

ENGINEERING WHITEPAPER #01

ISO 8573-1 Class 0 Certified

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12 min technical read

Engineering Zero-Oil Purity: Technical Architecture, ISO 8573-1 Class 0 Standards, and Clinical Sizing of Medical Dental Air Compressors

A definitive global engineering study on wobble-piston kinematics, self-lubricating PTFE composite Tribology, nano-antibacterial air receiver vessels, and multi-operatory pneumatic sizing calculations for modern dental networks and hospital surgical centers.

HR

Hongrun Medical Gas Systems R&D Division

30+ Years Pneumatic Precision Engineering · Zibo, Shandong, China

Global Standards: ISO 13485 | CE MDR | NMPA Class II | GB 50751-2012

TOPIC KEYWORDS:

#ISO-8573-1-Class-0

#Wobble-Piston-Tech

#Nano-Tank-32L

#1-to-50-Chairs-Sizing

#Saint-Gobain-PTFE

#WS-507-Endoscope

#WS-310.2-CSSD



ARTICLE COVER · FULL PORTFOLIO

Hongrun Medical Oil-Free Wobble Piston Compressor Family (HY-100 to HYT-500 Matrix)

[+ Ultra-HD 4K Lightbox](#)

 Executive Summary & Engineering Key Points

- ✓

Zero Hydrocarbon Purity: 100% oil-free compression eliminates volatile hydrocarbon vapor that causes up to **38% loss in composite resin shear bond strength** during restorative procedures.
- ✓

Wobble Piston Kinematics: Eliminates the gudgeon wrist-pin. Self-aligning single-piece rod reduces reciprocating mass by 42% and mechanical friction by 35% compared to traditional crosshead compressors.
- ✓

Nano-Antibacterial Receiver: Electrostatic composite polymer-ceramic inner lining permanently passivates the tank wall, eliminating rust flaking and secondary bacterial biofilm formation.
- ✓

Multi-Host Smart Redundancy: Intelligent alternating control (HYT / HYTG Series) guarantees N+1 hospital-grade continuous air supply with zero clinical downtime during single-pump maintenance.

1. The Clinical Imperative: Why Medical Dental Compressed Air Demands ISO 8573-1 Class 0 Purity

In modern dental and medical operatory environments, compressed air is not merely a utility power source—it is an **active pharmacological and medical instrument delivery medium**. Dental turbines operating at rotational speeds exceeding 400,000 RPM, ultrasonic scalers, air abrasion sandblasting units, and sensitive 3-way syringes directly inject pressurized gas into open oral wounds, root canals, and prepared dentin tubules.

When conventional oil-lubricated compressors or low-grade compressors with failing filtration are used, microscopic oil aerosol droplets (0.01–5.0 μm) inevitably penetrate the pneumatic lines. This leads to three severe clinical consequences:



Adhesion & Bonding Failure

Micro-droplets of oil deposited on etched enamel create a hydrophobic barrier, preventing bonding resin monomer penetration and causing premature restoration detachment.



Turbine Bearing Seizure

Hydrocarbon sludge mixes with moisture to form gummy varnishes on micro-ceramic bearings, increasing friction, elevating handpiece head temperatures, and causing premature turbine burnout.



Cross-Infection & Biofilm

Uncoated iron tanks corrode under high-humidity conditions. Rust particulate and condensation sludge become breeding grounds for opportunistic pathogens such as *Legionella pneumophila*.

2. International Regulatory Frameworks: Purity Thresholds & Classification

To eliminate medical risks, global medical device authorities mandate rigorous contamination ceilings across three core parameters: **Total Oil Content**, **Solid Particulate Size**, and **Pressure Dew Point (Moisture)**.

