

B. Braun Melsungen AG
Division Aesculap
Vascular Systems

Sieversufer 8
12359 Berlin

Contact: Dr. Christian Sperling

Fon: +49 30 568207-120

Email: vigilance-vs@bbraun.com
Internet: <http://www.bbraun.com>

Date: November 20, 2023

B. Braun Organization / Distributor

Your customer no.: [...]

Our reference no.: FSCA-VS-2023-01

Letter to B. Braun Organizations / Distributors

regarding an Urgent Field Safety Notice for Combitrans® / Combidyn® Monitoring Sets

- Changes to the instructions for use -

Dear B. Braun Organization / Distributor,

We would like to inform you about an urgent Field Safety Notice issued by B. Braun Melsungen AG - Vascular Systems regarding the change of the instructions for use of our Combidyn® / Combitrans® Monitoring Sets.

One or more of the Combidyn® / Combitrans® Monitoring Sets listed in Appendix 1 have been distributed to you in the last 3 years.

We therefore kindly ask you to perform the following actions:

- 1) Please identify all customers in your country who are currently using the affected products.
- 2) If you have active customers:
 - a. Please finalize the attached Field Safety Notice and Appendices (provided additionally as MS Word file in English language) with your local contact information and signature.
 - b. Please inform the identified customers with the Field Safety Notice including the Appendices.
 - c. Please make sure that the receipt of the Field Safety Notice is confirmed by each customer on the attached Appendix 3.

Chairwoman of the Supervisory Board:
Dr. Annette Beller

Executive Board:
Markus Strotmann
(Chairman)
Priv.-Doz. Dr. Stefan Ruppert
Jürgen Stihl

Corporate Office: Melsungen
Register Court:
Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

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[B. Braun organization / Distributor]

- d. If you require further information on correct product use or training, please contact your responsible B. Braun marketing/sales representative.
 - e. Please report this Field Safety Corrective Action to your local authority, if required. You will find a reporting template (used in European Union) attached to this email. Please add the name of your authority in section 1 and your local contact details in section 5.
 - f. Please confirm receipt of this Field safety notice **until 24. November 2023**.
 - g. Please send an update about the progress of customer information until **20. December 2023**.
- 3) If you do not have active customers in your country please confirm via email **until 24. November 2023**

The described change of the instructions for use is currently being implemented. You will be informed as soon as the affected products are delivered with the new instructions for use.

Please send confirmations / updates to the following email addresses:

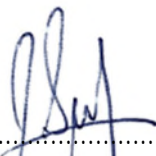
vigilance-vs@bbraun.com

fscs-vs@bbraun.com

We apologize for any inconvenience this may cause you. If you have any questions, please do not hesitate to call us on +49 30 568207-120 or contact us at vigilance-vs@bbraun.com. Thank you very much in advance for your understanding and support.

B. Braun Melsungen AG

i.A.



.....
Dr. Christian Sperling
PRRC-Vigilance
CoE Vascular Systems Berlin

i.V.



.....
Dr. Susanne Vogelbein
Head of Quality Management
CoE Vascular Systems Berlin

[Customer address]

[B. Braun Country Organization
or Distributor]

Urgent Field Safety Notice

Combitrans® / Combidyn® Monitoring Sets

Changes to the instructions for use

Combitrans® / Combidyn® Monitoring Sets are invasive, disposable monitoring systems for measuring physiological blood pressure and blood sampling. They are supplied sterile and for single patient use.

As users already know, prolonged contact with organic solvents (spray disinfectants) can promote the formation of stress cracks in plastic tubing connectors and multidirectional stopcocks.

A corresponding warning for the Discifix multidirectional stopcocks integrated in the affected sets was already distributed by the manufacturer (see Appendix 2). However, it is not yet distributed with the sets as we were only recently informed about it by the manufacturer. We would therefore like to inform you that in the future the affected Combitrans® / Combidyn® monitoring sets will include also a separate warning notice for the Discifix multidirectional stopcocks.

Risk for the patient

In extremely rare cases, stress cracks can lead to fluid leakage and the risk of an associated change in pressure signal transmission. Furthermore, air entry with the risk of an air embolism cannot be ruled out.

