Colors and Modes

To show clearly whether you are working with saved or unsaved data, the font color will change depending on the mode you are currently in.

Saved data that you have called up to observe or edit are shown in black. As soon as you change anything in the present data record, the color of the font changes from black to blue, which indicates to you that the data have not yet been saved. Once you have saved edited and/or new data, or rejected your changes, the font color will turn black again, notifying you that the data have been saved in the displayed form.

#### Search Mode

To be able to search in forms, you must be in *Search Data* mode. You access this mode by clicking the *Magnifier* icon or by changing to the menu item under **File > Search** or by pressing the shortcut *Ctrl+F* (for *Find*).

Only those entry fields are active in *Search Data* mode that represent a search criterion, that is, searches can be undertaken according to them. You can now, for example, enter the name or first few letters of the company which you want to have displayed into the designation field of the *Company* form (see *Searching For a Company* on page 7).

#### Display Mode

In *Display Data* mode, the entry fields are filled in with the corresponding saved information of the data record selected.



**ATTENTION!** To search for another data record in *Display Data* mode, for example another company, you must in all cases first change to the *Search Data* mode (*Magnifier* icon or shortcut *Ctrl+F*). It is a common mistake for novice users to try to search in display mode by entering search criteria, for example, in the *Company designation* field. This will not, however, display a list of the matching companies, but changes the designation of the company currently displayed.

See chapter "*Display Data*" Mode on page 8.

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### 1.3.3 Barcodes

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In BD Cato™ TPN, checks and working steps in various program modules can be facilitated using a barcode scanner. Before using a barcode scanner, it is necessary to add corresponding barcodes to the different data records. The code type is irrelevant; however, it is impossible to process more than 400 characters.

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## 1.4 Start Program and License Administration

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You must have valid licenses to use BD Cato™ TPN. There are various user groups for different license types, each of which authorizes the user to use certain or all program modules. Add-on licenses are also available that expand the scope of the program and are not tied to particular users. For more information, see the BD Cato™ TPN installation plan.

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### 1.4.1 First Start

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In the course of the installation process, licenses should have already been installed and at least one user should have been created. When you start the program, a login screen is displayed. Depending on the installation settings, login and password now have to be entered and/or a user barcode has to be scanned.

According to license and permissions of the user, specific program modules will be displayed. In all descriptions of the manual it is presumed that an administrator with all permissions is logged on. Should different main menus or program items not be displayed on your screen, you either do not have the necessary license or you are not authorized to use this function.

See chapter *Users and Permissions* on page 35 in this manual.

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### 1.4.2 Switching Users

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All actions in BD Cato™ TPN are saved for the currently logged on user for monitoring purposes. However, you must make sure that:

- You are always correctly logged on and do not work with the login of a previously logged on user.
- You always log off when you finish working or leave your work station temporarily.

It is not imperative to close the program. To enable a quick change or to lock the program for a break, you can select the **Close and Log In with Another Account** function in the **File** main menu. The login screen is displayed again and another login is required to continue working.



This function may not be available if you start BD Cato™ TPN using an interface module.

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## 1.5 Changing Own Password

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In most cases, a system administrator will have assigned you a password for the first time you start BD Cato™ TPN. You should replace this assigned password with one that is known only to you. In addition, system settings may require you to change your password after a certain length of time.

To change your own password, click the menu item **File > Change own password**.

After entering the old password, a new password can be entered.

To avoid typing errors, the new password must be entered a second time in the *Confirm new password* line. Uppercase and lowercase letters are irrelevant for the password. However, the system administrator can set various other requirements for the password in the settings (see *Security* on page 43).

## 2. MASTER DATA

### 2.1 Introduction: the Master Data Sheet "Companies"

This chapter deals with the maintenance of master data stored in BD Cato™ TPN. Since the basic handling is identical with all master data, we will demonstrate how to search for records, create new records, edit current records or delete them with the less complex file **Companies**.

Go to the **Companies** form via the **Master data** menu item. All manufacturers and suppliers of the various medical products (products, infusion solutions, etc.) are stored in this file.

After calling up the menu item, the empty **Companies** form is displayed and you will be in *Search Data* mode (see *Different Font Colors and Modes* on page 4).

#### 2.1.1 Searching For a Company

To be able to search for a specific company, you must be in *Search Data* mode.



How to look for a company:







1. Click the *Magnifier* icon. Alternatively, the menu item **File > Search** or the shortcut *Ctrl+F* (for *Find*) can be used.
2. You are now in *Search Data* mode.
3. Enter the first letter or the first few letters of the company you are looking for. If you enter more than just the first letter, this will result in a shorter list.
4. Press "Enter" (+key) or click the arrow button on the right corner of the input field. A list of all companies matching your filter criteria is displayed.
5. Select a company by just marking it in the list: use the cursor keys and press "Enter" again. (Alternatively, you may use the mouse to select an entry from the list.) If there is only one company matching the initial letter(s) you have entered, then that company record will be opened immediately.
6. Once a company has been selected, the form will be automatically in *Display Data* mode.

Only those entry fields are active in *Search Data* mode that represent a search criterion, that is, searches can be undertaken according to them.

### 2.1.2 "Display Data" Mode

In the *Display data* mode, the entry fields are completed with the information that has been saved for the selected company. In addition to the ability to change the displayed data (see *Editing Data* on page 8) the following options are also offered:

-  Allows the entry of a new company
-  Switches back to the *Search for data* mode (see *Searching For a Company* on page 7).
-  Irrevocably deletes the displayed company from the database after a query (see *Deleting a Company* on page 9).
-  Displays the next or previous company in alphabetical order. These arrow buttons allow the user to scroll through the company file. Instead of the arrow buttons, you can also use the *Page Up* or *Page Down* buttons on your keyboard.



**ATTENTION!** To search for another company in *Display Data* mode, you must in all cases first change to the *Search Data* mode (*Magnifier* icon or shortcut *Ctrl+F*). It is a common mistake for novice users to try to search in display mode by entering search criteria, for example, in the *Company designation* field. This will not, however, display a list of the matching companies, but changes the designation of the company currently displayed.

### 2.1.3 Editing Data

To change data, simply edit the associated fields of the company that is currently displayed. To do this, you must be in the *Display data* mode. After a change is made, the font color changes to **blue**, which signals that the changes have been adopted but not yet saved.

To move from one field to the next, you do not necessarily have to use the mouse. You can also use the tab key (**↹** key) to move to the next field or use Shift+tab (**⇧** key) to move to the previous field.



The input fields will have different color backgrounds depending on their status:

- Green** Currently active field, i.e. the field where the cursor is currently located and which contains the correct entries. The entries can be checked for logical errors only; actual content is not checked. An entry may be incorrect if an entry is missing (but not mandatory), for example if the company designation is missing.
- Red** Incorrect entry in the active field: The field is active, but the entry is not correct (for example incomplete postal code).
- Yellow** Incorrect entry: Saving was attempted but not all entries were correct. Those fields that contain incorrect entries have a yellow background.

### 2.1.4 Printing Master Data

Entered master data can be printed directly from the form at any time and is not visible in the **Reports** menu due to space reasons (Exception: Patient List and Product List which can be opened as well in the form and using the Report menu item).



To print the company data, use the corresponding icon in the menu bar. This icon is active for all master data and opens directly either a preview pane or a form with the corresponding selection options.

### 2.1.5 Event Log

The changes to the master data can have a large-scale effect on other parts of the program. Therefore it is not only possible to permit only certain persons to make such changes through the assignment of permissions, but also to trace who made which changes when. For that purpose the **Event log** menu item in the **File** menu can be selected.

Any changes to the master data will be shown here in table format. This makes it easy to trace who made which entries to the system on which work station.

### 2.1.6 Entering a New Company



To create a new company, switch to the *New data* mode (by clicking the button shown at the left, by using the *Ctrl+N* key combination, or by clicking **File > New**).

This will give you an empty form into which the data for the new company can be entered.

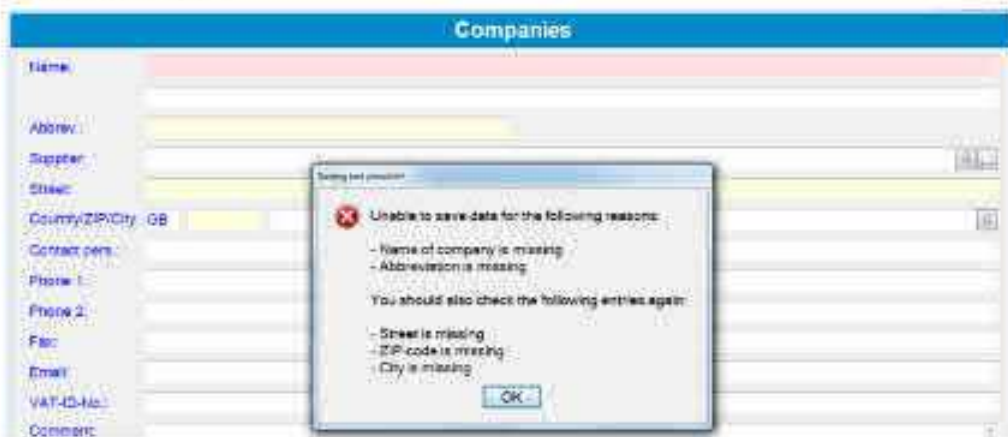
### 2.1.7 Saving or Rejecting the Data of a Company




Click this icon in the menu bar or use the key combination *CTRL+S* to save the changes and switch to the *Display data* mode. The font color switches back to black and indicates that the company data have been saved as shown.

If essential data have been entered incorrectly or incompletely, BD Cato™ TPN will reject saving and indicate the reason:

If certain information, which appears important but is not mandatory, was omitted, BD Cato™ TPN will display a warning. In this case, the data record can be saved despite the missing information.



 Discards the changes made after a query and switches to the *Display data* mode. The font color changes to black and the data are displayed again in the original (saved) version. BD Cato™ TPN shows another security query asking if you really want to discard the entered data.

### 2.1.8 Deleting a Company

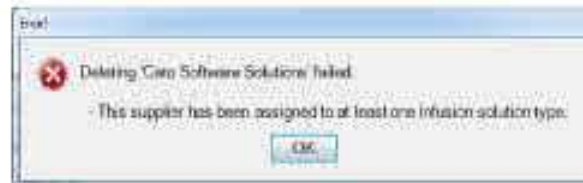


To delete a particular company from the file, call up the file (see *Searching For a Company* on page 7). Then click the *Recycle bin* icon.

After a confirmation the current company will be irrevocably removed from the database.



In many cases it will not be possible to remove master data (for example a company) from the file. This is always the case when the data are needed by other master data.



In this case, the data record of the company cannot be deleted because one or more of this company's products is still in the database. Therefore, to delete this company, you must first delete the product. However, for documentation reasons, a product can be deleted only if it has not yet been prescribed to a patient. If it has already been prescribed, it will no longer be possible to delete the product and the associated company.

Despite this, the data, including the company designation, can be edited at any time.

### 2.1.9 Additional Remarks Regarding the “Companies” File

General data can be entered not only on the manufacturer companies but also on the supplier companies. Before a supplier can be used, it must be saved under **Master data > Companies**. As a result, manufacturers and suppliers are saved in the same file.

## 2.2 Centers and Units (Advanced Introduction)

In the **Centers and Units** form, all departments that send requests to the pharmacy or are supplied with cytotoxics or co-medications by the pharmacy, are maintained. For a better overview and/or a more detailed cost allocation, each center can be listed with a different number of units.



This chapter requires knowledge about the general handling of master data forms. Therefore, please read the previous chapters.

Prior to registering units you have to register at least one center in the database first.

Several tabs are available below the basic data set as an enhancement to the master data forms. In such tabs separate lists can be found (to manage such lists more information below) or certain data groups are saved.

Basic data

- **Designation:** Mandatory field for the hospital designation (two lines of text are optionally available).
- **Abbreviation:** The short code is mandatory as well, as it is displayed at several places for which usually not much space is available (labels, part of the unit designation, etc.).

Unit assignment tab

See below in chapter *Unit Management* on page 11.

Master data tab

- **Database number:** Field for data matching with external systems.
- **Address data:** Input fields for street, country, zip code and hospital location. This data

can be printed for example on invoices.

- **Comment:** Field for free text.

### 2.2.1 Creating Centers and Units



How to create a (new) center:

1. Select **Master data > Centers and units**.
2. Click the *New center* icon or press *Ctrl+N* or select the menu **File > New center**.
3. Enter all required data (designation and short designation).
4. In the Unit assignment tab click the *New* button. You can save all relevant data concerning the unit. If you click the *Add* button, you save the entered data in the tab.
5. Save all entries by clicking the *Save center* icon or by pressing *Ctrl+S* or by selecting the menu **File > Save center**.

### 2.2.2 Unit Management

A section with tabs for managing units is located in the lower half of the screen. These functions can be used to assign units to a center or to change or delete the assigned units. The list contains all currently assigned units as well as separate buttons for managing the list.

Unit name	Chief physician	Cost unit	Unit no.	Preparation site no.	Type	LTPH	Phone	Place of delivery	Cost Centre



These *Lists* are located in many other places in the program whenever one or more detail data must be assigned to a higher level entity (several units per center, several dose limits for an active ingredient, etc.).

**New**

Use the buttons for example to assign a new unit to the current center. Click to open the available input fields:

Unit name	Text Line 1	Unit no.	Text Line 2
Chief physician	Text Line 3	Preparation site no.	Text Line 4
Preparation site no.	Text Line 5	Type	Text Line 6
Type	Text Line 7	Phone	Text Line 8
Place of delivery	Text Line 9	Cost Centre	Text Line 10
Buttons: <i>Add</i> , <i>Change</i> , <i>Delete</i>			

**Add**

In addition to some fundamental data, you can also set whether it is a unit, an outpatient department, or an oncological practice. This is particularly important for the Cost unit accounting supplemental module. The remaining fields can be used optionally, but designations are required.

To add the data record to the list, click the *Add* button. Only then is the entry truly saved.

**Edit**

Use the *Edit* and *Change* buttons to modify existing data. To change an entry, double-click the corresponding entry in the list or click the *Edit* button. Then the data of the desired unit will be read into the input fields, where they can be edited. To update the selected list entry with your changes, click the *Change* button.

**Delete**

To remove (delete) the selected unit from the list of the center's units, click the *Delete* button.



A unit may be deleted only if no single patient has an assignment for this unit.

## 2.3 Basic Data

BD Cato™ TPN provides a high degree of flexibility. For example, a medication is entered in the master data and the infusion containers are not entered as additional text entry, but selected from a master data list of possible containers. In the case of the medications, the infusion container is not entered as simple text, but is selected from a list of *possible* containers. The basic data set is often used in conjunction with the word *possible* (Possible infusions, possible containers, etc.) to make clear that any selection deviating from the data entered is not possible.

This feature makes sure that identical containers are labelled identically (for example not at one time *infusion container* and the next time *inf. container*).

In this section you will learn how the basic data set is maintained. BD Cato™ TPN provides a basic data set so the time required to maintain the data is insignificant. All basic data can be found in the **Master data** menu.

As master data forms are used for BD Cato™ TPN and BD Cato™, some entries have no effect in BD Cato™ TPN. This is specifically mentioned in the text.

### 2.3.1 (Possible) Medical Results

When in BD Cato™ TPN medical result data shall be assigned to a patient, the user selects the medical results from a list of *Possible medical results*. This list is formed from all medical results stored in this form.

Thereby, BD Cato™ TPN distinguishes between


- measured numerical results (for example height, weight)
- calculated numerical results (for example body surface - "body surface" is also considered a medical result with respect to BD Cato™ TPN) and
- selected text results (for example HIV positive and HIV negative).

In addition to the medical results already contained in the database, authorized users can also create additional medical results, which can then serve as a basis for dosing.

#### Field designations for (possible) medical results

The following are descriptions of the individual fields of the (possible) medical results.

- *Designation*: Name of the medical result as it appears when prescribing a medication.
- *Medical result UID*: A unique medical result identifier can be saved here (for example: a unique medical result number). Such a clear definition is necessary to transfer medical result data from other software systems via an interface.
- *Permissible age of medical result in days*: Establishes the period for which the medical result remains valid. After expiration of the time period assigned to a medical result, the medical result can no longer be referred to as a basis for dosage or calculation of other medical results. For security reasons, an entry is mandatory, but it can have up to 4 digits. **Example**: A measured body weight has a maximum permitted validity of 10 days. After these 10 days, the body weight has to be measured (verified) again in order to be able to continue to calculate doses on the basis of body surface. This field is not active for the numerically (calculated) type of medical result, as in this case the permitted medical result age of the medical results used in the formula is relevant.
- *Medical result group*: Category of the medical result. You may choose from a list of

medical result groups. To adapt this list, select the menu item **Master data > Medical result groups** or click the  button. The list of medical result groups can be adjusted to individual requirements by adding, changing or deleting entries in the list. However, the deletion of a medical result group is only possible if no medical result has been assigned to it yet.

- *Remark:* You can save any explanatory text regarding the medical result here.

#### **Tab for (possible) medical results**

The individual tabs for (possible) medical results are described in this section. Depending on the selected type of medical result, these deviate from each other. This is, however, identified in the subsequent description.

#### **Tab *Type of medical result:***

- *Type of medical result:* Establishes whether a measured numerical, calculated numerical or text selection medical result is involved.
- *Unit:* Unit for the medical result to be stated as a numerical value (for example kg, cm, m<sup>2</sup>,...).
- *Places in front of the decimal point / Places following the decimal point:* Establishes the format of the numerical value of the medical result. The number of places in front of and behind the decimal point affects the measured numerical data and also the display with calculated medical result values. *Example body weight:* Before the decimal point 3, after the decimal point 0. This means that weights can be entered only in whole numbers (in kg) with no more than three digits.
- *Minimum / Maximum possible value:* Establishes the smallest and largest possible value of the medical result. For example, for "body weight," you can limit the maximum possible value to 300 kg. As a result, a body weight value of 301 kg cannot be entered.
- *Display warning if new value differs more than [x]% from the last entry:* A plausibility check can be established with regard to a change in the value of the medical result. The percentage value entered states by how much any newly entered value of a medical result may differ from the last entry without triggering a warning message. This value helps prevent transposed digits or confusion of specific medical results (only with the numerically measured type of medical result).
- *Formula:* Field for entering the formula for the calculation of a certain value.
- *Formula aid:* Key mathematical operators to provide support (see *Calculated Numeric Medical Results* on page 15).
- *Num. value:* Enter the numerical value for the text selection (only with the medical result type *Text selection*).
- *Text selection:* Enter the chosen text selection (only with the medical result type *Text selection*).

#### **Tab *Use for:***

- *Dosage determination in BD Cato™ TPN:* Establishes that this medical result can be referred to as a relative basis for calculation for determining the dose of the medication.

- *Dosage determination in BD Cato™ TPN*: Establishes that this medical result can be referred to as a relative basis for calculation for determining the dose in BD Cato™ TPN.
- *Dose limitations*: Establishes that the value of the medical result can be referred to as a reference size in calculating a maximum dose to be administered (for example maximum of 10 mg/m<sup>2</sup> BSA).
- *Dose modification and cycle postponement rules*: Establishes that the value of the medical result can be used as an operand in rules relating to dose modification as well as cycle postponements (for example: If the *body weight* is smaller than 50 kg, then the dose is to be reduced to 70%).

#### Tab *Miscellaneous*:

- *Display designation next to the usual dose in therapy plan and regimen*: If this field is activated, the medication bar in regimens and therapy plans shows next to the usual dose not just the unit but also the designation of the medical result (for example, 50 mg/kg *body weight*).
- *Always display in the "medical results" form in the therapy plan (even without value)*: Establishes whether this line in the medical result is always displayed in the overview of the medical result of the patient, even if there is still no value for displaying the line. In this way, frequently used medical result values can always be edited directly without first having to be added.
- *Display on the therapy plan printout*: Establishes whether this medical result value is to be displayed on the printout or not or only if it is used in the therapy plan for calculating a dose.
- *Sequence option*: Provides the option of displaying the medical result values on the therapy plan printout in a certain sequence. For example, it can be determined on the basis of this setting that body weight, size and BSA are to be shown next to each other.

#### 2.3.1.1 Measured Numeric Medical Results

In order to enter a numeric type of result, the *numeric (measured)* setting has to be activated for the type of medical result. Then you have to fill out the corresponding fields (see *Field designations for (possible) medical results* on page 12) and have to enter the appropriate inform-

ation and choose the settings in the respective tabs (see *Tab for (possible) medical results* on page 13).

### 2.3.1.2 Calculated Numeric Medical Results

The following chapters will show you the possibilities of BD Cato™ TPN. BD will be glad to assist you with the creation of additionally required formulas.

Type	Designation	Info
Operation	+	Addition
Operation	-	Subtraction
Operation	x y	Multiplication
Operation	: y	Division
Operation	+ +	Addition
Operation	- -	Subtraction
Operation	x y	Equal to
Operation	x > y	Greater than
Operation	x < y	Smaller than
Operation	x <= y	Greater than or equal to

With the result type *Numeric (calculated)* you can define medical results with values which are derived from other measured or calculated medical results by means of a formula. To this end, you first have to enter an appropriate formula in the input field *Formula*.

The formula shown above for the calculation of body surface refers to the Dubois formula which depends on body weight and body size. The relevant components are always quoted in brackets  $\{ \}$ . When calculating the body surface area, BD Cato™ TPN first checks the two results for validity and then calculates the body surface area with the registered formula according to basic mathematical principles (for example division prior to addition).



Please note that in formulas, the *point* must be used as a decimal sign, differing from what is otherwise the case in the German language version of BD Cato™ TPN.

The following mathematical operators are used:

$^y$	Exponentiation		NOT x	Logical Not
-x	Unitary Minus		x AND y	Logical And
x * y	Multiplication		x OR y	Logical Or
x / y	Division		x EQV y	Logical Equivalence Operator
x \ y	Integer Division		x IMP y	Logical Implication Operator
x MOD y	Integer Modulus		x XOR y	Logical Exclusive Or
x + y	Addition		=, <, >, <=, >=	Comparative Operators
x - y	Subtraction			

The following mathematical or BD Cato™ TPN-specific formulas are also available:

ABS(x)	Absolute Value of x
ATN(x)	Arc Tangent of x
COS(x)	Cosine of x
EXP(x)	Exponential of x (to the value raised to the nth power)
FIX(x)	Integer part of x (if x is negative, then FIX(x) returns the next number greater or equal to x)
IFF(x,y,z)	(Returns y if x is true), otherwise z is returned. (For example, the expression IFF (x>2,y,z) means: if x is greater than 2, y is returned. In the case of values which are smaller than two, z is returned)
INT(x)	Integer part of x (if x is negative, INT returns the next number smaller than or equal to x)
LOG(x)	Base-10 Logarithm
LN(x)	Natural Logarithm of x (Base-e Logarithm)
MAX(x,y)	Compares x and y and returns the greater number
MIN(x,y)	Compares x and y and returns the smaller number
PI()	Returns the value of the constant pi (3.1415...)
ROUND(x,y)	Returns x rounded to the number of decimal places specified in y
SNG(x)	Returns 1, if x is greater than 0, 0 if x is equal to 0 and -1 if x is less than 0
SIN(x)	Sinus of x
SQR(x)	Square Root of x
TAN(x)	Tangent of x
AGE()	Age of patient in years
ISMALE()	Returns 1 ("true"), if patient is male, otherwise 0 ("false")
ISFEMALE()	Returns 1 ("true"), if patient is female, otherwise 0 ("false")



Important note on the rounding of calculated medical result values (for example BSA): BD Cato™ TPN always calculates the formulas very accurately but displays results only to 2 decimal places. Due to this fact, some confusion may arise, for example when the usual dose is converted into an absolute dose. Example: 1000 mg per m<sup>2</sup> BSA. A BSA of 1.876454 m<sup>2</sup> is calculated but the value rounded as 1.88 m<sup>2</sup> is displayed. When calculating the absolute dose, the value 1876.45 mg is displayed, instead of 1880 mg as one would have expected. Should this degree of precision not be desired, then the result can be rounded by means of the round(x,y) function. If is desired, for example, to round the result of the body surface calculated to two places following the point, the formula would need to look like this: round (BSA,2).



Formula assistance helps with the creation of individual calculated medical results in BD Cato™ TPN. Depending on the filter setting in the selection field "Type", either all data records, possible operators, functions or medical results, which have already been saved in the system, are shown in a list. Using the selection field "Search" one can also specifically search for certain values.

With calculated medical results it is not possible to determine a *Lowest possible value* or a *Highest possible value*.

### 2.3.1.3 Alternate Medical Results for Numerically Calculated Medical Results

In the previous example the medical result *BSA Dubois* is derived from the results *Body Size* and *Body Weight*. These results are part of the formula and appear in brackets (for example {Body Weight}). But it is also possible to enter *several* medical results within the brackets in one formula, which have to be separated from each other by a vertical bar. The vertical line can be found on the German keyboard to the left next to the *Y* and can be reached by pressing the *AltGr* key at the same time.

Example: Though regimens and therapy plans determine medications on the calculated body surface of the patient, the prescribing physician may determine a body surface value which differs from the calculated value. In the program module **Possible Medical Results**, in addition to the formula based result *BSA Dubois*, another medical result called *BSA Physician* can be added without a formula. Subsequently, in the same form a *Body Surface* result with the formula: {*BSA Physician*|*BSA Dubois*} can be added. If the usual dose relates to *Body Surface*, BD Cato will choose the values in their order within the brackets, that is, first the value *BSA Physician*, and only if this value has not been entered, the next value will be considered for calculation; in our example, this is the body surface according to the body surface formula.

You can add that for several options. The formula used in BD Cato™ TPN for the medical result *Body Surface* is:

**{BSA Physician|BSA Selection|BSA Dubois}**

For information on *BSA Selection* see the following chapters.

#### Examples for the use of the iif() function

The *iif()* function can be used to implement conditional instructions (If..., then...) and branches. It is possible in this way, for example, to limit the body surface to 2 m<sup>2</sup>. Let us assume there is already a *BSA Dubois* medical result which calculates the body surface in m<sup>2</sup>. In order to maximize the calculated body surface to 2m<sup>2</sup>, the following formula can be created:

**iif({BSA Dubois }>2.2,{BSA Dubois})**

The formula reads as follows: If the medical result value *BSA Dubois* is greater than 2, BD Cato™ TPN will show the result 2. If this is not the case, the medical result value is calculated using the *BSA Dubois* formula and used, for example, for further calculations. Let us take Vincristin, which is usually dosed at a rate of 1.4mg/m<sup>2</sup>, as an example. You can also limit the dosage according to the age of the patient: Assume with product X a usual maximum dosage of 2 mg. However, for patients older than 65 years the maximum dosage is 1 mg only. You can solve this problem with the following formula:

**iif(age()>=65,{BSA (max. 1mg)},{BSA (max. 2mg)})**

The formula reads as follows: If the patient's age is greater than 65 years, use the result *max 1mg*, otherwise the result *max 2mg*.

### 2.3.1.4 Text Selection Results

Text selection medical results (medical result type: *Text selection*) are a special form of numerically measured medical results. In the *Text selection list* area, under the *Medical result type* tab, you can define a list of various text selection options (for example *yes* and *no* for the possible medical result *Limit BSA*). You must simultaneously assign a unique numerical value (of your choice) between 0 and 99 to each of these medical result characteristics.

The selection texts will always be shown when entering and displaying text medical result values. However, the numerical values are also saved in the database. These values can be referenced in the formulas for calculated medical results.

The example above shows the possible medical result *Limit BSA*. In this case, the values *no*, *to 1m<sup>2</sup>*, and *to 2m<sup>2</sup>* can be assigned to a patient. Internally, these values are saved as 0, 1, and 2 in the database.

Using the medical results discussed in the previous chapter, the user can, for example, limit the calculated body surface area for a patient to 1 m<sup>2</sup> or 2 m<sup>2</sup> due to an overall poor condition (possible medical result *BSA selection* in the BD Cato™ TPN database of possible medical results; discussed above under the medical result *Body surface area*):

$$\text{iif}(\{\text{limit BSA}\}=1,\{\text{BSA max 1m}^2\},\text{iif}(\{\text{limit BSA}\}=2, \\ \{\text{BSA max 2m}^2\},\{\text{BSA Dubois}\}))$$

This formula is read as follows; If the medical result is *Limit BSA to 1m<sup>2</sup>*, then never deliver a body surface area greater than 1m<sup>2</sup>. If the value is *BSA to 2m<sup>2</sup>*, then use this limit and if it is set to *no* or is not present, then calculate the body surface area according to the Dubois formula.

### 2.3.2 (Possible) Dosage Forms

Saving can also be viewed as the first step in creating a product. If the dosage form of the product (for example concentrate for infusion preparation, powder) is not yet in the database, it can be created as a new dosage form here.

Liquid and non-liquid forms can be created in BD Cato™ TPN. However, currently only liquid products can be used for internal preparation. Therefore, substances that will later have to be reconstituted must be entered as *reconstituted*. Non-liquid products can be prescribed *orally* only and shall enable the entry and planning for example of tablets.