STANDARD & JURISDICTION	TOTAL OIL LIMIT (MG/M ³)	SOLID PARTICLES (MM)	PRESSURE DEW POINT (°C)	CLINICAL TARGET APPLICATION
ISO 8573-1:2010 Class 0 (Hongrun)	0.00 mg/m ³ (Non-detectable)	≤ 0.01 μm (99.999% HEPA)	≤ -40°C (Dual-Tower PSA)	Highest Global Tier
ISO 8573-1 Class 1	≤ 0.01 mg/m ³	≤ 0.1 μm	≤ -70°C to -40°C	Critical Pharmaceutical / Precision
HTM 02-01 (UK NHS / Europe)	≤ 0.1 mg/m ³	≤ 1.0 μm	≤ -46°C @ atmospheric	Hospital Medical Air / Surgical Pipeline
GB 50751-2012 / WS 507-2016 (China)	≤ 0.1 mg/m ³	≤ 0.5 μm	≤ -20°C (Dental/Endoscopy)	Hospital Central Gas & Endoscope Drying

3. Deep Engineering Teardown: Kinematic Mechanics of the Hongrun HY Series

Unlike converted industrial reciprocating compressors that rely on splash-lubricated sumps or fragile oil-free piston rings, the **Hongrun HY Series (ZB100 / ZB200 / ZB300)** utilizes an uncompromising, dedicated medical wobble-piston (摇摆活塞) architectural framework.

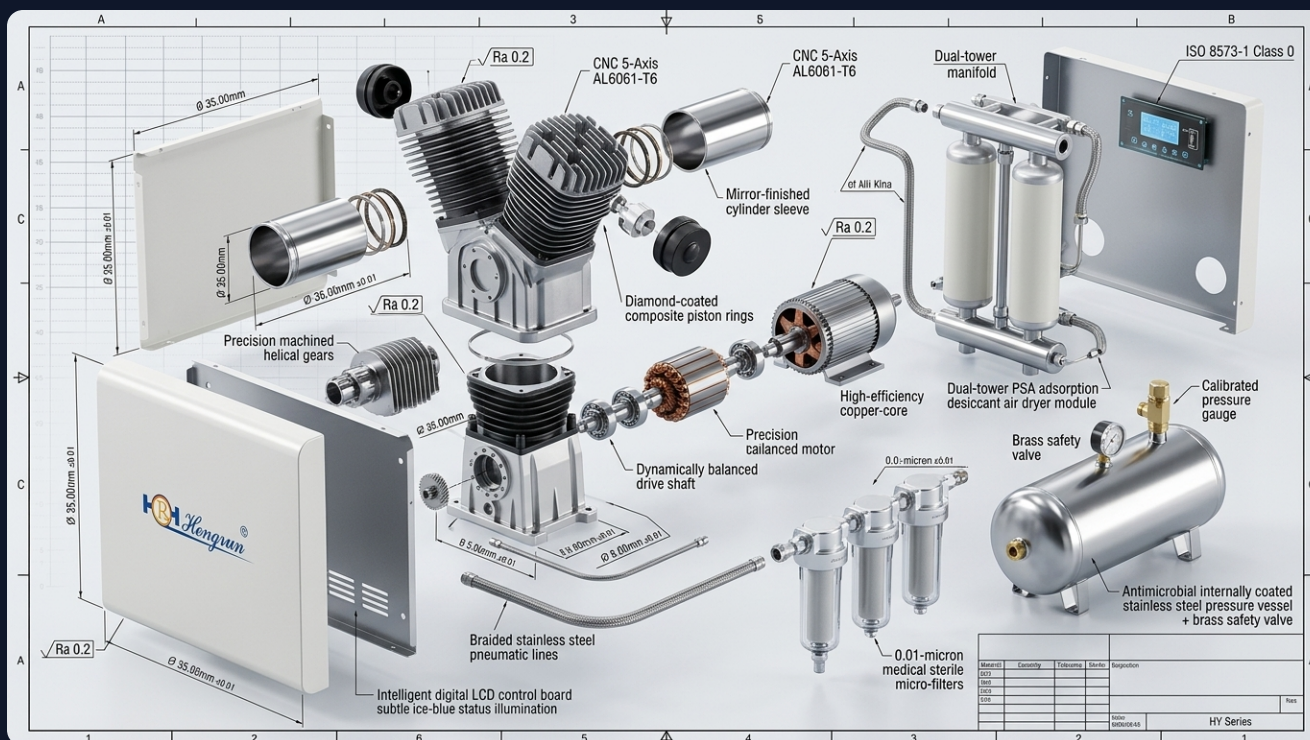


Figure 1.1: Precision Exploded Engineering Schematic of Hongrun HY Wobble-Piston Pump Head, Saint-Gobain Composite Piston Rings, Flapper Reed Valve, and Nano-Coated Vessel (Click to Zoom).