The risks mentioned in connection with leaky connections are generally known and are already listed in the current instructions for use:

"Risks: Potential complications include infection, embolism caused by air bubbles or blood clots, over-infusion or leakage. A leaking connection will allow air to enter the system and produce incorrect low pressure readings. (...) Furthermore, air bubbles may have a negative effect on the pressure reading. Air bubbles should carefully be removed from the flush reservoir and tubing to prevent any air bubbles from entering the transducer."

Measure by B. Braun Melsungen AG

In order to further reduce the actual occurrence of these risks, the instructions for use will contain a corresponding additional note in the future:

"Multidirectional stopcocks and tubing connections may tend to crack formation when influenced with alcohol-based disinfectants. These cracks can result in leaks or air ingress. We recommend inspecting the entire infusion line for these hazards."

Due to a requirement from the manufacturer of the Discofix multidirectional stopcock, the products listed in Appendix 1 will contain an additional separate warning (see Appendix 2).

Recommended measures until the new instructions for use are available

- 4) If components of the Combitrans® / Combidyn® monitoring system are being disinfected in your hospital, please pay attention to the formation of stress cracks in tubing connections and multidirectional stopcocks during further use.
- 5) If you notice stress cracks and/or fluid leakage, please change the entire monitoring system.
- 6) If you require further information on correct product use or training, please contact your responsible B. Braun sales representative. They will contact you and provide you with the information you require.
- 7) Please ensure that all users of the above-mentioned products and other persons to be informed are informed of this urgent safety information. If you have given the products to third parties, please forward a copy of this information to them.
- 8) Please note the warning notice for the Discofix® multidirectional stopcock (Appendix 2).
- 9) Please confirm receipt of the Field safety notice on the enclosed form (Appendix 3).

B. Braun Melsungen AG - Vascular Systems has informed the Federal Institute for Drugs and Medical Devices (BfArM) about the distribution of this urgent safety information.

We apologize for any inconvenience this may cause you. If you have any questions, please do not hesitate to call us on +49 30 568207-120 or contact us at vigilance-vs@bbraun.com. Thank you very much in advance for your understanding and support.



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[B. Braun organization / Distributor]

Signed by
[Local B. Braun Organization / Distributor]

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Appendix 1

REF no.	Product name
5010244	SET POUR CHAMBRE IMPLANTABLE
5010741	HAEMOFIX-COMBITRANS CBSS MONO CARCHIR
5011297	COMBITRANS SET ARTERIELL MIT BEH
5011298	COMBITRANS-SET 2-FACH BEH
5012707	CONTRAST / PRESSURE SYSTEM WITH SYRINGE
5012875	MITRA - SET KARLSBURG
5012943	MITRACLIP-SET ROBERT-BOSCH-KH
5013116	ADD ON INFUSIONSSET KSSP AARAU
5013302	MITRACLIP-SET UMR
5013583	MITRA CLIP SET BAD ROTHENFELDE
5014530	MITRACLIP SET CKU
5017392	INFUSIONSSET KLINIKUM OLDENBURG
5017833	ARTERIEN SET BOCHUM
5018353	COMBITRANS KIT PAED
5018642	INFUSIONSLEITUNG MIT DWH 250 CM
5018686	ARTERIOFI SET 22G/80MM Hubertus Berlin
5019603	MONITORING-SET HKL HOMBURG
5019764	SET CT AN. CRÉAT.18G VERT CL.GENOLIER SA
5019765	CT AN.CRÉAT. 20G ROSE GRENOLIER LAUSANNE
5019766	Set IRM, CLINIQUE DE GENOLIER SA
5019767	SET PET-CT (CLINIQUE DE GENOLIER SA)
5200004	COMBITRANS-SET HERZ-LUNGEN-MASCHINE
5200010	COMBITRANS 1-FACH MONITORING-SET
5200011	COMBITRANS 2-FACH MONITORING SET
5200031	EXADYN MONITORING SET
5200032	COMBITRANS MONITORING SET 2-FACH HELIOS
5200033	COMBITRANS MONITORING SET 3-FACH
5200034	COMBITRANS MONITORING SET HELIOS
5200040	COMBITRANS ROYAL NORTH SHORE HOSPITAL
5200050	HÄMOFIX CM EXADYN SET BAD HERSFELD
5200059	SET V3 LA FE
5200181	HAEMOFIX-MONITORING-SET 2-FACH, BEH
5200182	HAEMOFIX-MONITORING-SET ARTERIELL, BEH
5200183	HAEMOFIX-MONITORING-SET ART/VEN BEH
5200184	HAEMOFIX EXADYN SET LANGE LEITUNGEN
5200253	SET PIC V1 LA FE
5200294	ARTERIOFI-SET FEMORAL CHEMNITZ
5200359	ADD ON MIT BEH
5200393	COMBITRANS-MONITORING-SET, ROT
5200427	COMBITRANS ARTERIELL KL.NEUMARKT OPF.
5200458	COMBITRANS-EXADYN SAFESET 200CM
5200671	ANTI-SHUNT-COMBITRANS MONITORING-SET ART
5200686	DRUCKDOM-SET OHNE COMBIDYN

