Water for DIALYSE

2.a

permo
TRAITEMENT DES EAUX

BW Group:
Head Office: Mondsee
AUTRICHE
Turnover - 399 Millions d'Euros

Workforce = 2900

International presence

Africa
Eastern Europe
Maghreb
French Overseas Departments
and Territories
North America
South America
Middle East
Western Europe excl. EU
Central and Southern Asia
European Union

Working through its export department coordinating a network of BWT subsidiaries and partner distributors, BWT France sets up custom engineered water systems in 5 continents and offers its customers:

- *Engineering systems according to field of activity,*
- *Studies, PID*
- *Laboratory: 14000 analyses / month,*
- *Sales engineering training,*
- *AFTER SALES,*
- *Local stocks.*

EXPERIENCE, THE CORE OF INNOVATION...

PERMO, CUSTOM-ENGINEERED WATER SYSTEMS

PERMO - BWT FRANCE

PERMO (BWT group), a leading point-of-use water treatment specialist for more than 80 years, has acquired Irreplaceable experience In the development of technical equipment and product solutions in the following broad areas: Industry, local authority and service Industry:

Innovation, technical optimisation, services... a three-prong target driven by the Increasing demands made by user Industries..

INFRASTRUCTURE

PERMO's wide-reaching operations and coverage and the quality of its specialists offer the best guarantee of service for PERMO product users. Special water treatments (ultra pure water, circuit conditioning) demand a precise technical match between the offer and the problem together with strict supervision of the installed treatment system. Those challenges can only be met through the know-how of experienced professionals such as the personnel in PERMO's Project and Water conditioning departments.

PERSONNEL

Our men and women, true professionals with specific technical product training guarantee their:

- skills,
- availibility,
- regional presence.

RESOURCES

More than 500 staff, an HQ and a factory in the Paris region and 16 regional offices in major centres enable us to cover effectively the whole country with a customized service. Our Export Department In partnership with local agents offer their support anywhere In the world. 1922
Launch of PERMO brand.

AFAQ ISO 9001 VERSION 2000

RESPONSABLE CARE
ENGAGEMENT DE PROGRES

permo
TRAITEMENT DES EAUX

1922
Launch of PERMO brand.

1957
PERMO, from being the «water» division of PHILLIPS et PAIN, becomes a subsidiary of DEGREMONT.

1985
PERMO joins the « WASSERTECHNIK » division of German firm BENCKISER.

1990
Foundation of the European group Best Water Technology through the MBO of BENCKISER BWT's « WASSERTECHNIK » division whose HQ is located at Mondsee, Austria. BWT becomes the first European point-of-use water treatment group. The subsidiary companies are based in major European countries; PERMO S.A Is one of those subsidiaries.

1992
Founding of BWT France S.A.

1995
Acquisition de la société AQUAFRANCE.

1997
Intégration de l'activité CHRIST.

1999
Fusion entre PERMO / AQUAFRANCE.

CURRENTLY...
even more innovative.

A chain of **excellence** ensuring **water quality**

The main mission of teams manning HEMODIALYSIS or AUTODIALYSIS units is:

PATIENT SAFETY

As water treatment specialist, PERMO's aim is to quarantee purified water quality in compliance with hemodialysis standards, on the one hand, and to provide a partnership with the various members of that team, on the other. In that way, the quality of water used in the dialysis generator optimises the performance of the machine and reduces the consequences of contaminating matter in the water. Indeed, the dialysis techniques are moving towards the use of in creasingly permeable membranes. Re-injection rates are variable even in contractual techniques.

REGULATORY CONTEXT

DIRECTIVES

In force 14th June 1998 - Directives 93 / 42 / EEC

THE TREATMENT OF PURIFIED WATER FOR HEMIODIALYSIS(PRODUCTION & DISTRIBUTION)IS RATED AS A CLASS IIB MEDICAL TECHNIQUE (Rule 3 of appendix IX of journal Vb of the public health code) AND MUST COMPLY WITH:

« Recommendations for the production of water for patients with renal insufficiency undergoing dialysis» Memorandum DGS/DH/AFSSAPS n°2000.337 of 20 June 2000 and if necessary memorandum DGS/DH/AFSSAPS n°2000.311 of 7 June 2000.