The designation of the possible dosage form later becomes part of the full designation of a product. It is also possible to depict the same products with different concentrations.

Example: Glucose is often used in varying concentrations. The concentrations 5%, 10%, 50%, etc. can be stored as a liquid form in the possible dosage forms. As a result, *Glucose* always remains the same product for the system and the individual concentrations can be easily exchanged in the therapy plan or preparation.

Adding, changing, and deleting are performed, as always, with the corresponding buttons.



A dosage form can be deleted only if no product has yet been prescribed!

### 2.3.3 (Possible) Container Materials

Container materials are recorded in order to enable later identify incompatibilities between products and materials. The specified material designation is also reflected in the designation of the infusion container (for example: *100 mL PVC bag*), so it should be as short (abbreviated) as possible. The material designation may be subsequently changed without difficulty and will affect all infusion containers of this material.

Use *Add / Change / Delete* to manage the container materials.

Name	UC
GA	
Gee	
PVC	
PVC-Ed	



A material may be deleted only if there are no containers (bags, syringes, etc.) of this material in the database!

### 2.3.4 (Possible) Empty Container Types

In this form, the types of containers that can be used are set. The specified designation is reflected in the designation of the infusion containers (for example *100 mL PVC bag*). For preparation with the scale (gravimetric preparation) a specific icon is defined for each container type; this icon is displayed during the subsequent preparation steps.

The corresponding buttons are used to add, change, and delete container types.



An empty container type may be deleted only if there are no containers (bags, syringes, etc.) of this type in the database!

Empty containers can be assigned a number of score points. A score point represents a certain unit of time (for example 1 score point = 1 minute). Using this time specification, BD Cato™ TPN can calculate the approximate duration of the preparation. This function is used especially for the preparation planning module and requires an add-on license.

### 2.3.5 (Possible) Routes of Administration

This form compiles the list of possible administration routes from which the physician or pharmacist can select when prescribing a medication.

Since the administration route will appear in the label of a medication, always choose the shortest possible designation.

When using a color label printer, a specific color can be assigned to the administration. To do this, check the box *Custom label color*. As soon as it is checked, a table of colors appears from which the desired color can be selected or a new color can be defined.

Administration routes are added, changed, and deleted only with the help of the corresponding buttons.



An application route can be deleted only if it has not yet been prescribed for any medication!

### 2.3.6 (Possible) Medical Result Groups

As described in the possible medical results, medical results can be assigned to certain groups, which are saved as a list in BD Cato™ TPN. This makes it possible to filter according to certain values when using many medical results data.

A list of all medical results present in the system (and for which the patient has entered values) can be shown in the therapy plan of a patient at any time. This list is in alphabetical order, so it may be useful to reduce them for example to blood results or to take ensure that only the most essential values, such as weight, size, and body surface, are shown by default.

### 2.3.7 (Possible) Active Ingredient Groups

In this data sheet, active ingredient groups can be defined and saved active ingredients can be assigned to these groups.

For the use of the supplemental module *Cost unit accounting*, in this form it is possible to assign accounting groups to the groups in order to depict the various preparation flat rates.

### 2.3.8 (Possible) IV Lines

The set catheter is of critical importance for the administration of the TPN. A list of all options with the corresponding maximum concentration of the glucose solution and the permitted osmolality can be depicted here.

Possible IV lines			
Name:			
Minimum glucose concentration:	<input type="text" value="4"/>		
Maximum catheter:	<input type="text" value="100000"/>		
UC:			
		<input type="button" value="New"/>	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
Name	max. conc.	max. osmolality	UC
original	10%	800.00mmol/L	
SK pasport	10%	800.00mmol/L	
SK pasport	20%	1000.00mmol/L	
pasport	20%	1000.00mmol/L	

This information can be assigned to the patient in the therapy plan.

The maximum concentration of the glucose solution and the osmolality are checked for each TPN therapy plan and may result in a warning message.

## 2.4 Product Master Data

Creation of a product is a multi-stage process, the first of which is the entry of its active ingredient(s). The product contains information about the manufacturer as well as the active ingredients, which may belong to various groups. Each product can then be assigned to one or more dosage forms, which contain information about energy content and osmolarity. One or more dosage strengths, which contain data about active ingredients and excipients, can be stored for each dosage form.

### 2.4.1 Active Ingredients

Before a product can be created, its active ingredients must be entered in **Master data > Active ingredients**.

In addition to the active ingredient designation with ATC code, dose limits can also be determined that refer to all products with this active ingredient.

**Short description:** Affects especially electrolytes and trace elements that shall be displayed itemized directly in the therapy plan form. To save space (when printing labels as well) we recommend using abbreviations (for example according to PSE).

**ATC:** The classification code can be entered here.

**Active ingredient group:** see *(Possible) Active Ingredient Groups* on page 20

**Order on label:** Permits definition of the order of active ingredients on the label.

**Dose limits:** Can be stated both in absolute terms as well as with reference to a medical result value. A single dose limit can be defined either as a maximum dose per administration or as a cumulative total dose.



Attention! Ensure that the checkbox *Medical result data are usable as basis for dose limits* is selected with the medical result. If this is not the case, then the medical result will not show up in the list *Relating to*.

### 2.4.2 Products

Basic information about a product is saved in the **Master data > Products** form. This includes the trade name and the manufacturer as well as the active ingredients contained and the units

in which they are prescribed and displayed.

The screenshot shows the 'Products' window with the following details:

- Designation:** NITRUM-SORBOSIN
- Short desc.:** NaCl
- Manufacturer:** Baxter-Immuno-Vertriebs GmbH
- Nutrient group:** Electrolytes

Below the details, there is a section for 'Active ingredients' with a warning: "ATTENTION! The active ingredient assignment cannot be changed anymore as strengths already exist for this product." Below this is a form to add an active ingredient with fields for 'Active ingredient', 'Dosage in', and a unit dropdown (currently 'mg').

The 'List of active ingredient assignments' table is shown below:

Pos.	Active ingredient
1.	Natrium (1 mmol = 22.99mg)
2.	Chlorid (1 mmol = 35.45mg)

**Designation:** Trade name of the product. With similar names of different manufacturers, a company code should also be integrated in the name.

**Short desc.:** The short name is displayed in some forms in the program instead of the long name.

**Manufacturer:** The manufacturer can be selected from the company list.

**Nutrient group:** The active ingredients are assigned to certain groups (see above). Since active ingredients of various groups can be contained in one product (see above), it is also necessary to define which group is critical for the therapy plan so that the product will be listed in the right nutrient group when prescribed (see *Therapy Days* on page 71).

#### 2.4.2.1 Active Ingredients

**Assigned active ingredients:** To assign a new active ingredient to the product, click the *New* icon. Select the product's active ingredient and add it to the list of assigned active ingredients. If the product contains several active ingredients (combination product), you have to pay attention to the sequence of the assigned active ingredients (primary active ingredient, secondary active ingredient(s)). The sequence can be revised later by means of the arrow buttons in the upper right corner of the list.

**Dosage in:** If the specification of the product's active ingredient is not given in units of mass (possible are ng, µg, mg, g, kg), the conversion factor should be entered at this point. This is in any case required if the product is to be prepared or the dosage is to be undertaken in the selected unit.

For the sake of compatibility, it is necessary to indicate the conversion factor even with *volumetric* preparation. The conversion factor is not required for medications that do not have to be prepared.

Currently the following units are available:

- International units
  - IU
  - Thsd. IU (= 1,000 IU)
  - mil. IU (= million IU)
- Units
  - U
  - Thsd. U (= 1,000 IU)
  - mil. U (= million IU)
- Additional
  - mmol
  - μmol
  - meq

#### 2.4.2.2 Miscellaneous

Most of these selection fields affect other modules, such as medical aids, co-payment waivers (both cost unit accounting), and trial products.

**Do not display primary active ingredient:** In principle, it is possible in BD Cato™ TPN to prescribe each product either with the trade name or with the primary active ingredient that it contains. If this is not practical with a product (for example if you do not want to prescribe "vitamin A" for a vitamin product) check this box to drop the primary active ingredient.

### 2.4.3 Dosage Forms of a Product

In the next step, one or more dosage forms will be saved for the product created in the previous chapter. To do this, switch to **Master data > Dosage forms of a product**.

If you are in the **Products** form (see *Products* on page 21) you can use the *Dosage forms* button to switch directly to the dosage forms of the current product:

The screenshot shows the 'Products' form with the following details:

- Designation:** Natriumchlorid 0,9%
- Short desc.:** NACL
- Manufacturer:** Bayer-Insulin/VernebergOH
- Nutrient group:** Electrolytes
- Buttons:** Dosage forms (highlighted), Strengths
- Active ingredients:** A warning message states: "ATTENTION! The active ingredient assignment cannot be changed anymore as strengths already exist for this product!"
- List of active ingredient assignments:**

Pos.	Active ingredient
1	Natrium (1 mmol = 22,99mg)
2	Chlorid (1 mmol = 35,45mg)



Note: For simplification, the term *Product* is almost always used as a synonym for the term *Dosage forms of a product*.

#### 2.4.3.1 Creating New Dosage Forms (New Product)



If a new product has been created, there will still not be any dosage forms for this product in the database. Click the *New* icon to create a new dosage form.

If you used the *Dosage forms* button (see above) to switch to this form, then BD Cato™ TPN will automatically detect that no dosage forms have been saved and suggest that you create a new one.

### 2.4.3.2 Administration of Existing Dosage Forms



To show data on existing dosage forms, enter the designation of the product in the *Find data* mode. The selection list will then show all dosage forms for this product.

### 2.4.3.3 General Dosage Form Data

- Product / Dosage form:** The *For product* field shows the designation of the product to which the dosage form is to be saved. The dosage form can be selected in the right input field from the list of Possible dosage forms (see *(Possible) Dosage Forms* on page 18). The dosage form then becomes part of the designation of the product: for example *Glucose 60% 1000 mL*.
  - Side note:** The "Dosage form" designation is not necessarily correct here and was selected only for reasons of compatibility with master data management in BD Cato™. Dosage forms of the same product are significant during therapy planning because they can be exchanged without changing the dose (see *Therapy Days* on page 71). Therefore, if the various concentrations of glucose are stored as dosage forms (as in the above example), it will be easy to switch between these in the therapy plan and achieve an optimal volume.
  - Reminder:** Non-liquid dosage forms can be prescribed only as oral administrations at this time. Powders must be stored as if they were already reconstituted (see *(Possible) Dosage Forms* on page 18).
- Strength indication:** If more than one active ingredient has been assigned to the product, you can set here how many active ingredients shall appear in the strength indication (see *Strengths of a Product* on page 25). Suggested is *mL* (because it is the regular specification).

### 2.4.3.4 TPN Values

Here you can set the following parameters:

**Dosage in:** In which units shall dosing be possible in the therapy plan module? With mixed products (several active ingredients) dosing is actually possible only in *mL*. Any data in another unit will therefore refer only to the primary active ingredient of the product (see *Active Ingredients* on page 22). For example: NaCl can be dosed only in mL. If a mmol dosage is permitted for the dosage form, only the primary active ingredient sodium can be dosed in mmol in the therapy plan; the proportion of Cl will simply be added to it.

**Related to:** Here you can enter the medical result value on which the calculation shall be based. A generally valid specification (for example *weight*) can be saved in the settings (see *Settings* on page 39), so that only any deviations from the rule must be entered (for example kg/min for carbohydrates).

**Energy:** The caloric content of the product is entered here in kJ/L. The overall energy balance per therapy day is then calculated automatically.



Please note that in BD Cato™ TPN kcal can also be entered and displayed for the therapy plan (see *Settings* on page 39). However, the underlying value in the "official" units of kJ must be entered here. In other words, you can also enter the value here in kcal/l, but in the background the joule value is always used for calculations, which can result in minimal rounding deviations.

**Osmolarity:** Saving the osmolarity of the individual products enables calculation of the theoretical overall osmolarity of the TPN preparation. Remember that this value does not represent the actual osmolarity and is intended only as a planning aid.

#### 2.4.3.5 Application

Allowed administration routes can be stored here for products that are used for the 24h medications (the general specification can be made in the settings for the TPN).

Only allowed administration routes can be assigned; if there is only one entry, it will always be suggested.

#### 2.4.3.6 Remarks

Any remarks concerning the master data can be entered here.

### 2.4.4 Strengths of a Product

In the next step, one or more strengths (10 mg, 50 mg, etc.) will be saved for the dosage form created in the previous chapter. To do this, switch to the form **Master data > Strengths of a product**.

If you are in the **Dosage forms of a product** form (see *Dosage Forms of a Product* on page 23) you can use the *Strengths* button to switch directly to the strengths of the current product:



If a new dosage form has been created, there will still not be any strengths for this product in the database. Therefore, create a new strength.

If you used the *Strengths* button (see above) to switch to this form, then BD Cato™ TPN will automatically detect if no strengths have been saved and suggest that you create a new one.



To show data on existing strengths, enter the designation of the product (including its respective dosage form) in the *Find data* mode. The selection list will then show all strengths for this product.

### 2.4.4.1 General Data

**Product:** Designation of the dosage form.

**Button *Additional strength*:** Opens the input form for the same dosage form.

**Active ingredients:** Defines the active ingredient amount and the unit in which it will be prescribed. The following are possible: kg, g, mg, µg, and ng as well as (if a conversion factor is provided under **Master data > Products** in the *Active ingredients* tab: IE, Tsd.IE, Mio.IE, mmol, µmol, meq, E, Tsd.E, and millions E.

**Total volume:** Target volume of the strength specified by the manufacturer.

**Actual:** An average overfill delivered by the manufacturer (referenced during planning of the preparation).

**Density:** An entry is required if a gravimetric check will be performed for the preparation (see *Preparation with Gravimetric Check* on page 90) or for some compounder interfaces.

### 2.4.4.2 Administration Tab

Supplementary information can be saved here.

**Article number:** You can enter a strength's article number derived from a third-party system. In most interfaces to compounding systems (see *Setting Up Preparation for a Compounder* on page 87) the used articles are aligned using this number.

**Barcode:** If a barcode scanner should be used for the identification of a strength, the barcode can be entered here. The barcode can be entered using the keyboard or by scanning the strength's barcode.

**UID:** This field can also be used for alignment with interfaces.

**Preferred:** Automatically suggests this strength for the parts list if several strengths are available for the dosage form.

**Blocked for use:** Blocks the strength (temporarily) so that it cannot be selected for preparation. The strength is *deactivated* but not deleted.

**Reorder level:** Here the amounts can be entered for different preparation sites at which a back-order needs to be placed for strengths. At the moment this is for information purposes only. A corresponding stock printout is being planned.

### 2.4.4.3 Package Sizes

Input fields for the planned cost unit accounting module are shown here.

### 2.4.4.4 Lots and Prices

Purchase prices and lots can be managed for the individual strengths. The links in the top right corner provide direct transfer to these program modules. As master data is not really involved here, these program modules are discussed at another part of the manual.

## 2.5 Empty Containers

In the **Master data > Empty containers** form, all (empty) infusion containers (empty bags, compounders, etc.), but also all (working) syringes are maintained. An empty container is defined by its content volume, container type, material and manufacturer. These data should be saved before selection (see *Basic Data* on page 12).

**Nom. volume:** Volume as printed on the package. This indication in milliliters becomes part of the empty container's or the syringe's designation.

**Maximum filling volume:** Determines how many milliliters at the most you can fill (for example vials) or may fill (for example bags) in the container.

**Average weight:** When using gravimetric check (of a preparation) this weight is used as basis for calculations. If no value is entered, the empty container has to be weighed before the preparation.

**Container type, container material, manufacturer:** Specifies the empty container or the syringe by selecting from the following registered basic data:

- Possible container materials: see *(Possible) Container Materials* on page 19
- Possible empty container types: see *(Possible) Empty Container Types* on page 19
- Manufacturers: see *Master Data* on page 7 (company file)

**Product no.:** The article number, for example, (such as the Pharmacy Packing Number) of the empty container in an external system (for example SAP) can be entered here. This feature is essential when data are to be exchanged with external systems (via interfaces), as in most cases, such numbers are used for unique identification of the product.

**Barcode:** If a barcode scanner is connected to the computer, the empty container's barcode can be entered here. The barcode can be entered via the keyboard or by scanning the empty container.

**Is the currently used working syringe/bolus for this volume / Is the currently used perfuser for this volume:** Defines which specific syringes are used as working syringes or bolus syringes and which as perfusers with perfuser preparations. These checkboxes can only be

selected with one empty container per target nominal volume. This ensures that, for example, in the event of three 50 mL syringes being available, it is clearly established which actual syringe ranks as a working or bolus syringe for the volume (for example 50 mL) and which as a perfuser.

**Preferred:** As the physician does not have to define the manufacturer of the container when prescribing a medication in an empty container (100 mL compounder cartridge), BD Cato™ TPN tries to convert these details into a specific empty container in the process of confirmation by the pharmacist (for example 100 mL compounder cartridge from test company). If there are several containers of a similar kind registered in the database, this option tells BD Cato™ TPN which empty container shall be recommended to the pharmacist.

**Blocked:** *Deactivates* the empty container in the system, but without deleting it. Blocked empty containers cannot be prescribed any more - blocked syringes are no longer recommended for use. As deleting the empty container cannot be considered any more in many cases, products which are no longer used cannot be blocked any more. Deleting would only be possible if the empty container has never been prescribed. Otherwise, this would have to be retained for reasons of seamless documentation in the system.

**Lots and prices:**

Purchase prices and lots can be administered for the individual strengths. The links above right provide direct transfer to these program modules. As master data is not really involved here, these program modules are discussed at another place.

## 3. REPORTS

### 3.1 Master Data Lists

Currently, the following master data lists can be printed:

- Active ingredients
- Products
- Empty containers
- Additional articles
- Companies
- Possible medical results

For the most important lists of master data (administration routes, container materials, etc.) lists can be printed and CSV files can be created.

The reports and printouts can be called up via the printer icon in the main menu bar when the corresponding form is open.

### 3.2 Preparation List

The preparation list provides an overview of preparations which were carried out and it shall serve as documentation of all preparations as printed and archived, for example, at the end of the day. The following parameters can be set:

**Period:** First and last day of medications to be printed, whereby according to the selection, the medications are either displayed by the medication's date of administration or date of preparation.

**Sorting:** The list can be sorted by different criteria:

- Preparation date
- Administration date
- Unit and preparation date
- Unit and administration date

- Medication number
- Preparation number

**Preparation site:** When using the add-on module for several individual preparation sites, the list can be filtered by certain preparation sites.

### 3.3 Requirements List

Creates a list of necessary products (in mL) and materials for a particular time period.

The list can be filtered according to the status of the TPN and the type in the therapy plan as well as by administration day.

### 3.4 Lot Tracking

With this report, a list of all patients who have received medications that used a particular lot can be generated quickly and easily. You can search not only for product lots, but also for lots of empty containers and standard bags.

### 3.5 Cost Center Accounting

With Cost center accounting (formerly Internal Billing), billing for preparations and dispenses for products and services consumed over a certain period can be carried out on a hospital-internal basis. If required, this billing can be carried out after being divided up between various cost centers (units). Since BD Cato™ TPN is prompted after each preparation as to which active ingredient has been withdrawn from which vial for a given patient, accounting can be carried out at any time and without further documentation efforts.

The prices to which BD Cato™ TPN refers for cost center accounting are derived from the (*internal*) *billing prices*, which have been entered for every strength, infusion solution, empty container and additional articles and services (see *Internal Billing Prices* on page 54). If prices have, however, been entered for the lots used, this are awarded preferential referral.

### 3.5.1 Establishing Product Consumption

To be able to understand the establishment of actual product consumption in regard to losses or overfills better, you will find more detailed information and examples in this chapter.

The accounting of active ingredients in the cost center accounting is made on the basis of the amounts actually used: If there have been 1000 mg prescribed for a patient, but preparation has been completed with a slight deviation with only 970 mg, then only these 970 mg are accounted as consumption. The mass actually *withdrawn* is invoiced, not the amount injected into the bag. This means the amount accounted does not necessarily have to equal the amount printed on the label, as there may be (slight) losses between the amount drawn up into the working syringe and the amount injected into the bag.

#### 3.5.1.1 Losses

In addition to the actually consumed amounts, losses can also be taken into account. This means the active ingredient amount that is considered to have remained in a discarded vial, that is, the amount of active ingredient of the strength stated less the withdrawn active ingredient amounts. If a vial with a nominal amount of 1000 mg was used for the above example, then, after deduction of the withdrawn active ingredient amounts, 30 mg or 3% loss is reckoned to remain in the vial (irrespective of whether the vial was overfilled). This loss can only be determined, when the used vial has been deducted, because it can then be established which proportion of the vial has been withdrawn. The amount of loss of a vial is divided proportionately between the cost centers, for which withdrawals from the vial have been effected. The proportion of the amount of loss which is credited to a cost center is the same in this process as the proportion of the amount used of the vial which was used for the respective cost center. If 100 mg was withdrawn from a vial with 1000 mg for a preparation for cost center A and then 700 mg for a preparation for cost center B, after the loss amount has been discarded, a loss amount of 200 mg remains. For cost center A, a proportion of 1/8 of the vial was consumed and for cost-center B 7/8. This means that the loss amounts to be credited are 25 mg (1/8 of 200 mg) for cost center A and 175 mg (7/8 of 200 mg) for cost center B respectively.

The loss amount stated can be shown separately from the actual consumption amounts.

#### 3.5.1.2 Overfills

It can, however, occur, on the other hand that a vial is overfilled. This means that a larger quantity of active ingredient is contained in a vial than a vial should contain according to the amount of active ingredient stated by the manufacturer. If, for example, 1030 mg has been prescribed and this amount of 1030 mg was withdrawn from a vial with a nominal content of 1000 mg, a consumption is calculated of  $1030 \text{ mg} / 1000 \text{ mg} = 1.03$  pieces. In actual fact, however, only one vial has been consumed. The amount consumed is therefore always capped in pieces. If 690 mg have initially been withdrawn from the vial and then 340 mg, for the initial preparation a consumption of 0.69 pieces has been expended and for the second preparation a consumption of 0.31 pieces. The overfill is therefore credited to the last preparation, or more precisely, the withdrawals or proportions of the withdrawals from the overfill are not billed for. This capping is always used, whenever the number of pieces used is stated. Configurations can be made for the statement of the amount of active ingredient used as to whether the amounts consumed have been capped or not. If no capping is effected, then the details of consumption can vary in terms of pieces and active ingredients. The costs are in any case calculated from the number of pieces displayed. Note that, due to the loss amount, the consumption cap and the difference between withdrawn and injected active ingredient in the cost center accounting, other amounts of active ingredient can be shown than the amounts actually applied.

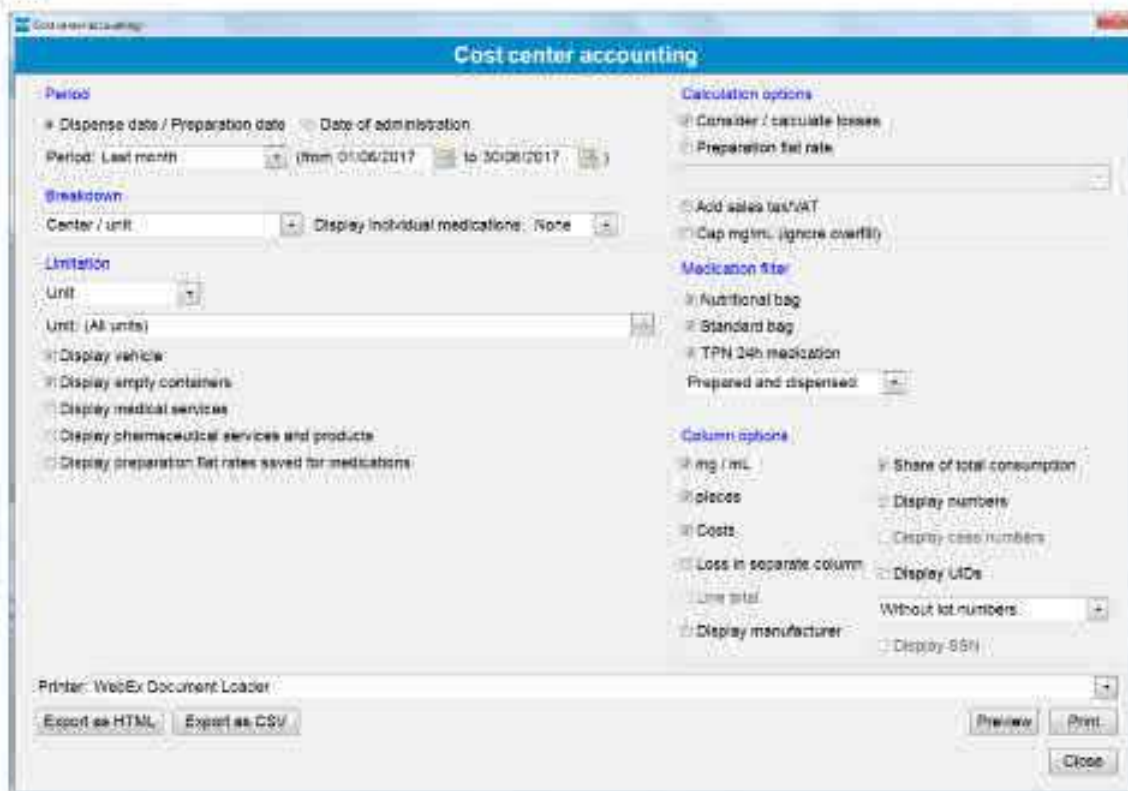
Cost center accounting: Delivery date / Preparation date from 1/7/2014 to 31/8/2014, Wards: (All Wards) printed on 22/02/14 17:03

(No Control)  
(No Ward)

Detail	September				Total			Consumption base	
	07	14	21	28	mg	pieces	cost base	TPN a/b	TPN c/b
TPN product 1 unit 0.4 100mg	3.00	5.00	4.00	4.00	40.00	1	0.00	4.00	0.00
Med No. 142-002-000-014-144102	1.00	1.00	1.00	1.00	1.00	20.00%	0.00	1.00	0.00
Med No. 740-002-000-014-144102	1.00	1.00	1.00	1.00	1.00	20.00%	0.00	1.00	0.00
Med No. 42-002-000-014-144102	1.00	1.00	1.00	1.00	1.00	20.00%	0.00	1.00	0.00
Med No. 34-002-000-014-144102	1.00	1.00	1.00	1.00	1.00	20.00%	0.00	1.00	0.00
<b>Total</b>	<b>6.00</b>	<b>8.00</b>	<b>7.00</b>	<b>7.00</b>	<b>44.00</b>		<b>0.00</b>	<b>4.00</b>	<b>0.00</b>
<b>Total (No Ward)</b>									<b>0.00</b>
<b>Total (No Control)</b>									<b>0.00</b>
<b>Total Cost center accounting: Delivery date / Preparation date from 1/7/2014 to 31/8/2014, Wards: (All Wards)</b>									<b>0.00</b>

### 3.5.2 Carrying Out Cost Center Accounting

To adapt the Cost center accounting to an individual situation, numerous parameters can be set: the parameters are saved for each work station as soon as the Cost center accounting is carried out.



**Period:** Determines a selected period which is based on the date of administration or the date of preparation.

**Breakdown:** Determines according to which criteria medications will be grouped. Subtotals are either grouped according to center/unit, patient, product and diagnosis respectively or they are structured according to the combination of active ingredient/product/patient. If structuring according to product is undertaken, only consumptions of the type of product selected through filtering are shown. This type of structuring serves as a replacement for the Consumption statistics report. In the case of grouping according to diagnosis, the first diagnosis assigned to a therapy plan is referred to first in each case.

**Limitation:** Allows - according to the structure selected - the limitation of the billing to certain centers, units (cost centers), patients, articles (product, dosage form, strength, ...) or diagnosis. It can furthermore be established here - according to the structure selected - which preparation

site should be considered and whether vehicles, empty containers and/or additional articles and services are to be shown in the statistics.

**Calculation options:** The following options can be determined here:

- **Consider / calculate losses:** Adds losses to consumption statistics. If this option is activated, losses are also displayed of those vials which have been deducted within the period selected.
- **Preparation flat rate:** Here a flat rate per preparation can be entered. The sum of these flat rates is multiplied by the number of preparations per unit (patient) and is added to the consumption costs. The services registered under additional articles and services as preparation flat rate are displayed.
- **Add sales tax/VAT:** Sales tax is also taken into account in billing as the value added tax is identified with each group total. The assumption is made in this process that the prices saved in BD Cato™ TPN are net prices.
- **Cap mg/mL (ignore overflow):** States whether the amounts used are to be capped in mg.

**Medication filter:** Filtering conditions allow a filtering of medications according to either *main medications* or *co-medications* (co-medications are marked by the *Invoice as co-medication* option in **Dosage forms of a product**) and, (independently of that) filtering according to *To be prepared medications* or *Not to be prepared medications* (for example: tablets). Every combination of both filters is possible.