REF no.	Product name
5209127	SPECIAL ARTERIAL MONITORING SET
5209135	SPECIAL CVP MONITORING SET
5209302	COMBITRANS MONITORING SET HAMBURG
5209364	COMBITRANS-EWT, BLAU
5209466	COMBITRANS-EWT, GELB
5209922	COMBITRANS HÄMOFIX MONITORING SET 3-FACH
5210044	COMBITRANS MONITORING SET 2-FACH PLUS
5210050	COMBITRANS-SET, KH STUTTGART
5210055	COMBITRANS ZUBEHOER SET
5210152	CMS ST.JOSEF KH SCHWEINFURT
5210349	COMBITRANS HAEMOFIX EXADYN MIT BEH
5210521	SCHANZER EXADYN SET OP_49 A_49 C
5210522	SCHANZER COMBITRANS SET 49 I
5210561	COMBITRANS-MONITORING-SET
5210571	COMBITRANS-MONITORING-SET
5210865	HAEMOFIX COMBITRANS SET ARTERIELL
5210976	COMBITRANS MONITORING-SET
5211090	HAEMOFIX 2-FACH COMBITRANS SET
5211110	COMBITRANS-SET ARTERIELL,PAEDIATRIE
5211247	COMBITRANS MONITORING-SET
5211298	COMBIDYN-Set
5211700	COMBITRANS MONITORING-SET, PVC-FREI
5212021	ADD ON SET HAEMOFIX ROT 2,4 ml
5212033	COMBITRANS MONITORING SET VENOES UNI HRO
5212045	COMBITRANS MONITORING SET WEHNER
5212055	EXADYN COMBITRANS DRUCKMESS-SET 202-1307
5212391	EXADYN-COMBITRANS PVC-FREI
5212782	COMBITRANS MONITORING PAEDIATRIE-SET VIL
5212795	EXADYN SET MIT BEH KL. ESSLINGEN
5212847	COMBITRANS-MONITORING-SET
5213256	HAEMOFIX EXADYN SET BAD HERSFELD II
5213330	EXADYN-MONITORING-SET PAEDIATRIE
5213460	COMBITRANS-MONITORING-SET
5213505	HAEMOFIX-COMBITRANS MONITORING-SET ARTER
5213516	HAEMOFIX-EXADYN MONITORING-SET ART. + VE
5213527	HAEMOFIX-COMBITRANS MONITORING-SET 2-FACH
5214010	COMBITRANS SET ROT ESSEN
5214020	COMBITRANS SET BLAU ESSEN
5214040	HAEMOFIX-COMBITRANS SET 2-FACH BEH 4,8ML
5214076	COMBITRANS-SET BAD WILDUNGEN
5214271	EXADYN-COMBITRANS-MS
5214319	CMS-LEOPOLD.KH SCHWEINFURT MED.ITS
5214335	COMBITRANS-MONITORING-SET 1-FACH