« Technical specifications relative to health safety in the practice of haemofiltration and on-line haemomodiafiltration in healthcare units».

DOCUMENTS OF REFERENCE

PHARMACOPEE EUROPEENNE IV Addendum 2003 - EAU POUR HEMODIALYSE AQUA AD CENTRATAS SOLUTIONES DILUENDAS HÆMODIALYSI.

LA PHARMACOPÉE EUROPÉENNE

Critères	Valeurs limites
Organoleptique	Inodore limpide insipide
Chlore total disponible	0,1 mg/l
Ca	2 mg/l
Mg	2 mg/l
Na	50 mg/l
K	2 mg/l
Métaux lourds	0.10 mg/l
Aluminium	0.01 mg/l
Etain	0.10 mg/l
Phosphate	5 mg/l
Cl^-	50 mg/l
SO_4^{2-}	50 mg/l
NO^{3-}	2 mg/l
NO^{2-}	0.005 mg/l
NH^{4+}	0.20 mg/l
Mercure	0.001 mg/l
Zinc	0.10 mg/l
Fluorure	0.20 mg/l
Contamination Bactérienne	100 germes/ml
Pyocyanique	0 / 100 ml
Endotoxines	0.25 UI/ml

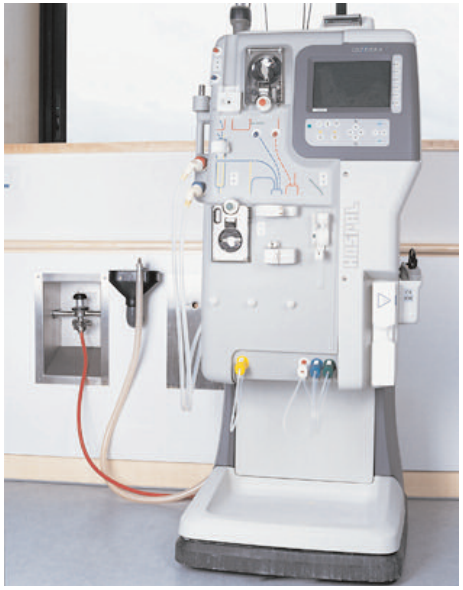
Acidity or alkalinity:

no red colouring on addition of 0.05 ml of methyl red to 10 ml of boiled and cooled water.

no blue colouring on addition of 0.1 ml of bromothymol blue to 10 ml of boiled and cooled water.

oxydizable substances:

less than 0.1 ml of KMnO4 0.02 M in 100 ml.



THE PERMO CHALLENGE

Our challenge is to produce and conserve purified water quality for HAEMODIALYSIS until used by the dialysis generator.

Knowledge of service operations

A certain number of service operations data must be available to draw up the specification sheet and for the study of the best system to be put In place: number of stations to be supplied, number of daily or weekly sessions, type of generator, dialysis technique,…

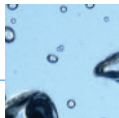
QUALITY • SIMPLICITY • SAFETY

THE CONCEPT OF QUALITY PRESERVATION

Waste water treatment technologies by reverse osmosis are now controlled. Conserving the quality of water until used by the dialysis generator is a real challenge. Key terms for design and operations are:

- Absence of retention and continuous rapid flow for maximal reduction of the risk of formation of biofilms,
- Homogeneousness and consistency of materials used,
- Integral decontamination throughout the installation (chemical, heat…),
- Maximal simplicity for chaining the equipment,
- Safety by the backup of all critical elements (risk analysis) with visual alerts (tactile LCD screen) or sound alerts with transmission to the dialysis department,
- Ease of operation of Installation.

For these reasons PERMO equipment is widely used by the pharmaceutical industry and hospital departments and acknowledged for their reliability, aesthetic appeal and simple, fast maintenance.



Compact water treatment system
for autodialysis unit.
Pure steam generator

MED
EN 13485

PERMO :

Concern for **safety** demand for **quality**

The PERMODIAL osmosis machine Is designed for **haemodialysis** within the context of **quality assurance.**

Water **pre-treatment**

Ongoing supervision and analysis of the total and free chlorine.