**Column options:** To be able to use the column options, these first have to be shown.

With the assistance of the column options, it can be determined which columns are to be shown in the cost-center accounting.

**mg/mL:** States whether the amounts used are to be displayed in mg for product consumptions.

**Pieces:** States whether the amounts used are to be displayed in pieces. Note that, for example, consumptions of infusion solutions can only be displayed in pieces.

**Costs:** Determines whether the costs of consumption calculated from the number of pieces and the lot or product price are to be displayed. If this option is activated, grouping takes place at the lowest level not only according to product, but also according to price. A product can thus appear twice if billing is to be made at different prices.

**Loss in separate column** (To be able to use this option, the calculation option of *Consider / calculate losses* must be selected): Shows whether the proportion of loss credited is to be shown separately from the actual amounts consumed in a column of its own.

**Line total:** Shows whether, if the loss is to be shown in a column of its own, the total of consumption and loss are also to be shown in a further column.

**Display manufacturer:** Shows whether the manufacturer is also to be shown with the designation of products.

**Share of total consumption:** States whether it should be shown in every line how high the share of the respective line is in the consumption of the product in the overall evaluation.

**Display numbers:** Shows whether, for example, article numbers, unit numbers, patient numbers etc. are to be displayed.

**Display case numbers:** If the option of medications break-down is chosen within structuring, the case number of the patient can be displayed next to the medication number at the administration time.

**Display UIDs:** Shows whether UIDs registered in the master data are to be displayed with the amounts consumed.

**Lot number/invoice number:** States whether the amounts consumed are to be divided up according to product, but in addition also according to lot or details of the lot and/or invoice number (with the use of two-part lot numbers).

**Display SSN:** Shows whether, if structure according to patient is to be effected, the social insurance number is also shown with the name of the patient.

**Export as HTML:** Offers the option of exporting the cost center accounting in order to display the report in a web browser.

**Export as CSV:** Exports the cost center accounting as a CSV file and can for example be integrated in a table calculation program. The CSV file basically contains the same information which is also available in the report. Note in particular, however, with regard to automated revision that output is not effected in a fixed format and the sequence and number of columns can change in a later BD Cato™ TPN version.

**Print:** The cost center accounting can be printed with this function.

### 3.6 Patient List

To get an overview of existing patients, a list of all patients can be printed. The **Patient List** form can also be opened directly via the **Patients** master data form via the *Print* function.

With a time filter it is possible to limit to therapy plans of a certain period. The list can also be extended or limited using the flags for blocked and deceased patients, and patients with co-payment waiver.

Data can be separated or limited by units or cost units.

Waiver of co-payment can also be determined as a criterion.

Furthermore, the following columns can also optionally be displayed:

- Patient's address
- Case number (if a corresponding interface is available)
- Admission number
- Social security number
- Insurance number (Germany)
- Diagnosis (all ever assigned diagnoses)

Example *patient list*:

28.07.2017 11:10:02

#### Patient List

with medications in the administration period 28.01.2013 to 31.01.2015

Filter criteria: alphabetical list, without blocked, without deceased

Name	Units	Pat. #	Case no.	Adm. No.	SSN
Doe Jane, d.o.b. 03.07.2012	KO - NICU DC				180312
Doe John, d.o.b. 24.08.2012	KO - IM G-Station F13				

## 4. ADMINISTRATION

### 4.1 Users and Permissions

As described in the chapter *Start Program and License Administration* on page 5, every user must log in with a user ID (*Login*) and a password when using BD Cato™ TPN. On the one hand, this serves recordkeeping purposes because a record is created in the various program modules that tracks which user has modified the data stock. On the other hand, flexible awarding of permissions ensures that the registered user is only allowed to access those program modules and functions that have been explicitly assigned by the Administrator.

To organize the allocation of permissions, each user may be assigned to a user group (for example pharmacist, technician) and may obtain further permissions individually as well.

#### 4.1.1 Special Password

Several areas exist in the application that cannot be changed unless the user has expert knowledge about the functionality. If the user changes one of these settings, it could lead to serious problems with the application. These features were intentionally disabled for use by BD (also for BD Cato™ TPN Administrators) and secured with a special password which changes daily. Changes can be made either by our BD employees (at the site or remotely) or (if this is not possible) through telephone.

If you have questions, contact our support team.

#### 4.1.2 User Groups

A user group defines what tasks assigned users are authorized to perform. For example, a system administrator can define specific permissions for a technician in BD Cato™ TPN. For example, when adding a technician user, only the *Technician* user group has to be stated and not the individual (usually numerous) permissions.

To manage user groups, go to **Administration > User groups**.

To change an existing user group, select the group from the *Designation* list in *Search data* mode. You can also create a new user group. BD Cato™ TPN comes with the default user groups *Pharmacist*, *Physician* and *Technician* (or *Lab Technician*). These have assorted permissions for each user group within the program. Before users can log on, authorizations or permissions must be checked by the system administrator and then modified if needed.

In addition, this program module features a search function. You can enter keywords to search for user permissions.

You can use the *Print* function to create a CSV file that lists either all permissions or all users of the selected user group.





To modify an existing user, retrieve the user data in the *Search data* mode by his/her login or identification code or create a new user.

The following data can be entered:

#### 4.1.3.1 General Data

**Can log on as user:** Only these users need to have data for the user login and can actually login to the program.

**Ordering physician:** To these users certain medications can be assigned later on in the therapy plan. This can be users with a login (see above), but also physicians that are only needed for documentation purposes. If *Ordering physician* is selected only for a record, NO data for the user login is required and the person cannot work with BD Cato™ TPN.



If both checkboxes are not selected the account is deactivated. Through this users can be removed from the program without endangering the documentation.

#### Last name, First name and Title

**Abbreviation:** The user's initials, as they shall be displayed in the documentation.

**UID:** For synchronization with external databases.

**Physician number:** This will appear together with the user initials in therapy plans and regimens.

#### 4.1.3.2 Data for User Registration

**Group:** Defines the user group of the user (see *User Groups* on page 35). An *Administrator* user group is inherent to the system even if it has not been created explicitly in **User groups**.

**Permissions:** Permissions are basically taken from the defined user group. When creating a new user, the individual permissions are therefore taken over only after saving. All permissions of a user that he/she has taken from the user group are displayed with a blue square and cannot be withdrawn. Permissions that have been assigned to the user in addition to those of the user group are marked by a selected checkbox. These permissions can be withdrawn, if necessary.



It is possible to turn permissions from the group into individual permissions. These will then be kept if they are withdrawn from the group.

**Login:** Designation by which the user can register in BD Cato™ TPN.

**Password / Confirmation:** The System Administrator can assign a password to the user or overwrite the user's existing password if the user has forgotten it. For reasons of confidentiality, the user may change his/her password him/herself after the first login (see *Changing Own Password* on page 5).

**Barcode:** Number that is checked with a barcode scan during login or when changing a status.

**Password does not expire:** If defined in the settings, passwords can be changed periodically. Select this checkbox if you do not want the setting to apply to the user.

**Do not block account when inactive:** If defined in the settings, user accounts are automatically blocked when the user does not login over a long period of time. Select this checkbox if you do not want the setting to apply to the user.

**Free text:** Input field for any purpose, for example, for entering additional information transferred via an interface.

#### 4.1.3.3 Unit Assignment for Users

Defines the user's (for example a physician's) "own" units. The user can be assigned to all units, several different units or just one single unit. This assignment filters the patients and therapy plans as well as the therapy regimens if these are grouped according to units. Certain statistics are also automatically restricted to the user's own units.

#### 4.1.3.4 Personal Data

Currently contains only one input field for address information. These are displayed in the therapy plan at the medications that were assigned to the user as *Ordering physician*.

The field can be described however desired and may therefore contain data other than just the address.

#### 4.1.4 Event Log for Users

If any changes have been undertaken in the user administration, these changes can be tracked. To call up the change protocol in BD Cato™ TPN, you have to be in **Administration > User management**. Then click on **File > Event log** in the menu bar and you will be presented with the following overview.

Event log

Chronology: Hierarchical

Events:

From date: 18/05/2017 To date: 18/05/2017 User: <Any> Workstation: <Any>

Date	Event	Comment	User	Workstation
18/05/2017 13:25:09	Patient data retrieved	John Doe (I.D. 010011911, 111)	ADM	VMAUTBN7102B
18/05/2017 12:45:16	Patient data retrieved	John Doe geb. 01.01.1911, 111	ADM	VMAUTBN7102B
18/05/2017 11:08:18	Medical result added	180cm Körpergröße (John Doe, 18/05/2017)	ADM	VMAUTBN7102B
18/05/2017 11:08:18	Medical result added	80kg Körpergewicht (kg) (John Doe, 18/05/2017)	ADM	VMAUTBN7102B
18/05/2017 11:08:18	Medical result added	58cm Kopfumfang (John Doe, 18/05/2017)	ADM	VMAUTBN7102B
18/05/2017 10:44:07	Patient data retrieved	John Doe (I.D. 010011911, 111)	ADM	VMAUTBN7102B
18/05/2017 10:44:06	Patient deleted	Doe John 1911 01 01, I.D. # 1111	ADM	VMAUTBN70000

Printer: WebEx Document Loader

Preview Print Close

Events such as login changes, name changes or the deactivation of an account are displayed in the event log.

## 4.2 Settings

To obtain the flexibility needed to adapt BD Cato™ TPN to the varying needs of individual hospitals and pharmacists, there are numerous basic settings that the administrator can adjust. All of these settings are compiled in the **Administration > Settings** form. Most settings are global (affect all computers), but some are only local. This is indicated below and to the right of each setting.

This section lists the settings and describes them more precisely.

Since new basic settings are added with almost every update, it is highly likely that not all settings are listed. If this is the case, please refer to the documentation for the update.

### 4.2.1 Basic Settings

**Own preparation site:** Assigns a preparation site to the work station.

**Own company:** Defines own address for invoices.

**Designation temperature level 1-4:** In BD Cato™ TPN, 4 different temperature levels can be saved for storage (for example room temperature or 15°-20°).

**Four-eyes principle with master data forms:** Establishes to the creation of which master data the four-eyes principle is to apply. In such cases the data entered can only be saved with the entry being made by two users. The following master data are affected:

- Patient data
- Company data
- Centers and units

- Lot management
- Other master data

**Position of center's abbreviation in unit designation:** Determines if and at which position the center abbreviation is inserted in the unit designation.

**Security query prior to ending BD Cato™ TPN:** Determines whether a security query is to be displayed regarding non-saved data when closing BD Cato™ TPN.

**Certificate number:** Determines whether the certificate number is displayed in the patient's unit assignment.

#### *4.2.1.1 Patient Master Data*

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**Patient search:** In order not to open patient data by mistake in large databases, a minimum number of letters to be entered can be given here, so as to have at least a corresponding filter for the data records.

**Mandatory data:** This establishes which data must be entered in addition to the patient name. Address, date of birth, SSN, insurance number and patient number can be selected.

**First character of last name:** Establishes whether the first letter of the last name is to be written automatically as a capital letter when entering or not.

#### *Number Assignment Patient*

**Check patient's SSN:** Establishes whether the social security number is to be checked for plausibility when entering.

**SSN format:** Establishes the format for entering the social security number.

**Prevent multiple SS numbers:** Establishes whether multiple entry of the same social security number is to be prevented.

**Patient number format:** The format of the patient number is entered in this setting.

### **4.2.2 Preparation / Dispense**

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#### *4.2.2.1 Set Up Preparation / Dispense*

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**Maximum number of vials per prep.:** Provides the maximum number of vials for a preparation. In this way, BD Cato™ TPN can be forced to select not necessarily the combination with the least remainder (normal setting) for several strengths, but larger and therefore fewer vials.

**Documentation of vehicle lots:** Activates the maintenance and display of vehicle lots.

**Documentation of diluent lots:** Activates the maintenance and display of diluent lots.

**Additional services and articles documentation:** Determines whether the lots of additional articles and services are to be recorded.

**Preparation date in "Set up preparation":** Activates a corresponding entry field in the program module mentioned.

**Warning when the preparation date is in the past:** Automatic warning, if a medication is selected with a corresponding deviation in terms of time for the preparation.

**Warning when the preparation date is in the future:** Automatic warning, if a medication is selected with a corresponding deviation in terms of time for the preparation.

**Label printing in "Set up preparation/dispense":** Should the possibility of a preliminary label print be displayed in **Set up preparation/dispense** or not.

**Gravimetric final check:** Here you can select whether a connected electronic scale should also be used during preparation. The weighing procedure can be made optional or mandatory and will trigger a check weigh of the finished product (see *Preparation with Gravimetric Check* on page 90).

**Documentation of empty container lots:** Defines whether the lots of empty containers are to be recorded.

**Preparation instructions:** Defines the information that will be printed on the preparation instructions.

**Activate printer selection:** Determines in **Set up preparation** whether printing will always run immediately on the selected default printer (for example because only this printer is accessible anyway) when the *Print* button is pressed or a query will appear that permits selection of a printer in a network, for example.

#### Settings Medication List

**Display release date by the pharmacist:** Defines whether in the *Set up preparation/dispense* program module in the medication list the *Approval date* column should be displayed.

**Display patient number column:** Defines whether in the *Set up preparation/dispense* program module in the medication list the *Patient number* column should be displayed.

**Signal with new medications:** Activates a signal field and an acoustic signal by means of which it is displayed in *Set up preparation/dispense* if a medication has been pharmacist-verified.

**Font size selection lists:** The font size in the forms for setup can be changed here.

#### 4.2.2.2 Remainders and Stabilities

**Microb. sterility of prepared products:** Establish here the generally valid microbiological sterility for products prepared by you. This value is a standard value which is applied every time when no deviating value has been stated with the dosage form of the product. For stability, the shorter value of microbiological and chemical-physical stability is always referred to.

**Microb. sterility of remainders:** Establish here the microbiological sterility for remainders which derive from the preparation conditions at the preparation site (clean room). As already mentioned under *microb. sterility of prepared products*, this value is a standard value that is always used if no deviating value is given with the dosage form of the product. For stability, the shorter value of microbiological and chemical-physical stability is always referred to. If a deviating microbiological sterility is supposed to be used for a remainder of a particular product (for example because a preservative has been added), then a deviating value can be entered for this product in **Dosage forms of a product**.

**Highest remainder number:** For each (recorded) remainder, a number is assigned by BD Cato™ TPN, based on which the preparer can identify the remainder. To avoid this number becoming "infinitely" big over time, it can be determined here from which number on the numbering is to start with "1" again. A value of 999 is recommended because even with long storage times there can be no mix-ups.

**Usable remainder in vials:** Since BD Cato™ TPN knows at all times during gravimetric preparation how much active ingredient is still left in the vials, the assessment as to whether a vial is empty or not is made automatically. As long as there is still an active ingredient left in the vial, BD Cato™ TPN assumes that this, too, should still be withdrawn. With this value, a

substance quantity can be set in mL, below which it is no longer justifiable to pierce the vial once more. In other words: this is the substance quantity in mL, which may remain in the vial and it will still be considered empty. Since in most cases (regardless of overfill with active ingredients), the entire quantity of active ingredient is not or cannot be withdrawn, this value represents an important prerequisite for an expeditious working process.

**Notice:** The value entered here is merely a standard value, because for each dosage form of a product a remainder quantity of its own can be stated. If nothing else has been entered for this dosage form, then this value applies.

**Time of administration:** Establishes a value which is to be used for calculation if no time is stated with the medication.

**Consider stability of remainders:** Establishes whether the stability of the remainder should be taken into account in calculating the stability of finished preparations.

**Save all vials as remainders:** Here it can be determined if vials selected for a preparation shall be automatically considered as a remainder (for example because it is customary in your company to provide all vials with a spike before the beginning of preparation), or if not yet reconstituted powders or solutions from which nothing was withdrawn during the preparation shall be posted back into inventory.

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### 4.2.3 Printers

Make sure that all users who are working with BD Cato™ TPN and want to print reports have a printer available in Windows.

**Printer for reports:** Local setting that determines on which printer statistics, audit trails, and reports are going to be printed on.

**Label printer:** Local setting that determines which printer labels are going to be printed on.

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### 4.2.4 IT Settings

#### 4.2.4.1 General Settings

**Network path for auto update:** If BD Cato™ TPN is installed on several work stations, it is recommended that a directory within the intranet is set up on the intranet that everybody is authorized to access and that shall be entered here. A unique path should be used here, which contains the name of the server, and not a linked network drive. If such a directory has been entered and an update is made by BD Cato™ TPN on one computer, then the update program checks if such a directory has been entered. If this is the case, then all program files of the new version will be copied by the update program into this directory automatically. If BD Cato™ TPN is subsequently started on a computer on which no update has been carried out yet, then BD Cato™ TPN will check if there are new program files in this directory and will update itself if need be. Therefore it will not be necessary to perform an update on each computer individually.

**BD Cato standard proxy:** Defines the standard proxy for all BD Cato™ TPN program modules.

**GS1 GTIN for medication barcode:** Determines which GTIN is to be referred to for the medication barcode. Selection in this process can be made from the GTIN of the center (which has been defined in the master data), in which the administration is being conducted or the use of the global GTIN, which you can define individually via this form.

#### 4.2.4.2 Number Assignment

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**Mandatory patient number:** This setting determines whether the entry of a patient number in the patient master file is mandatory or not.

**Patient number format:** Here a format for the patient number can be entered. A "0" is a placeholder for a digit, an "X" for an alphabetical character and any other character (such as / or -) will be used as a fixed separator. A format of "0000-0000/00/000000" would determine that, for example,

"1234-5678/02/564567" would be a valid number; however, "1234-5678/02-5645AB" would be an invalid patient number.

**Mandatory therapy plan numbers:** Here it is determined whether the entry of a therapy plan number shall be mandatory or not.

#### 4.2.4.3 Security

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**Password expiration:** Regulates the duration of validity of the passwords. The user receives a warning if the password expires in the next 30 days. A new password must be different from the last four passwords previously used by the user.

**Password definitions:** A minimum length and minimum number of numeric and non-numeric characters which can be used to form a password can be saved. In addition, it is established whether the password is allowed to contain the user name or the first and last name of the user.

**Maximum number of user identification attempts:** A number which can be configured (standard value: 10, no entry deactivates the function) of wrong login or authentication attempts. If this number is exceeded, then the user account is automatically blocked (*Intrusion prevention*).

- Successful and failed login attempts as well as logout attempts are recorded in the event log (*Intrusion detection*). In the user's event log it is possible at any time to see the successful as well as the failed login attempts.
- The last successful or unsuccessful login is displayed on the splash screen for the user after logging in.

**User account inactivity block:** Accounts that have not been used for longer than a certain period (standard value: unlimited, an entry range between 14 – 999 days is possible) are set to *Account deactivated*. If necessary this block can be canceled in the User management.

- In the User management it can be determined that the inactivity block does not apply for individual users. IT staff, for example, who only rarely access the system to provide support of interface adjustments, can be exempted from the block.

**Inactivity check:** Defines after how many minutes of inactivity BD Cato™ TPN is to log off the current user.

**Preparation inactivity check:** This setting has an effect both in volumetric and in gravimetric preparations and is particularly intended to enable an inactivity check during this to be switched off.

**Close and log-on under different name:** As mentioned under *Allow cancel on user change*, it is possible in BD Cato™ TPN to change users without closing the program. This setting determines whether this function should be available.

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#### 4.2.4.4 Data viewing log

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**Individual patient data:** Determines whether, for data privacy reasons, a log should be kept of when a user views the master data, diagnoses, medical results, or therapy plans of a patient. These access events can then be retrieved in the event log.

#### 4.2.4.5 Optimization

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##### Database Connection Parameters

Determines the *transaction security* with which the connection to the database is established. These values may be changed only in consultation with BD.

##### Resource Management

**Unload therapy plan and regimen dialogs:** Used to adapt to limited system resources (for example in certain Citrix environments).

**Screen resolution adjustment:** Indicates whether the screen resolution shall be stored when adjusting the input form.

**Caching times:** To increase the working speed of BD Cato™ TPN in large databases, here you can set the intervals at which

- rarely changing *Basic master data* (for example possible containers, infusion solutions),
- *master data* (for example products, dosage forms),
- and *settings*

will be reconciled with the database. These data are stored locally during the intervening time.

##### Cache Cleaner

**Cache cleaner settings:** Here you can choose settings (interval and minimum age of an object) for removing "old" objects from the cache.

#### 4.2.4.6 File Export (CSV)

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With BD Cato™ TPN, many evaluations and statistics can be exported to comma separated value (CSV) files. You can adjust this data export using the following settings:

**Separator for values:** Sets the ASCII code for the character which separates the values (for example 44 for comma, 59 for semicolon, 9 for tabulator, and 13 for CR).

**Record separator:** Sets the ASCII code for the character which separates the data records (for example 44 for comma, 59 for semicolon, 9 for tabulator, and 13 for CR).

**Decimal separator:** Determines whether a decimal point or a comma is used as a separator of decimals.

#### 4.2.4.7 File Export (Fixed Field Length)

---

Users of the consumption export add-on module can adjust the export file:

**Decimal separator:** Determines whether a decimal point or a comma is used as a separator of decimals.

**File type:** Determines the file type of the export file.

**File header:** Determines which file header is to be used.

#### 4.2.4.8 Export Files

---

Users of export interfaces can set the directory name where the export files can be copied.

#### 4.2.4.9 User Verification

**Multiple user verification:** States if during (1) a user check at login and (2) during the status change of a medication one successful check suffices, or if all configured checks have to be carried out successfully.

**Barcode for login:** States if during login, the authentication is possible using a barcode.

### 4.2.5 BD Cato™ TPN Basic Settings

**BD Cato™ TPN basic settings:** The following settings can be made here:

*Energy unit:* Specifies whether energy values are displayed in kcal or kJ in the program.

*Check dose limits:* Specifies whether the dose limits that are stored with active ingredients will lead to warning messages or not.

*Glucose active ingredient for the therapy plan:* Specifies which active ingredient will be referenced for the calculation of the total glucose concentration. In the therapy plan of parenteral solutions, the maximum glucose concentration will be monitored, based on the catheter that is used. To give the users as much freedom as possible when naming the products (after all, BD Cato™ TPN is used in many countries), it is necessary to specify which active ingredient shall be referenced for the calculation.

*Aqua dosage form for dilution of the glucose in the therapy plan:* For a parenteral bag, the glucose that is used can be automatically diluted with Aqua up to the prescribed nominal volume. Here you can define the product (or dosage form of a particular product) with which this shall occur.

*Preferred underlying medical result:* Specifies which medical result under **Possible medical results** will be used as the basis of calculation for the overall overview. In addition, this medical result is automatically suggested for dose calculations (see also *Preferred dose determination* below). Since changing this value would change all existing templates and therapy plans, this value may be modified only by an employee of BD. The medical result *Weight*, which permits entry of kilograms or grams as the body weight, is entered here by default.

*Standard administration route:* Automatically fills the field *Administration route* of parenteral medications and standard bags with the entered value. However, this can still be changed there.

**Ionogram:** A list of the electrolytes and trace elements that are displayed in the therapy day form (and which must be checked) can be compiled here.

**Fill up with Aqua:** Specifies whether this function is set automatically with new therapy days or must always be called up manually.

**Minimum volume for 24h medications:** For 24h medications, BD Cato™ TPN will only permit therapy plans with at least this volume.

**Optional required fields:** Defines which data must be entered for a therapy day in order to save the day. The following values can be set:

- Nominal volume
- Administration route
- Administration duration
- IV line (main IV line)

**Display of medication number:** The medication number unambiguously defines each medication in BD Cato™ TPN. However, many users do not wish to see this number in the list of therapy days because the many numbers can be confusing. Of course, the user can still search for these numbers in the system and also print them on labels, for example.

**Preferred dose determination:** Determines for new medication entries whether an absolute value or a calculation according to the underlying medical result (see above) shall be referenced as the calculation of the dose.

**Warning when nominal values are exceeded:** Permits switching off of this warning, which is irrelevant for many users.

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#### 4.2.6 BD

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These settings are predefined and must only be changed under specific circumstances. They can substantially impact the behavior of the software and are only relevant for specific installations. For security reasons, changing these settings can only be effected by BD support representatives and are locked with a special password. However, it is possible to print the settings for documentation purposes. For further information, contact our support team. You can see these settings under **Administration > Settings > BD**.

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##### 4.2.6.1 Basic Settings

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**ICD code:** Here you may enter if you want to use the ICD-9 or ICD-10 diagnosis catalog.

**Density for ready-made solutions mandatory:** Here you can define if the entry of a density should be mandatory for ready-made solutions in **Strengths of a product** or not.

**Final verification by inspecting physician:** Replaces the term *pharmacist* with *inspecting physician* in the entire program.

##### Medication List

**Medication list: status change:** Determines if the possibility of a change of status should be shown in the **Medication list**.

**Medication list: automatic refresh:** Determines if the list of medications should be updated automatically in case of a change to the **Medication list**.

**Medication list: automatic refresh when inactive:** Determines if the list of medications in the **Medication list** should also be updated if BD Cato™ TPN is not currently active.

**Dose calculation for relative dosages:** Determines whether in the list of medications in the **Medication list** the currently resulting final dose should be displayed for planned medications which are dosed in relation to a medical result.

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##### 4.2.6.2 Regimens and Therapy Plans

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**Dose left of product designation:** Determines if the dosage entry in mg for medications in therapy plans and regimens shall be shown before or after the product designation.

**Cycle number:** Defines whether it should be possible to edit the cycle number in the **Therapy Plans** program module.

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##### 4.2.6.3 Therapy Plans

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**Linking product-specific documents:** If a path to a document is entered under **Products**, then it can be set here whether this document should be available through the link in the therapy plan and also possibly be printed automatically.

**Paste copied medications as planned medications:** Defines if a copied medication should normally be pasted as *planned* or if the current status should be adopted (depends on the permission of the user).

**Display "initially planned cycle interval":** Defines whether after a cycle postponement the original distance to the previous cycle should be displayed in the therapy plan or not.

**Display administration approval:** Determines whether an available or unavailable administration approval should be shown in the title bar of medications or not.

**Default value administration approval:** Determines which status new medications should initially have by default.

**Preselection regimen checkbox:** Determines whether BD Cato™ TPN should assume that normally therapies are applied according to an existing regimen or if therapy plans should be entered rather freely.

**Warning upon change of regimen:** Defines if BD Cato™ TPN should display a warning if inserting a cycle into a therapy plan would also involve a change of regimen.

**Display profitability index:** Determines if upon the creation of a therapy plan from a regimen the profitability index of the selected regimen should be shown or not.

**Suggestion new therapy plan:** Determines whether the creation of a new therapy plan should automatically be suggested for a patient who does not have an assigned therapy plan yet in case of a change to **Therapy plans**.

**Direct dispense and administration:** Determines if medications that have not been verified by a pharmacist, but are to be dispensed may be dispensed and administered by users with appropriate permission.

**Prefill administration time:** Regulates whether during administration the time is to be pre-filled with the current time or not.

**Display beginning of cycle:** Regulates the display of the cycles in the therapy plan at the beginning of the cycle.

**Display medication order number:** Determines if the medication order number should be displayed. This entry can be mandatory or optional.

**Pre-selection for diagnosis filter:** Determines whether the *Diagnosis filter* checkbox should be preselected when creating a therapy plan from a regimen. This means that only regimens with the same assigned diagnosis as the patient are displayed.

#### 4.2.6.4 Medications

**Veh. volume mandatory in regimen med.:** Determines whether a vehicle volume has to be established in the regimens or not.

**Veh. volume mandatory for medication selections:** Determines whether a vehicle volume has to be entered already as mandatory with a medication selection.

**Veh. volume mandatory in planned med.:** Must a vehicle volume be entered mandatory already in the planned status?

**Veh. volume mandatory in phys. med.:** Determines whether a vehicle volume must already be entered as mandatory during verification by the physician.

#### Additional Warnings

**Time of administration before cycle start:** Defines whether a warning message should be displayed if the time of administration is before the beginning of the cycle.

**Administration time in the past:** Defines whether a warning message should be displayed if the time of administration is in the past.

**Warn of cycle overlap:** Determines whether a warning is to be given when cycles overlap.

**Administration warning for linked medications:** Defines whether a warning should be displayed for relative linked medications if the order is not kept during administration.

#### 4.2.6.5 Preparation / Dispense

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**Lot management:** Here the following settings can be adjusted:

**Lot barcodes:** Defines which barcodes for products or product lots, infusion solutions or infusion solution lots as well as for empty containers or empty container lots should be used.

**Behavior when scanning:** Defines how the lot management shall react upon scanning of a barcode.

**Barcode search:** Defines how a search is supposed to be carried out after a barcode has been scanned.

**Preparation site selection during preparation:** Determines whether the selection list for the preparation site should be shown in **Gravimetric preparation** and **Volumetric preparation**.

**Error message for administration times in the past:** Determines whether an error message should be displayed in **Set up preparation** and **Gravimetric preparation** if the time of administration of the medication is in the past.