REF no.	Product name
5200809	COMBITRANS MONITORING SET, ROT
5200830	COMBITRANS MONITORING-SET 2-FACH
5200849	COMBITRANS MONITORING-SET 3-FACH
5200872	COMBIDYN MONITORING KIT WITH PRESSURE DO
5200880	COMBITRANS EC HLM WIEN
5201024	COMBITRANS SET PAEDIATRIE
5201025	UKE SET EINFACH ART/VEN GBE
5201030	UKE SET ZWEIFACH ART/VEN GBE
5201035	COMBITRANS UKE 3-FACH BES
5201120	ART/VEN DRUCKMESSSYSTEM 2-TRANSDUCER H9
5201130	ART/VEN DRUCKMESSSYSTEM 1-TRANSDUCER
5201152	COMBITRANS MONITORING-SET 2-FACH
5201209	COMBITRANS ARTERIELL.PEAD SET FREIBURG
5201406	COMBITRANS EC DRUCKMESSSET 3-FACH
5201428	CMS HÄMOFIX BEH 2-FACH PLUS
5201432	ADD-ON-SET HÄMOFIX BLAU
5201493	CTBK SDL + CTA
5201500	COMBIDYN SPUELSYSTEM 3ML/H
5201667	COMBITRANS 2-FACH SET MOD.I UNI GIessen
5201675	COMBITRANS 1-FACH SET MOD.II UNI GIessen
5201819	HAEMOFIX EXADYN SET (1 ENTNAHMEPORTS)
5202018	Combitrans Haemofix EVK
5202022	COMBITRANS-SET SCHULTHESSKL. ZUERICH
5202024	COMBITRANS-SET SCHULTHESSKL. ZUERICH 2-F
5202059	COMBITRANS KINDER SET FULDA
5202088	ITS HAEMOFIX BEH SET
5202115	INTRAFI ASSEMBLY SWEDEN
5202124	COMBITRANS SET LATEX/PVC FREI-OLGAHOSPIT
5202286	COMBITRANS-SET INTENSIV SCHWARZWALD BAAR
5202407	COMBITRANS HAEMOFIX ARTERIELL 2,4ML BEH
5202408	COMBITRANS EXADYN HAEMOFIX 2,4ML BEH
5202409	COMBITRANS 2-FACH HAEMOFIX 2,4ML BEH
5202500	COMBITRANS MS 2+ UNI MD
5202507	EXADYN-COMBITRANS MONITORING-SET
5202604	COMBITRANS MONITORING-SET VENOES
5202614	COMBITRANS-MONITORING-SET VENOUS LONG
5202617	COMBITRANS MONITORING-SET PULMONALARTERI
5202620	COMBITRANS MONITORING-SET ARTERIELL
5202706	CTBK SDL + CTV
5202766	HÄMOFIX CM SET DIAKONIE KL. KASSEL
5203032	HLM SET BEAU SITE 2
5203033	COMBITRANS UKE EXADYN
5203034	COMBITRANS UKE 1-FACH ARTERIELL
5203036	COMBITRANS UKE 3-FACH
5203037	COMBITRANS PA ALBERTINEN HH
5203041	COMBITRANS UKE 1-FACH ERGAENZUNG