Purified water Is produced from water Intended for human consumption. Full knowledge of the physicochemical and microbiological parameters of untreated water and contaminating elements, while bearing In mind seasonal variations, Is required to design a suitable pre-treatment system.
The selection and sizing of chaining together with pre-treatment operating conditions will be based on that knowledge.
The aim of pre-treatment Is firstly to condition the water for Its purification, in compliance with US Pharmcopoeia, by processes such as reverse osmosis while preserving It for as long as possible In total safety and at minimal cost.

Cooling and pressurizing of tap water.

Pre-treatments designed by PERMO offer decisive advantages for the user:
A parallel but not alternating PERMO softener set up to avoid any stagnation. Disinfection at every regeneration stage with the PERMO chlorination biosystem involving the electrolysis of the regeneration brine.

Upgrading capability and adaptability

Pre-treatment operations are as simple as possible(changing filtration cartridges, regeneration salt topups) and are linked to contamination control (chemical disinfection). Daily supervision of operating parameters will guarantee optimal and consistent waste water treatment by reverse osmosis for long periods.

Sand pre-filtration for heavily loaded water.

Complete pre-treatment skid. PERMO 6000 series.

Water **Purification**: **Permodial** range

Permodial control and settings unit.

The **PERMODIAL range** is made up of units with the capacity of producing purified water with flow rates of from 250 to 2500 litre / hr corresponding with dialysis units with 5 to 40 stations. Our EC certified medical range is made up of two-stage osmosis machines (permeate series) WITH THE CAPACITY FOR MASS PRODUCTION OR FOR EMERGENCIES IN MANUAL SIMPLE REVERSE OSMOSIS MODE. That enables constant quality of the produced water (two mass production stages of treatment) whatever the conditions (variations in quality, temperature, untreated water, …).

The units are pre-assembled, integrate the automatic operating and supervision system for the whole station along with decontaminating filtration system loop output and input.
USING POLYAMID MEMBRANES WITH AN OPERATING PRESSURE OF LESS THAN 15 BARS (LOWER ELECTRICITY CONSUMPTION) AND HIGH REJECTION RATE.

PERMODIAL	OSMOSIS 1 Taux de conversion 75 %			OSMOSIS 2 Taux de conversion 90 %			CHASSIS			
MODELE	Débits Alim	Débits Prod	P	Débits Alim	**Débits Prod**	P	Long	Larg	Haut	Poids
A 15°C	m³/h	m³/h	kW	m³/h	**m³/h**	kW	mm	mm	mm	kg
10/10	0,37	0,28	3	0,28	**0,25**	2,2	750	750	1550	150
20/20	0,74	0,56	3	0,56	**0,50**	2,2	750	750	1550	200
40/30	1,11	0,83	3	0,83	**0,75**	2,2	2435	700	1650	300
60/40	1,48	1,11	2,2	1,11	**1,00**	2,2	2435	700	1650	350
80/60	2,22	1,67	4	1,67	**1,50**	3	2435	700	1650	420
100/80	2,96	2,22	5,5	2,22	**2,00**	2,2	2500	900	1880	450
120/100	3,70	2,78	5,5	2,78	**2,50**	4	2500	900	1880	480

PERMODIAL RANGE IS INTENDED FOR:

Haemodialysis centres and medicalized dialysis units: Permodial 250 to 2500 l/h double reverse osmosis (5 / 40 stations),

Simple or assisted autodialysis unit, acute dialysis (reanimation): Permodial 500 l/h single reverse osmosis (maximum 12 stations.).

Sterilizing filtration loop output and input.

Analog sensor of loop flow rate and bacteriological sampling.

Purified water output in 316 L stainless steel.

Distribution of **purified** water

The concept of implementation of a purified water network with integrated tracking **(EC medical certified) consists firstly in selecting a MATERIAL VALIDATED FOR ULTRA-PURE WATER OPERATIONS.**

A salting-out-free material and with documented validation compatible with potential upgrades (disinfection, water quality).

That option enables **TRACKING** (Qualification dossier) of:

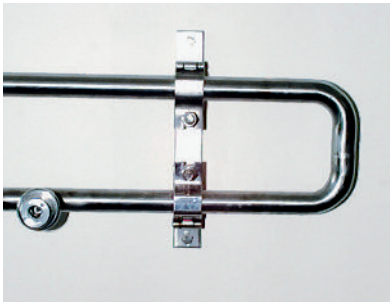
- the matter certified material, compliance, implementation, operator qualification, reproducibility and recording of welding parameters,
- design calculations, isometric drawings and assembly location identifiers.