**Preparation barcode:** Defines which number should be used as preparation barcode (the barcode saved during the preparation or the preparation number can be selected).

**Confirmation with volumetric remainders:** Enables the assignment of volumetrically created remainders in the parts list. A volumetrically reconstituted powder cannot be used for a gravimetric preparation. A respective parts list is therefore provided with the note *Volumetric preparation only*.

**Volumetric remainders for gravimetric preparation:** Enables the use of volumetrically prepared remainders for gravimetric preparation. This applies only to remainders of ready-made solutions, since BD Cato™ TPN can carry out a check of the amount of active ingredient based on the master data. Reconstituted powders, however, cannot be re-used gravimetrically (during the selection of such remainders a notice will appear - *Prepare only volumetrically* - or the medication will no longer be displayed in the form for gravimetric preparation).

**Multiple assignment of strength barcode:** Determines whether it should be possible to assign the same barcode to several strengths.

#### 4.2.6.6 Reports

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Different fields can be changed for the listed reports and printouts.

Furthermore, there is the possibility to use a different browser (for example "Opera"), for example to define page breaks (this is not possible with Internet Explorer). This way it can be avoided for therapy plan reports that the details of a medication are printed on different pages. The browser must be installed on the computer and the path must be saved here. That way it can be achieved that only BD Cato™ TPN uses it, but otherwise Internet Explorer will still be used as default browser.

**Group parts lists:** Defines whether for parts lists one report should be printed per preparation set or a grouped report for several preparation sets.

### General Settings

**External browser:** A path to an external browser can be defined here.

**Header on reports:** Determines the text that should appear in the header of reports that have no context-specific header.

**Multiple printout:** Determines whether an attempt should be made to print several labels at once.

**Header on lot register report:** Determines the text which should be shown in the header of the lot register report.

### Style Sheets (CSS)

Different layouts can be assigned to different reports here and they can be adjusted upon request (for example color print). Reports for billing, preparation summary and therapy plan can be selected. Contact BD directly if required.

### 4.2.6.7 IT Settings

**Process monitoring:** Activates trace logging.

**Process monitoring for label and report printing:** Activates trace logging for label and report printers.

## **4.3 Dosing Rules**

Various dosing rules, for example rules based on certain mixing ratios of various active ingredients, can be saved in BD Cato™ TPN. This module requires an experienced user, so speak to our support team before using it.

## **4.4 Preparation Site Administration**

With an add-on license, various preparation sites and stock sites can be managed in BD Cato™ TPN.

The user can define whether a stock site is a main stock (storage only, without preparation) or stock with a preparation site (sub-stock). Various sub-stocks can also be assigned to one main stock. In addition, a manufacturer (for example another external pharmacy), for which the medications are prepared, can be specified.

## **4.5 Manage Statuses/Flags**

This module is also protected with a special password. Additional control steps can be set up for lot management. Please contact our support team if you are interested.

## 4.6 Determine Layout of Labels

See chapter *Labels* on page 107.

## 4.7 Compounder Configuration

In BD Cato™ TPN it is possible to simultaneously operate as many compounders as desired, even from different manufacturers. Data records must be created for the individual devices in the **Compounder configuration** menu item. In **Set up preparation**, the user can define the compounder for which the preparation shall apply. Different data will be necessary depending on the generator.

### 4.7.1 ExactaMix 2400® (TPN Compounder from Baxter)

This unit is not activated directly through BD Cato™ TPN. The compounder has its own control software that performs the preparation. However, files can be created in BD Cato™ TPN with the required quantities and transferred to this software (see also the section on preparation).

The following parameters must be defined:

**Designation:** Give the compounder a name that uniquely defines it. This designation will then be shown under **Set up preparation**.

**Compounder type:** As compounder type, select *Baxa*.

**Preparation site:** A supplemental module from BD Cato™ TPN permits operations at geographically distinct preparation sites that also have separate stock keeping. If this module is activated, you will have the option here to tell the system where the compounder should work.

**Blocked:** Prevents assignment under **Set up preparation** or permits no additional preparation on this compounder.

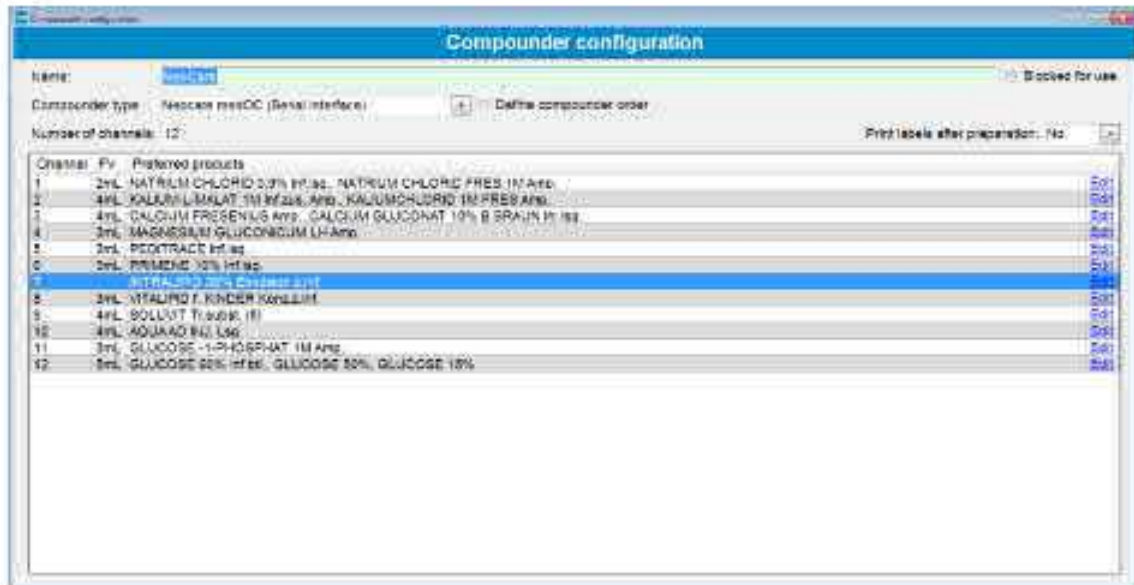
**Network share:** A network path in which BD Cato™ TPN places a directory with activation files for the control software (PAT files). These files are imported by the compounder control software and used for filling.

**Database file path:** The path to the BD Cato™ TPN database where the compounder can place a preparation report following preparation. This report can then be retrieved from BD Cato™ TPN and printed.

**Automatically print labels:** If set to *yes* labels for the affected preparations will be automatically printed when the compounder files are sent (see *Setting Up Preparation for a Compounder* on page 87). A barcode can also be printed onto the labels. This barcode can be read by the compounder's barcode scanner to start the preparation.

## 4.7.2 Neocare medOC®

The medOC machines connected through a serial interface can be controlled directly through a preparation module in BD Cato™ TPN.



The following parameters must be defined:

**Designation:** Give the compounder a name that uniquely defines it. This designation will then be shown under **Set up preparation**.

**Compounder type:** In this case, select *Neocare medOC®*.

**Preparation site:** A supplemental module from BD Cato™ TPN permits operations at geographically distinct preparation sites that also have separate stock keeping. If this module is activated, you will have the option here to tell the system where the compounder should work.

**Number of channels:** Number of channels of the connected medOC® compounder.

**Print labels after preparation:** Labels can be printed always, never, or when requested by the user.

**Blocked:** Prevents assignment under **Set up preparation** or permits no additional preparation on this compounder.

### 4.7.2.1 List of Channels

In the **Set up preparation** program module, BD Cato™ TPN automatically calculates a quantity suggestion for the preparation and distributes the substances to the existing channels. This is initially done "randomly", whereby the channel assignments can vary from one preparation set to another. While the channel assignment can be modified as desired, it is useful for the assignment to be performed right away, at least in large part, to keep the workflow as fast as possible.

*Preferred* dosage forms can be saved in the compounder configuration for each channel and will be taken into consideration as such when creating the parts list. For example, glucose shall always be pumped on channel 1, while water will be pumped to channel 3.

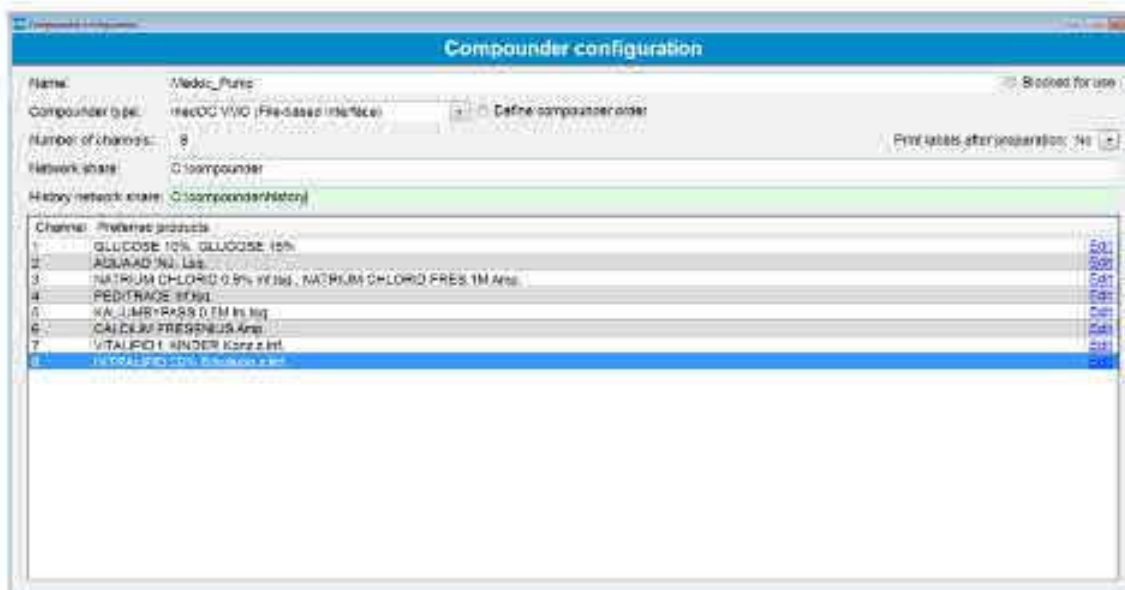


Multiple dosage forms can be stored as alternatives (if both appear in the parts list, BD Cato™ TPN will select the one that is first in the list).

**Flushing volume per channel:** A flushing volume can also be defined for each channel (volume used to flush the channel after an equipment change). When *Flush* is pressed at the compounder, this volume specification is forwarded to the compounder.

### 4.7.3 medOC VMC

The more modern compounders from medOC have a file-based interface, i.e. they independently work through the preparations and a file is created in BD Cato™ TPN and sent to the compounder as an order. But in contrast to the EM2400 described above, the channel assignments from BD Cato™ TPN are adopted and must therefore be adjusted. Unlike the series compounder described above, these assignments cannot be modified at a later time.



**Designation:** Give the compounder a name that uniquely defines it. This designation will then be shown under **Set up preparation**.

**Compounder type:** In this case, select *medOC VMC*.

**Preparation site:** A supplemental module from BD Cato™ TPN permits operations at geographically distinct preparation sites that also have separate stock keeping. If this module is activated, you will have the option here to tell the system where the compounder should work.

**Number of channels:** Number of channels of the connected compounder.

**Print labels after preparation:** Labels can be printed always, never, or when requested by the user.


**Network share:** A network path in which BD Cato™ TPN places a directory with activation files for the compounder's software. These files are imported by the control software and used for filling.

**Network share history:** Currently has no function and is implemented as preparation for return transmission of data.

**Blocked:** Prevents assignment under **Set up preparation** or permits no additional preparation on this compounder.

#### 4.7.3.1 List of Channels


In the **Set up preparation** program module, BD Cato™ TPN automatically calculates a quantity suggestion for the preparation and distributes the substances to the existing channels. This requires assigning the existing products to certain channels.

 **Attention:** Products not included in the list will not be assigned in the preparation.

As many products as desired can be assigned to each channel (for example glucose from various manufacturers), but each product may appear in the list only once.

#### 4.7.4 IMF

Compounders from the company IMF also work through the preparations independently. A file is likewise created in BD Cato™ TPN and sent to the compounder as an order. But in contrast to the EM2400 described above, the channel assignments from BD Cato™ TPN are adopted and must therefore be adjusted. Unlike the compounder described above, these assignments cannot be modified at a later time.



Channel	Preferred products	Del
1	GLUCOSE 60% w/w, GLUCOSE 10%, GLUCOSE 5%	Del
2	RED TRACE Inf. Inf.	Del
3	FRUMENTUM 10% w/w	Del
4	NATRIUM CHLORID PRES. 1M Amp.	Del
5	KALCIUM CHLORID 1M PRES Amp.	Del
6	CALCIUM GLUCONAT 10% S. ORALIN Inf. Inf.	Del
7	GLUCOSE -1-PHOSPHAT 1% Amp.	Del
8	MAGNESIUM SULFONDIUM CH. Amp.	Del
9	VITAMIN D 1000ER KANZ. Inf.	Del
10	OMEGA 3EN PRESENUS 10% Emulsion Inf.	Del
11	PROPOFOL PRESENUS 1% Emulsion Inf. Inf.	Del
12	AGLAADIN Inf.	Del

**Designation:** Give the compounder a name that uniquely defines it. This designation will then be shown under **Set up preparation**.

**Compounder type:** In this case, select *IMF*.

**Preparation site:** A supplemental module from BD Cato™ TPN permits operations at geographically distinct preparation sites that also have separate stock keeping. If this module is activated, you will have the option here to tell the system where the compounder should work.

**Number of channels:** Number of channels of the connected compounder.

**Print labels after preparation:** Labels can be printed always, never, or when requested by the user.

**Network share:** A network path in which BD Cato™ TPN places a directory with activation files for the compounder's software. These files are imported by the control software and used for filling.

**Network share history:** Currently has no function and is implemented as preparation for return transmission of data.

**Blocked:** Prevents assignment under **Set up preparation** or permits no additional preparation on this compounder.

#### 4.7.4.1 List of Channels

In the **Set up preparation** program module, BD Cato™ TPN automatically calculates a quantity suggestion for the preparation and distributes the substances to the existing channels. This requires assigning the existing products to certain channels.



Attention: Products not included in the list will not be assigned in the preparation.

As many products as desired can be assigned to each channel (for example glucose from various manufacturers), but each product may appear in the list only once.

## 4.8 Hardware Configuration

Here special hardware can be defined, for example scales for gravimetric preparation, barcode scanners, and compounders.

See BD Cato™ TPN Installation Plan.

## 4.9 Internal Billing Prices

As already mentioned in the master data, BD Cato™ TPN provides an option of recording internal billing prices and of referring to these for various accounting purposes.

Internal prices can be entered for products, infusion solutions, empty containers and for additional articles and services. Registration of these prices can be undertaken in BD Cato™ TPN in various ways. The internal billing prices module can be reached directly via the master data forms or this module can be accessed via the **Administration > Internal billing prices** menu.

It is possible to create new internal billing prices, then they can be edited and deleted.

**Display prices of:** Filtering can be undertaken here according to products, infusion solutions, empty containers and additional articles and services.

**Display blocked products:** Determines whether blocked products are to be displayed as well or not.

**Designation:** Filtering for certain products can be undertaken in this field.

**VAT/sales tax:** The sales tax can be stated here and applies to all strengths of the product.

**From:** Is a mandatory field and determines the date from which the price applies. Via the *Calendar* icon, you can conveniently select a certain date in the calendar, which is then automatically adopted in the *From* field.

**Price:** Is a mandatory field and determines the price of a certain product.



## 5. TEMPLATES



Click the *Templates* button in the header or use the **Therapy** menu.

In BD Cato™ TPN, three different types of templates can be created.

**Therapy days:** Here you can store medical result-dependent templates for entire therapy days which can then be prescribed to the patients. These templates can be modified as needed when making a prescription.

In the therapy day templates, templates for standard bags and 24h medications (see below) as well as enteral administrations can also be stored for the planning.

**Standard bags:** For the documentation of many standardized products that are held in stock and are assigned to the patients as needed. These mixed bags can then be either prepared internally or purchased ready to use.

**24h medications:** Co-medications that, although they have nothing to do with the actual nutrition, are still considered in the total volume of a therapy. On the other hand, they may also contain nutrition-relevant parts (for example dilution with glucose or NaCl).

### 5.1 24h Medication Templates

These medications can be viewed as a type of pool for the individual therapy plan. This can ensure, for example, that an unsuitable diluent is not mistakenly assigned. To make it easier to work in the actual therapy plan, you can also enter a designation that can be used for search purposes in the therapy day.

If the corresponding tab is marked, a list of the existing templates will be displayed. Buttons for the following functions are located below the list:

- Create new template
- Edit and change existing template
- Delete template from the list

#### 5.1.1 Creating New 24h Medication Template

This input form appears:

**Designation:** As previously mentioned, any desired designation can be entered. If nothing is entered, the designation displayed in the search lists will be comprised of the components of the medication. Therefore, entry of a designation is not mandatory.

**Product:** Here a selection can be made from the list of all saved liquid products and dosage forms. Dosages can be either in milliliters or in the units saved for the product. The amount can be stored as an absolute value or as a reference to a medical result value (for example weight of the patient); since the medication can ultimately be prepared for individual patients.

Of course, only an absolute final volume can be prescribed.



Use the Plus key to add more lines for additional products; use the red X to remove lines.

As a result, as many products as desired can be mixed.

The indicated vehicle (*fill up with*) is always assumed to be a *q.s. to*-filling. If, for example, glucose or NaCl is used, the nutrition-relevant data will be added to the overall view of the therapy day (see Therapy days section).

**Container:** Here you define the container into which the mixture will be filled. In the list, container designations alone (*Bag*), with material (*Bag PVC*), and as a specific product (Bag 1000mL PVC Baxter) are available for selection. Depending on this, a specific bag will be suggested (or not) when a preparation is set up.

**Overfill:** To cover for the possibility of greater needs and/or account for long feed hoses for the required amount, it is possible to specify an overfill amount (as absolute amount or in percent). This makes it easy to have amounts that are ready for preparation or administration on hand at all times. A minimum volume can also be saved for these medications under **Administration > Settings**, so that a warning will be triggered if the amount is not met.

The additional catheter can be defined only in the therapy day and is explained there.

Route and duration of the administration as well as a guaranteed stability of the final product, which will be printed onto the preparation label, can be entered under the link for the administration specifications.

Click the *OK* button to save the template in the database.

### 5.1.2 Editing 24h Medication Template

Re-open the entry form by double clicking a template in the list or by pressing the *24h medication template* button.

All fields are available for changes because once the medication is prescribed, it is no longer connected to the template.

### 5.1.3 Deleting 24h Medication Template

If a template is no longer needed, it can be easily deleted from the list. Use the corresponding button for this.

## 5.2 Standard Bag Templates

### 5.2.1 Displaying and Editing Standard Bags

After selecting the corresponding tab, the existing templates are shown in a list. Similar to the 24h medication templates, double click or use the *Edit standard bags* button to open and edit the template.

Unlike the medications, these can **no longer** be modified once a therapy plan has been completed through the use of this template because otherwise the prescribed amount may deviate from the actual amount.

### 5.2.2 Creating New Standard Bag

A new template can be added using the *New standard bag* button. First a form appears that gives the user the option of basing the new template on an existing one. For example, if a product already in use is switched, this makes it very easy to create a template that is otherwise the same.

Then an input form will open:

This form corresponds to the entries for 24h medications so the user's procedures are as much the same as possible. However, some fields have no function. The description takes this into account.

**Designation:** Enter the desired designation for the template.



**Barcode:** Used for barcode identification, if present.

**Anticipated weight:** When using a gravimetric check at the end of the preparation, it can be compared to this weight. The specification is shown on the preparation instructions.

**Energy:** Displays the calculated energy value.

**Block:** Removes the template from the selection list for therapy plans.

**Product:** Here a selection can be made from the list of all saved liquid products and dosage forms. Dosages can be either in milliliters or in the units saved for the product. This amount can be saved **only in absolute values** and not with reference to a medical result, since the bag is not prepared for an individual patient. In other words, it does not matter whether the dose is entered into the *Amount per* or *Amount abs* field.

  Use the Plus key to add more lines for additional products; use the red X to remove lines.

**Container:** Here you define the container into which the mixture will be filled. In the list, container designations alone (*Bag*), with material (*Bag PVC*), and as a specific product (Bag 1000mL PVC Baxter) are available for selection. Depending on this, a specific bag will be suggested (or not) when a preparation is set up.

If necessary, an overflow and a stability can also be specified for the standard bag. In contrast, the additional catheter and the administration specifications can be defined only when planning a specific therapy.

### 5.2.3 Deleting Standard Bags

A template can be removed from the list with the *Delete standard bag* button. A security query will be performed:



Here as well, if the template has already been used for a therapy, it can no longer be deleted (this time for documentation reasons).

## 5.3 Therapy Day Template

A therapy day template is a plan for what is ultimately a complete therapy day for an individual patient with parenteral and enteral nutrition portions as well as oral and other medications. For example, special templates can be created for premature infants in various stages of development and then prescribed to patients with these needs. This greatly simplifies entries for therapy cases (see *Therapy Days* on page 71).

### 5.3.1 Creating New Therapy Day Template

Use the *New template* button to create a new template. The following input form will open:

Planning the Therapy Day:

To make as much information as possible available when it is needed yet remain well-organized, the form is divided into several parts which show or hide various additional information as necessary.

### 5.3.1.1 General Information

**Designation:** Name the template whatever you prefer. This designation will later be shown for selection in the therapy plan, so it should be as clear as possible for users who will later encounter it (for example premature infant <1000g, growth phase).

**Nominal volume:** Enter the value for the nominal volume (this is mandatory!). In the individual therapy day a check will see if this volume has been exceeded or not reached. In the template itself, the value can be checked only if all dosages are specified the same (meaning all per kg or all absolute). Accordingly, the actual value can also be calculated or not.

Whether or not osmolarity and glucose concentration can be checked or not also depends on this. All of these fields are then also displayed for a therapy day and are filled there, since the medical result data for the patient will also have to be present.

### 5.3.1.2 Check Values

In addition, standard values for energy, carbohydrates, proteins, fats, and the electrolytes defined in the *Settings* can also be stored. These values will be checked at a later time when the template is used for a patient. In other words, unlike the maximum values in the master data of the products, special values for certain groups of patients can be stored here.

To enter the values, click the blue link *Edit* at the right in the light gray line.

Enter the target values in the following units:

- Volume: mL/kg/day
- Energy: kcal or kJ (depending on the setting)/kg/day
- Carbohydrates: mg/kg/minute
- Protein and fat: g/kg/day
- Electrolytes/trace elements: depending on the setting

### 5.3.1.3 Parenteral

In the center section, the individual products can be selected and dosed. Unlike the standard bags, it is possible to set dosages not only in absolute values, but also based on a medical result, such as body weight. Depending on this, a final volume may be displayed, or not.

The corresponding target values of the template can be displayed here only if all components are dosed according to body weight. The concentration of glucose does not yet have an effect because no catheter has yet been assigned (see the planned therapy day for information).

The *nutrient groups* known from the master data are displayed initially. To assign products to this group, click the *Plus* in front of the group designation to open an input field:



Entry proceeds in the same manner as with the medication templates, although the products are filtered to show only members of the respective group.



To assign more than one product or to delete an unnecessary entry, use the buttons located to the right of the line or the "+" in front of the nutrient group heading.

In this way, the template can be filled with all planned products.



To calculate the volume or calculate the active ingredient amount from the volume, you must always work with unambiguous products in BD Cato™ TPN. In other words, even if an active ingredient is prescribed (for example calcium in mmol), the specific product with which it shall be added must also be clear. For this reason, the product designations are always given in parentheses.

In the lower section of the form, the solution can now be divided into as many containers as desired in order to avoid stability problems, for example.



Depending on the quantity of final containers used, numbered columns with radio buttons will appear on the side. To assign individual components to the desired containers, activate the radio button in the corresponding column.

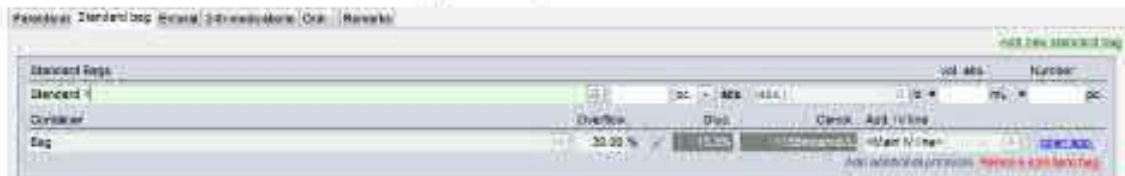
Furthermore, after opening the link *Open adm.* the following parameters can be entered: Administration route (from the list of *Possible administration routes*), administration duration, flow rate and stability of the end product.

**Overfill:** To cover for the possibility of greater needs and/or account for long feed hoses for the required amount, it is possible to specify an overfill amount (as absolute amount or in percent). When there are different starting amounts, this makes it easy to have amounts that are ready for preparation or administration on hand at all times.

#### 5.3.1.4 Standard Bags

Ready-made standard bags (purchased or prepared in-house) can also be used for planning of the therapy days. Use the green link *Add new standard bag* for this purpose. The corresponding content will be displayed under the input form and adopted into the overall calculation.

The amount can be entered as units, per mL, and with or without reference to medical results:



Several such administrations can be stored for planning of the day. The products contained therein are listed below.



Make sure that the appropriate templates are actually stored here (see above). This is the reason why, once assigned, they may no longer be changed because something would change here without being seen.

Use the red link *Remove standard bag* to delete a mistakenly inserted entry.

#### 5.3.1.5 Enteral

One of the special characteristics of BD Cato™ TPN is that even enteral administrations are taken into consideration to enable the most precise nutritional planning possible. Enteral administrations are planned in this section of the input form. Of course, this is only a suggestion that can be later deactivated in the therapy plan as desired.

Nevertheless, it makes sense to save plans here for example for 50% enteral nutrition because the corresponding limit values can also be entered, which will vary depending on the proportion of enteral administrations.

Enteral administration can be planned for several times each day.

Only those products that are marked as enteral in the master data are available for this purpose.

### 5.3.1.6 24h Medications

The concomitant medication can also be included in the template. But since it is usually assigned within a patient context, there is a separate template manager (see above), which can also be accessed here. Either templates or individual medications can be entered.



Unlike the standard bags, the medication's template is assigned here, but stored as an independent medication. Therefore, any change to the 24h medication template will have no effect on medications in the therapy day templates or even in planned therapy days.

### 5.3.1.7 Oral

Oral medications can be planned here:

The entry is not different in principle, but there are differences:

- Oral products can be prescribed in units.
- In the administration data, dispenses for morning/afternoon/evening and night can be entered.
- Oral medications are not considered for the total energy value, since this value is calculated by volume.

### 5.3.1.8 Remarks

Finally, free text of any length can be entered here.

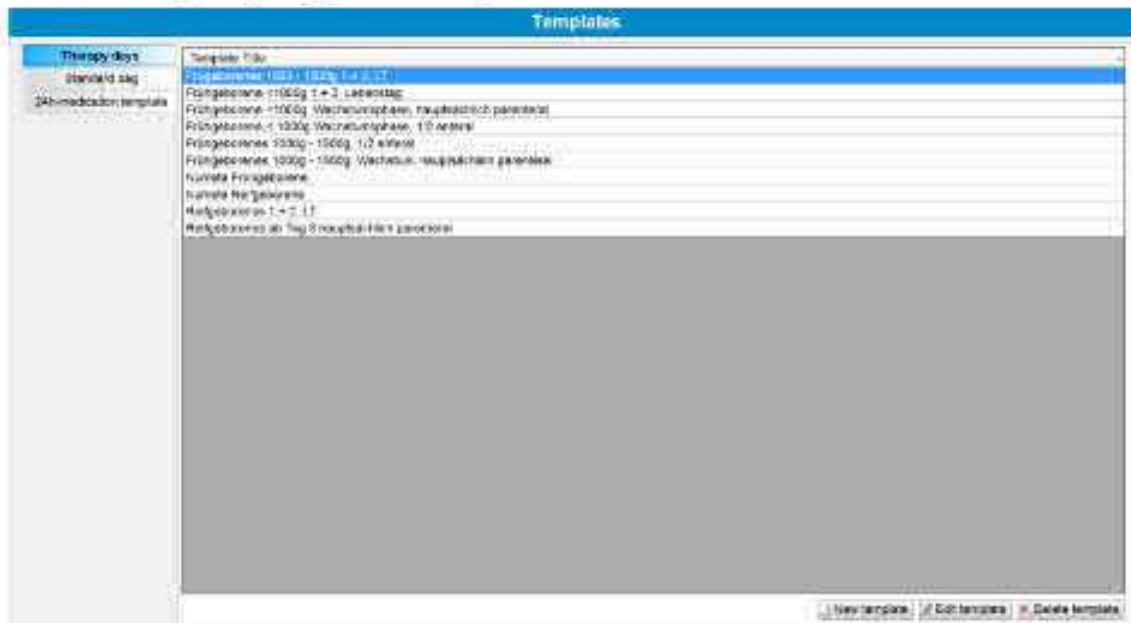
### 5.3.1.9 Saving a Template

To save a template, use the buttons at the lower right of the screen:

Click *OK* to save the template in the database or *Cancel* to discard all previously made entries.