REF no.	Product name
5214378	COMBITRANS SET 2-FACH PLUS
5214433	COMBITRANS SET ARTERIELL MIT BEH
5214580	COMBITRANS-MS +1+ UNI MD HTC AN
5214637	CMS LEOPOLDINA KH SCHWEINFURT ANÄST.-OP
5214700	COMBITRANS-MONITORING-SET 1-FACH, JENA
5214777	EXADYN-COMBITRANS-MONITORING-SET AUGSBG.
5214807	COMBITRANS-HIRNDRUCK-SET. JENA
5214884	COMBITRANS SET EXADYN VBW
5215013	COMBITRANS MON.-SET ST.GALLEN I.
5215050	HAEMOFIX-COMBITRANS SET 3-FACH BEH 4,8ML
5215300	COMBITRANS EXADYN SET MODELL F.
5215454	HAEMOFIX COMBITRANS SET ARTERIELL 4,8ML
5215514	EXADYN SET KLINIKUM MITTELBADEN
5215555	HAEMOFIX-EXADYN SET BEH 4,8 ML
5215859	Hämofix-CMS Set 2-fach, BEH art. + ven.
5216200	COMBITRANS MONITORING-SET KLETTBAND
5217857	TYKS PRESSURE KIT
5218347	COMBITRANS SET PS MAGDEBURG
5218598	COMBIDYN DRUCKSCHL.M. DWH ROT 15 CM PE
5218655	HAEMOFIX-EXADYN-SET ST. GALLEN
5219208	COMBITRANS SET MIT ENTNAHMEHAHN
5219525	CMS SET 3-FACH PLUS ZYPERN
5219730	DRUCKMESS-SET-NOTTWIL
5231999	COMBITRANS 2-FACH ADD ON HCI ESSEN
5311010	COMBITRANS EC TYP MUENCHEN ARTERIELL
5311325	COMBITRANS EC HÄMOFIX-EXADYN SET MIT BEH
5311630	Double CMS EC Set (ART/CVP/Add-ON)
5311631	SINGLE CMS EC SET
5311632	ADD-ON CMS-EC SET
5311633	DREIFACH CMS-EC SET (ART/CVP/LAP/ADD-ON)
5312020	COMBITRANS EC TYP MUENCHEN VENOES
5313030	COMBITRANS EC TYP STUTTGART
5313720	COMBITRANS EC HAEMOFIX 2-FACH PLUS
5313730	COMBITRANS EC HAEMOFIX 3-FACH PLUS
5318575	COMBITRANS EC EXADYN SET
5318765	COMBITRANS-EC ADD ON PAP
5318768	COMBITRANS-EC UKE 3-FACH
5318776	COMBITRANS MONITORING EC ADD ON SET
5319280	COMBITRANS EC HLM HZ KARLSBURG
5319289	COMBITRANS EC ARTERIELL
5319290	COMBITRANS EC VENÖS
5319291	COMBITRANS EC ART/BEH
5319292	COMBITRANS EC ART+VEN / BEH
5319295	CEC HAEMOFIX SET ARTERIELL BEH
5319300	CEC HAEMOFIX-EXADYN SET
5319305	COMBITRANS EC MIT BEH

REF no.	Product name
5203043	SET DOUBLE Q-6 10.150
5203044	COMBITRANS PÄDIATRIESET KL. AMBERG
5203111	COMBITRANS MONITORING KIT PAEDIATRIC
5203567	NOTFALLSET
5203579	Combitrans ITS-Set Meppen
5203611	COMBITRANS-SET 2-FACH PLUS REGENSBURG
5203617	COMBITRANS EC HAEMOFIX BAD HERSFELD II
5203633	COMBITRANS-SET 3-FACH PLUS REGENSBURG
5203644	COMBITRANS ADD-ON-SET WEISS
5203647	CT 3FACH BEH AUGUSTA BOCHUM
5203653	CMS MONITORING SET ARTERIELL HIRSLANDEN
5203654	CMS MONITORING SET 2-FACH HIRSLANDEN
5203655	COMBITRANS SET ARTERIELL
5203656	CMS MONITORING SET 3-FACH HIRSLANDEN
5203666	HAEMOFIX-BAUGRUPPE
5203677	HAEMOFIX COMBITRANS SET ARTERIELL
5203688	COMBITRANS ADD-ON-SET GELB
5204030	COMBITRANS-SET 3 1/2-FACH
5204332	COMBITRANS VEN.PAED.SET UNI FREIBURG
5204604	MONITORING SET-2FACH HTG UNI JENA
5204781	HAEMOFIX SET TICINO
5205022	DOUBLE MONIT.SET (ART/CVP/ADD-ON)
5205117	COMBIDYN LEITUNG M/M, ROT, 200 CM
5205581	COMBIDYN-SET EV.JOHANN.DUISBURG
5205689	COMBIDYN MONITORING SET OHNE DRUCKDOM
5205848	EXADYN-MONITORING-SET KL. DRESDEN
5205850	COMBITRANS HIRNDRUCKMESS SET DRESDEN
5206000	COMBITRANS 1-FACH MIT BEH/HAEMOFIX
5206011	COMBITRANSSET LUND 1-LINJE ARTAER
5206066	COMBITRANSSET LUND 2-LINJE
5206100	COMBITRANS ADD ON PAP
5206131	MHH ADD ON NACH DR.GRAS
5206482	COMBITRANS-SET 2-FACH HÄMOFIX BEH KS ZUG
5206530	COMBITRANS HÄMOFIX SINGLE KS ZUG
5206610	Combitrans 2fach R.B.KH HerzOP GBE
5206620	ART/VEN DRUCKMESSSYSTEM 2-TRANSD. H9 GBE
5206630	ART/VEN DRUCKMESSSYSTEM 1-TRANSDUCER GBE
5206767	COMBITRANS SET 1-FACH ZVD MIT BEH/HA
5206831	COMBITRANS-SET KS ZUG
5206988	HAEMOFIX SET BRANDENBURG
5206994	EXADYN-MONITORING-SET(LANGE LEITUNGEN)
5207032	COMBITRANS SET 4-FACH DUESSELDORF
5207051	COMBITRANS-SET 3-FACH UNI MUENSTER
5207069	COMBITRANS MONITORING SET
5207080	COMBITRANS MS, 2-FACH
5207167	COMBITRANS MONITORING SET ADD-ON
5207410	COMBIDYN MONITORING SET SENSOR 840
5207466	FRÜHGEBORENEN SET FRANZISKUS MÜNSTER
5207590	SET V4 LA FE (COMBITRANS)