MATERIALS PROPOSED BY PERMO:

- 316 L stainless steel (Pharma series)
- PVDF (Vinylidene polyfluoride.)

316l stainless steel loop with « pharma » rated welding – EC certified Orbital TOG.

Loop output and input in PVDF with triple clamps on the EC medical device certified PERMODIAL osmosis machine.



Quick stainless steel self-sealing connection.

TABLEAU COMPARATIF DES MATÉRIAUX

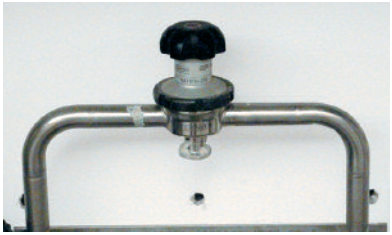
	PVC	PEX	Inox 316L	PVDF
Coût d'installation	F	F	M	M
Facilité d'installation	H	H	M	H
Sanitisation				
Vapeur	N	N	O	O
Pasteurisation	N	O	O	O
Ozone	N	N	O	O
Chimique	O	O	O	O
Possibillité de Rouging	N	N	O	N
Rugosité de surface	M	F	F	F
Résistance à la corrosion	H	H	H	H
Relargage d'Extractibles	H	H	M	N
Dilatation thermique	O	O	N	O
Raccordement dialyseur				
Raccord rapide	O	O	O	O
Vanne à membrane sanitaire	N	N	O	O
Supportage	H	H	F	H
Connection des tubes				
Tri-clamps	N	N	O	O
Collage	O	N	N	N
Vissé	O	O	N	N
Polyfusion sans bourelet	N	N	N	O
Soudure sans métal d'apport	N	N	O	N
Traçabillité des composants et de leur mise en œuvre	N	N	O	O
Agréments				
Eau potable	O	O	O	O
Pharmaceutique/FDA	O-N	N	O	O

O : oui - N : non - H : haut(e) - M : moyenne - F : faible

The concern for comprehensiveness is taken into account by PERMO down to the dialysis machine connections; alternatives to conventional systems, these fast self-sealing connectors are offered with the « pharma » sanitary valves and no dead legs (stainless steel or PVDF) and with flexible silicon tubing. The unit enhances the hygiene chain as close as possible to the generators.

The selection of the ultra-pure character of the material must be backed without fail by a connection system ensuring distribution piping homogeneousness (polyfusion welding).

Sanitary « pharma» valve in PVDF or stainless steel with no dead legs.



Contamination Control

Different technical approaches proposed by PERMO ensure contamination control and define the safety level to extend the installation's performance over time through from the preventive design (direct distribution, constant flow, controlled pre-treatment, component homogeneousness) to the equipment's overall decontamination capability.

SYSTEM DECONTAMINATION METHODS

METHOD	ADVANTAGES	DISADVANTAGES
Steam sterilization. 121 °C. 15 min minimum.	Preventive or curative. Very efficient. No chemical products on the loop.	Cost of investment. Personnel safety. Emptying of system. No action on constituted biofilm. Cannot be used for reverse osmosis. Interruption of reverse osmosis.
Overheated water disinfection. 121 °C. 15 min minimum.	Preventive or curative. Very efficient. No chemical products on the loop. Can be automatic.	Cost of investment. Personnel safety. No action on constituted biofilm. Cannot be used for reverse osmosis.
Pasteurisation. 20 mn minimum. 	Preventive or curative. Efficient. No chemical products on the loop. Can be automatic.	Cost of investment and operating. Personnel safety. No action on constituted biofilm. Cannot be used for reverse osmosis. Operating time. Difficulty in making the temperature uniform at all points. Calories must be discharged. Sporulation of certain pathogenic micro-organisms. Elimination of non-sporulated forms only of micro-organisms.

METHOD	ADVANTAGES	DISADVANTAGES
Chemical disinfection. Peracetic acid. 	Preventive or curative. Very efficient throughout treatment of water and loop. Can be automatic. Disinfectant used for haemodialysis (generators).	Chemical product. Rinsing time. Only method for decontamination for reverse osmosis. Relative action on constituted Biofilm.
Disinfection with ozone. Ozone produced by electrolysis. 	Very efficient. Ozone is the most powerful disinfectant for purified water. (elimination of biofilm). Fast and can be automized. Validated for dialysis in USA. Tracking.	Cost of investment. Generator compatability tests not yet ready.