### 5.3.2 Displaying and Editing Therapy Day Templates

All existing templates are displayed in the overview. They can be opened and modified by double-clicking or by using the *Edit template* button.



### 5.3.3 Deleting a Template

A template can be removed from the list with the *Delete template* button. A security query will be performed.

## 6. PATIENTS

Patient data compilation is the first step in commencing every new therapy. To do this, change to the **Therapy > Patient Data** form.

Searches can be made not only according to name but also according to social insurance number and patient number. There is also the option of simplifying searches by using barcodes.

To simplify searching for data records or difficult patient names, there is also the option of filtering by entering a date of birth.

### 6.1 Maintaining Patient Data

Due to the technological progress, in most hospitals patient data is maintained using a central system. In this case all relevant data is transferred to BD Cato™ TPN via an interface (in most cases HL7) and can then only be edited to a limited extent.

However, there is always data that is not maintained or the users want to create additional test patients who are not saved in the HIS. For these cases go to the **Patient data** form in the **Therapy** menu.

The master data form corresponds to the usual structure in BD Cato™ TPN (see *Master Data* on page 7) and has general data fields and several tabs for data entry.

As opposed to other data records, patient data cannot only be scrolled in alphabetic order, but also by social security number or patient number.

Depending on the settings (see *Settings* on page 39) it is mandatory to fill different fields (last name and first name are always mandatory):

- Date of birth
- Social security number
- Insurance number
- Address

For patient data it is even more relevant than for other master data that treatments are concluded at some point, but need to remain in the system due to documentation reasons. To reduce the content displayed in search lists, two checkboxes can be used that are available for most search lists of patient names:

**Deceased on:** Can be entered including a date.

**Blocked:** Only removes the patient from search lists.

### 6.1.1 Unit Assignment

Unit name:	Test: Unit name	Chief phys.:	Test: Chief phys.
Cost center:	Test: Cost center	List no.:	Test: List no.
Preparation site no.:	Test: Prep. site no.	LANP:	Test: LANP
Type:	<input type="radio"/> Unit <input type="radio"/> Outpatient unit <input type="radio"/> Oncological practice	Phone:	Test: Phone
Reprinted as:	<input type="checkbox"/> Place of delivery <input type="checkbox"/> Cost center <input type="checkbox"/> Blocked for assignment		

All unit assignments of the patient to date and currently in place appear in this list. Especially with accounting it is essential that not only the patient's current unit assignment is saved, but also all other previous assignments. If the patient changes the unit, a new list entry must be added. By entering the assignment period, the patient should be attributable to a unit at any point of administration. Determining the time of day is not essential.

If required, it is also possible to determine the place of delivery or the cost center of a medication directly with the medication and therefore to skip the unit assignment.

If a new entry is added, BD Cato™ TPN automatically adds the *Until* column of the preceding entry.

### 6.1.2 Cost Unit Assignment

Only displayed for users of the **Cost Unit Accounting** module and described in the respective manual.

### 6.1.3 Case Assignment

This table can only be filled via an interface.

Patient data are very often transferred from a leading HIS to BD Cato™ TPN via an interface (for example HL7). BD has a lot of experience with integration into existing software solutions and would be happy to advise you with regard to an individual solution, for example transferring

- Patient data
- Unit assignment
- Cases
- Diagnoses
- Laboratory data

### 6.1.4 Address

As mentioned above, filling these fields may be mandatory.

**Appointment reminder:** BD Cato™ TPN offers the possibility to remind patients of appointments via e-mail. To be able to utilize this function, special add-on licenses and interfaces are necessary.

**Send appointment reminder to:** Activates or deactivates the appointment reminder.

### 6.1.5 Comments

Internal comments can be entered in this field regarding the patient concerned.

## 6.2 Medical Results

Medical results can be assigned to a patient in various ways in BD Cato™ TPN:

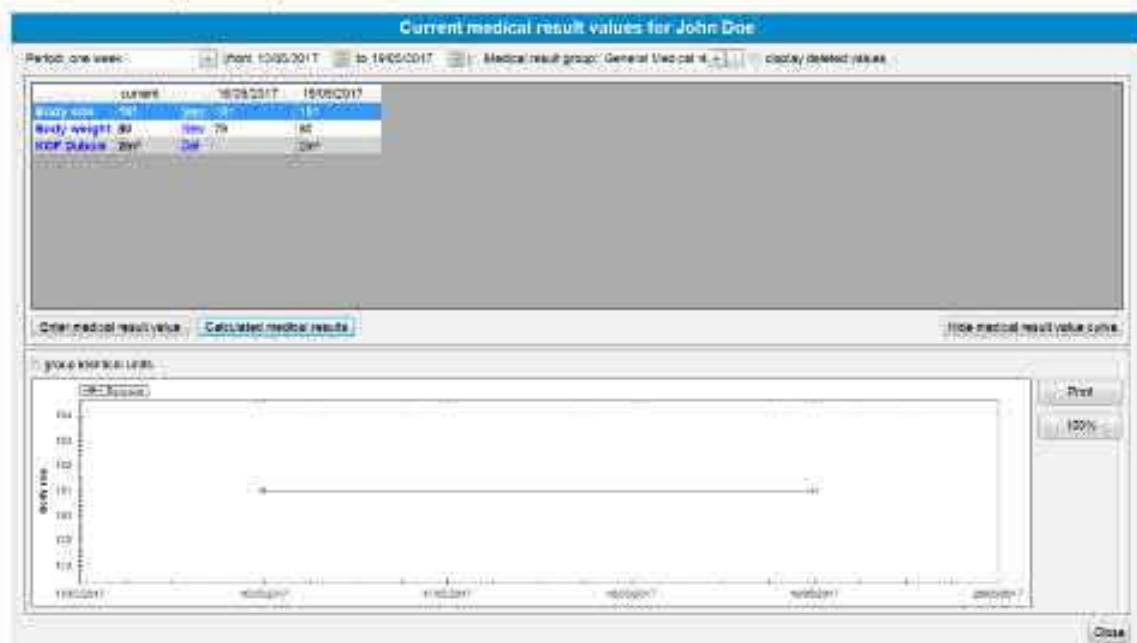
- Directly via a link in the patient form
- In the therapy plan via a corresponding tab
- In the medication form via a link

That way it is possible to access the medical results at any time for verification.

On the basis of the values entered (body weight, body surface area, etc.) and the calculated medical results derived from this (for example body surface), subsequently

- usual dosages can be undertaken
- maximum dosages can be checked for each result (for example body surface)
- cycle postponements can be suggested (for example due to problems with the leukocytes)
- dose adjustments can be suggested (for example blood readings or also due to age)
- warnings can be generated if any deviation from the marginal values is detected.

As described in chapter *(Possible) Medical Results* on page 12, BD Cato™ TPN differentiates between measured medical results (body weight, body height, etc.) and calculated medical results (for example, body surface).



The values of the measured medical results can now be displayed, entered and edited in this form. Calculated medical results that are used in the therapy plan are all automatically

displayed in the list. Additionally, you can enter all those values of the patient that you want to keep constantly in view for dose calculation. It is however not necessary to enter any medical results here in order to be used for dose calculations!

To limit the displayed data and gain a better overview of them, some filters can be used:

**Period:** By entering a certain period, the values displayed can be filtered according to the dates they were entered. The default setting for the period for displaying medical results is one week. This default setting can be changed in the settings of BD Cato™ TPN.

**Medical result group:** This filter enables limiting the data displayed to a certain group of medical results.

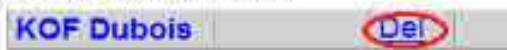
### 6.2.1 Current and Expired Medical Results

When saving a *Possible medical result* (see *(Possible) Medical Results* on page 12) a *Permissible age of medical result in days* (from measuring or date of entry) can be determined for measured medical results. After the expiration of this period, the measured medical result is no longer valid. Expired medical results remain available as a history, but no value will be shown in the *Current* column.

	current	16/05/2017	19/05/2017
Body size	181	New 181	181
Body weight		New 79	80
KOF Dubois		Del	2m <sup>2</sup>

Calculated medical results can only be determined on the basis of current (valid) measured medical results. Therefore, if not all measured medical results that are required for calculation are available with current values (as shown in the example above with body weight), then no results are displayed.

After adding a current value for body weight, the calculated medical results are automatically updated. If a calculated value shows up in the list, which is of no interest, it can be hidden to maintain good visibility. Use the *Del* link for that.



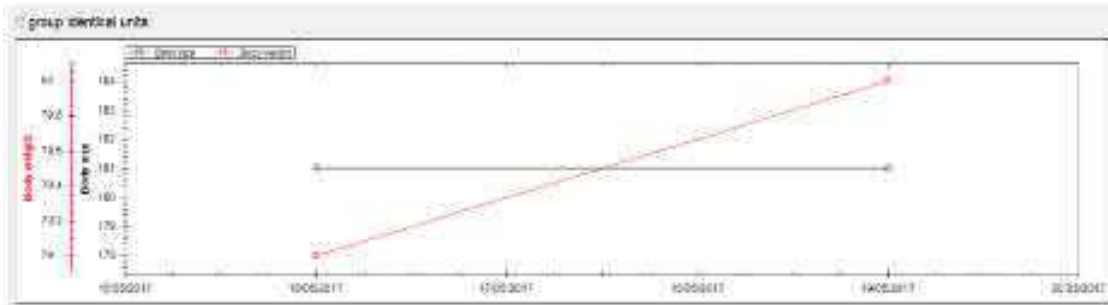
### 6.2.2 Entering and Editing Medical Results

If you click *New* in the row, a window opens for entering a further value of the selected result, while additional medical results can be entered in the list by using the buttons for *Enter medical result value* or *Calculated medical results*.

Double-clicking an existing value allows this to be edited further and canceled (see further below).

### 6.2.3 Medical Result Graph

In the lower part of the form the corresponding development of the values is shown as a graph. If several values are selected, then several graphs can be shown concurrently for comparison purposes.



If many different medical results are shown in the list, then the graph can also be hidden, so that all entries can be seen. It is possible by using the mouse (by drawing a square over a certain area) to enlarge certain parts. By clicking the *100%* button on the right side next to the graph, you will be redirected back to the original graph overview. There is also the option of printing the graph so as, for example, to include it with a medical record.

#### 6.2.4 Canceling a Medical Result

By double-clicking a value in the list, a separate form will be opened in which a result value can be overwritten. If you wish to overwrite a result value, then enter the new value and click *OK*. If you wish to cancel the result value and do not wish to enter a new value, then click the *Cancel* button.

To display canceled values in the overview of medical results, the *Display canceled values* checkbox must be selected. These are then identified as canceled values in the list by square brackets.


[84] 84,5kg

#### 6.2.5 Preliminary Medical Result Data

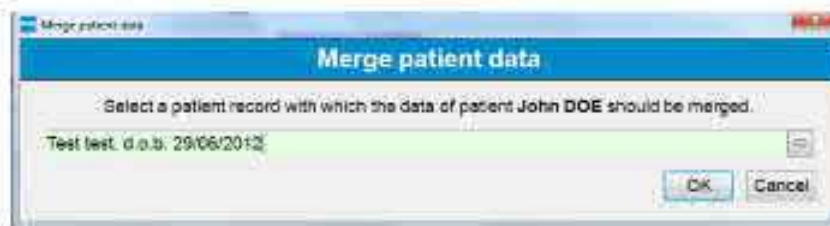
Especially when using interfaces it can often happen that a medical result is available, but that a definite confirmation is still expected. In such cases, these values can be identified as *Preliminary* (or this identification is automatically set with the interface). The corresponding value will be displayed in gray color and in italics; a point in the chart will be marked with a red X. The appropriate marking can be removed again in the *Edit* form (double-click the entry).

### 6.3 Merging Patient Data

For various reasons it can occur that a patient is unintentionally entered into BD Cato™ TPN several times and that these data have to be summarized into one data record.

To carry out this step, you must open the **File > Merge With Another Patient** menu item or use the  icon.

You will then see the following form, in which you can search for the data record with which you can merge the already opened patient record.



Confirm this step with *OK*. A warning will appear asking if you are really sure that you wish to carry out this step.

The data of the merging patient (including all diagnoses, therapy plans, medical results, etc.) are transferred to and *merged* with the other patient's data. The therapy plan sheets will, however, not be compiled into one, but both assigned.

## 6.4 Report Patient List

A report of patient data can be called up via the printer icon. For additional information about this report please refer to the chapter *Patient List* on page 34.

## 7. THERAPY DAYS

### 7.1 Overview

Now that we have learned how patients and therapy templates can be created, we turn to creating actual therapies that are adapted to specific patients. In this program module, therapy days for 24h can be planned, edited, and released for preparation. Once created, these plans can no longer be modified.



BD Cato™ TPN is therefore a tool for planning and preparing TPNs and is not designed for documenting the administration of these therapies.

Click the *Therapy days* button in the header or select the corresponding entry in the **Therapy** menu.

You will first see an overview in which all entered therapy days are displayed according to the search criteria. When the form is opened for the first time in a day, all therapies planned for this day will be listed, but the list can also be filtered or expanded according to the following criteria:

**Name** (or Social sec. no. or Pat. no.): Selects a specific patient and sets the time filter to <unlimited> to display all the patient's therapy days.

**Unit:** Only the patients of a particular unit or all accepted outpatients or inpatients will be displayed. For users who may only see their "own" patients, this filter can be set to display only "own units" (see *Creating and Maintaining Users* on page 36).

**Status:** The medications can be entered planned and then (depending on permission) be physician- and/or pharmacist-verified at a later time. Finally, they are prepared. The currently set status is displayed at the right in its own column (additional information on the various statuses can be found in chapter *Planning the Therapy Day* on page 73). The filter limits the results to one of the statuses, for example you can choose to see only *planned* to determine how many therapies must still be verified.

**Period:** Time period within which prescribed therapy days shall be displayed. You can choose from a selection list (for example *this week*), or enter any desired time period.



Once a filter option has been changed, the *Refresh* button will turn orange and must be confirmed to reload the list.

The list itself shows in each line:

- the name of the patient (last name in all uppercase letters, first name below last name)
- the planned date of administration
- the individual medications that are contained therein (each on one line). These may be:
  - enteral administrations
  - parenteral administrations to be prepared individually
  - standard bags



*Canceling Therapy Days* on page 79). However, it is possible to reorder individual products (see *Reorders* on page 80).

In the lower section of the form, the patient's medical results that were marked for dosage determination in BD Cato™ TPN are displayed. If no value is present or if the allowed age of the medical result is exceeded (see *(Possible) Medical Results* on page 12), no value will be displayed and a new entry can be made directly into the entry field.

However, it is also possible to change medical result data directly in this form. To do this, select *Re-measured* at the corresponding value. BD Cato™ TPN now allows an entry into the corresponding field; the value is automatically saved in the database.

Clicking *OK* confirms the data and then BD Cato™ TPN generates a therapy day based on this data. The form is largely the same as the form that we know from creation of templates. But now patient data are available, so all fields can be filled appropriately.



The description focuses on the differences from the template. Therefore, it is essential that you work through this chapter first.

If a medication shall be generated without a template, this form will be empty and you can enter the desired parameters similar to chapter *Creating New Therapy Day Template* on page 60.

## 7.2.1 Planning the Therapy Day

To make as much information as possible available when it is needed yet remain well-organized, the form is divided into several parts which show or hide various additional information as necessary.

### 7.2.1.1 General Information

**Patient information:** The patient's name, age, and unit association are shown in the header bar.

**Template used:** If the therapy plan is based on a template, its designation will be shown here.

**Nominal volume:** Enter the value for the nominal volume. The actually prescribed volume will be shown next to it and adjusted with each entry. This way it is checked to see if this amount

would be exceeded, or not reached. The data is augmented by a percentage that turns red if the permitted volume is exceeded. The entry can be in mL/kg or as a total volume.

The values for osmolarity and glucose concentration are always based on an administration of all correspondingly marked liquids simultaneously through the specified main catheter (see *Tab Line* on page 74) and likewise change the color if the limit values of access are exceeded (see master data).

### 7.2.1.2 Check Values

The following total values are also calculated immediately with each entry and (if associated data are available) percentage deviations from the standard values:

- energy
- carbohydrates, proteins, and fats
- the electrolytes defined in the **Settings**

In addition, a tooltip that separates the data for parenteral and enteral administrations, and also contains the concentration per liter, is displayed. To change the values or jointly compare them, click the blue link *Edit* at the right in the light gray line:

	Energy	91.33 kcal/kg/d	Carbohydrate	3.30 mg/kg/min	Protein	1.00 g/kg/d	Fat	1.49 g/kg/d		
parenteral:		90.96 kcal/kg/d		3.25 mg/kg/min		1.00 g/kg/d		1.48 g/kg/d		
enteral:		0.37 kcal/kg/d		0.05 mg/kg/min		0.00 g/kg/d		0.01 g/kg/d		
Standard values:		1 kcal/kg/d		1 mg/kg/min		1 g/kg/d		1 g/kg/d		
Difference:		unknown		unknown		unknown		unknown		
<b>Electrolytes</b>										
	Na	4.18 mmol/kg/d	K	2.75 mmol/kg/d	Ca	1.25 mmol/kg/d	PO4	2.25 mmol/kg/d	Mg	0.40 mmol/kg/d
Standard values:		4 mmol/kg/d		3 mmol/kg/d		1 mmol/kg/d		2 mmol/kg/d		0.5 mmol/kg/d
Difference:		unknown		unknown		unknown		unknown		unknown

The values will be checked in the following units:

- Energy: kcal or kJ (depending on the setting)/kg/day
- Carbohydrates: mg/kg/minute in 24h
- Protein and fat: g/kg/day
- Electrolytes/trace elements: depends on the setting (here mmol/kg/day).

### 7.2.1.3 Tab Line

Here you can switch between the various forms described below.

In addition, there are two input or information fields:

- Main catheter

Use the blue link to set or edit a main catheter.

BD Cato™ TPN considers a main catheter to be the access point into which all parenteral solutions connected for example by T-pieces will ultimately be delivered. If there are separate access points, they can still be separated at the individual containers (see further below).

You can choose from the list of catheters stored in the master data. The calculation fields for osmolarity and glucose concentration will then be checked with respect to the data stored there (see above).

- Medical results

Use this button to switch to the medical result data of the patient whenever needed.

### 7.2.1.4 Parenteral Tab

Entries are made similar to the template.

However, medical result data must be present if a calculation must be performed.

Another difference from the template: In a specific therapy, the function for filling up the daily volume to 100% with Aqua can be activated. This is always displayed in the group of carbohydrates because in most cases the glucose shall be diluted as much as possible:



Since the products may contain, in addition to the primary active ingredient, other active ingredients (for example glucose phosphate with PO but also Na and glucose) the dose input fields always have a tooltip that will display the hidden values.

In the lower section of the form, the solution can be divided into as many containers as desired in order to avoid stability problems, for example.

The user can also decide whether all solutions will be administered through the main catheter (see *Tab Line* on page 74) or through several individual access points. In this case, glucose concentration and osmolarity are calculated per container and deducted from the main catheter.

A warning may appear, as with the main catheter.

Depending on the quantity of final containers used, numbered columns with radio buttons will appear on the side. To assign individual components to the desired containers, activate the radio button in the corresponding column.

It is also possible to mark individual components within a container as *ext.* (external). This means that these components shall be injected only at the unit and are skipped during preparation. For this reason, they also do not appear in the preparation instructions.

However, deviating labels are printed automatically which note the absence of the components or are intended for the external product:

<b>Sample, John (1,34kg)</b>		Pat. # 49009
d.o.b. 20/11/1966	Sec. Sec. # 1116290678	<b>KI - IMC-Station E12</b>
Glucose 10% 70.00mg / 105.00mg	Aqua db inj. 15.00mL / 22.50mL	
Inject: 40ml (Prescribed 20ml)		
Prescribed energy value: 1234kcal		

Administration: ADM: 23.04.2011, i.V. over 24h (22.3ml/h)  
IV line: peripher

Inject into med. no. 3 prior to administration

Best before: 22.12.2012      Prep.: 21.12.2012

Furthermore, after opening the link *Open adm.* the following parameters can be entered: Administration route (from the list of *Possible administration routes*), administration duration, flow rate and stability of the end product.

**Overfill:** To cover for the possibility of greater needs and/or account for long feed hoses for the required amount, it is possible to specify an overfill amount (as absolute amount or in percent). When there are different starting amounts, this makes it easy to have amounts that are ready for preparation or administration on hand at all times.



In case of relative overfilling, a form can also be called up through this icon in which the overfilled values required during preparation can be viewed and adjusted. Dosages will then be recalculated as appropriate.

currently prescribed volumes in container	Actual volumes to
Glucose (GLUCOSE 50%): 1162000mg = 2304mL + 22.63% = 2825.67mL	2825.67 mL
Aminosäure (AMINETA 6.13% E): 240g = 7741.94mL + 22.63% = 9494.19mL	9494.19 mL
Säureelektrolyt (PEDITRACE Inf.ig.): 80mL = 80mL + 22.63% = 98.11mL	98.11 mL
Calcium (CALCIUM GLUCONAT 10% B.BRALIN Inf.ig.): 80mmol = 353.99mL + 22.63% = 434.1mL	434.10 mL
Phosphat (GLUCOSE -1-PHOSPHAT 1M Amp.): 30mmol = 90mL + 22.63% = 98.11mL	98.11 mL
Vitamine (SOLLVIT Trauset. Inf.): 180mL = 180mL + 22.63% = 196.21mL	196.21 mL
Vitamine (VITALIPID f. KINDER Kurz z.Inf.): 320mL = 320mL + 22.63% = 392.43mL	392.43 mL
Aqua (AQUA AD Inf. ig.): 80mL = 80mL + 22.63% = 98.11mL	98.11 mL

### 7.2.1.5 Standard Bags

Ready-made (purchased or made in-house) standard bags can also be used for planning of the therapy days. Use the green link *Add new standard bag* for this purpose. The corresponding content will be displayed under the input form and adopted into the overall calculation.

The amount can be entered as units, per mL, and with or without reference to medical results:

Use the red link *Remove standard bag* to delete a mistakenly inserted entry.

Prescribed standard bags are further documented with the **Dispense** module.

### 7.2.1.6 Standard Bag Extensions

In the therapy plan, additional products can be assigned or the contained amounts of individual products can be increased for a selected standard bag. If this is the case, during the preparation

the standard bag will be displayed as the container, appropriately filled, and its own labels printed.

Click the link *Add additional products* to open a corresponding input form:

All products, with the contained amounts, of the selected part of the standard bag will be displayed. If, for example, only a half bag is prescribed, only the amounts of a half bag will be displayed. These can now be increased up to the nominal value (also valid for one half bag). This eliminates the need to laboriously calculate the required amounts if only one portion of the total solution shall be administered.

Below this list the user has the ability to add any desired products. Here as well, the desired final amount, calculated according to the total amount that will ultimately be administered, shall be entered as the dose.

Continuing with our example, if only half the bag shall be administered in total, but the amount of calcium (therefore only 1 mmol) remains the same, it will be sufficient to enter the required 2 mmol. BD Cato™ TPN then independently calculates how much solution must be added to obtain the desired amount while administering only half of the total solution.

After clicking *OK* to save, the increased volume will be calculated and referenced for the overall view.

The added amounts will be printed on additional labels after preparation.

In the therapy day view, these bags are specially identified with the entry *[extended]*:

Patient	Date	RO	Day
DOE John	20/05/2017		NUMETA G 13% E (20mL = 0.07 pcs.) (18.2kCal)
DOE John	19/05/2017		85 Multivitamin-Glasbeugung 1ml (0.09kCal) Reg. 11119.50ml (7100.19kCal) NUMETA G 13% E (extended) (158.87mL = 0.5 pcs.) (136.9kCal) 24 Int. HEPARIN IMMUJNO 1000 IE/ml DFL (R) 3840INTL units; GLUCOSE 5% 4.16mL

### 7.2.1.7 Enteral Administrations

One of the special characteristics of BD Cato™ TPN is that even enteral administrations are taken into consideration to enable the most precise nutritional planning possible. Enteral administrations are planned in this section of the input form.

Enteral administration can be planned for several times each day.

Only those products that are marked as enteral in the master data are available for this purpose.

### 7.2.1.8 24h Medications

The 24h medications are entered following the same procedure as for the templates.

### 7.2.1.9 Oral Medications

Oral medications can be entered here. Use the green link *Add oral medication* for this purpose.

Please note:

- Oral products can be prescribed in units.
- In the administration data, dispenses for morning/afternoon/evening and night can be entered (of course, the two entries must correspond with each other).
- Oral medications are not considered for the total energy value, since this value is calculated by volume.

### 7.2.1.10 Remarks

Here a free text with any amount of characters can be entered.

### 7.2.1.11 Administration Dates

There are additional input fields for the planned date of administration at the bottom of the form. This day was actually entered previously, but can be changed here. Or, prescribe the same therapy for several days by making an entry into the *Until date* field. Of course, these later therapy days can still be edited individually.

### 7.2.1.12 Statuses

As previously mentioned, the therapy days pass through several statuses. It is not always necessary to actually pass through all of them, but here is a brief overview of the options:

- **Planned:** The therapy day has been created, but has not been checked by a physician or pharmacist or current medical result values are still expected. Planned therapies cannot be prepared or dispensed.
- **Physician-verified:** An authorized physician has checked the therapy and released it for further processing. The preparations are "ordered". Nevertheless, even physician-verified therapies can be neither prepared nor dispensed.
- **Pharmacist-verified:** The therapy has been released from a pharmaceutical perspective as well. The status can be set alone, or together with:
- **Preparation/dispense approved:** The final approval for preparation or dispense. When there are several preparation sites, this must also be set.

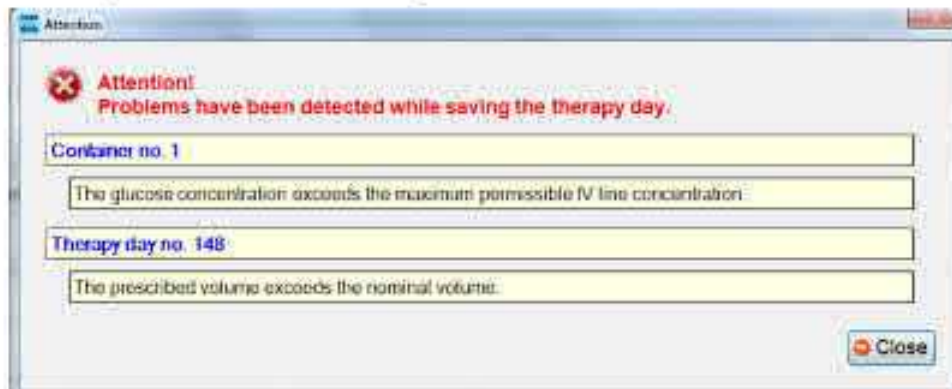
As mentioned at the beginning, if a therapy day is appropriately authorized, it can be entered directly as pharmacist-verified and released for preparation.

### 7.2.1.13 Saving a Therapy

To save a template, use the buttons at the lower right of the screen:

Click *OK* to save the therapy or *Cancel* to discard all previously made entries.

If the planning shall be saved, all parameters will be checked. Depending on the settings and any special rules, warnings may appear that either prevent saving (for example overwriting of the nominal volume) or can be skipped (exceeding the nominal value of carbohydrates). To create such rules, please contact BD directly.



Once all entries have been confirmed, the therapy plan will appear in the medication list in the selected status.

### 7.3 Editing a Therapy Day

To edit a therapy, you can click the *Edit therapy day* button or double-click the line in the list. You can also right click to open the context menu and then select the appropriate function.



However, a therapy day that has already been marked for preparation or has even been prepared already can no longer be edited.

An input form for the medical results will again open and then the form (possibly recalculated with new values). Editing then proceeds similar to *Create new*.

If a product is overridden by another product, BD Cato™ TPN will automatically delete the dosage of the old entry. But if only the dosage form is changed (for example from glucose 10% to glucose 60%) the dosage remains intact, although the calculated volume may change.

### 7.4 Setting Statuses via the Context Menu

The status of a therapy can also be set through the context menu, without opening the therapy day form. You can also select several days at once and confirm them together.

All of the checks that are performed when saving the therapy day will be performed on them. Therefore, all warning messages (overdose, special rules) will be repeated.

### 7.5 Deleting and Canceling Therapy Days

To delete a therapy day, right click to open the context menu and then select the appropriate function. Or click the Edit icon at the far right. The common Windows keyboard shortcut *Shift+Delete* works here as well.