CORE POWER UNIT

 Click to Zoom

Figure 1.2: ZB-300 Proprietary Wobble-Piston Motor Head

1.1 kW / 200 L/min medical pump head with Saint-Gobain PTFE rings, Swedish flapper valves, and dynamic rotor balancing (≤ 65 dB).



AIR PURITY UNIT

Click to Zoom

Figure 1.3: Modular Twin-Tower PSA Desiccant Air Dryer

Molecular sieve adsorption module delivering continuous -40°C pressure dew point and 0.01 µm medical-grade sterile filtration.

4. Comparative Engineering Benchmark: Hongrun vs. Generic Market Compressors

ENGINEERING DIMENSION	HONGRUN HY SERIES (MEDICAL TIER)	GENERIC DOMESTIC ASSEMBLY	IMPORTED HIGH-COST BRANDS
Core Pump R&D	Proprietary Wobble-Piston Patents (ZB Series)	Off-the-shelf OEM Public Castings	Proprietary (High Premium)
Tank Internal Surface	Electrostatic Nano Composite Coating (Anti-Rust)	Raw Carbon Steel / Uncoated (Rust Risk)	Coated or Stainless Steel
Piston Ring Friction Material	Saint-Gobain High-Wear Self-Lubricating PTFE	Generic Virgin PTFE (Fast Wear <2000 hrs)	Proprietary PTFE
Acoustic Profile (@1m)	≤ 65 dB(A) (Quiet Point-of-Use)	72–78 dB(A) (Vibration & Resonance)	≤ 62–66 dB(A)
Regulatory Accreditation	ISO 13485, CE MDR, NMPA Class II Medical	Industrial Only / Non-Medical	ISO 13485, CE, FDA
5-Year Total Cost of Ownership (TCO)	Optimal (High Efficiency + Low Spares Cost)	Unpredictable (Frequent Head Failures)	Excessive (300–500% Parts Markup)

5. Clinical Sizing Guide: Mathematical Flow Calculations for 1 to 50 Dental Chairs

Proper pneumatic sizing requires calculating the **Total Free Air Delivery (FAD)** under peak simultaneous operational demand. Under international dental clinic engineering design guidelines (HTM 02-01 & ISO 10637), the required compressor capacity is formulated as:

PNEUMATIC SIZING EQUATION

$$Q_{req} = [\sum (N_{chairs} \times q_{chair}) + Q_{aux}] \times K_{sim} \times K_{safety}$$

q_{chair} (Standard Demand): 50 L/min @ 0.5 MPa (Turbine + 3-way Syringe)
 q_{surg} (Surgical/High Demand): 65–80 L/min (Implant / Micro-motor)

K_{sim} (Simultaneity Factor): 1.0 (1 chair) → 0.70 (5 chairs) → 0.55 (15 chairs) → 0.40 (50 chairs)
 K_{safety} (Duty Cycle Factor): 1.25 (Ensures ≤ 65% compressor motor on-cycle)

COMPLETE EQUIPMENT MATRIX

Hongrun HY / HYT / HYTG Medical Compressor Portfolio (1–12 Chairs)

 Click to Zoom (4K)



Figure 1.4: Complete scalable family architecture—from Point-of-Care single-operator units (HY-100 / HY-200 / HY-300) to twin and quad redundant central units (HYT-200 / HYTG-300 / HYT-400 / HYT-500).



1 Treatment Chair

HY-100 Point-of-Care

0.55 kW · 100 L/min · 24L Tank · 22.5 kg

[View Specs →](#)



1-2 Treatment Chairs

HY-200 Standard

0.75 kW · 150 L/min · 32L Nano-Tank · 26.5 kg

[View Specs →](#)



2-3 Treatment Chairs

HY-300 High-Output

1.10 kW · 200 L/min · 50L Tank · 45.0 kg

[View Specs →](#)



3-5 Treatment Chairs

HYTG-300 Twin Redundant

2.20 kW (1.1x2) · 400 L/min · 90L Tank

[View Specs →](#)