Semi-automatic chemical disinfection is the basic method proposedfor all our systems. Injection is by means of **dosing pumps,** various protocol stages are managed by a **programmable automaton** with validation by an **access code** at start and end of operation. Disinfection tracking can also be performed.

DISINFECTION AND ANALYTICAL MONITORING PROTOCOLS ARE FINE-TUNED WITH THE PHARMACIST AT THE DIALYSIS CENTRE.

Alert report and indication/ validation of disinfection operations in the dialysis dept.

New **technologies**

The PERMO network is part of BWT, European front runner for WATER TREATMENT. PERMO develops cutting edge technologies to meet new Ultrapure water quality conditions in areas such as microelectronics and pharmaceutics. PERMO strives for the transfer of those technologies in the field of renal treatment.
The approach is in line with the upgrading of dialysis techniques (HDF) and standards that will lead to an increase in specifications for water quality.

Our European R&D department is engaged in ongoing development in partnership with universities and with future technology users to meet those new conditions :

Ultra-Pure quality of water,

Ultra-pure materials (PVDF, electropolished stainless steel),

Septron (deionizer) electrodialysis process,

Distilling apparatus for the manufacture of "EPPI" (Water preparation for injectable solutions),

Disinfection processes: UV and ozone sterilizers (Steritron)

Ultrafiltration for pre-treatments or depyrogenisation ,

Supervision or interfacing with dialysis monitoring software,

Procedures and qualification / validation dossiers (European or American Pharmacopoeia),

Upgrading to future dialysis standards (Afnor standard now being validated) or technological advances in the areas of tracking and security of medical facilities (FDA, GAMP, electronic record and signature, standard 21 CFR). PART 11).

Ultrafiltration, loop output. CH Saint-nazaire.

Septron Electrodesionisation, Clinique Cabestany.

Quality **Assurance** system

EC CERTIFICATION of medical system by Permo

Definition of EC marking methods

Involves all items used for the purposes of diagnostics, testing, treatment, etc… 2 possible certification paths, viz:

through an authorized body (Gmed, TUV):
Type examination (appendix III): standard product, constant characteristics,

through a complete quality assurance system (appendix II):
upgradable system (implemented by PERMO).

The treatment of water for dialysis must be EC MEDICAL stamped and certified throughout (purification and distribution system).
It is unnecessary for all the elements to be marked. It must guarantee that it complies with the standard for the design, manufacture and final inspection.
It is subject to the putting in place of a full QUAlITY ASSURANCE SYSTEM as per STANDARD ISO 9001 version 2000: 94 with the knowledge that this is a special process that cannot be checked retrospectively, that deficiencies might appear during use and that ongoing testing of the water quality is impossible (microbiological, above all).

The notion of upgrading and retrofitting a legacy installation is included in this context.
The materials vigilance and tracking for certain components (osmosis membranes, HP pumps, loop,…)must be taken into account with an obligatory declaration of incidents with AFSSAPS.
The distribution loop of purified water is included in certification.

All stages of implementation are involved:

Design (Design calculations, risk analysis) and implementation.
INSTALLATION QUALIFIACTION – QI,

Testing - OPERATIONAL QUALIFICATION – QO (test bench in factory)

Validation - PERFORMANCE QUALIFICATION- QP. (performed by user)

Along with:

USER TRAINING IN: WATER TREATMENT, INSTALLATION UTILISATIONS,

OPERATIONS, MAINTENANCE AND CORRECTIVE ACTIONS.

FINE-TUNING OF DISINFECTION AND ANALYTICAL MONITORING PROTOCOLS.
The **standard protocols** proposed by PERMO are validated and upgraded if required by the Pharmacist in charge of water quality at the dialysis centre.

Certification documents include:

Qualification stage reports.
A USER MANUAL, covering the basic operating principle, paramaterizations, operations settings, alerts and faults and maintenance management by means of daily monitoring.
A TECHNICAL DOSSIER containing the equipment technical data sheets, hydraulic and wiring diagrams and program lists.