Once prepared, a therapy day cannot be deleted so the documentation of the preparation remains intact. However, you can *cancel* it at any time.

A canceled therapy remains in the program for documentation and will be identified as such. Days with a "canceled" therapy plan can have a second therapy plan assigned to them (for

example if the patient's values deteriorate and a new therapy must be considered), otherwise BD Cato™ TPN prevents two plans for the same day.

## 7.6 Reorders

If (even only a portion of) a therapy day has already been prepared, nothing else can be changed in the original prescription because the overview calculations can then no longer be adjusted.

In addition, for security reasons a second therapy plan can also not be created for a therapy day for the same reason of the overall view.

However, if it is necessary to request something else for a "started" calendar day, use the *Reorder* function. This can be called up through the context menu (active only if a preparation has been started).

A normal input form will open in which everything can be prescribed in the same way as under *New therapy day*. However, the prescription date cannot be changed. A new line is saved to the therapy day overview, with the *RO* column highlighted.

Patient	Date	RO	Day
TEST test	27/07/2017	X	Bag: 5000mL (225.32kCal)
TEST test	27/07/2017		8x Muttermilch Oralösung: 1mL (0.68kCal) Bag: 779mL (3.54kCal) Perfusor: 5mL (0kCal) 24 hr.: HEPARIN IMMUNO 1000 IE/ml DFL



Please note that the data of the two therapy plans will not be added. There will not be any warning messages, for example due to joint overdosing.

## 7.7 Printing Therapy Days

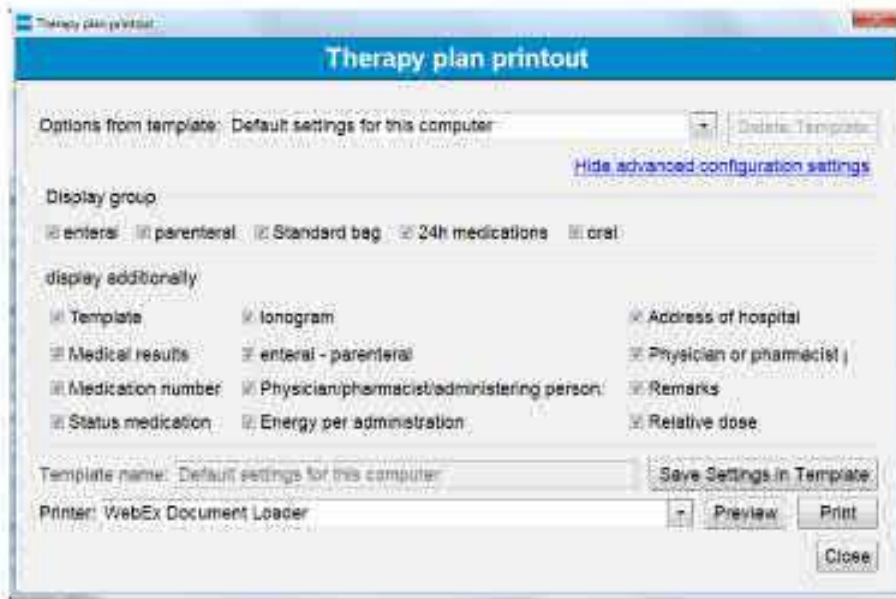
The *Print therapy day* button is below the list of therapy days.

A form opens in which a template (see below) and a printer can be selected. There is also a blue link that shows or hides the configuration options.

### 7.7.1 Creating Templates for Printout

Considering that a variety of user groups work with BD Cato™ TPN and individual operators have widely varying needs for printouts, we attempted to keep the therapy plan printouts as flexible as possible by providing the ability to show and hide various information.

Several different templates can be created for this purpose, with default settings for the logged in user (default only for me) or the work station (default for this computer), with names freely set.



7.7.1.1 Printout

This printout is also intended to be an aid when inspecting the administration of individual nutrition parts and contains certain fields for manual documentation as well as information on medical results of the patient, set catheters, and the ingredients of the bags:

TPN no.: 146 (Parent)

Patient <b>Doe John (Male): 5 kg</b>		Date of birth (age): <b>29.06.2012 (5,1 Years)</b>	
kg/m: 120kg/m	Körpergewicht (kg): 5kg (27.07.2017)	Kopfumfang: 50cm (27.07.2017)	Schwangerschaftswoche: 38/38 (27.07.2017)
Körpergewicht (g): 5000g (27.07.2017)	KOP Dubois: 0,24m <sup>2</sup>	Körpergröße: 50cm (27.07.2017)	KOP/Fläche: 0,25m <sup>2</sup>
Administration date: <b>27.07.2017</b>	Unit: <b>KI - NICU E10</b>	Total volume: <b>1000,00mL/kg = 5000,00mL</b>	parent in %: <b>100:0</b>
Main IV line: <b>peripher</b>	Gluc. main IV line: <b>(Unknown)</b>	Comp. main IV line: <b>(Unknown)</b>	
<b>Nutritional calculations:</b>			
total ene. g: 44.66kCal/gc	Carbohydrate: 7.8.ene/g gmm	Protein: 0.00ng/gc	fat: 0.00ng/gc
parental: 44.66kCal/gc	parenteral: 7.8.ene/g gmm	parental: 0.00ng/gc	parental: 0.00ng/gc
enteral: 0.00kCal/gc	enteral: 0.00ng/g gmm	enteral: 0.00ng/gc	enteral: 0.00ng/gc
Na: - K: - Ca: - PO4: - Mg: -			
Physician-verified by:		Pharmacist-approved by:	
<b>separate IV line: SK peripher</b>			
Parenteral:	5000,00mL (1000,00mL/kg) i.v. over 1 h (Pass-through rate: 5000mL/h)	Medico: 885	Planned
Total filling:	5010,00mL (incl. 10,00mL air-R)	Energy: 44.66kCal/kg = 223.32kCal	Gluc: 1.1%
Product	Quantity	Quantity abs.	vol. abs.
AQUAD N.I. Lsg:		3900,00mL	3900,00mL
GLUCOSE 5%	11,00g/kg	55,00g	1100,00mL
Physician-verified by:	Pharmacist-approved by:	Administered by:	

If **Remarks** have been entered for the therapy day, (see *Editing a Therapy Day* on page 79), these will be printed at the end of the printout.



## 8. SET UP PREPARATION

This program module is used to plan preparations, create parts lists and work instructions. Also, users who do not have a special preparation computer directly in the clean room can confirm finished preparations and print labels.

If compounder systems are connected to BD Cato™ TPN, interface files can be generated and sent for them in this program module.

Select the menu item in the main menu **Preparations** or click the *Set up preparation* button in the header. The following selection form will open:

The upper list contains all medications (that is those matching the filter criteria above) verified by the pharmacist. The lower list shows all medications already set up for preparation.

Click a column's heading to sort the entries; another click will invert the sorting order. The columns can also be dragged to another position using the mouse and can thereby be customized.

Medications displayed in white background have already been approved and can be set up for preparation. Medications that are displayed in gray color in the list are still waiting for approval.

If a medication is clicked the detailed data of the selected medication are displayed in the lower (yellow) part of the window:

### 8.1 Individual Parenteral Solutions

Set up manual preparation

Set up compounder preparation

One or more medications can be highlighted in the list. Then click the corresponding button, based on whether you will prepare manually or with a TPN compounder.

The particular characteristics of the various compounders are explained later in the description of each device. However, the general procedure is always as close as possible to the manual preparation.

For our example, three bags were compiled to create one preparation set. This means that the calculation of the required material for all three medications is performed and we assume that these medications will also be later prepared together.


Click the *Set up manual preparation* button.

### 8.1.1 Creating a Parts List

A list of all required products will appear with a suggestion suitable for the demanded amount.

Set up manual preparation			
Preparation identifier: 2822817242			
<b>PREPARATION</b>			
GLUCOSE 50% 300mg	14.9mL	14.9mL (27/07/2017)	[Edit]
HEPARIN MMMD 1000 IU/100mL (1000 IU/100mL)	3.0mL	3.0mL (27/07/17)	[Edit]
INSULIN 100 U/ml (100 U/ml)	10.0mL	10.0mL (28/07/2017)	[Edit]
SECACORON 100mg (100mg)	0.2mL	0.2mL (27/07/17)	[Edit]

Each line displays a product with the required amount and the remainders resulting from selection of the strengths. These strengths or their required quantity and the selected lot will be displayed for this purpose.

 To change the suggestion, click the Edit icon. A corresponding form will open:

GLUCOSE 50%			
required quantity	14.9mL	Reserved stability	27/07/2017 15:00
achieved	10.0mL (Remainder: 05.1mL)		
pcs.	Strength	Lot	
1 pc. [ + ] [ - ]	100mL (500mg/mL)	GLUCSO (Janssen) 27/07/2017 free (99 pcs.)	[Edit]
0 pcs. [ + ] [ - ]			[Edit]

[Close]

You can use this form to assign a different strength and/or a different lot for this preparation. If too little of a substance has been assigned, the missing amount will be shown in red (both in this form as well as in the list after closing the form). In addition, it will not be possible to save the incomplete list.

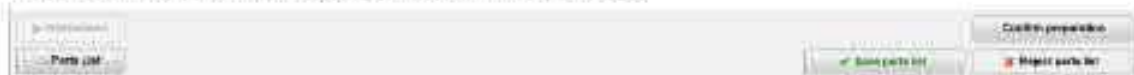
The required containers and additional articles for each medication are displayed below the list of products. Here as well, you can use the Edit icon to change the selected container. You can also use the icon in the header list to set the same container for several or all medications.

Here you can switch all medications with the same container at once:



### 8.1.2 Buttons

The following buttons are located below the products:



- **Print instructions**

Creates a printout with preparation instructions for the set up products. All required products are listed as well as the total volumes required for the preparation or the amount of the primary active ingredient in the prescribed unit, as well as the volume to be withdrawn per vial. In addition, check fields to be written by hand can be displayed (see *Settings* on page 39):

Preparation instruction / preparation protocol no. 140

Printed on: 27/07/2017 15:48

Med. no.: 882

Page: 1/1

DOE John, dob: 29/05/2012 (TPN: 147, Med no: 882, Thu, 27/07/2017)					Unit: KI - NCU E10
Perfusor 50mL PVC-trial CSS				Assistant (mL)	
AQUA AD INJ Lsg	5.0mL	5.00mL	5.0mL from vial: 10.0mL (Ch: A100)		
on:	at:	SC:	Prep.:	Err.:	

- **Print parts list**

Generates a printout of the required materials for the entire set.

- **Print labels**

Prints a label for all medications contained in the set.

- **Save parts list**

Saves the completed parts list. After preparation is complete, any deviations that may have appeared can still be documented.

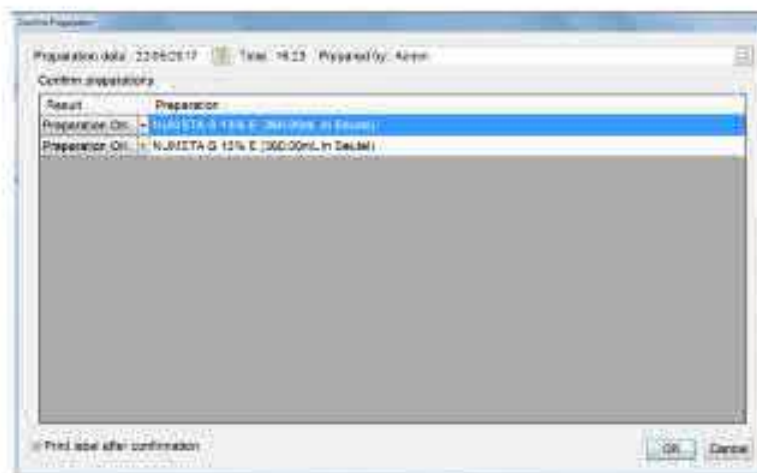
- **Reject parts list**

Resets the entire list and discards the completed product assignments. The medications must be set up again later.

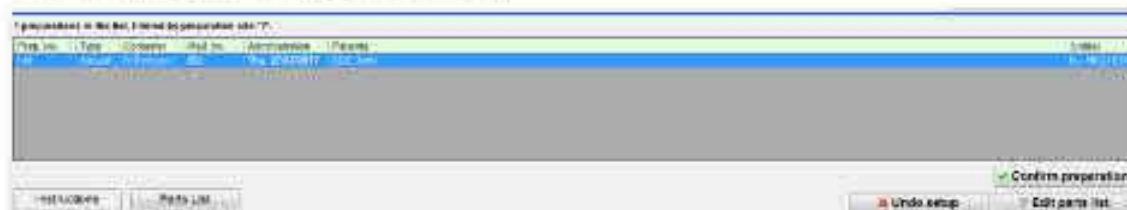
- **Confirm preparation**

Conclusively confirms the completed preparation and saves all materials as consumed. This is intended for installations whose preparation occurs without access to the software in the clean room. A list of all contained medications is displayed and the user has the following options to mark preparations:

- **Preparation OK:** The materials are booked, the medication is considered prepared.
- **Not prepared:** The medication is removed from the list, the materials are booked back into stock, and preparation must be repeated.
- **Waste:** The preparation was performed and the consumptions were therefore booked. However, there was an error and the medication must be set up and prepared again.



Once the parts list has been saved, the buttons for the printouts and for *Confirm preparation* will be available also in the overview list:



The parts list can also be re-edited or discarded completely.

## 8.2 Setting Up Standard Preparation

Standard preparations are prepared for stock. In other words, we do not wait for these bags to be ordered by a patient (the finished bag is therefore not assigned here, but instead in the **Dispense** program module).

To do this, click the corresponding button in the **Set up preparation** form. You will then be asked which template shall be prepared and in what amount.



The parts list is created in a way similar to an individual preparation. Only the instructions are different since of course the same amount must be drawn up for all medications. Instead, the individual preparations can be checked off:

Preparation instruction / preparation protocol no. 150

Printed on: 22/05/2017 18:27

Page:1/1

Med. #: 895, 896, 897, 898, 899, 900, 901, 902, 903, 904

Standard Bags: Standard 1		Preparation from 10 pos.		
Bag 500mL EVA CSS				
NUMETA G 13% E	10 x 360mL	12 x NUMETA G 13% E	300mL (N13)	
Already prepared:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
on:	at:	SC:	Prep.:	Enr.:

### 8.3 Setting Up Preparation for a Compounder

There are various products on the market, which must also be triggered differently. Therefore, there are various interfaces in BD Cato™ TPN and these are regularly expanded. Please do not hesitate to contact our support team if you have any questions.

Please read chapter *Compounder Configuration* on page 50 for more information on the configuration of the different models.

#### 8.3.1 ExactaMix 2400® (EM2400, Baxa Compounder)

Compounders from Baxter Healthcare (formerly Baxa) use their own, integrated software for preparation. In other words, preparation is not managed in BD Cato™ TPN. Instead, only the utilized articles and the required quantities are forwarded to the compounder software. For this to work, the utilized article numbers must be reconciled in the two databases, since reconciliation occurs through them.

In other words, the process in **Set up preparation** remains essentially unchanged. But there is one additional button for sending the data to the compounder:



When this button is pressed, the individual files are sent to the compounder's database. At the same time, labels can be printed with a barcode, which the compounder can read and then use to start the corresponding preparation.

The system will retract the compounder file if something is changed in the therapy after printing. In other words, if a label is printed with the old (incorrect) quantity, preparation will be rejected.

The parts list can then be saved as always and will wait for later confirmation of the preparation (see there).

### 8.3.2 Other Compounder Systems

With most other systems, a channel assignment occurs in addition to the transfer of articles and volumes. In other words, a compounder file is generated, but the channels to be assigned are predetermined by BD Cato™ TPN. This requires predefining certain products for the individual channels (see *Compounder Configuration* on page 50). The selected channels are displayed in the list for **Set up preparation**. Depending on the compounder used, it may be possible to change these manually as well.

Set-up preparation by pump (Pump MF)	
Planned preparation time: 02/06/21 09:14	
<b>Preparations</b>	<b>Channel</b>
HEPARIN 1000 IU/100 mL 0.1 g/l 0.1 g/l 1000 IU/100 mL	Channel 4
INSULIN 100 IU/100 mL 0.1 g/l 0.1 g/l 100 IU/100 mL	Channel 1
GLUCOCORTICOID (Prednisolone) 0.25 mg/l 0.25 mg/l 0.25 mg/l 0.25 mg/l	Channel 2
SODIUM CHLORIDE 0.9% w/v 45.7 g/l 45.7 g/l 1000 mL (1.50)	Channel 3
<b>Components and additional articles (per medication)</b>	
HEPARIN 1000 IU/100 mL 0.1 g/l 0.1 g/l 1000 IU/100 mL	
INSULIN 100 IU/100 mL 0.1 g/l 0.1 g/l 100 IU/100 mL	
GLUCOCORTICOID (Prednisolone) 0.25 mg/l 0.25 mg/l 0.25 mg/l 0.25 mg/l	
SODIUM CHLORIDE 0.9% w/v 45.7 g/l 45.7 g/l 1000 mL (1.50)	

### 8.3.3 Confirming Preparation

Of course, BD Cato™ TPN cannot determine whether or not a preparation has been completed with an external device. Therefore, preparations with a compounder must ultimately be confirmed. This can be done in the same way as manual preparations. Only then are the medications considered actually prepared and all data are booked. In other words, changes may still be made to the parts list after the actual preparation.

## 9. PERFORMING PREPARATION

This program module is intended for users who use a separate work station in the clean room; it enables on-site preparations with simultaneous documentation. Of course, it is then no longer necessary to confirm the preparation in **Set up preparation**.

A gravimetric check of the final product can also be performed under this menu item if an electronic scale is connected to the system.

Start the program module as usual through the preparation menu or the button in the header.

### 9.1 Manual Preparation without Gravimetric Check

When the appropriate button is clicked, a window with a list of all set up medications will open (see *Set Up Preparation* on page 83):

Perform preparation			
Preparation list 1			
No.	Type	Device	Block
121	Preparation	Preparation in advance, 2x HUMECTA G (2x L2)	Block
122	Preparation	Preparation in advance, 10x Biotinid 1	Set up
123	Preparation	Preparation in advance, 2x HUMECTA G (2x L2)	Set up
124	Preparation	Preparation in advance, 10x Biotinid 1	Set up

Resume preparation

A set up preparation can now be selected and the preparation started. A screen appears. It displays the corresponding information and offers the following options for concluding the preparations:

The screenshot shows a window titled 'Perform preparation' with the following content:

Preparation 1 of 1  
# 999, Patient John Doe  
Patient PVC-hr

2.5ml, LUDOCORT 1% (20mg/ml Amp.)	0.25ml, NaCl 0.9% (10ml, (2x L2))
0.1ml, HEPARIN 1000 IU/ml (DPL, 10)	0.05ml, NaCl 0.9% (10ml, (2x L2))
45.7ml, NaCl 0.9%	45.7ml, NaCl 0.9% (1000ml, (2x L2))

Buttons: **Preparation OK (F12)**, **DO NOT PERFORM preparation (ESC)**, **Preparation FAILED (F8)**

Preparations already completed:

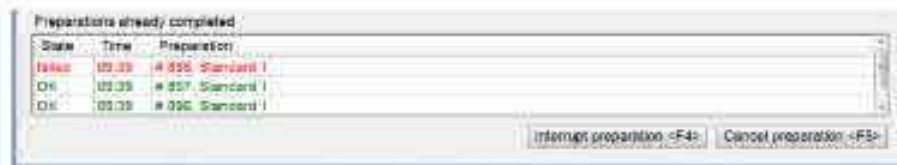
Date	Time	Preparation

Buttons: **Manual preparation (F4)**, **Cancel preparation (F5)**

- **Confirm with *Preparation OK*** : The corresponding lots are booked, a label is created and printed. The medication is shown accordingly in the lower portion of the form (see further below).
- **Do not perform**: The medication requiring preparation at the moment will be reset and a new parts list must be created. If several medications were compiled into one preparation procedure, you can continue with preparation of the remaining medications.

- **Failed:** Resets the medication and discards the bag as damaged goods. The products selected in the parts list are booked. The medication is shown accordingly in the lower portion of the form (see below).
- **Interrupt preparation:** Enables a break and intermediate preparation of a different medication. An interrupted preparation will be marked appropriately in the list of set up preparations. Preparation can be continued at any time or canceled.
- **Cancel preparation:** Ends all preparations of a shared parts list and resets the medications. New parts lists must be created.

If several medications were compiled into one preparation procedure, the completed preparations will be shown appropriately in the lower portion of the preparation form.



Once the final preparation is confirmed, BD Cato™ TPN returns to the selection form and a new preparation can be started.

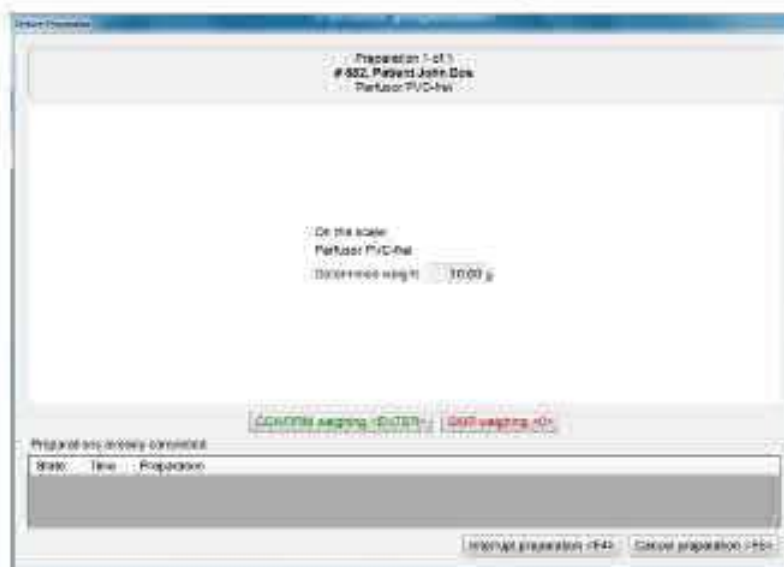
## 9.2 Preparation with Gravimetric Check

In the settings it is possible to define whether a gravimetric final check should be performed. The check can be optional or the preparer can be forced to perform this step.

To perform a check at all, it is essential for a density to be entered in the master data of the utilized strengths. Otherwise, a warning will appear at the beginning of the preparation. A reference weight can be entered into the master data of the empty containers. If this is done, weighing of the empty container at the beginning of the preparation will be skipped.

In addition, a scale must be connected directly to a preparation computer and BD Cato™ TPN. To do this, use the menu item **Hardware configuration**.

After preparation starts, BD Cato™ TPN switches to a separate screen:



Depending on the setting, a weight can be confirmed here (external scale) or the empty container can be placed on the scale (integrated scale). If weighing is optional, this step can also be skipped. If a reference weight is stored in the master data of the empty container, then this step is eliminated completely.

The individual components are confirmed as described above; after *Preparation OK*, a new input form opens that displays the calculated, expected weight. The filled container can now be weighed and the difference is indicated:

Preparation 1 of 1  
# 002 Patient John Doe  
Particular PUC-001

On the scale  
Pre-filled container  
Original weight: 1000 g  
Expected weight: 10g  
Difference: (Not set)

CONFIRM weighing (F12) SKIP weighing (F10)

Preparations already completed

Date	Time	Preparation

Interrupt preparation (F14) Cancel preparation (F13)

Depending on the results, the preparation can now be confirmed or canceled if necessary. The determined weights are documented in the preparation log.



Unlike preparation of the cytotoxics in BD Cato™, in BD Cato™ TPN confirmation of the preparation will not be blocked if the determined weight is different, since a true check would require weighing of all steps.

## 9.3 Neocare Compounders (Serial Interface)

When preparing with Neocare compounders, it is not essential to have a PC in or next to the safety cabinet; preparation can be controlled entirely with the touch display of the Neocare compounder. Reciprocally, all preparation instructions are shown in BD Cato™ TPN and the preparation can be controlled from the PC.

The same procedure will run for all medications that are compiled in a preparation.

### 9.3.1 Equipment

When it is necessary to change the equipment of a channel, a prompt is shown on the screen.

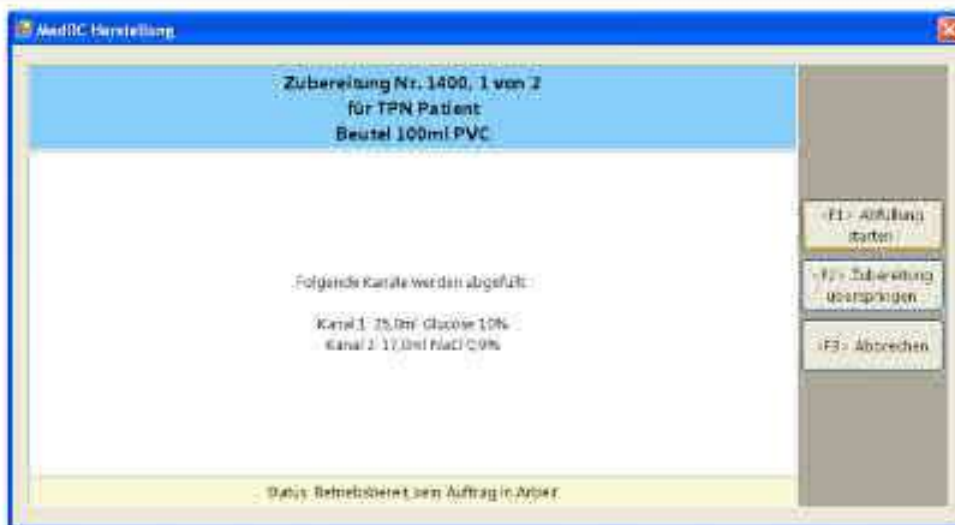


Information about the current medication is shown in the upper section, for example unique number, patient name, and container information.

In the middle section, equipment information for the individual channels is shown.

After changing equipment, flushing can occur automatically; the desired flushing volumes can be defined for each channel in the settings. Press the F1 button to start flushing; press F2 to skip over this.

### 9.3.2 Filling Process



Before filling is performed, the components to be filled and the associated volumes are listed. Press the F1 button to start filling; press F2 to skip over the entire medication.

### 9.3.3 Manual Injection

After successful automatic filling, any remaining components that require manual injection will be displayed to the user.



The user can confirm manual injection with F1 or mark it as faulty with F2.

### 9.3.4 Gravimetric Check

In the settings it is possible to define whether a gravimetric final check should be performed. The check can either be optional or the preparer can be compelled to do it.

To perform a check, it is essential that the user enter a density into the master data of the utilized strengths (**Master data > Strengths of a product**). Otherwise, a warning will appear at the beginning of the preparation. A reference weight can be entered into the master data of the empty containers. If this is done, the first step in weighing (see below) will be eliminated.

There are two options: You can either connect the scale directly to BD Cato™ TPN or just confirm the external weighing in the program.

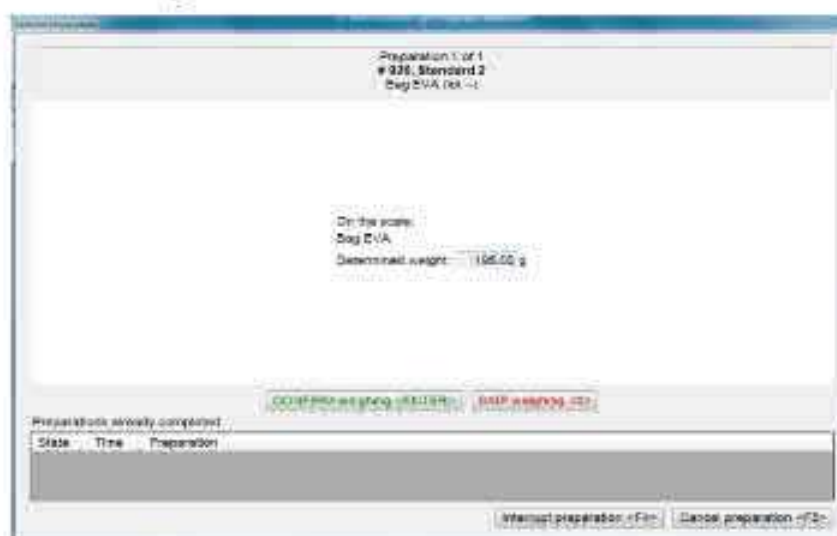
After starting the preparation, BD Cato™ TPN switches to its own screen:



Depending on the setting, a weight can simply be confirmed here (external scale) or the empty container can be placed on the scale (integrated scale). If this step is optional, it can be skipped. If a reference weight is stored in the master data of the empty container, this step is eliminated completely.

The two buttons are also shown on the compounder's display and can be confirmed from there.

The individual components are prepared with the compounder as described above; after *Preparation OK*, a new input form opens that displays the calculated, expected weight. The filled container can now be weighed and the difference is indicated:



Depending on the results, the preparation can now be confirmed or canceled if necessary. The determined weights are documented in the preparation log.

### 9.3.5 Printing Labels

In the settings, you can define how the labels will be printed at the end of a successful preparation. You can define in advance whether no label will be printed, the user must confirm each printout, or that a label will be printed automatically.