REF no.	Product name
5319310	CMS EC 1-FACH ARTERIELL OHNE RESERVOIR
5319311	CMS CT-EC 2-FACH OHNE RESERVOIR
5319312	CMS EC ADD-ON PAP - GELB
5319315	CMS EC ADD-ON WEISS
5319553	COMBITRANS EC HÄMOFIX SET HKZ ROTENBURG
5440001	COMBITRANS ART/VEN GBE 4,8 PRO BEH
5440003	COMBITRANS ART/VEN PLUS BBE 4,8 PRO BEH
5440004	COMBITRANS SET BAD NEUSTADT
5660040	ZVK SET CHARITÉ
5770001	COMBIDYN PVC 20 CM M.DISCOFIX PLUS ROT
5770002	COMBIDYN PVC 20 CM M.DISCOFIX PLUS BLAU
5770003	COMBIDYN PVC 20 CM M.DISCOFIX PLUS WEISS
5770027	ERGAENZUNGSSET SIEGBURG
5770038	DRUCKMESSSET FUER NEONATOLOGIE
5770063	COMBITRANS ART / VEN HF BEH
5770064	COMBITRANS ART HF BEH
5770093	COMBITRANS 3 PLUS HELIOS HZ KA
5770104	COMBITRANS 2 PLUS GBE ROTES RES. HZL
5770533	COMBITRANS 1 BEH KLAR HZL
5770543	COMBITRANS 2 GBE HZL
5770544	COMBITRANS 1 GBE ROT HZL
5770545	COMBITRANS 1 PA ADD ON HZL
5770546	COMBITRANS 2 PLUS GBE HZL
5770586	COMBITRANS ARTERIELL EPU HZ LEIPZIG
5770599	DRUCKMESSSET NEONATOLOGIE NEU
5771551	COMBITRANS-SET HERZ-LUNGEN-MASCHINE
5771734	COMBITRANS-SET ARTERIELL
5880001	SANA ADD-ON MIT BEH
5880004	SANA 1-FACH ZVD MIT BEH/HAEMOFIX
5880007	COMBITRANS 1-FACH MIT BEH/HAEMOFIX
5880009	SANA 2-FACH MIT BEH UND HAEMOFIX
5880012	CT PÄDIATRIE SET SANA
5880100	SANA 1-FACH ART/VEN MIT BEH/HAEMOFIX/OP
5880105	SANA 3-FACH MIT BEH/HAEMOFIX/OP
5880110	SANA 1-FACH ARTERIELL BEH/ HAEMOFIX/OP
5880115	SANA 2-FACH MIT BEH/HAEMOFIX/OP
5880120	SANA 3-FACH MIT BEH/HAEMOFIX
5880125	SANA HZ DRESDEN COMBITRANS 4-FACH
5880130	SANA COMBITRANS SET 3-FACH OP
5880135	SANA COMBITRANS SET 2-FACH OP
5880140	SANA COMBITRANS SET ART/VEN - OP
5880145	SANA COMBITRANS SET ARTERIELL OP
4897002A	PROSET VORBEREITUNGSSET ZVK
4898497A	PROSET VORBEREITUNGSSET ZVK
4899061A	PROSET VORBEREITUNGSSET ZVK
5200830M	COMBITRANS MONITORING SET 2-FACH
5202507-1	EADYN-COMBITRANS MONITORING-SET CHILE
78226F	ZVK-KIT UNIVERSITAETSKLINIK KIEL
PL4000088	Combitrans Safe Set