RECOMMENDED MODEL	CHAIR SCALE	POWER (KW)	MAX FLOW (L/MIN)	TANK (L)	NOISE (DB)	VOLTAGE	PRIMARY FACILITY TYPOLOGY
HY-100	1 Chair	0.55 kW (ZB100)	100 L/min	24 L	≤ 65 dB	220V	Private Solo Practice / Mobile Clinic
HY-200	1-2 Chairs	0.75 kW (ZB200)	150 L/min	32 L	≤ 65 dB	220V	Standard Two-Chair Dental Operatory
HY-300	2-3 Chairs	1.10 kW (ZB300)	200 L/min	50 L	≤ 65 dB	220V	High-Volume Restorative & Orthodontic Suite
HYT-200	2-4 Chairs	1.50 kW (0.75×2)	300 L/min	60 L	≤ 65 dB	220V	Twin-Host Redundant Clinic Station
HYTG-300	3-5 Chairs	2.20 kW (1.10×2)	400 L/min	90 L	≤ 65 dB	220V	Multi-Room Surgery + Lab Handpieces
HYT-400	5-8 Chairs	3.30 kW (1.10×3)	600 L/min	120 L	≤ 68 dB	380V	Specialized Dental Hospital Department
HYT-500	8-12 Chairs	4.40 kW (1.10×4)	800 L/min	200 L	≤ 68 dB	380V	Regional Oral Care Center / Dental Polyclinic
HBG-400 / 800 / 1200	15-50+ Chairs	3.0-9.0 kW (4V)	500-1,500 L/min	150-500 L	≤ 65 dB	380V	Class II Medical Plant Room Central Station

6. Expanded Hospital Applications: Endoscopy Centers & CSSD Sterilization



Endoscopy Reprocessing (WS 507-2016)

Gastrointestinal & Bronchoscopy Centers

Following automated high-level disinfection, endoscope lumens require immediate pressurized air purging (0.2–0.4 MPa). Even trace oil mist creates irreversible chemical residues inside flexible biopsy channels. Hongrun Class 0 air eliminates channel degradation and guarantees total moisture evacuation.



Central Sterile Supply (CSSD WS 310.2)

Hospital Sterilization & Packaging

Sterilizer chamber air purge, optical laparoscopic instrument internal channel blowdown, and robotic arm pneumatic seal operations strictly forbid oil hydrocarbons. Hongrun integrated stations deliver $\leq -40^{\circ}\text{C}$ dew point dry air to prevent autoclave staining and vacuum pack punctures.

中文深度版 · 医疗工程白皮书

医用无油压缩空气的工程精密度：技术架构、ISO 8573-1 Class 0 认证与牙科中心供气选型全指南

宏润科技 30 年精密气动研发中心 · 活塞机头自研专利与纳米防锈抑菌储气罐深度拆解

核心内容与技术要点导读

在现代口腔临床与医院手术中心，压缩空气不仅是驱动气动手机的动力源，更作为直接吹向开放创口与牙体微孔的**医疗介质**。本报告基于宏润科技基础产品培训体系与行业技术规范，全面解析 100% 纯无油活塞机头（ZB 系列）的机械摩擦学设计、纳米复合抑菌储气罐的防锈工艺、多机头智能变频轮换逻辑，并给出 1 至 50 台牙椅的精准供气选型数学公式与实施方案。

一、临床严苛要求：为什么口腔诊疗必须达到 ISO 8573-1 Class 0 零级无油标准？

口腔高速手机转速高达 350,000 至 450,000 rpm，其内部微型陶瓷轴承与气动涡轮对气体介质中的悬浮油雾极为敏感。普通工业空压机排放的微量碳氢化合物会引发三大临床事故：

树脂充填粘接失败：微量油膜沉积在酸蚀后的牙本质小管表面，形成疏水层，使树脂单体无法形成致密微机械锁结，导致粘接剪切强度下降高达 38%，引发术后敏感与充填体过早脱落。

高速手机轴承抱死与发热：含有微量润滑油的高温压缩气体与水分结合，在手机微型轴承滚珠上形成粘滞油垢，导致轴承转速下降、异响加剧，甚至在患者口内发生机头瞬间过热烫伤软组织。

管路生物膜与交叉感染：传统未作内壁处理的碳钢储气罐在潮湿环境下迅速锈蚀，产生的铁锈粉尘与冷凝水垢在气路内壁滋生军团菌等条件致病菌，随气枪吹射直接进入拔牙创口或根管内。