### 9.3.6 Conclusion

After successful preparation of a medication, the process continues with the next medication in the preparation package, i.e. all medications compiled through selection. If no additional medications must be prepared, the preparation will be concluded.

## 9.4 Treatment of Reminders From Preparation

If there are remainders in the last vial after preparation, BD Cato™ TPN automatically displays a dialog for the storage of remainders or their rejection. The preparer can now decide whether the remainder will be retained for future use.

In case the preparer decides to retain the remainder for future use, the vial needs to be placed on the scale for checking for any active ingredient loss during gravimetric preparation.

After examination a new remainder number is assigned to the remainder and a label printed. The remainder is now saved in BD Cato™ TPN and using it will be automatically suggested, if possible, with future preparations as long as it is not expired.

For calculating the remaining active ingredient amount, any previously recorded overfill is also taken into account, which allows each vial to be used to the last drop.

In case the preparer has decided not to keep the remainder, the remaining quantity, including the average amount of overfill, is posted as a loss and can not be used during future preparations. If a remainder has been deducted erroneously, it can be activated again under **Remainders** (see *Remainder Management* on page 103).

You can read about the various basic settings regarding remainders in the chapter *Set Up Preparation / Dispense* on page 40.







## 11. LOT MANAGEMENT

In order to prepare with BD Cato™ TPN, it is necessary to save available lots for the created products. These lots are documented during preparation and enable rapid tracing of their use.

You can switch to lot management either directly from the affected strength or from the empty container that was just displayed. Or you can also call up the program module through the **Preparation > Lot management** menu.

In BD Cato™ TPN, documentation of lots is mandatory or possible for the following articles:

- Mandatory: Products and standard bags (purchased or made in-house)
- Optional: Empty containers

### 11.1 Lot Management of Products

Before the first preparation, BD Cato™ TPN must be given the information on existing lots and their stock status.

#### 11.1.1 Creating a New Lot

The **Lot management** form offers the special feature that a dosage form and a certain lot (to be edited) can be selected in the upper screen area. Once this selection has been made, the lower screen area behaves in the same way as every other list in BD Cato™ TPN.

First select the desired strength for the medication. Click the appropriate button to create a new lot. The following data are saved for the lot:

Lot number, barcode, expiration date, number of vials to be added, internal billing price.

The weight is not relevant in BD Cato™ TPN.

**Preferred:** Defines this lot as the current one (that is, currently used) in the event of several lots being registered (at one dosage form strength). That way it is determined which lot should automatically be suggested in BD Cato™ TPN.

**Blocked:** (Temporarily) blocks the lot for use. Lots marked as *Blocked* can no longer be selected in other program modules. Additionally, the lot can be blocked from release and be set in quarantine below the list to enforce another check prior to its first use.

#### 11.1.2 Determining a Vial's Average Weight

If you wish to use the gravimetric preparation module, you have the ability to determine a vial's average weight. During the preparation process, the average weight serves as an identification feature and allows (in most cases) to check if the correct product vial is being used.

You can either enter a weight previously determined externally or click the *Determine Weight* button to establish the average weight. Before completing this step, make sure that the scale is working correctly (see BD Cato™ TPN Installation Plan).

To establish an average value, it is recommended that more than one vial be weighed. The number of vials used for determining the average weight must be set before weighing. Weigh the vials the way you will use them in the safety cabinet, which means remove possible closing caps or similar if they have a relevant effect on the vial's weight.

Place the vials on the scale and wait until the scale has stabilized (weight is displayed in green). Now click the *Determine Average Weight* button to send the weight to BD Cato™

TPN. Alternatively, you can also press the Enter key (+key). Close the form after the procedure has been completed.

This value is now used automatically when creating a new lot for this strength, which means that the average weight does not need to be determined for new lots, unless the vial's weight has changed (due to a change of its size or material).

### 11.1.3 Lot Status

Lots can receive two different kinds of statuses in BD Cato™ TPN: *Approved* and *Quarantine*. Which of these statuses is awarded automatically can be established in the settings. According to this, a newly entered lot appears either straight away as *Approved* or as in *Quarantine*:

Lot no	X	Status	S	Type	Expiry	Total
048RUT04857		Quarantine		Purchase	23/07/2015	50
L12		Approved		Purchase	22/09/2020	100

- **Quarantine:** The lot still has to be checked and approved. This lot cannot be used in the preparation parts.
- **Approved:** This lot can be used without restriction.

Additionally, the *Blocked* flag can be used. The idea behind this is to be able to differentiate between "do not use because not yet checked (= Quarantine)" and "this lot must not be used due to a warning by the manufacturer (= blocked)".

*Blocked* overwrites the respective status in the corresponding column. An "X" is also displayed in the column provided for this. If *Blocked* is removed again, the lot is once again in the respective status in which the block was imposed.

To make the functionalities available only for certain users, the user groups can be adapted to establish who can enter, approve, and block/unblock lots.



It is also possible to introduce additional statuses before the actual approval or to create electronic questionnaires with an add-on module that have to reveal positive outcomes before approval. Contact our support team if you would like any further information about this.

### 11.1.4 Editing an Existing Lot

The lots saved are displayed in the **Lot management** form according to the selection of a certain strength:

Lot Management													
Show lots from: Products										Show blocked articles			
Designation: GLUCOSE 5% 100ml													
Lot no: <input type="text"/>										Expiry: <input type="text"/>			
Title: <input type="text"/>										Weight: <input type="text"/>			
Preferred: <input type="checkbox"/> Blocked: <input type="checkbox"/> Trial product: <input type="checkbox"/>										New Edit Delete			
Lot no	X	Status	S	Type	Expiry	Total	In prep.	Used	In Use	Manufacturer	Avg	Price	
048RUT04857		Approved		Purchase	23/07/2015	50	0	3	0	0	0	47	
L12		Approved		Purchase	22/09/2020	100	0	17	0	0	0	0	

In addition to the lot number and the expiration date, the consumption status of the lot is displayed:

**Total:** Overall number (original number) of vials in the lot

**In prep.:** Number of stock batch productions and stock solutions that still must be released after preparation through status administration

**Used:** Number of the vials used

**In use:** Number of the vials that are currently in use (that are currently being used for preparation)

**Remainders:** Number of the vials that are currently stored as remainders

**Avail.:** Number of vials still available

**Price:** Display of the registered price

Vials can be added to or deducted from the lot by selecting a line and clicking the corresponding button. Moreover, it is possible to move vials between stock locations.



All other information can still be changed by means of the *Edit* button.



If vials of a lot have already been used for a preparation, the *Lot no.* and *Expiry* fields can no longer be edited (exception: marked trial product).

## 11.2 Lot Management of Empty Containers

In BD Cato™ TPN, lots of empty containers can be managed in addition to product lots. Unlike the products, though, use of this is optional and must be activated in the **Settings**.

Which product group should be displayed can be determined in the list of selections at the top part of the form. In addition, this group is automatically reconciled when switching from the corresponding master data form directly to lot management.

Unlike the products, neither expiry date nor quantity are documented for the empty containers. Only the batch number and (if appropriate) price and barcodes are entered.

## 11.3 Lot Management of Standard Bags

For standard bags, there are basically two options:

- The standard bag is prepared in BD Cato™ TPN.
- The standard bag is purchased like a product.

However, in both cases it is necessary to first create the bags under **Therapy > Templates** (see *Templates* on page 57).

If the bag itself is prepared, BD Cato™ TPN automatically assigns a unique lot number and independently enters the lot into the list after confirmation of the preparation. The lot will be identified in a separate column Type as *Stock solution*.

Purchased bags are entered as described for the products. "Purchase" is shown in the Type column.

The lots are then deducted through dispense (see *Dispense* on page 97).

## 11.4 Event Log for Lot Management

Since repeated entries have to be made for lots and the possibility of an erroneous entry is especially large (complicated lot numbers, expiration dates, etc.), checks on the persons inputting

are particularly important at this stage. BD therefore would like to particularly point out the event log function in the **File** menu.

## 12. REMAINDER MANAGEMENT

To display a list of all current remainders, select the **Remainders** menu item from the **Preparations** menu.

The following information is listed for the vials:

- **No.:** A unique number automatically assigned by BD Cato™ TPN after usage that will be printed on the label of the remainder (optionally also as barcode). During preparation and setup of a preparation this number is used for identification. For the barcode an encrypted number is used, not the remainder number.
- **Product (lot):** The used strength and its lot number are listed here.
- **Remainder:** Information in unit and volume concerning the remaining amount of active ingredient or solution in the vial.
- **Expiry:** Information concerning the expiration (if stabilities have been saved in the master data).



The expiration is calculated as minimum value of the following information: expiration date of the lot, microbiological sterility for remainders according to the setting (under **Preparation / dispense > Remainders and stabilites > Microb. sterility remainders**) or time of administration.

Different colors indicate different conditions of the remainders (a key of these colors can be accessed at any time via a link in the upper right corner of the form):

- **Black:** "Normal," meaning not expired, and not blocked remainders (additionally displayed in **bold** if they were used today)
- **Green:** Remainders currently in use
- **Red:** Expired remainders
- **Orange:** Blocked vials that currently may not be used
- **Blue:** Remainders already deducted that are displayed for the *Reactivate remainders* function (see below)
- **Olive:** Blocked and expired remainders where deducting seems to have been forgotten

**Remainder management**

Preparation no. 1 -> Daily report remainder (past 2 weeks) New

Refresh data

Product ID	Remainder	Copy
1 NACL 0.9% 1000ML (0.9%)	1000ml	22052007 01:07
0 Tetracycl Leg 150mg (L071)	0mg	-
0 Tetracycl Leg 150mg (L071)	0mg	-
0 NACL 0.9% 2 1000L (0.9%)	0L	-
0 NACL 0.9% 2 1000L (0.9%)	0L	-
0 NUBETA 0.1% R 300ML (0.1%)	0g	-
0 NUBETA 0.1% R 300ML (0.1%)	0.5kg	-
0 NUBETA 0.1% R 300ML (0.1%)	0g	-
0 NUBETA 0.1% R 300ML (0.1%)	0.5kg	-
0 GLUCOSE 5% 100ML (L12)	4.5kg	-
0 GLUCOSE 5% 100ML (L12)	0g	-
2 GLUCOSE 5% 100ML (L12)	0g	22052007 23:00
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	1.5g	-
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	0g	-
0 GLUCOSE 5% 100ML (L12)	0g	-

**Details**

Expiration: 22052007 10:23  
 Remainder volume (400ml)  
 Diluent:  
 First use 22052007 10:23  
 Last use 22052007 10:23

**Withdrawal**

Med no. 491.22050017 10:23 11935.20mg

Select a remainder to display details concerning the vial below the list. These are:

- Indication in days/hours/minutes until or since expiry
- Remainder as volume (in mL)
- The used diluent
- Date of the first and last use of the vial
- Information concerning the medications for which withdrawals were effected (medication number, date and time of the withdrawal, withdrawn amount).

To the right side of the details there is a bar of buttons that enable different actions:

- **Printing labels:** It is possible to reprint a remainder label. If for any reason a remainder was not assigned a number (for example, this can happen due to the cancellation of a preparation), now a number is assigned (the button then reads *Assign no.*).
- **Reactivate:** By selecting the corresponding checkbox above the list, the remainders deducted during the past two weeks can be displayed in the list (these are displayed in blue fonts). Use the button to include a remainder deducted by mistake during the preparation in the active list again.
- **Block/Unblock:** This button can be used to temporarily block certain vials for further use.
- **Deduct/Transfer** (in case of several storage locations): Removes expired remainders from the list (that would otherwise remain in red fonts) or enables a transfer from one storage location to another. A remainder is kept in the system until the vial's complete content has been withdrawn or it has been deducted manually here. This means an expired remainder will not be deducted automatically and is still available in **Set Up Preparation**, but such a remainder will not be recommended automatically.



In some cases it is possible that the list may contain a remainder without a number, which is not blocked (that is, not displayed in green). Vials currently in use do not have a remainder number, if they have been recently reconstituted or opened. If a preparation is interrupted after the reconstitution of the vial, there are "temporary remainders" in



stock, for which no remainder number has yet been assigned (and possibly will never be assigned a number). In this case, a number is assigned automatically before the label is printed. It is rarely possible that the above-mentioned remainders displayed in brown are actually shown. These vials are considered to be blocked; however, they can be posted as a loss as they have not been used for a longer period of time. It can be presumed that no preparation has taken place using these vials.

## 12.1 Printing a Remainder List



To print a list of the current remainders, use the *Print* icon in the toolbar or go to **Print** in the **File** menu.



## 13. LABELS

Open the entry form for the label layout in the **Administration > Define layout of labels** menu.



In BD Cato™ TPN, the layout of labels cannot be significantly modified (for example the positioning of text fields or font size and type or additional information). The basic layout of a label can be defined using the included program **List & Label**. BD can provide assistance in redesigning or changing label designs.

The provided default labels can be used right away. Certain adjustments of default labels can also be carried out easily (see below).

### 13.1 Entry Form

As with a few other program modules, the **Define label layout** module is used both in BD Cato™ TPN as well as BD Cato™. Therefore, entries can be made for both software solutions.

In the main menu, a default printer can be defined for the work station. All labels will be printed from this printer. However, other printers can be saved for certain labels if for example labels of varying sizes will be printed for 24h medications.

A list of all label templates in the system is located below the printer assignment area. To the right, there are buttons for exporting or importing layouts as well as for editing, deleting, or printing them with test or medication data.

The *Title* field is not used in BD Cato™ TPN, the other fields can be filled with text as desired (for example emergency numbers in case of further inquiries).

#### 13.1.1 Showing and Hiding Label Information

Within the specified label design it is possible to show or hide various medication data on the label. Although the content of a label is generally dependent on and defined by the layout, the label can be easily and quickly adapted in this way without having to design a new layout. For

example: If no field has been provided for the lot number on the label layout, this cannot be shown or hidden through an option.

These options can be shown or hidden using the checkboxes. The changes are immediately visible on the printout of a preview label. The options are grouped under several tabs:

#### **13.1.1.1 Patient Name**

---

**Last name in upper case letters:** This determines whether the patient's last name will be printed in upper case letters on the labels.

**Last name first:** Sets whether the last name will be printed first.

**Comma between last and first names:** Sets whether the first and last name (or vice versa, depending on the setting) will be separated by a comma.

**Title:** This determines whether the title saved in the patient file will also be printed on the label.

**Title when the patient is older than XX years:** BD Cato™ TPN prints the title *Mr.* or *Ms.* before the last name on the label. Using this option, BD Cato™ TPN can be configured so that this title is not printed for small children.

#### **13.1.1.2 Date Format**

---

**Date of administration with weekday:** Inserts the abbreviated weekday name onto the label (Mon., Tues., Wed., etc.).

**Time for stability/preparation date:** Expands the date specification with a precise time.

**Preparer abbreviation:** Writes the preparer's abbreviation next to the date of preparation.

#### **13.1.1.3 Dose Information**

---

Defines whether the volume or the prescribed units or both will be printed for the dosage of the individual active ingredients/products and with or without separately indicated overfill.

#### **13.1.1.4 Miscellaneous**

---

Here you can set which barcode and whether the TPN underlying medical result (for example weight) shall be printed on the label.

### **13.1.2 Assigning a Label Layout**

---

Select the corresponding medication type (for example *TPN parenteral*) from the selection list at the left and enter into the list appearing at the right the desired design (for example *pan standard*). The number of labels to be printed can also be defined before the layout.

In individual cases it may be desirable to print different labels (layouts) for certain medications. For example, an additional patient label may be printed for a standard bag. In these cases, simply enter a second design into the next line.

## INDEX

**2**

24h medication template .....	57
creating .....	57
deleting .....	58
editing .....	58

**A**

active ingredients .....	22
active ingredient groups .....	20
address .....	66
administration .....	35
administration route .....	20
administrator .....	36, 39
appointment reminder .....	67
article number .....	26
average weight of a vial .....	99

**B**

barcode .....	5, 27, 38
barcode scanner .....	5
basic data .....	12
billing .....	30
billing prices .....	30, 54
body surface .....	15, 17
BSA Dubois .....	17

**C**

case assignment .....	66
centers and units .....	10
commissioning list .....	97
companies .....	7
compounder configuration .....	50
list of channels .....	53-54
container materials .....	19
context menu .....	79
deleting therapy day .....	79
set status .....	79
conversion factor .....	23
cost center .....	30, 66
cost center accounting .....	30, 32
cost unit .....	
assignment .....	66
costs .....	33
CSV .....	34, 44

**D**

data .....	
creating new .....	9
deleting .....	9
discarding .....	9
displaying .....	8
modifying .....	8
saving .....	9
searching .....	7
date field .....	4
density for ready-made solution .....	46
departments .....	10
diluent .....	
lots .....	40
dispense .....	40, 97
dosage rules .....	49
dose .....	
adjustments .....	67
limit .....	14, 21
purpose .....	13
dose modification rules and cycle post- ponement rules .....	14

**E**

empty containers .....	27
lots .....	41
types .....	19
event log .....	9
for users .....	38
ExactaMix 2400 .....	87
compounder configuration .....	50
export files .....	44

**F**

file export .....	44
fixed preparation fee .....	33
font color .....	4
formula .....	15
formula aid .....	13
four-eyes principle .....	39

**G**

GSI GTIN .....	42
----------------	----

- H**
- hardware ..... 54
- I**
- ICD code ..... 46
- icons ..... 3
- IMF compounder ..... 53
- inactivity check ..... 43
- indicator ..... 49
- infusion container ..... 27
- intended use ..... 1
- IV lines ..... 20
- L**
- label ..... 20
- defining layout ..... 50, 107
- design ..... 108
- entry form ..... 107
- label printer ..... 42
- printing ..... 97
- label information ..... 107
- date format ..... 108
- dose information ..... 108
- patient name ..... 108
- standard values ..... 108
- license administration ..... 5
- login ..... 35, 38
- losses ..... 31, 33
- lot management ..... 99
- empty containers ..... 101
- event log ..... 101
- products ..... 99
- standard bag ..... 101
- lots ..... 27-28
- blocked ..... 99
- creating ..... 99
- expiry date ..... 99
- lot number ..... 99
- lot status ..... 100
- lot tracking ..... 30
- modifying ..... 100
- preferred ..... 99
- M**
- master data ..... 7
- creating new ..... 11
- printing ..... 8
- mathematical operators ..... 15
- maximum dosages ..... 67
- medical result group ..... 12, 68
- possible ..... 20
- medical result type ..... 13
- medical result values ..... 12
- preliminary ..... 69
- medical results ..... 67
- alternate medical results ..... 17
- calculated numerical ..... 15
- canceling ..... 69
- editing ..... 68
- entering ..... 68
- expired ..... 68
- measured numerical ..... 14
- medical result curve ..... 68
- possible ..... 12
- rounding ..... 16
- text selection results ..... 18
- medOC compounder ..... 52
- menu bar ..... 3
- N**
- Neocare compounder ..... 91
- compounder configuration ..... 51
- conclusion ..... 94
- equipment ..... 91
- filling process ..... 92
- gravimetric check ..... 93
- list of channels ..... 51
- manual injection ..... 92
- printing labels ..... 94
- network path ..... 42
- O**
- ordering physician ..... 37
- overall dose
- cumulative ..... 21
- overfill ..... 31, 94
- P**
- parts list
- creating ..... 83-84
- password ..... 5, 38
- password expiration ..... 43
- patient data ..... 65
- patient list ..... 70
- patients ..... 65
- comments ..... 67
- double ..... 69
- maintaining data ..... 65
- master data ..... 40
- merging ..... 69

- number ..... 43
  - patient list ..... 34
  - perfusor ..... 27
  - permitted validity ..... 12
    - maximum permitted in days ..... 68
  - place of delivery ..... 66
  - preparation ..... 40
    - carrying out ..... 89
    - confirming ..... 88
    - preparation list ..... 29
    - with gravimetric verification ..... 90
    - without gravimetric verification ..... 89
  - preparation site ..... 49
  - primary active ingredient ..... 22
  - printer ..... 42
  - product ..... 21, 26
    - combination product ..... 22
    - consumption ..... 31
    - master data ..... 21
    - standard values ..... 23
  - product's dosage form ..... 23
    - administration ..... 25
    - comments ..... 25
    - creating new ..... 23
    - general data ..... 24
    - managing existing ..... 24
    - possible ..... 18
    - TPN values ..... 24
  - purchase prices ..... 27-28
- R**
- remainder ..... 41
    - booking ..... 42
    - canceling ..... 94
    - creating ..... 94
    - discarding ..... 94
    - printing list ..... 105
  - remainder management ..... 103
  - remainder number ..... 41, 94
  - remainders ..... 94
  - reports ..... 29, 48
  - requirements list ..... 30
- S**
- sales tax/VAT ..... 33
  - scale ..... 99
  - selection lists ..... 3
  - setting up preparation ..... 83
    - buttons ..... 85
    - default preparation ..... 86
    - for compounder ..... 87
    - individual parenteral solutions ..... 83
    - other compounding systems ..... 88
  - settings ..... 39
    - additional warnings ..... 47
    - basic settings ..... 39
    - BD ..... 46
    - BD Cato TPN basic settings ..... 45
    - file export ..... 44
    - IT optimization ..... 44
    - IT settings ..... 49
    - medication list ..... 46
    - medications ..... 47
    - recording data sighting ..... 44
    - regimens ..... 46
    - therapy plans ..... 46
  - shortcut ..... 2
  - shortcuts ..... 3
  - special password ..... 35, 46
  - stabilities ..... 41
    - microbiological ..... 41
  - standard bag ..... 57
    - enhancing ..... 76
  - standard bag template ..... 58
    - creating ..... 59
    - deleting ..... 60
    - displaying and editing ..... 58
  - statuses ..... 49
  - stock ..... 99
  - strength of a product ..... 25
    - package sizes ..... 27
    - usage blocked ..... 26
  - style sheets ..... 49
  - suppliers ..... 10
  - symbols
    - used ..... 2
- T**
- tab key ..... 8
  - tabs ..... 4
  - temperature ..... 39
  - templates ..... 57
  - text highlights ..... 2
  - therapy day ..... 71
    - 24h medication ..... 78
    - administration data ..... 78
    - check values ..... 74
    - comments ..... 78
    - deleting and canceling ..... 79
    - editing ..... 79
    - enteral administrations ..... 77
    - general information ..... 73
    - oral medication ..... 78

parenteral tab .....	75
planning .....	73
prescribing .....	72
printing .....	80
reorders .....	80
report .....	81
saving therapy .....	78
standard bag .....	76
statuses .....	78
tab line .....	74
templates for printout .....	80
therapy day template .....	60
24h medication .....	63
check values .....	61
comments .....	63
creating .....	60
deleting .....	64
displaying and editing .....	64
enteral .....	62
general information .....	61
oral .....	63
parenteral .....	61
saving .....	63
standard bag .....	62
therapy plan number .....	43
therapy plan printout .....	14
toolbar .....	2-3
TPN template .....	57, 64

**U**

unit	
maintaining .....	11
unit assignment .....	66
unit assignment user .....	38
units .....	23
International Units (IU) .....	23
update .....	39
usable remainder .....	41
user .....	5
switching users .....	5
user name .....	35
user verification .....	45
user administration .....	36
personal data .....	38
user groups .....	35

**V**

vehicle	
lots .....	40

**W**

weight display .....	99
----------------------	----



**Zadávací dokumentace k veřejné zakázce malého rozsahu zadávané dle interní směrnice  
č. 2 o zadávání veřejných zakázek v souladu s ust. § 31  
zákona č. 134/2016 Sb., o zadávání veřejných zakázek, ve znění pozdějších  
předpisů (dále jen „zákon“)**

**Název veřejné zakázky:**

**Software pro parenterální výživu ve FN HK**

**Kód CPV:** 48180000-3 Balík programů pro zdravotnictví,  
72212180-4 Vývoj programového vybavení pro zdravotnictví  
**Druh veřejné zakázky:** Dodávky

#### **IDENTIFIKAČNÍ ÚDAJE ZADAVATELE**

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Adresa profilu zadavatele: <https://www.egordion.cz/mihjukaGORDION/profil/FNHK>

Žádosti o vysvětlení zadávací dokumentace musí být doručeny písemně v elektronické podobě na e-mailovou adresu [vaclav.jamski@fnhk.cz](mailto:vaclav.jamski@fnhk.cz) nejpozději 2 pracovní dny před koncem lhůty pro podání nabídek. Případné další informace k textu zadávací dokumentace a odpovědi na dotazy k zadávací dokumentaci budou uveřejňovány na profilu zadavatele.

#### **!!!UPOZORNĚNÍ!!!**

**Nově jsou avíza o uveřejnění nových dokumentů k příslušnému zadávacímu řízení na profilu zadavatele zájemcům automaticky zasílána pouze v případě, že si účastník stáhne z profilu zadavatele alespoň jeden dokument (v rámci předmětné veřejné zakázky) jako registrovaný a současně přihlášený zájemce. V případě zájmu o účast v daném zadávacím řízení doporučuje zadavatel stáhnout dokumentaci k veřejné zakázce až po přihlášení zájemce do systému.**

**Veřejná zakázka není, s ohledem na charakter předmětu plnění veřejné zakázky, rozdělena na části.**

#### **1. Předmět plnění veřejné zakázky:**

Předmětem plnění této veřejné zakázky je dodání a implementace softwarového řešení pro podporu preskripce, plánování a přípravy parenterální výživy (dále jen PV) ve Fakultní nemocnici Hradec Králové (dále jen FN HK), včetně jeho integrace do stávající IT infrastruktury FN HK. Součástí předmětu plnění je i přizpůsobení nabízeného softwarového řešení dle požadavků zadavatele (přizpůsobení potřebám zadavatele).

Dále je předmětem plnění této veřejné zakázky softwarová údržba dodaného informačního systému po dobu neurčitou.

Zadavatel požaduje postupnou implementaci dodávaného systému včetně zavedení softwarového řešení, které je předmětem této zakázky, a to ve dvou fázích. Zhotovitel uvede předmět plnění do zkušebního provozu nejpozději do 1 měsíce od nabytí účinnosti smlouvy o dodávce software. Předpokládaná doba trvání zkušebního provozu je 1 měsíc. Celková doba trvání implementace může být maximálně 2 měsíce.

Zadavatel požaduje všestranně moderní systém, který bude bez významnějších změn provozuschopný po řadu let. Nabízený systém musí být v době dodávky plně funkční ve všech svých deklarovaných vlastnostech a musí především zvýšit bezpečnost, dokumentovatelnost celého procesu rozpisu, přípravy a aplikace parenterální výživy.

Zadavatel požaduje systém založený na moderních a všeobecně uznávaných technologiích a standardech – včetně platformy pro vývoj systému, typ a verze využívané databáze, bezpečnostních standardů apod.

Systém musí umožňovat eventuální rozvoj dle budoucích požadavků FNHK např. formou akvizicí již hotových dalších softwarových modulů. Naším požadavkem je tedy především co nejširší funkčnost a škálovatelnost již otestovaných a stabilních softwarových modulů. (Předmětem poptávky tedy není vývoj software „na míru“ dle našich specifických požadavků, který by byl teprve vyvíjen v době provozování systému ve FNHK, nevylučuje se však možnost drobných úprav stávajícího systému podle specifických požadavků zadavatele).

### **Technická a funkční specifikace softwaru pro veřejnou zakázku:**

#### **• Obecné požadavky**

- Systém musí poskytovat jednotné grafické uživatelské prostředí a jednotné ovládání pro všechna uživatelská pracoviště provádějící plánování, předpis a přípravu PV.
- Všechny části systému musí být navzájem integrované a modulárně koncipované. Musí umožňovat vyhledávání souvisejících dat napříč jednotlivými moduly.
- Systém musí být kompatibilní se stávajícím plnicím automatem ve vlastnictví zadavatele (tj. ExactaMix 2400).
- Systém musí být kompatibilní minimálně se dvěma dalšími plnicími automaty od různých výrobců. Účastník ve své nabídce uvede seznam kompatibilních plnicích automatů včetně uvedení jejich výrobců.
- Všechny části systému musí s uživatelem komunikovat v českém jazyce. Při ovládání funkcí vyhrazených administrátorům a správcům systému se připouští komunikace v anglickém jazyce.
- Funkcionalita a ovládání systému musí být vhodnou formou dokumentována. Např. Příručka pro uživatele a Příručka administrátora.
- U vstupních údajů, kde je to z logiky věci možné, musí systém provádět kontrolu správnosti zápisu dat a opticky zvýrazňovat povinné pole.
- Systém musí obsahovat kontextovou nápovědu (v českém jazyce) pro obsluhu jednotlivých funkcí a zadávání vstupních údajů.
- Systém musí mít nástroje na logování činnosti uživatele.
- Update aplikačního SW na klientských stanicích musí probíhat automaticky (např. při spuštění aplikace), bez zásahu obsluhy, a to i bez administrátorských práv k operačnímu systému (Microsoft Windows).
- Systém musí umožňovat tvorbu výstupů (reporting) uložených v databázi a tvorbu definovaných exportů dat do běžných typů souborů (zejména docx, xlsx, xml, rtf, csv, txt, pdf).
- Systém musí být schopen provádět úkony údržby (zálohování a archivace dat, správa číselníků apod.) za provozu, v automatickém i manuálním režimu.
- Systém musí umožňovat přístup ke všem datům po celou dobu provozu.