REF no.	Product name
5207710	COMBIDYN-DRUCKMESS-SET MODELL UKB
5207722	COMBITRANS 2-FACH ROBERT-BOSCH-KH HERZOP
5207730	COMBITRANS-SET MODELL MUENCHEN, VENOES
5207744	COMBITRANS ADD-ON-SET BOSCH-KH HERZOP
5207902	COMBITRANS SET V.R.2
5208291	COMBITRANS 3-FACH HAEMOFI BEH
5208388	HAEMOFIX-COMBITRANS-SET 2-FACH
5208525	HAEMOFIX-COMBITRANS TRIPLE SET S.CAMILLO
5208575	COMBITRANS EXADYN SET M.ENTNAHMEHAHN
5208599	COMBIDYN DRUCKSCHL.MIT DWH ROT/20CM PVC
5208706	IABP-Set, Kssp.St.Gallen
5208800	COMBITRANS SET ART/VEN MIT BEH
5209000	COMBITRANS SINGLE KIT (1)
5209011	COMBITRANS MONITORING SET ARTERIELL
5209012	COMBITRANS MONITORING SET ARTERIELL BEH
5209022	COMBITRANS MONITORING SET VENOES
5209060	COMBITRANS DOUBLE KIT
5209090	COMBITRANS TRIPLE KIT
5209092	COMBITRANS EXADYN SET

REF no.	Product name
PL4000107	ABLAUF 300CM FÜR TROPF
PL4000116	SET ZUR DRUCKMESSUNG SENSOR 844
PL4000144	COMBITRANS UMWANDLER, EINFACH
PL4000222	SCHENKELARTHROSKOPIE SET FUER PRZEMYSL
PL4000239	COMBITRANS&COMBIDYN SET FUER IBP MESSUNG
PL4000284	SET FUER DRUCKMESSUNG, MIT DOM
PL4000323	COMBITRANS SET
PL4000366	MONITORING SET 1-FACH
PL4000367	MONITORING SET 2-FACH
PL4000368	MONITORING SET 2-FACH
PL4000384	COMBITRANS VENOS
PL4000395	COMBITRANS ARTERIELL
PL4000425	SET COMBITRANS
PL4000427	COMBITRANS ARTERIELL
PL4000430	COMBITRANS EC
A=!!%&	4@> 3:EC? D 2CE6C:6= H ŽC272ú <C2<ŸH
PL4000468	SET FÜR SENSOR 844
A=!!%&"	4@> 3:EC? DE E?:4K@ J=?J
PL4000482	COMBITRANS UMWANDLER, EINFACH 150 cm



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[B. Braun organization / Distributor]

Appendix 2

Discofix Warning Notice

See separately attached document "15328312_Discofix_A3_IFU_0520"

Appendix 3

**Confirmation of the receipt of the Field Safety Notice for
Combitrans® / Combidyn® Monitoring Sets from November 20th, 2023**
Ref. no. FSCA-VS-2023-01

Please return this completed form by email back to the following email address immediately, even if you no longer have any of the listed products:

✉ [Please add your local email address]

Name:
Position:
Hospital:
Address:
Country:

We hereby confirm receipt of this information.

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Date

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Signature