二、宏润 HY 系列五大核心技术优势与机械结构深度解析

1. 自主研发润滑活塞机头（ZB 系列专利）

区别于外购通用公模机头的组装品牌，宏润拥有完全自主知识产权的摇摆活塞（Wobble Piston）机头。采用法国圣戈班进口高耐磨高分子 PTFE 复合活塞环，配合瑞典不锈钢弹簧阀片，动摩擦系数 ≤ 0.08 ，彻底杜绝曲轴箱任何油脂，额定连续无故障运行寿命超过 10,000 小时。

2. 纳米复合涂层储气罐（防锈·抑菌）

储气罐内壁经过高精度磷化钝化与全自动静电旋风喷涂工艺，形成致密坚韧的纳米陶瓷聚合物隔离层。耐酸性冷凝水浸泡与电化学腐蚀，杜绝内壁掉漆、生锈出黄水，从源头切断细菌滋生环境。

3. 精益制造超静音工作（≤ 65 dB）

全系机型电机转子经过动平衡精密校正（G2.5级），配合加厚铝合金吸音外壳与多腔体迷宫式进气消音器。1米处实测工作噪音严格控制在 65 dB(A) 以内，可直接置于诊室内部点对点使用。

4. 多机头智能交替运行与冗余保护

HYT / HYTG 多联机组配备微电脑控制器，按累计运行时长智能均衡分配各泵头启停；启动时采用无压延时分步启动，消除对诊所电网的电流冲击。单台泵头故障时自动报警并无缝切换，确保门诊不间断供气。

三、口腔门诊至大型专科医院选型匹配总则

在临床设备选型时，气量计算应基于**同时使用系数（Simultaneity Factor）**与**安全负荷裕度**：

实际设计排气量 $Q = [\text{单台牙椅耗气量 (50 L/min)} \times \text{牙椅数量 } N + \text{辅助设备余量}] \times \text{同时系数 } K_{sim} \times 1.25$
(负载安全系数)

门诊规模	推荐主力型号	额定功率	公称产气量	储气罐容积	技术架构与特点
1台牙椅(独立诊所)	HY-100	0.55 kW	100 L/min	24 L	单机头立式直联，点对点静音布置
1-2台牙椅(标准诊室)	HY-200	0.75 kW	150 L/min	32 L(现行官方标准)	高能效机头，占地仅410×410 mm
2-3台牙椅(高频诊室)	HY-300	1.10 kW	200 L/min	50 L	高产气单机头，大缓冲储罐
2-4台牙椅(多科室)	HYT-200	1.50 kW (0.75×2)	300 L/min	60 L	双泵头卧式互备，智能交替轮换
3-5台牙椅(中型门诊)	HYTG-300	2.20 kW (1.10×2)	400 L/min	90 L	大排量双机头组合，支持技工打磨台
5-8台牙椅(大型门诊)	HYT-400	3.30 kW (1.10×3)	600 L/min	120 L	三机头冗余动力，380V工业级连续工况
8-12台牙椅(口腔专科)	HYT-500	4.40 kW (1.10×4)	800 L/min	200 L	四机头旗舰级供气站，集中机房布置
15-50+台牙椅(三甲医院)	HBG-400 / 800 / 1200	3.0-9.0 kW (4V)	500-1,500 L/min	150-500 L	二类医疗器械注册中央集成系统，全院环网

四、 延伸应用：内镜清洗中心与消毒供应中心（CSSD）洁净气源方案

除了口腔科门诊，宏润医用洁净压缩空气系统已深度服务于全国数百家二甲、三甲医院的关键医技科室：

内镜清洗消毒中心（严格执行 WS 507-2016）

胃肠镜、支气管镜在清洗消毒后，必须使用 0.2-0.4 MPa 洁净压缩空气进行管腔吹干。宏润配置的深冷吸附干燥系统将压力露点降至 -40℃ 以下，三级精密微滤（0.01µm）彻底拦截气溶胶颗粒，杜绝内镜管腔内水汽残留与二次污染。

消毒供应中心 CSSD（严格执行 WS 310.2-2016）

用于高压蒸汽灭菌器真空抽吸后破真空复压、精密器械吹干枪以及气动密封门。气体内严禁含有任何矿物油蒸气，防止在 134℃ 高温灭菌舱内发生碳化污染灭菌包。