- Tiskové výstupy musí obsahovat náležitosti zdravotnické dokumentace dle platné legislativy ČR (aktuálně vyhláška č. 98/2012 Sb. o zdravotnické dokumentaci) a vyhl. 84/2008 Sb. z pohledu dokumentace přípravy léčiv.
  - Administrátor (správce) zadavatele musí mít přímý přístup do databáze na úrovni databázového administrátora (možnost zadávat SQL dotazy za účelem získání dat, například v případě MS SQL Serveru prostřednictvím SQL Management Studia) a v dokumentaci musí být popsán datový model.
- Požadavky na funkční vlastnosti
    - Plánování a předpis PV
      - Plánování a příprava PV pro lůžkové pacienty, pacienty v tzv. domácí péči a pro externí odběratele PV. Přitom jedna PV se může skládat z jednoho nebo více sterilních vaků.
      - Možnost převést vyrobenou PV z režimu „Domácí péče“ do režimu „Lůžkový pacient“.
      - Plánování a předpis PV přímo z pracoviště lékaře a zajišťování komunikace mezi lékařem a Nemocniční lékárnou.
      - Definování vlastních předloh PV, jejich správa a aktualizace.
      - Sestavování individuálních předpisů PV, výpočet dávek pro jednotlivé pacienty, a to na základě uložených předloh nebo individuálně.
      - Vytváření a ukládání vzorů pro výpočet dávek pro jednotlivé pacienty na základě individuálních parametrů (např. hmotnosti).
      - Kontrola na překročení limitních hodnot v předpisu PV (např. limitní hodnoty u každé účinné látky, koncentrace, objemu, kumulace apod.) s povinností zaručit výrazné upozornění na porušení limitních hodnot.
      - Uložení diagnóz a nálezů jednotlivých pacientů s možností časového omezení platnosti jednotlivých parametrů (např. hmotnosti pacienta apod.).
      - Využívání různých měrných jednotek v předpisu PV (minimálně však g, mg, ml, µg, mmol).
      - Připojování různých komentářů a pokynů k předpisu pro přípravu a aplikaci PV ze strany uživatele.
      - Dokumentování PV pacienta včetně její historie a neustálou dostupnost dat předepisujícímu lékaři.
      - Jmenovité dokumentování procesů plánování a přípravy PV – předpis, schválení, předání k přípravě, příprava PV a dostupnost o aktuálním stavu žádanky („plánováno“, „čeká na schválení“, „schváleno“, „čeká na přípravu“, „připraveno“, „expedováno“, „aplikace potvrzena“).
      - Systém musí poskytovat souhrny a sestavy týkající se PV. Sestavy musí umožňovat získání přehledu o použití PV podle jednotlivých pracovišť, uživatelů, léčivých přípravků apod.
      - Systém musí umožňovat zpětnou dohledatelnost všech dat týkajících se předepsání přípravy a aplikace PV.
    - Žádanka
      - Identifikační část žádanky musí obsahovat identifikační údaje o pacientovi (rodné číslo pacienta, jméno a příjmení pacienta, diagnóza), identifikaci pojišťovny, IČP, identifikaci žádajícího interního pracoviště, eventuálně identifikaci externího odběratele.
      - Identifikační část žádanky musí umožňovat zadání nálezů (hmotnost, výška).
      - Identifikační část žádanky musí umožňovat údaje zadat přímo a tam, kde to bude možné i výběrem z číselníku, například diagnózy ze seznamu diagnóz MKN10, pojišťovny z číselníku pojišťoven pracoviště z číselníku pracovišť apod.

- Na žádance musí být graficky odlišena povinná a nepovinná pole. Vyplnění povinných údajů musí být systémově vyžadováno. V případech, kde je to možné, musí systém při získávání údajů provádět kontrolu validity proti číselníkovým hodnotám (např. diagnóza – číselník diagnóz, pojišťovna – číselník pojišťoven, variabilní symbol pracoviště – číselník pracovišť apod.)
  - Prvotně pořízené identifikační údaje pacienta musí zůstat uloženy v databázi a musí být možné podle nich pacienta při opakované návštěvě vyhledat, a to na základě rodného čísla nebo příjmení a jména s automatickým doplněním ostatních údajů.
- Tvorba žádanky
- Systém musí umožňovat vystavení elektronické žádanky na přípravu PV a její tisk.
  - Žádanka musí, kromě identifikačních údajů pacienta a žádajícího pracoviště, obsahovat výčet léčiv a jejich dávek a typů a objemů. Žádanka musí obsahovat informaci o tom, kdo ji vystavil a příp. kdo ji schválil.
- Příjem žádanek
- Systém musí umožnit řazení požadavků dle časového sledu a s případným předřazením lékařem upřednostněných požadavků.
  - Systém musí vyžadovat po doručení žádanky její kontrolu a schválení lékárníkem. Teprve potom může pokračovat žádanka do přípravy.
  - Systém musí umožňovat zadání spotřebovaných léčiv a materiálu k žádance s možností identifikovat léčiva a materiál pomocí čtečky čárových kódů s respektováním kusové kontroly (identifikace šarží). Systém musí při zadávání automaticky nabízet balení otevřená, s ohroženou expirací a ekonomicky výhodnější.
  - Systém musí poskytovat automatický tisk štítků (volitelného množství) s možností tyto štítky podle potřeby vhodně definovat – navolit požadované údaje či např. barevné rozlišení zohledňující různý způsob podání.
  - Systém musí poskytovat přehled plánovaných požadavků - informaci o aktuálním stavu žádanky („plánováno“, „čeká na schválení“, „schváleno“, „čeká na přípravu“, „připraveno“, „expedováno“, „aplikace potvrzena“).
- Příprava PV v Nemocniční lékárně
- Sdílení dat pro přípravu PV mezi předepisujícím lékařem a Nemocniční lékárnou.
  - Zachování možnosti manuální přípravy vaku.
  - Podporu přípravy vaků jak pro pacienty individuálně tak i podporu přípravy standardních vaků.
  - Tisk štítků s možností vytvoření a použití různých předloh.
  - Dokumentování výroby PV včetně použitých materiálů, přípravků a jejich šarží s vazbou na konkrétního pacienta.
  - Kompletní a jmenovité dokumentování procesu přípravy vaků v Nemocniční lékárně.
- Skladové hospodářství
- Systém musí obsahovat číselník HVLP a musí umožňovat jeho aktualizaci ze Seznamu léčiv a PZLÚ hrazených ze zdravotního pojištění vydávaného s měsíční periodicitou Státním ústavem pro kontrolu léčiv.
  - Systém musí umožňovat vedení skladového hospodářství pracoviště centralizované přípravy Parenterální výživy.
  - Systém musí umožnit generování objednávek dle zadaných norem pro hlavní sklad v mateřské lékárně.
  - Systém musí umožnit dle objednávky elektronické převedení zásob z hlavního skladu v mateřské lékárně (vedeného v lékařském informačním systému Mediox) na sklad pracoviště centralizované přípravy Parenterální výživy (vedený v systému pro přípravu Parenterální výživy).

- Tok dat o léčivech mezi systémem a lékárenským informačním systémem musí být v plné šíři (název přípravku, kód SUKL, cenové informace, kusy, expirace, šarže, EAN....).
  - V okamžiku ukončení přípravy musí systém odepsat použítá léčiva a ostatní materiál ze skladu vedeného v systému pro přípravu Parenterální výživy.
  - Systém musí umožňovat jednoduchou kontrolu expirací.
- o **Integrační vazby**
- Systém musí být prokazatelně schopen komunikovat s okolními systémy prostřednictvím HL7 standardu.
  - Účastník musí zajistit integrační vazby vytvořením datových můstků na ostatní relevantní systémy využívané ve FN HK, případně vytvořením tiskových výstupů v obvyklých formátech (zejména docx; xlsx; rtf, csv, txt, pdf). Účastník může navrhnout i jiný způsob řešení vazeb, bude-li zachován jejich účel.
  - Datový můstek IS MEDIOX – IS PV. – vazba ④ a ⑤  
Skladová agenda léčiv a SZM je ve FN HK vedena v IS pro lékárnou „MEDIOX“. Tímto datovým můstkem se předpokládá zajištění předávání dat o léčivech a SZM pro přípravu parenterální výživy z IS MEDIOX do IS PV, a to včetně údajů o nákupní ceně, šarži, expiraci, fakturační skupině, výši DPH, identifikaci dodacího dokladu.
  - Datový můstek IS PV – IS NAVISION. - vazba ⑦  
Tímto datovým můstkem se předpokládá zajištění předávání dat o nákladech na PV v interní spotřebě (lůžkoví pacienti FN HK), jako cenový údaj agregovaný za nákladové středisko, fakturační skupinu a období (měsíc) do ekonomického IS NAVISION.
  - Datový můstek IS PV – IS SOPHIS. Tímto datovým můstkem se předpokládá předávání dat o nákladech na léčiva a SZM pro PV v interní spotřebě (lůžkoví pacienti FN HK) do manažerského IS SOPHIS, jako cenový údaj agregovaný za pracovní kód přípravku, nákladové středisko a období (měsíc).
  - Datový můstek IS PV – IS SOPHIS + tisková sestava s přehledem PV v domácí péči za dané období (měsíc), jako přehled NS po jednotlivých pacientech s uvedením počtu výživ (vaků) a nákladu.
  - Musí být zajištěna možnost zjištění/zajištění:
    - a) Stavů denního provozu (přehled o počtu požadavků z jednotlivých pracovišť, přehled o rozpracovanosti požadavků na jednotlivých úsecích apod.).
    - b) Statistiky o počtech a charakteru požadavků za zvolené období pro jednotlivá pracoviště.
    - c) Statistiky výkonů nebo režimů podle předem nastavených statistických skupin (souhrnná statistika za pracoviště, jednotlivá oddělení, kliniku nebo účetní skupinu) za požadované období (měsíce, roky).
    - d) Exportu statisticky vybraných dat do souborů v obvyklých formátech (zejména docx; xlsx; rtf, csv, txt, pdf).

Podrobnosti k vazbám viz. příloha č.4.

#### • Technické požadavky

- o **Požadavky na vlastnosti systému v oblasti bezpečnosti**
- Nastavení různých úrovní přístupových práv pro jednotlivé role uživatelů. Možnost nastavit jednotlivým uživatelům povolenou funkcionalitu systému a množinu dat, ke které mohou přistupovat. Systém musí obsahovat nástroje na správu těchto funkcí.
  - Povinná identifikace a autentizace každého uživatele při přístupu k systému.
  - Logování činnosti uživatele a změn dat konkrétním uživatelem.

- Možnost nastavení časového intervalu, kdy dojde k ukončení aplikace pro nečinnost uživatele.
- Technologické požadavky
  - Předmětem zakázky není dodávka HW, ani systémového SW.
  - Účastník specifikuje technologické prostředí pro provoz systému (hardware, systémový software, nároky na síťovou komunikaci, bezpečnostní a provozní podmínky a opatření).
  - Účastník specifikuje sizing serveru, - počet a typ doporučených procesorů, velikost RAM, velikost požadovaných diskových prostor pro dvouletý provoz a předpokládaný roční inkrement. Dále typ a verzi operačního systému a databáze případně jiné požadované produkty pro provoz systému.
  - Účastník dále specifikuje požadovaný sizing pracovních stanic.
- Ostatní požadavky
  - Účastník zajistí v rámci implementace systému inicializaci databáze, prvotní nastavení, zavedení číselníků apod.
  - Účastník vytvoří testovací databázi, která bude umožňovat replikaci dat z ostré databáze.
  - Účastník provede školení uživatelů a správců systému. Uchazeč v nabídce navrhne přiměřený rozsah školení a zakalkuluje do nabídkové ceny.
  - Účastník dodá uživatelskou dokumentaci v rozsahu potřebném pro běžný provoz a běžnou správu systému (tištěná dokumentace minimálně ve 2 vyhotoveních a dokumentace na CD nebo jiném vhodném médiu). Dokumentace pro správu systému musí zahrnovat popis datových struktur (tabulek, jednotlivých údajů a vazeb). Každá změna v chování systému nebo uložení dat musí být dokumentována minimálně vydáním zprávy upozorňující na změnu uživatele a změnou kontextové nápovědy. Zpráva může být předána v elektronické podobě.
  - Účastník navrhne postup implementace systému, hlavní postupové kroky, jejich návaznost a časovou náročnost.
  - Zadavatel požaduje dodání časově a místně neomezených licencí potřebných pro provozování a užívání dodaného dfla v rozsahu:
    - 1 x Nemocniční lékárna – Oddělení přípravy léčiv
    - 9 x klinická pracoviště provádějící preskripci a plánování PV.

## 2. Doba a místo plnění

### Doba plnění:

Realizace plnění **dle kupní smlouvy na dodávku zboží** musí být dokončena do 2 měsíců od data nabytí účinnosti smlouvy o dodávce software.

Pozáruční servis **dle servisní smlouvy** bude zajišťován průběžně po dobu neurčitou od doby nabytí její účinnosti.

Realizací se pro tuto veřejnou zakázku myslí dodání softwarového produktu, který je předmětem plnění této veřejné zakázky, jeho instalace a implementace včetně provedení školení uživatelů, dodání veškerých vyžadovaných dokladů a likvidace obalů a odpadu, které byly součástí dodávky, či jakýchkoliv materiálů, použitých účastníkem při realizaci této veřejné zakázky. Likvidace výše uvedených obalů a ostatních materiálů, použitých účastníkem při realizaci této veřejné zakázky, bude uskutečněna dodavatelem veřejné zakázky plně na jeho náklady.

Za den splnění zakázky je považován den protokolárního předání předmětu veřejné zakázky.

Zápis o převzetí potvrdí zodpovědný pracovník Nemocniční lékárny – Mgr. Jiří Kotlář a pracovník OVS, který bude k předání přizván.

## 3. Ostatní obchodní podmínky

Obchodní podmínky pro dodávku předmětu plnění jsou definovány v kupní smlouvě, která je přílohou č. 2 této zadávací dokumentace. Tento návrh smlouvy je pro účastníka veřejné zakázky závazný a není možné jej upravovat v neprospěch zadavatele. V takovém případě bude účastník vyloučen z další účasti v zadávacím řízení.

Účastník musí, jako součást nabídky, předložit zároveň návrh servisní smlouvy. Předložený návrh servisní smlouvy musí obsahovat minimálně tato ustanovení:

1. Účastník se smluvně zaváže k poskytování dalšího servisu předmětu plnění po akceptaci díla na dobu neurčitou. Tím je chápána zejména běžná údržba systému včetně aktualizace číselníkových dat, řešení závad poruch a nestandardních stavů systému vzdáleně i na místě, poradenská služba, poskytování nových verzí systému.
2. V smlouvě budou také ujednány o podmínkách poskytování služeb nad rámec pořizovací ceny (cenu za příp. realizaci úprav aplikačního programového vybavení podle požadavků zadavatele nezahrnutých do zadání a nabídky) a za práce a služby nad rámec sjednané servisní podpory např. cena za hodinu práce specialisty a sankční ujednání.
3. Účastník musí garantovat, že zálohování dat a jejich případná obnova musí být proveditelné vlastními prostředky zadavatele, bez podpory uchazeče nebo jiné osoby. Uchazeč dodá jako součást dokumentace popis postupu a rozsahu zálohování.
4. Účastník musí garantovat poradenskou servisní linku (helpdesk) v českém jazyce pro poradenství a zajištění rychlé pomoci v případě poruch, chyb nebo jiných selhání minimálně v rozsahu běžné pracovní doby.
5. Zadavatelem požadovaná maximální doba nástupu dodavatele na řešení závady, to jest doba, za kterou zahájí řešení problému od okamžiku, kdy se o problému prokazatelně dozví v pracovní den v době od 08:00 do 16,30 je 4 hodiny. Mimo uvedenou dobu a o sobotách, nedělích a svátcích, v nejbližší pracovní den dodavatele do 10 hodin. Po nástupu na řešení závady odstraní dodavatel závadu neprodleně, to jest v termínu úměrném příčině a podstatě závady.
6. Účastník musí garantovat možnost dálkové správy systému podle zvláštní smlouvy, každý vstup přes dálkovou správu a provedené zásahy/záznamy musí být archivovány.
7. Pro vzdálený přístup zadavatel požaduje využít stávající infrastrukturu FN HK – založenou na přístupech přes VPN koncentrátory, které jsou vlastněny zadavatelem.
8. Nebude-li ve sjednaných časových mezích dostupný helpdesk (web, mail, telefon), zadavatel oprávněn uplatnit sankci 2000,- Kč za hodinu.
9. Nebude-li zahájeno řešení požadavku ve stanoveném limitu, je zadavatel oprávněn uplatnit sankci 2.000,-Kč za hodinu.
10. Sankce vůči zadavateli: Pokud bude vůči zadavateli uplatňována uchazečem sankce, tak pouze v případě prodlení s úhradou ceny – úrok z prodlení ve výši 0,025 % z dlužné částky za každý den prodlení.
11. Účastník musí garantovat v rámci paušální servisní péče nasazení nových verzí SW řešení a jeho instalaci v rámci paušálně placené podpory, a to za podmínek výše stanovených.
12. Každá významná změna systému musí být dokumentována a to minimálně vydáním zprávy o změně systému a změnou kontextové nápovědy, každá změna systému musí být před instalací vyzkoušena (zkoušky nesmějí probíhat na ostré databázi), každá nainstalovaná změna musí být akceptována. Akceptace musí být součástí každé změny SW (např. záznam v helpdesku, akceptační protokol apod.).
13. Po dobu placené podpory má zadavatel právo na nové verze systému.

### **Porucha**

je stav, kdy je předmět plnění zcela nefunkční. Uchazeč se zavazuje zahájit práce bezodkladně po jeho nahlášení a jeho odstranění v nejkratší možné době.

### **Závada**

je stav, kdy nefunguje některá část předmětu plnění, ale systém je omezeně použitelný. Uchazeč zajistí adekvátní reakci na hlášení Zadavatele. Adekvátní reakce na hlášení znamená návrh postupu řešení problému, či požadavku s odhadem termínu vyřešení.

## **4. Požadavky zadavatele na prokázání kvalifikace:**

V nabídce musí účastník doložit prosté kopie dokladů, které prokazují splnění kvalifikace, resp. způsobilosti.

### **1. Splnění základní způsobilosti**

Splnění základní způsobilosti prokáže účastník, který předloží:

- Čestné prohlášení prokazující splnění základní způsobilosti. Účastník může využít vzor čestného prohlášení, který je přílohou č. 3 této zadávací dokumentace.

### **2. Splnění profesní způsobilosti**

Splnění profesní způsobilosti prokáže účastník, který předloží:

- Výpis z obchodního rejstříku, pokud je v něm zapsán, či výpis z jiné obdobné evidence, pokud je v ní zapsán.

### **3. Splnění technické kvalifikace**

Splnění technické kvalifikace prokáže účastník, který předloží:

- Seznam minimálně 1 významné dodávky poskytnuté za poslední 3 roky před zahájením zadávacího řízení, kterými se pro účely této veřejné zakázky myslí dodávka software pro přípravu parenterální výživy minimálně se stejnými parametry, jako jsou požadovány v této ZD nebo servis jím dodaného řešení za poslední 3 roky před zahájením zadávacího řízení. Z předloženého seznamu musí vyplývat alespoň:

- obecná specifikace – název a druh,
- typ plnicího automatu
- rozsah dodávek (uveďte v Kč bez DPH),
- doba plnění,
- kontaktní údaje na oprávněné osoby odběratelů za účelem případného ověření předložených informací (alespoň v rozsahu jméno, telefonní číslo a e-mail).

Seznam musí být podepsaný osobou oprávněnou jednat jménem či za účastníka.

- Popis nabízeného produktu musí být alespoň v takovém rozsahu, aby byl zadavatel schopen posoudit splnění minimálních požadavků uvedených v bodě 1. této zadávací dokumentace.

## **5. Požadavky zadavatele na způsob zpracování nabídkové ceny:**

**Předpokládaná hodnota za dodávku a instalaci software pro parenterální výživu, včetně implementace zaškolení a servisní péče na 48 měsíců po skončení záruky, činí 2.000.000,- Kč bez DPH. Tato částka je zároveň maximálně přípustnou cenou. Překročení maximální přípustné ceny vede k vyloučení účastníka z další účasti v zadávacím řízení.**

**Součástí nabídkové ceny musí být veškeré náklady účastníka nezbytné pro řádnou a úplnou realizaci předmětu veřejné zakázky. Součástí nabídkové ceny musí být i práce či činnosti, které v této zadávací**

dokumentaci nejsou explicitně uvedeny, ale které účastník musí s ohledem na jim nabízený předmět veřejné zakázky a jeho řádnou a úplnou realizaci provést k dosažení zadavatelem požadovaného cílového stavu.

Nabídkové ceny uvede účastník v členění dle krycího listu (Příloha č. 1 této zadávací dokumentace).

**Celková nabídková cena musí být uvedena v Kč bez DPH.**

#### UPOZORNĚNÍ:

Zadavatel nepřipouští nulové položky, které tvoří celkovou nabídkovou cenu. V případě uvedení nulové ceny bude nabídka účastníka vyloučena z další účasti v zadávacím řízení.

#### 6. Další podmínky a požadavky zadavatele:

**Z předložené nabídky musí být zřejmé, že účastník svojí nabídkou plní všechny body zadání.**

Účastník podáním nabídky uděluje zadavateli souhlas k ověření a prověření údajů uvedených v nabídkách.

Zadavatel si vyhrazuje níže uvedená práva a podmínky:

- v kterékoli fázi zrušit výběrové řízení bez udání důvodů; a to do okamžiku podpisu smlouvy s vybraným účastníkem,
- vyloučit účastníka v případě nesplnění podmínek uvedených v zadávací dokumentaci či uvedení nepravdivých údajů,
- zadavatel nepřipouští varianty řešení,
- účastník sám ponese veškeré své náklady spojené s účastí ve výběrovém řízení, zadavatel nhradí jakékoli náhrady nebo výdaje vynaložené účastníky v souvislosti s jejich účastí v řízení,
- zadavatel nebude účastníkům vracet nabídky.

#### PODMÍNKY A POŽADAVKY NA ZPRACOVÁNÍ NABÍDKY

Účastník ve své nabídce uvede své identifikační údaje, a to v krycím listu, který je přílohou č. 1 této zadávací dokumentace.

Účastník ve své nabídce předloží vyplněný návrh smlouvy kupní a návrh smlouvy servisní. Tyto smlouvy musí být podepsané osobou oprávněnou jednat jménem či za účastníka. Pokud návrhy smluv podepíše zmocněná osoba, musí být součástí nabídky účastníka též příslušná platná plná moc.

Součástí nabídky musí být rovněž další dokumenty požadované zadavatelem v této zadávací dokumentaci.

Nabídka musí být předložena v českém jazyce v jednom vyhotovení (v listinné podobě). K dokladům a listinám předloženým v jiném než českém (či slovenském) jazyce musí být připojen jejich překlad do českého jazyka. Za správnost takového překladu odpovídá účastník.

Čestná prohlášení, požadovaná zadavatelem, musí být podepsána osobou oprávněnou jednat jménem či za účastníka. V případě podpisu jinou osobou na základě plné moci, musí být prostá kopie zmocnění této osoby součástí dokladů, kterými účastník prokazuje splnění kvalifikace.

Nabídka účastníka nesmí obsahovat přepisy nebo opravy, které by mohly uvést zadavatele v omyl.

Účastník předloží nabídku též v elektronické podobě na CD nebo DVD (zadavatel požaduje, aby na CD nebo DVD byly naskenovány veškeré dokumenty po podpisu oprávněné osoby, jež jsou předkládány v listinné podobě a dále návrhy smlouvy kupní, servisní a smlouvy o dílo v editovatelném formátu - např. \*.doc nebo \*.docx – v tomto formátu nemusí být návrhy smluv podepsány). V případě rozporů mezi listinnou a elektronickou podobou nabídky je rozhodující listinná podoba.

Nabídka musí být pevně svázaná, zabezpečena proti nežádoucí manipulaci s listy a stránky musí být očíslovány. Za dostatečné zabezpečení nabídky proti manipulaci s jednotlivými listy považuje zadavatel opatření svazku takovými bezpečnostními prvky, které zabezpečí spolehlivé sebepoškození v případě výše uvedené manipulace. Použité bezpečnostní prvky musí být dále dostatečně jedinečné tak, aby byla vyloučena možnost jejich neoprávněného nahrazení. Zadavatel doporučuje jako jeden z možných bezpečnostních prvků použití provázku a přelepek opatřených podpisem statutárního orgánu účastníka a jeho razítkem.

Zadavatel doporučuje všechny listy nabídky včetně příloh řádně očíslovat vzestupnou číselnou řadou a na poslední stránce nabídky uvést podepsané prohlášení o celkovém počtu stran nabídky.

Zadavatel doporučuje účastníkovi ve své nabídce použít toto pořadí dokumentů:

- 1) Krycí list nabídky
- 2) Doklady prokazující splnění kvalifikace v rozsahu dle bodu 4. této zadávací dokumentace
- 3) Návrh smlouvy kupní a servisní
- 4) CD nebo DVD [scan nabídky, návrhy kupní smlouvy, servisní smlouvy a smlouvy o dílo v editovatelném formátu (např. \*.doc, \*.docx)]
- 5) Ostatní dokumenty – dle požadavků zadavatele a uvážení účastníka
- 6) Prohlášení o počtu stran.

## PODÁNÍ NABÍDKY

Účastník podáním své nabídky souhlasí se zveřejněním všech náležitostí budoucího smluvního vztahu (vlastní smlouva, atd.) a s poskytnutím veškerých nezbytných informací pro naplnění povinnosti zadavatele stanovené zákonem.

Účastník může podat pouze jednu nabídku.

### 7. Místo a doba pro podávání nabídek:

**Lhůta pro doručení nabídky: Nabídky doručte do 15. 10. 2018 do 10:00 hodin**

Místo pro doručení nabídky: Fakultní nemocnice Hradec Králové, odbor výpočetních systémů  
adresa: Sokolská 581, 500 05 Hradec Králové – Nový Hradec Králové

Přebírající osoba: Mgr. Václav Jaroš

Nabídku je možné doručit **osobně** (od 8:00 do 15:00 hod.) **nebo zaslat doporučeně poštou** na výše uvedenou kontaktní adresu **v zalepené obálce**, která bude opatřena nápisem „Nabídka – Software pro parenterální výživu ve FNHK – NEOTVÍRAT před uplynutím lhůty pro podání nabídek“.

Pokud nebyla nabídka zadavateli doručena ve lhůtě stanovené v zadávací dokumentaci, nepovažuje se za podanou a v průběhu zadávacího řízení se k ní nepřihlíží.

## 8. Způsob hodnocení nabídek:

Hodnocení nabídek bude provedeno dle ekonomické výhodnosti nabídek, a to na základě jediného hodnotícího kritéria - nejnižší celkové nabídkové ceny v Kč bez DPH.

Posouzení splnění požadavků vymezených zadavatelem v této zadávací dokumentaci provede zadavatel až po hodnocení nabídek, a to pouze u vybraného dodavatele.

Přílohy:

- 1) Příloha č. 1 - Krycí list
- 2) Příloha č. 2 - Návrh smlouvy
- 4) Příloha č. 3 - Čestné prohlášení – Prokázání základní způsobilosti
- 5) Příloha č. 4 – Integroční vazby

V Hradci Králové dne 2. 10. 2018

Ing. Miroslav Procházka  
vedoucí odboru výpočetních systémů



FAKULTNÍ NEMŮCNICE  
500 05 HRADČI KRÁLOVÉ  
Odbor výpočetních systémů  
(1)



Fakultní nemocnice Hradec Králové

Sokolská 581  
Hradec Králové  
500 05  
CZ

Ve Vidni 09.10.2018

**Cenová nabídka na:**

Software pro parenterální výživu ve FN HK

<b>Položka</b>	<b>Cena bez DPH v Kč</b>	<b>Cena za údržbu 48 měsíců bez DPH v Kč</b>
BDTPN Licence pro neomezený počet uživatelů	875.000,-	275.000,-
Rozhraní CDE VA Sofis	166.250,-	20.250,-
Rozhraní CDI Mediox	137.500,-	14.500,-
Rozhraní CDE VA Navision	137.500,-	14.500,-
Mezisoučet	1.316.250,-	648.500,-
<b>Celkem nabídková cena</b>	<b>1.964.750,-</b>	

Systém je kompatibilní s plnicími automaty

1. NeoCare (ICU)
2. ExactaMix2400 (Baxter)
3. IMF