CE 0459

MED EN 13485

PERMODIAL EQUIPMENT TO PROVIDE A TRACKING CAPABILITY FOR THE INSTALLATION

Quality check at purified water output

Ongoing monitoring of vital parameters by:

3 conductivity meters: osmosis machine waste 1 + osmosis machine output 1 and 2; to check the TREATMENT RATE of the INSTALATION'S WASTE WATER,

2 analog sensors of osmosis machine waste flow rate 1 + osmosis machine output 2; to check the INSTALATION CONVERSION RATE,

1 analog return loop temperature transmitter.

Supervision using a tactile colour LCD screen

COORDINATED control (diagram, operating status, alerts, water quality),

OPERATIONS ALERTS LOG,

TRACING OF OPERATIONS PARAMETER CURVES,

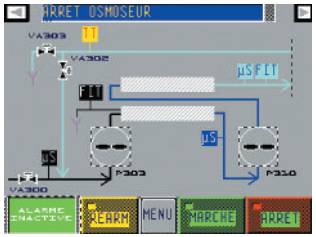
INPUT OF ACCESS SECURITY PASSWORDS.

Options:

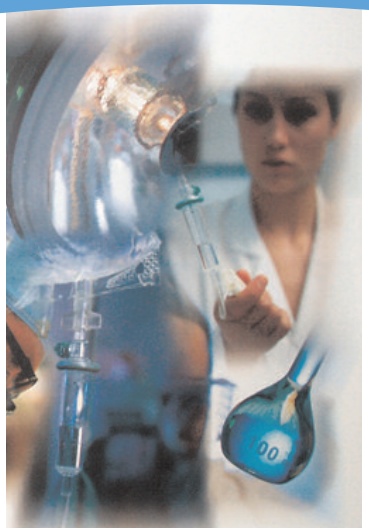
Output to printer,

Flash memory data storage,

Modem Remote Supervision or connection to IT network (specific to water treatment or with dialysis centre supervision software).



Les **services PERMO**



A team of professionals to manage the various stages of the haemodialysis water treatment:

Installation audit for upgrades and retrofits.

Maintenance and telephone support contract.

Remote Supervision of installations by user by means of a modem.

Local after sales service with 60 water treatment specialist technicians.

An export department managing a network of exclusive agents in French overseas departments and territories and abroad.

Consumables supply management (filters, reverse osmosis membranes…).

Permanent spares stock.

Regular diagnostic of the installation as per the performance analysis.

User personnel training.

Ongoing technical information communications through the Website.

RESPONSE IN LINE WITH YOUR NEEDS

The solutions put in place by PERMO in the healthcare sector are both multiple and unique because in all cases they are customized:

Through the assembly of standard equipment,

Through the building of specific equipment.

That approach means that manufacturers' specification sheet conditions are fully met to guarantee constant quality of water production while complying with current regulations.
The company's immense experience and its infrastructure enable PERMO to propose turnkey installations.

A TEAM AT YOUR SERVICE

8 project engineers to design solutions,

10 chargés d'affaires to deliver projects,

6 project draughtsmen,

1 R&D dept,

1 central analysis laboratory,

1 assembly workshop (electrical and hydraulic assemblies, orbital welding, endoscopics,...)

1 quality control dept,

1 spares and products store,

1 logistics dept,

1 central and local After Sales,

16 local agents for follow-up.

PERMO leader in Europe for water treatment, is a member of the International Office for Water, the S.I.E.P (National Syndicate for Drinking Water and Process Water Industries), the SYPRODEAU and the WQA.

PROXIMITY.

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e-mail : BWT @ wanadoo.fr

- **Commissioning**
- **Technical support**
- **Spare parts**
- **Contracts**

The excellent coverage of the Permo network has led to the development of a true guaranteed accessible service, on a regional basis, with fast, often very selective interventions where the maintenance of water quality cannot wait (food industry, pharmaceutics, hospitals, …). Our engineers and technicians on call locally under those emergency conditions offer their skills and availability to meet customer conditions, whatever the field of activity. From diagnostics to prescription, from commissioning to the supervision and maintenance contract, our major concern is to make this service our most comprehensive.

DOMESTIC AND INTERNATIONAL PRESENCE.

EXPERIENCE, THE CORE OF INNOVATION...

permo
TRAITEMENT DES EAUX

103, rue Charles-Michels 93206 Saint Denis cedex
Site Internet : www.permo.tm.fr

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